Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Evidence summary for face mask use by healthy people in the community

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Key points

- Face masks aim to reduce the spread of infection by acting as a source control to stop the spread of infection by the person wearing the mask (including those who do not know they are infected) or to protect the wearer from droplet splashes or inhaling airborne contaminants including small (aerosol) and large particle droplets. Mask grades include respirators (classified as PPE designed to also protect against aerosols), medical face masks and non-medical facemasks.
- Since the start of the current COVID-19 pandemic, the use of face masks by persons going out in public has been recommended by an increasing number of countries. In Ireland, cloth face coverings are recommended in situations where physical distancing may not be possible, and are mandatory on public transport and in shops and other retail outlets.
- Nineteen studies that provide direct evidence on the effectiveness of face mask use in community settings to reduce transmission of respiratory viruses were identified.
- Four studies were conducted in the context of the COVID-19 pandemic, the remaining studies considered influenza, influenza-like illness (ILI), or SARS-CoV-1. Eight studies examined the effectiveness of medical masks, nine studies did not specify the type of mask used, one study included both medical and non-medical masks and one study included all types of masks.
- Four observational studies conducted during the COVID-19 pandemic, suggest that face masks may reduce the risk of SARS-CoV-2 infection. Two observational studies that examined the effectiveness of wearing face masks when going out in public suggested that face masks may have been protective against SARS-CoV-1 infection.
- Six randomised control trials (RCTs) set in households provide some weak evidence that medical masks worn by both index cases and healthy household contacts can reduce the risk of secondary household infections, when implemented early and combined with intensified hand hygiene.
- There was no evidence from the included studies that face masks increase harm or introduce a false sense of security leading wearers to neglect hand hygiene.
- The quality of evidence from the studies included was low; two of the studies conducted during the COVID-19 pandemic have not yet been formally peer-reviewed.

Key points (continued)

- There is limited, low certainty evidence based on four observational studies conducted during the COVID-19 pandemic that face masks may reduce the risk of transmission of SARS-CoV-2. Studies from previous pandemic settings and for other respiratory viruses also provide low certainty evidence that the wearing of face masks in community settings reduces the risk of transmission of respiratory pathogens. However, their applicability to COVID-19 is uncertain given possible differences between viruses in their pathogenicity and infectivity and the potential differences in the relative contribution of the different modes of transmission (droplet, aerosol, contact).
- National and international public health guidance is based on low certainty direct evidence of clinical effectiveness and indirect evidence that supports the plausibility of effectiveness of face masks. In addition, SARS-CoV-2 appears to be more infectious than many other respiratory pathogens studied to date based on its basic reproduction number, highlighting the necessity of considering a range of infection prevention control measures, including face masks, to reduce the spread of infection.
- There is an urgent need for more research, particularly high quality studies that provide direct evidence on the use of face masks by healthy people in the community.

Evidence summary for face mask use by healthy persons in the community

The Health Information and Quality Authority (HIQA) has developed a series of 'Evidence Summaries' to assist the 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 (RQs). This evidence summary was developed to address the following research question:

> **What evidence is available to indicate that routine wearing of face masks by healthy persons in the community reduces the transmission of respiratory pathogens?**

Below is the summary of all relevant studies from 1 January 2000 until 24 June 2020.

Background

The use of face masks is one of a suite of infection prevention and control measures intended to limit the transmission of respiratory viral diseases.[1] Respiratory viruses can be spread through droplets and or aerosols. Direct droplet transmission refers to virus transfer from an infected person to a susceptible individual through droplets generated during coughing, sneezing, breathing or talking. Aerosol transmission is distinct from direct droplet transmission as it is based on smaller particle size (generally defined as <5 micrometres in diameter),[2] enabling a greater travel distance and the potential to remain suspended in the air for prolonged periods.[2, 3] The potential for aerosol transmission of SARS-CoV-2 is currently subject to much debate.[4] HIQA has recently reviewed the evidence on airborne transmission of SARS-CoV-2 via aerosols and the relative importance of direct versus indirect droplet transmission for the spread of SARS-CoV-2 in two separate evidence summaries.[5, 6] Face masks aim to reduce the spread of infection by acting as a source control to stop the spread of infection by the person wearing the mask (including those who do not know they are infected) or to protect the wearer from droplet splashes or inhaling airborne contaminants including small (aerosol) and large particle droplets. Mask grades include respirators (classified as PPE designed to also protect against aerosols), medical (surgical) face masks and non-medical or cloth masks.[7]

Since the start of the current COVID-19 pandemic, the use of face masks in public places has been recommended by an increasing number of countries,[8] with several jurisdictions introducing mandatory mask wearing in community settings such as public transport or shops. In a report published on 8 April 2020, the European Centre for Disease Prevention and Control (ECDC) suggested that 'the use of face

masks in the community could be considered, especially when visiting busy, closed spaces, such as grocery stores, shopping centres, or when using public transport', but only as a complementary measure, to be implemented alongside physical distancing and hand-hygiene.[8] The ECDC also suggests that in areas of sustained community transmission of COVID-19, the use of face masks by patients and customers should be considered at all times when visiting general practices, community health centres or pharmacies, and inside the building and in waiting areas when visiting dental clinics.[9]

On 6 June 2020, the World Health Organization (WHO) released interim guidance on the use of masks in the context of COVID-19, updating previous interim guidance from 5 April 2020.[1] The updated guidance highlighted the lack of 'direct evidence (from studies on COVID-19 and in healthy people in the community) on the effectiveness of universal masking of healthy people in the community to prevent infection with respiratory viruses, including COVID-19'. The guidance advises that individuals with symptoms of COVID-19 should wear face masks as a source control measure. The WHO also suggested that 'to prevent COVID-19 transmission effectively in areas of community transmission, governments should encourage the general public to wear masks in specific situations and settings as part of a comprehensive approach to suppress SARS-CoV-2 transmission', including as a potential source control measure in situations where close contact cannot be avoided. The WHO further advises that if community transmission is known or suspected, those who are 60 years and over or who have underlying conditions that increase their risk from COVID-19 should wear medical masks for their own protection, where close contact cannot be avoided.

In Ireland, the Department of Health recommends wearing a cloth face covering in situations where physical distancing may not be possible.[10] Cloth face coverings became mandatory on public transport in Ireland on 13 July 2020,[11] and in shops and other retail outlets on 10 August 2020.[12] Public health guidance recommends that individuals who are self-isolating due to symptoms or a confirmed diagnosis of COVID-19 or after travel overseas and their household contacts should wear a face mask when in the same room.[13]

This evidence summary considers the direct evidence from studies in community settings that compare the effectiveness of wearing face masks to not wearing face masks on the transmission of respiratory pathogens, including SARS-CoV-2.

Methods

The processes as outlined in HIQA's protocol (available at https://www.hiqa.ie/reports-and-publications/health-technology-assessment/protocol-evidence-synthesis-support-covid-19) were followed. A review

of published peer-reviewed articles and non-peer-reviewed pre-prints was initially undertaken up to 9 April 2020. This review was updated to 24 June 2020. This evidence summary considers the direct evidence of the effectiveness of the routine wearing of face masks by healthy people in the community to reduce the transmission of respiratory pathogens. Indirect evidence from experimental volunteer or laboratory studies, or mathematical modelling studies, is not included. Studies conducted in the context of the Hajj pilgrimage mass gatherings, which are characterised by exceptionally high levels of close contact and have focused on influenza infection, are excluded, as these are unlikely to be applicable to the current context in Ireland.

Results

A total of 19 studies were identified, reported across 20 publications.[14-33] Four observational studies were conducted in the context of the COVID-19 pandemic.[28, 29, 31, 33] Nine RCTs or cluster RCTs,[14-17, 19, 21-23, 25] one case-control study[32] and two cross-sectional studies[18, 26] considered influenza or influenza-like illness, while two case-control studies[20, 27] and one cross-sectional study[30] were conducted during the SARS pandemic. Details of all included studies are listed in Appendix 1. Eight studies examined the effectiveness of medical masks, nine studies did not specify the type of mask used, one study included both medical and non-medical masks, and one study included all types of masks. In the majority of studies, face mask use was self-reported. Table 1 summarises the available evidence in terms of the pandemic setting and intervention type by study design.

Eighteen systematic reviews were also identified; these were based on the same primary studies included in this report, but also included studies of healthcare settings, with conclusions based on evidence from across all settings.[34-51] Further details of these systematic reviews are provided in Appendix 2 of this report.

Table 1. Summary of current evidence of efficacy and effectiveness according to pandemic setting and study design

Pandemic setting	Intervention	Study designs	
		RCTs	Observational studies
SARS-CoV-2	Face masks worn in the community in addition to other measures (hand hygiene and physical distancing), type of mask not specified		N=1
	Medical masks worn in the community, status of other measures not specified		N=1
	Face masks worn in the community, type of face mask not specified, status of other measures not specified		N=1
	Face masks (all types) worn in household settings, status of other measures unclear		N=1
Other pandemic respiratory virus (e.g. SARS or Influenza A (H1N1) pdm09)	Medical masks worn in the community in addition to other measures (hand hygiene and physical distancing)		
	Medical masks worn in the community, status of other measures not specified		
	Face masks worn in the community, type of face mask not specified, status of other measures not specified		N=3
	Medical masks worn at home, in addition to hand hygiene	N=1	
	Face masks worn in schools, type of face mask not specified		N=1
Non-pandemic respiratory virus (e.g. seasonal influenza)	Medical masks worn in university halls of residence, in addition to hand hygiene	N=2	
	Medical masks worn in household settings, in addition to hand hygiene	N=4	
	Medical masks worn in household settings, no other measures	N=2	
	Face masks worn in schools, type of face mask not specified		N=1

Note: Shaded areas indicate currently available evidence according to setting and study design

Evidence from studies conducted during the COVID-19 pandemic

Four observational studies that examined the use of face masks during the COVID-19 pandemic were identified.[28, 29, 31, 33] These studies were conducted in Hong Kong,[31] China[29, 33] and Thailand.[28] Cheng et al.[31] reported that among 961 confirmed COVID-19 cases in Hong Kong until 8 April 2020, there were 11 clusters of 113 persons engaged in 'mask-off' activities such as dining or karaoke, compared to three clusters of 11 people in 'mask-on' workplace settings. The authors further compared the incidence of COVID-19 per million population in Hong Kong (where the authors state the general public adopted face mask wearing soon after the first imported case of COVID-19 was reported) with that of countries the authors considered comparable in terms of population density, healthcare system, and physical distancing measures, but without community-wide mask wearing.[31] The authors reported that the incidence of COVID-19 in the first 100 days in Hong Kong (129 per million population) was significantly lower than in Spain (2,983), Italy (2,250), Germany (1,242), France (1,152), US (1,103), UK (832), Singapore (260), and South Korea (201). The authors concluded that face masks may contribute to the control of COVID-19, although the type of mask was not specified.[31] The authors did not report testing rates, which would facilitate between country comparisons. Given the observational nature of this study, there are likely to be other, unmeasured differences between the countries included in this studies, as well as between the identified clusters of cases.

A case-control study by Doung-ngern et al. published as a pre-print included 1,050 contacts of 18 COVID-19 patients from nightclub, boxing stadium or enterprise office clusters identified through contact tracing in Thailand.[28] A total of 211 contacts (20.1%) subsequently tested positive for SARS-CoV-2. In unadjusted analyses, wearing a medical mask was associated with a significantly reduced risk of infection compared with not wearing a mask, (OR 0.25, 95% CI 0.12 to 0.53). However, wearing non-medical masks (OR 0.78, 95% CI 0.32 to 1.90) or alternating between medical and non-medical masks (OR 0.46, 95% CI 0.13 to 1.64) were not associated with a reduced risk of infection compared with not wearing masks. Of note, the numbers of cases and controls who reported wearing non-medical masks or alternating between different types of masks were substantially smaller, resulting in greater levels of uncertainty around the point estimates.

In a separate adjusted analysis, the authors explored the impact of wearing a mask all the time or sometimes compared with not wearing a mask, regardless of the type of mask worn. For contacts who self-reported wearing any type of mask all of the time, the risk of infection was significantly lower compared with contacts who did not wear a mask during the contact period (OR 0.23, 95% CI 0.09 to 0.60), although it is not clear what other factors were adjusted for. Wearing a mask

sometimes was not associated with a lower risk of infection compared with not wearing a mask (OR 0.87, 95% CI 0.41 to 1.84). The type of mask worn was not independently associated with infection in a multivariable model that also included frequency of mask wearing (all the time, sometimes or not wearing a mask); however, due to a high degree of correlation between the two mask variables, type of mask was excluded from the final multivariable model. The authors concluded that consistently wearing masks combined with washing hands and physical distancing in public could substantially reduce SARS-CoV-2 infections.[28]

In a cross-sectional online survey of 8,158 Chinese adults, recruited through snowball sampling conducted using three social networks, 57 (0.7%) reported having been infected with SARS-CoV-2.[29] Of the survey respondents, 5,054 individuals also provided data on face mask use, with 97.9% reporting wearing a mask when going out. The type of mask was not reported. Compared with wearing a mask, not wearing a mask, was associated with a significantly increased risk of SARS-CoV-2 infection (OR 7.20, 95% CI 2.24 to 23.11), controlling for socio-demographic variables, hand washing, coughing etiquette, and physical distancing. The authors further reported that wearing a mask compared with not wearing a mask was associated with a significantly reduced risk of SARS-CoV-2 infection among those who practiced hand washing (RR 0.11, 95% CI 0.04 to 0.29), proper coughing etiquette (RR 0.18, 95% CI 0.05 to 0.57) and social distancing (RR 0.03, 95% CI 0.01 to 0.11). The authors concluded that mask wearing was the most effective protective measure against COVID-19 among the four non-pharmaceutical interventions considered, with added preventive benefit among those who reported practicing all or some of the other three behaviours (hand-washing, cough etiquette and physical distancing).[29]

Wang et al. included 124 families in China with at least one laboratory confirmed COVID-19 case.[33] Data were collected using self-report questionnaires. Secondary transmission occurred in 41 families, with 77 secondary cases among 335 individuals. In unadjusted analyses, household transmission was significantly reduced when all family members (compared with no family members) wore any type of mask (respirator, medical or cloth) all the time at home after the primary case's illness onset date (OR 0.20, 95% CI 0.07, 0.60), but not if only some family members wore masks (OR 0.72, 95% CI 0.30 to 1.73). Transmission within families was also less likely when the primary case wore a mask at all times (OR 0.30, 95% CI 0.11 to 0.82) after illness onset, but not when the primary case and or family members wore a mask some of the time (OR 1.15, 95% CI 0.46 to 2.87), compared to never wearing a mask. In multivariable analysis, face mask use before the primary case's illness onset date by one or more persons in the household reduced transmission by 79%, compared with no face mask use (OR 0.21, 95% CI 0.06 to 0.79), although it is not clear if masks were worn all of the time or sometimes. Wearing a mask after illness onset of the primary case was not significantly

protective in multivariable analysis, although it is not clear which covariates were adjusted for. The authors suggest that their findings could inform 'precautionary guidelines' for households to reduce transmission in areas of high community transmission.[33]

Evidence from studies of other respiratory viruses

Of the remaining 15 primary studies included in this evidence summary, eight were randomised controlled trial (RCTs) or cluster RCTs (reported across nine publications),[14-17, 19, 21, 23-25] three were case-control studies[20, 27, 32] and three were cross-sectional.[18, 26, 30] One additional RCT reported observational data on face mask use as part of a study of the efficacy of sucking tablets containing human saliva enzymes in alleviating symptoms of the common cold and or influenza infection.[22]

Thirteen of the 15 studies focused on influenza or influenza-like illness (ILI), or a variety of respiratory viruses (for example, influenza A and B, respiratory syncytial virus (RSV), adenovirus, parainfluenza viruses (PIV) types 1–3, coronaviruses 229E and OC43, human metapneumovirus (hMPV), enteroviruses and rhinoviruses[21]); cases were either self-reported or laboratory-confirmed. One RCT was conducted across two influenza seasons, one of which coincided with the influenza A (H1N1)pdm09 pandemic.[25] One cross-sectional study focused on the 2009 Influenza A H1N1 infection in South Korea.[18] One case-control study involved air travel during the influenza A (H1N1)pdm09 pandemic.[32] Three studies were conducted during the Severe Acute Respiratory Syndrome (SARS) pandemic.[20, 27, 30] The studies were set in Hong Kong,[16, 17, 20] China,[27, 32] South Korea,[18] Japan,[22, 26] Thailand,[23] Vietnam,[30] US,[14, 15, 19] Australia,[21] and Germany.[24, 25] None of the studies specifically examined the effectiveness of reusable cloth masks worn in the community. Nine studies did not report the type of mask used;[18, 20, 22, 26, 27, 29-32] eight (reported across nine publications) involved the use of medical masks[14-17, 19, 21, 23-25] and one included both medical and non-medical masks.[28] In the majority of studies, face mask use was self-reported, with observation of mask wearing in one study,[31] and some limited observation in addition to self-reporting in another.[15]

Transmission in household settings

Six RCTs (reported across seven publications) reported on transmission of respiratory infection in household settings.[16, 17, 19, 21, 23-25] One of these included data from a previously reported pilot study.[24, 25]

Masks worn by both index patients and their household contacts

Five of the six RCTs in household settings reported interventions which involved both index patients and healthy household contacts wearing medical masks in the home compared with controls who did not wear masks.[16, 17, 19, 23, 25] Three of these

studies included both a medical mask plus hand hygiene intervention group and a hand hygiene only group.[16, 19, 23] One study included a medical mask only intervention group and a hand hygiene only group,[17] and one study included a medical mask plus hand hygiene intervention group and a medical mask only group.[25]

Cowling et al. 2009[16] found no significant difference in the risk of influenza between the intervention and control groups. However, when the intervention was applied within 36 hours of symptom onset in the index patient, the risk of secondary infections was significantly lower in the medical mask plus hand hygiene group (OR 0.33, 95% CI 0.13 to 0.87). Larson et al. 2010[19] similarly reported a significant decrease in secondary attack rates (defined as the probability that infection occurs among susceptible persons within a reasonable incubation period following known contact with an infectious person) of URI, ILI and influenza in the medical mask plus hand sanitiser group compared with the control group (OR 0.82, 95% CI 0.70 to 0.97). Simmerman et al. 2011[23] found no difference in laboratory-confirmed secondary influenza infection between the intervention (hand washing plus medical masks or hand washing only) and control groups in a study of household infections set in Thailand. However, self-reported ILI was more likely in both the hand washing arm (OR 2.09, 95% CI 1.25 to 3.50) and hand washing plus medical mask arm (OR 2.15, 95% CI 1.27 to 3.62), compared with the control group. The authors noted that in 90% of households in the study, index patients slept in the same bedroom as household contacts, with participants instructed not to wear face masks while sleeping, which may have contaminated their results.

Cowling et al. 2008[17] found no difference in the laboratory-based or clinical secondary attack ratios between the intervention (medical mask only or hand hygiene only) and control groups. The authors noted that adherence in the intervention group was often poor, while more than 25% of index cases in the control group reported wearing face masks at home, which may have contaminated the results.

Suess et al. 2012,[25] which incorporated data from an earlier pilot study,[24] included 84 influenza positive index cases and their household contacts. Of the index cases, 65 had influenza A(H1N1)pdm09. The authors found that for laboratory-confirmed cases, secondary attack rates were not significantly lower in the medical mask only (9% [6/69]) or medical mask plus hand hygiene group (15% [10/67]) compared with the control group (23% [19/82]). In index cases with influenza A(H1N1)pdm09, secondary attack rates were not significantly lower in the medical mask (10% [6/58]) or medical mask plus hand hygiene group (8% [4/50]) compared with the control group (23% [13/56]). In households with index cases of influenza A(H1N1)pdm09, there was a significant reduction of laboratory-confirmed secondary infection in the medical mask plus hand hygiene group (aOR 0.27, 95% CI 0.07 to 0.99), when adjusted for age, sex, timely antiviral therapy of the index case and

vaccination of household contacts. In a per-protocol analysis of all cases (regardless of influenza strain) there was a significant reduction of secondary infection among participants in the mask only group compared with the control group (aOR 0.30, 95% CI 0.10 to 0.94). Similarly, in a per-protocol analysis of households with index cases infected with Influenza A(H1N1)pdm09, there was a significant reduction of laboratory-confirmed secondary infection in both the mask only (aOR 0.28, 95% CI 0.08 to 0.97) and the mask plus hand hygiene group (aOR 0.26, 95% CI 0.07 to 0.93).

Masks worn only by the household contacts of index patients

The final household RCT compared medical masks with P2 masks (almost identical to N95 respirators) worn by healthy adult household contacts of index patients only.[21] An intention-to-treat analysis showed no difference between intervention and control arms. However, a per-protocol analysis (which excludes intervention participants who did not wear masks) found that mask users who were adherent for more than three days had a significant reduction in the risk of clinical infection compared with the control group and non-adherent participants (RR 0.42, 95% CI 0.18 to 0.95).

Transmission in university residential accommodation

Two RCTs were conducted in university halls of residence in the US.[14, 15] Both included a medical mask only and a medical mask combined with hand hygiene intervention group. Both studies noted a reduction in self-reported ILI from week 3[15] or week 4[14] of the intervention (medical mask only or medical mask combined with hand hygiene) compared with the control group (neither intervention), although the cumulative rate of reduction in laboratory-confirmed influenza over the six week study period was not significantly associated with either medical mask use plus hand hygiene (RR 0.57, 95% CI 0.26 to 1.24) or face mask use alone (RR 0.92, 95% CI 0.59 to 1.42).[15]

One RCT[22] set in a Japanese university included healthy student and faculty volunteers, and evaluated the efficacy of sucking tablets containing human saliva enzymes in alleviating symptoms of the common cold and or influenza infection. Habitual wearing of unspecified face masks was reported by 35 participants (27%) in the enzyme treatment group and 40 participants (29%) in the non-treatment group. They observed that 31% of those who wore a face mask in the treatment group reported common cold symptoms, compared with 35% of those who did not wear a mask; while 35% of those who wore a mask in the non-treatment group reported cold symptoms, compared with 37% of those who did not wear a mask. This study was not designed to detect a difference in cold symptoms between wearers of face masks and non-wearers, and no further analysis was conducted.

Transmission during other pandemics

Two case-control studies were conducted during the SARS pandemic in Hong Kong and China and one cross-sectional study was conducted in Vietnam. Both case-control studies reported that the use of unspecified face masks was protective against SARS-CoV-1 infection.[20, 27] Wu et al. reported that always wearing a face mask when going out in public spaces was associated with a 70% reduction in risk compared with never wearing a mask (OR 0.3, 95% CI 0.1 to 0.6); while wearing a mask intermittently was associated with a smaller, but still significant risk reduction (OR 0.4, 95% CI 0.2 to 0.9).[27] However, it is not clear what behaviours or risk factors were controlled for in their analysis. Lau et al. found that, after controlling for other significant risk and protective factors (including visiting affected areas or hospitals, frequent hand washing and disinfecting of living quarters), SARS cases were significantly less likely than controls to have frequently worn a face mask in public (OR 0.36, 95% CI 0.25 to 0.52).[20] The cross-sectional study involved close household and community contacts of laboratory-confirmed SARS-CoV-1 cases.[30] Of 163 contacts who reported household contact with a confirmed SARS case and for whom data on mask wearing were available, seven had serological evidence of SARS-CoV-1 infection. None of the seven contacts with evidence of SARS-CoV-1 infection reported wearing a mask sometimes or most times when in contact with the index case, while nine of 156 contacts (5.8%) with no evidence of SARS-CoV-1 infection reported wearing masks.[30] There was no evidence of an association between wearing a mask during contact with a SARS patient and transmission of SARS-CoV-1 in bivariate analysis (OR 0.0. 95% CI 0.0 to 15.4); however, the number of secondary cases in this study was very low.

Transmission in a school setting

Two cross-sectional studies were conducted in school settings and both reported that wearing face masks was protective against influenza.[18, 26] The types of face masks worn were not specified in either study. Kim et al.[18] conducted a study in 7,448 school children aged 7 to 18 years in South Korea to investigate demographic and epidemiological factors associated with influenza A (H1N1) infection. Self-reported continuous use of face masks was associated with lower risk of influenza infection compared with non-use of masks (OR 0.51, 95% CI 0.30 to 0.88). Uchida et al.[26] conducted a 'census' of all elementary school children (n=10,524) in 29 public schools, of whom 20.4% were reported to have had influenza. Self-report of wearing masks was associated with significantly lower risk of influenza (OR 0.86, 95% CI 0.78 to 0.95) in multivariable analysis (adjusted for sex, school grade, having a sibling, vaccination status, self-reported measures of hand washing, frequency of going out, presence of underlying condition and influenza during the previous season).[26] The duration or frequency of mask wearing was not reported.

Transmission during a long haul flight

Zhang et al. reported a case-control study of passengers who travelled on a long haul flight during the influenza A(H1N1) pandemic.[32] The study included nine case passengers and 32 control passengers who travelled on connecting flights from New York to Hong Kong (with a stopover in Vancouver), and from Hong Kong to Fuzhou, China. The case-control analysis focused on the journey from New York to Hong Kong. The authors reported that on the flight from New York to Vancouver, one of nine case passengers (11%) wore a face mask compared with 16 of 28 control passengers (57%), while from Vancouver to Hong Kong, none of the case passengers reported wearing face masks, while 15 of 32 control passengers (47%) did. The authors concluded that face masks were associated with a decreased risk of acquiring influenza infection during this long haul flight, although data were missing for some passengers, and given the observational nature of the study and lack of control for confounding, there are likely to be other differences between cases and controls that are not accounted for.[32]

Compliance with face masks

Six of the 19 studies did not report compliance with face masks.[14, 20, 23, 26, 27, 32] Compliance was self-reported in 12 studies (reported across 13 publications);[16-19, 21, 22, 24, 25, 28-30, 32, 33] one study used self-reporting and observation,[15] while one study used observation.[31] Definitions varied across studies. In one study, detailed compliance rates were not reported and compliance was deemed as 'observed'.[15] Seven studies reported compliance rates as follows: a German study that also included data from a pilot study[24] reported that daily adherence reached a plateau of over 50%, with a gradual decline from day six of the index patient's illness,[25] and 50% or less of participants were adherent to mask use in studies from Australia,[21] the US[19] and Hong Kong.[16, 17] Less than 30% of participants reported habitually wearing face masks in the enzyme treatment RCT set in Japan.[22] Face mask use was also reported in the cross-sectional study set in schools in South Korea,[18] where 44% of participants self-reported irregular or continuous face mask use. In the case-control study of passengers on a long haul flight, Zhang et al. reported that among control passengers who used face masks, four did not use them during the New York to Vancouver trip, and three did not use them during the Vancouver to Hong Kong trip, although the total number of controls wearing masks is not clearly reported.[32] For the four studies conducted during the COVID-19 pandemic, reported observed compliance rates among the general public in Hong Kong ranged from 95.7% to 97.2% across three days,[31] while 97.9% of participants in a Chinese study self-reported wearing a mask when they went out.[29] In the study set in Thailand, 14% of cases and 24% of controls reported wearing a mask all of the time.[28] In the study set in households in China, 37.1% of all included family units (primary cases and/or their household contacts) reported wearing masks all the time at home after illness onset, 29.8% reported wearing

masks sometimes, and 33.1% of families reported never wearing masks.[33] Data for individual family members were not presented.

Duration of mask use

Daily mask use (hours per day) was reported in two[15, 23] of the 19 studies and ranged from 3.5 hours per day[23] to 5.1 hours per day.[15] Six studies reported on the number of masks used as either per day (mean of 2[19]), per week (median of 9 for index cases and 4 for contacts,[16] median of 12 for index cases and 6 for contacts,[17] and mean of 12 masks per week[23]), or over eight days (median of 2.9 for mask group and 12.6 for mask plus hand hygiene group,[25] and median of 13 for mask group and 15 for mask plus hand hygiene group[24]).

Harms or adverse outcomes

Two of the 19 studies (reported across three publications)[21, 24, 25] reported on harms or adverse outcomes of face mask wearing. A study conducted in Germany (including data from an earlier pilot study)[24, 25] reported that 62% of participants did not report any problems with medical mask wearing, although children were significantly more likely to report problems than adults. The main problems noted by both adults and children were heat or humidity and pain. MacIntyre et al.[21] reported that around half of medical mask users reported some concerns with wearing masks, most commonly that they were uncomfortable. Participants also reported forgetting to wear the mask, and that children did not like them.[21] Simmermann et al. 2011[23] reported that although secondary laboratory-confirmed influenza infection was not significantly different between the intervention and control groups, there was an increased risk of self-reported ILI in both the hand washing only and the medical mask plus hand washing groups relative to the control group. Doung-ngern found that individuals who reported wearing masks all the time were more likely than those who did not wear masks to wash their hands regularly and practice physical distancing. Those who only reported wearing masks sometimes were more likely to wash their hands than those who did not wear masks, but were also more likely to have physical contact and a longer duration of contact.[28] No other harms or adverse outcomes were reported.

Comparisons of different types of masks

Eight of the studies included in this evidence summary were based on the use of standard medical or surgical masks (referred to collectively in this report as medical masks), with nine studies not reporting on the types of masks worn by participants. One study compared medical masks with P2 masks (which are almost identical in specification to N95 masks), finding no differences in ILI or laboratory-confirmed infections between the two types of masks.[21] One study included both medical and non-medical masks.[28] This study reported that while wearing medical masks was

associated with a significantly reduced risk of SARS-CoV-2 infection compared with not wearing a mask, wearing non-medical masks or alternating between medical and non-medical masks was not. One study included all types of masks (N95, medical and cloth), but did not present separate data.[33]

Risk of bias and study quality

The primary studies included in this evidence summary were of low quality with a high risk of bias. Allocation concealment was unclear in all nine RCTs, with a high risk of bias from lack of blinding of study personnel, participants and outcome assessments due to the nature of the interventions (Appendix 3). A common limitation of included RCTs was that they contained limited sample sizes with low infection rates. Compliance with face masks was reported to be poor by some studies, while a substantial number of control participants reported using face masks. Another common issue in household settings was the delay in implementing the interventions, which could lead to an underestimation of the true effect of the interventions.[25] For the case-control studies, it is not clear how well cases and controls were matched, and wearing of face masks was based on self-report in nine of ten observational studies. Observational studies are subject to selection and reporting biases as well as difficulties with controlling for all potential confounding factors. The cross-sectional survey by Xu et al. was based on a non-random snowball sample, and while the authors reported that the web page hosting the survey was accessed over 21,000 times, it is not known how many people received the link, leading to potentially high reporting and selection biases. It is not possible to establish causal links between wearing of face masks and respiratory virus infection based on observational studies. Two of the four studies conducted during the COVID-19 pandemic are published as pre-prints, so they have not been formally peer-reviewed[28, 29] and it is possible that the data could change prior to publication. Findings from these studies should be interpreted with caution.

Discussion

This evidence summary included 19 studies providing direct evidence in community settings that compared wearing face masks with not wearing face masks on the transmission of respiratory pathogens, including SARS-CoV-2. Four observational studies explored the effectiveness of face masks during the present COVID-19 pandemic. While the findings across these four studies are consistent and suggest that face masks may reduce the risk of infection in community and household settings, the quality of the evidence is low. Two of the four studies have as yet only been published as pre-prints, so have not been formally peer-reviewed. The remaining direct evidence on the use of face masks by healthy people in the community comes from studies of SARS, influenza, or influenza like illness (ILI). Two case-control studies conducted during the SARS pandemic reported that wearing

face masks when out in public was protective against SARS infection. All nine RCTs conducted to date have investigated the effectiveness of face masks against influenza or ILI infections, and have mainly been set in households, with a smaller number conducted in schools and university halls of residence. The RCTs provide some weak evidence that medical masks worn by both index cases and healthy household contacts can reduce the risk of secondary household infections, when implemented early, combined with intensified hand hygiene and subject to good levels of compliance. Overall, the findings across the included studies are broadly consistent and suggest that face masks may reduce the risk of infection in community settings. However, the included studies were of poor quality, with a high risk of bias, therefore, it remains difficult to reach a definitive conclusion on the effectiveness of face masks in the community.

Systematic reviews of the direct evidence on the use of face masks

In addition to the 19 studies included in this summary, 18 systematic reviews[34-51] that included studies of face mask use in community settings were identified (Appendix 2). These systematic reviews include studies conducted in healthcare settings, in addition to those included in this evidence summary, with conclusions of the systematic reviews based on evidence from across all settings. While 11 of the 18 reviews have been published since the beginning of 2020, none have included studies on the use of face masks in the community during the COVID-19 pandemic. The findings and conclusions of these systematic reviews have varied depending on the studies included in each review, although most agree that there is a lack of high-quality evidence. Table 2 displays the individual studies included in each of the systematic reviews conducted to date.

None of the systematic reviews fulfilled all items of AMSTAR-2.[52] The confidence in the results was graded as critically low for ten of the systematic reviews.[34-37, 40, 42, 45, 48, 49, 51] Saunders-Hastings et al. noted performance, detection and reporting biases in the studies included in their systematic review, and suggested that cases and controls may misjudge their adoption of personal protective measures in order to rationalise their infection status.[41] A 2011 Cochrane review highlighted a lack of reporting of virus circulation in the reference population of included studies, making interpretation and generalisability of conclusions questionable.[38] The best evidence comes from this 2011 Cochrane review,[38] which was graded as moderate, with the non-peer reviewed 2020 update graded as low to moderate,[39] and a systematic review by Chu et al., which was graded as moderate.[50]

The 2011 Cochrane review included 67 studies conducted in both healthcare and community settings of physical interventions to interrupt or reduce the spread of respiratory viruses.[38] Based on pooled results of case control studies, the authors concluded that masks were the best performing of a range of physical interventions

to prevent respiratory virus transmission. However, this conclusion was based mainly on studies of healthcare workers, as only five[14, 16, 19, 20, 27] of the included studies reported on use of face masks in community settings. An update to this Cochrane review, which has not been peer reviewed, included 14 RCTs focusing on face mask use in the general population, and found that there was no reduction of influenza-like illness (ILI) cases (RR 0.93, 95% CI 0.83 to 1.05) or influenza (RR 0.84, 95% CI 0.61 to 1.17).[39] Based on observational evidence from the SARS epidemic included in the 2011 Cochrane review, the authors recommended the use of masks only when combined with other measures.[39]

The systematic review by Chu et al., published on 1 June 2020, examined physical distancing, face masks, and eye protection to prevent person-to-person transmission of COVID-19. This review suggested that wearing face masks could result in a 'large reduction in risk of infection'.[50] However, only three of 30 included studies were conducted in non-healthcare settings; all three studies were conducted during the SARS-CoV-1 pandemic and are included in this evidence summary.[20, 27, 30]

Table 2. Primary studies included in each systematic review

Primary study	Wei 2020[49]	Liang 2020[46]	Gupta 2020[45]	Chou 2020[44]	Chu 2020[50]	MacIntyre 2020[51]	Stern 2020[48]	Brainard 2020[36]	Xiao 2020[42]	Jefferson 2020[39]	Saunders-Hastings 2017[41]	MacIntyre 2015[40]	Wong 2014[43]	Bin-Reza 2012[35]	Jefferson 2011[38]	Cowling 2010[37]
Aiello 2010[14]	■			■		■	■	■	■	■		■	■	■	■	■
Aiello 2012[15]	■	■	■	■		■		■	■	■		■	■			
Cheng 2020[31]																
Cowling 2008[17]	■	■	■	■		■		■	■	■		■		■		■
Cowling 2009[16]		■	■	■		■	■	■	■			■	■	■	■	■
Doung-ngern 2020[28]																
Kim 2012[18]								■			■					
Larson 2010[19]			■	■		■	■	■	■			■	■	■	■	
Lau 2004[20]			■	■	■			■						■	■	
MacIntyre 2009[21]	■		■	■		■	■	■	■	■		■		■		■
Shin 2018[22]								■								
Simmerman 2011[23]			■	■		■	■	■	■			■	■			
Suess 2012[25]	■	■	■	■		■		■	■	■	■	■	■			
Tuan 2007[30]				■	■											
Uchida 2017[26]							■	■								
Wang 2020[33]																
Wu 2004[27]		■	■	■	■			■						■	■	
Xu 2020[29]																
Zhang 2013[32]		■														

Note: Shaded areas indicate the primary studies in each review.
The review by Aledort 2007[34] is not included, as it did not clearly state which studies were included. The 'empty' review by Marasinghe 2020[47] is not included as it does not contain any studies.

Face masks in other settings

A number of studies have explored the effectiveness of face masks against respiratory infections in the context of the Hajj pilgrimages, with a meta-analysis reporting that face masks were significantly protective against respiratory infections (RR 0.89, 95% CI 0.84 to 0.94).[53] However, there was significant heterogeneity in study questions, assessment methods, study designs, quality, and endpoints, leading to high levels of uncertainty around the pooled estimates.[53] The Hajj mass gatherings, which are attended by over two million people a year and are characterised by exceptionally high levels of close contact[53] are also unlikely to be applicable to other contexts.

Face masks in the context of COVID-19 transmission

The direct evidence on face mask use in the community is limited to heterogeneous studies of poor quality and a high risk of bias. Findings from many of these studies are based on per protocol or post-hoc analyses, with important methodological differences that make it difficult to interpret the body of evidence and reach definitive conclusions. All previous systematic reviews conducted to date are based on the same pool of primary studies, many of which focus on influenza and influenza-like illness. The extent to which findings from studies of other respiratory viruses are applicable to the current pandemic is unclear, and there is a limited number of studies that have explored the effectiveness of face masks worn by healthy people in the community to reduce the spread of COVID-19. Four studies were identified that reported on direct use of face masks during the COVID-19 pandemic. These studies suggest that wearing face masks may reduce the risk of transmission, although the quality of the evidence is low.

A number of studies estimating the impact of policies mandating face mask use in public on COVID-19 incidence were identified, but were not included in this review. These studies provide indirect evidence on transmission, and it is not possible to control for the effects of other simultaneous societal level interventions. A non-peer reviewed report by Mitze et al. analysed the effect of face mask use on the spread of COVID-19 in Germany using synthetic control methods.[54] Following the early introduction of compulsory face masks on public transport and in retail outlets in the city of Jena on 6 April 2020, there was an observed reduction of 23% in the cumulative number of reported COVID-19 cases after 20 days, relative to a synthetic control group. No other public health measures were introduced or eased until 20 April 2020, suggesting that the effect was a result of the introduction of the mandatory use of face masks. The authors further reported that for other regions in Germany that introduced mandatory use of face masks prior to their introduction at the federal level, the cumulative number of registered COVID-19 cases was reduced

between 2.3% and 13.0% over a period of 10 days. This study could not control for the different types of masks that may have been worn in public.

Lyu and Wehby reported a natural experiment on the effect of US state-level mandates for face masks in public between 8 April and 15 May 2020.[55] The authors compared the changes in COVID-19 spread in 15 US states (plus the District of Columbia) that had issued mandates for the use of face coverings in public settings, including public transport and retail, to 15 states that had not issued such mandates. Mandated face mask use in public was associated with a significant decline of 2 percentage points in the daily growth rate of COVID-19 after 21+ days. The authors highlighted that their findings described the intention to treat effect of face mask mandates at a community or state level, and do not indicate the effect of wearing a face mask in public at an individual level. In an analysis of potential predictors of per-capita coronavirus-related mortality, Leffler et al. identified 18 countries with recommendations for mask wearing.[56] In an unadjusted analysis, the authors reported that the duration of mask-wearing by the public was negatively associated with mortality. A number of studies have reported similar positive findings, suggesting that policies mandating face masks are associated with a subsequent decrease in COVID-19 cases.[57, 58] However, these policies are rarely introduced in isolation, and it can be hard to disentangle the effects of multiple measures targeting reduced transmission. One non-peer reviewed quasi-experimental study of non-pharmaceutical interventions in Europe found that wearing face masks in public was not associated with any independent additional impact on incidence of COVID-19, once other public health measures were accounted for.[59] However, the authors noted that the specific settings in which face masks were made either mandatory or voluntary varied between countries. As with the reports by Mitze et al. and Lyu and Wehby, this study does not provide direct evidence of the effectiveness of wearing face masks at an individual level.

A modelling study by Bouchnita et al. used a multi-scale social force model to quantify the effects of population movement restrictions and mandatory face mask use on COVID-19 transmission dynamics in Morocco.[60] The model predicted that adopting both measures would lead to a 64% reduction in the cumulative number of infected cases. However, the authors note that the model relies on a number of assumptions that are difficult to verify. A mathematical model for assessing the population-level impact of control and mitigation strategies in New York, estimated that the use of medical masks in public could lead to the elimination of the pandemic if at least 70% of the residents used them, based on a high compliance rate.[61] The authors also suggested that the use of cloth masks could lead to a significant reduction, but not elimination, of the burden of COVID-19. Again using data from the US in a compartmental model for assessing the community-wide impact of mask use, Eikenberry et al. reported that broad adoption of even relatively ineffective face

masks may meaningfully reduce community transmission of COVID-19 in both healthy and asymptomatic persons.[62]

Indirect evidence on face mask use in the community

Recommendations for the use of face masks in the community are mainly based on indirect evidence and physiological plausibility regarding the potentially protective effects of face masks. An analysis published in the British Medical Journal on 9 April 2020 highlighted that the small number of heterogeneous studies on face mask use in the community have been interpreted inconsistently by policy-makers.[63] The authors suggested that 'substantial indirect evidence exists to support the argument for the public wearing masks in the COVID-19 pandemic', and argued that, on the basis of the precautionary principle, face masks worn both in and outside of the home 'could have a substantial impact on transmission with a relatively small impact on social and economic life.'[63] Wearing face masks in community settings is posited to lead to reduced droplet transmission from individuals who have mild disease or who are pre-symptomatic or asymptomatic, thereby acting as a form of source control.[64] A review that examined the evidence in relation to transmission characteristics of COVID-19, filtering characteristics and efficacy of masks, estimated population impacts of widespread community mask use, and the sociological considerations for policies concerning mask wearing, similarly recommended 'the adoption of public cloth mask wearing, as an effective form of source control, in conjunction with existing hygiene, distancing, and contact tracing strategies'.[65, 66]

An observational study published on 3 April 2020 of 246 participants with medically-attended acute respiratory virus illnesses (not COVID-19) found that the detection of influenza virus RNA in respiratory droplets was significantly reduced during a 30 minute exhaled breath collection when participants wore surgical face masks.[67] There was a trend toward a reduced detection of coronavirus RNA in respiratory droplets, leading the authors to conclude that surgical face masks could be effective when used by ill individuals to reduce onward transmission.[67] A 2013 study reported that both homemade cloth masks (made from 100% cotton t-shirts) and medical masks significantly reduced the number of microorganisms expelled by 21 healthy volunteers in a controlled setting, although medical masks were three times more effective in blocking transmission compared to cloth masks.[68] The authors concluded that cloth masks should be considered only as a last resort, but may be more effective than not wearing a mask at all.

The extent to which studies conducted on other respiratory pathogens are applicable or generalisable to SARS-CoV-2 is questionable. HIQA's previous evidence reviews[69] have highlighted that there is evidence to suggest COVID-19 can be transmitted before symptom onset, and laboratory-confirmed cases can remain asymptomatic, but infectious.[70] In addition, it is speculated that SARS CoV-2, with an estimated

basic reproduction number (R_0) ranging from 1.94 to 5.81,[71, 72] is more infectious than a number of other pathogens causing respiratory diseases. More recent studies have indicated a higher transmission potential for SARS-CoV-2 than anticipated earlier in the pandemic. Other respiratory pathogens, including SARS CoV-1 (estimated reproduction number (R_0) of 1.77),[73] pandemic 2009 H1N1 (estimated R_0 1.46), 1918 pandemic H1N1 (estimated R_0 1.8), seasonal influenza (estimated R_0 1.27),[74] and MERS-CoV (estimated R_0 <1)[75] are less transmissible than SARS-CoV-2. These data emphasise the increased risk of transmission with SARS-CoV-2 compared with other respiratory viruses and the necessity of considering a range of infection prevention control (IPC) measures, including face masks, to reduce the spread of infection. It has been suggested that, in the absence of other data, community wide wearing of masks should be promoted according to the precautionary principle.[63, 76]

A growing number of studies have also considered the potential modes of transmission of SARS-CoV-2, with important implications for recommendations for appropriate personal protective equipment (PPE), including face masks. HIQA's evidence summary on airborne transmission of SARS-CoV-2 via aerosols included epidemiological case series, air sampling and microbiological studies.[5] The review identified limited, low certainty evidence from a small number of retrospective epidemiological studies that suggest possible aerosol transmission of SARS-CoV-2. Results from air sampling and microbiological studies added plausibility to the potential for SARS-CoV-2 to transmit via aerosols; however, evidence of clinical infectivity was not shown in these study types. Overall, the review concluded that while there is some evidence to suggest a potential for SARS-CoV-2 to transmit via aerosols, it is not known if this is restricted to specific contexts, for example, enclosed or poorly ventilated environments. The contribution aerosols make relative to other transmission modes (contact and droplet) to the COVID-19 pandemic was also noted to be uncertain. While the potential for aerosol transmission is acknowledged, others have suggested that it does not appear to be the primary route of transmission of SARS-CoV-2.[77]

Potential harms of face masks

The WHO has suggested that face masks may introduce a false sense of security and lead wearers to neglect hand hygiene and physical distancing.[78] While this has generally not been supported from the evidence reviewed for this summary, one case-control study conducted during the COVID-19 pandemic reported that while individuals who reported wearing masks all the time were more likely to wash their hands regularly and practice physical distancing than those who did not wear masks, those who reported sometimes wearing masks were more likely to have physical contact and longer duration of contact, although they were also more likely to wash

their hands.[28] A pre-print systematic review of the 'downsides' of face masks posted on 19 June 2020, which has not yet been peer-reviewed, found no studies that directly investigated or quantified risk compensation behaviour.[79] In the context of COVID-19, Howard et al. have argued that any risk compensation that may occur in some individuals would be dwarfed by the potential protective impact at the population level.[65]

Where wearing face masks is recommended, this should be accompanied by a comprehensive strategy to address safe wearing, handling and disposal of face masks to reduce the potential for self-contamination. While a limited number of potential harms of wearing masks were reported by some studies, mainly related to discomfort, heat, humidity and pain, none of the studies included in this evidence summary specifically commented on safety. Where the supply of medical or respirator masks is low, these must always be reserved for use in healthcare settings. This acknowledgement has led some to advocate wearing reusable cloth masks.[8, 65, 80] However, this recommendation is mainly based on the precautionary principle and hypothetical plausibility of the potential effectiveness of cloth masks as outlined by Howard et al.[65] One study that included both medical and non-medical masks, reported that while wearing medical masks was associated with a significantly reduced risk of SARS-CoV-2 infection compared to not wearing a mask, wearing non-medical masks or alternating between medical and non-medical masks was not.[28] Few included studies reported on compliance rates across the general population, and the extent to which the public has consistently adopted recommendations is unknown. Based on observing shoppers in 26 US grocery stores (3,271 individuals), Arp et al. reported that 40% used face coverings, with higher odds of using face coverings for females or older adults.[81] A study of mass face mask use during COVID-19 in low and middle income countries published in July 2020 reported adherence rates greater than 90% in countries where face masks were mandatory or 'highly encouraged' during the early phase of the pandemic, although data on effectiveness were not reported.[82]

Findings from studies of face masks to reduce transmission of influenza or ILI in households suggest that compliance with wearing face masks may play an important role in determining their efficacy. While compliance with face masks in two of the four studies conducted during the COVID-19 pandemic was very high, these studies were set in Hong Kong and China, where there is a stronger tradition of mask use in community settings. It is not clear to what extent the findings from these studies are applicable to the Irish setting.

Conclusion

There is limited, low certainty evidence based on four observational studies conducted during the COVID-19 pandemic that face masks may reduce the risk of transmission of SARS-CoV-2. Studies from previous pandemic settings and for other respiratory viruses also provide low certainty evidence that the wearing of face masks in community settings reduces the risk of transmission of respiratory pathogens. However, their applicability to COVID-19 is uncertain given possible differences between viruses in their pathogenicity, infectivity and potential differences in the relative contribution of the different modes of transmission (droplet, aerosol, contact). Elsewhere, epidemiological, air sampling and microbiological studies have been noted to provide some low certainty evidence for possible aerosol transmission of SARS-CoV-2, although its contribution relative to droplet and contact transmission is uncertain. National and international public health guidance on the use of face masks is based on low certainty direct evidence of clinical effectiveness, indirect evidence that supports plausibility of effectiveness, as well as a consideration that SARS-CoV-2 appears to be more infectious than many other respiratory pathogens studied to date. Chou et al. identified five studies that are ongoing, however, only one of these is set outside of healthcare settings.[83] Further research is urgently required, particularly high quality studies that provide direct evidence on the use of face masks by healthy people in the community. The WHO has urged countries that have recommended the wearing of face masks by healthy people in community settings to 'conduct research on this important topic'.[1]

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Appendix 1: Characteristics of studies included in this summary

Author Country Study Design DOI	Population setting, Intervention and Comparison	Primary Outcome Result	Other results	Other points to note/limitations
Aiello 2010[14] **US** **Cluster RCT** **https://doi.org/10.1086/650396**	**Population setting** *Included for analysis* 1,297 young adults living in university residence halls during 2006–2007 influenza season included for analysis **Participant demographics** *Age:* Mean 18.7 years (SD 0.8) *Sex:* Male, 436 (34%); Female, 861 (66%) **Respiratory virus** Incident ILI (self-reported and or detailed in clinic visits) and throat swab detected influenza (laboratory-confirmed influenza A or B using RT-PCR) **Randomisation** Randomisation at residence hall/hall group level. N=7 residence halls randomised into 3 arms of study. **Intervention/s** *Face mask alone* Residence halls: n=4; Participants: n=367 *Face masks and hand hygiene (sanitiser)* Residence halls: n=1; Participants: n=378	**ILI based on survey report or clinic visit** ***Face mask alone group:*** Reduction in ILI versus control group during weeks 4-6, but rate ratio estimates adjusted for vaccination and other covariates were not statistically significant (at p threshold <.025): Week 4: RR 0.72 (95% CI 0.53-0.98), Week 5: RR 0.65 (95% CI 0.43-0.98), Week 6: RR 0.58 (95% CI 0.34-1.00). No significant reduction in weeks 1, 2, or 3, or cumulatively over the full 6 weeks: Cumulative adjusted RR 0.90 (95% CI 0.77-1.05). ***Face mask plus hand hygiene group:*** Significant reductions (at p threshold <.025) in ILI versus control group during weeks 4-6: Week 4: RR 0.65 (95% CI: 0.47–0.91), Week 5: RR 0.56 (95% CI: 0.36–0.88), Week 6: RR 0.49 (95% CI: 0.27–0.87), adjusting for vaccination and other covariates. No significant reduction in weeks 1, 2, or 3, or cumulatively over the full 6 weeks: Cumulative adjusted RR 0.87 (95% CI 0.73-1.02).	**Adherence/compliance** Reported in Appendix (not available online) **Duration/frequency of mask wearing** Reported in Appendix (not available online) **Harms** Not reported.	Study not powered to detect small differences between the intervention groups. Largely based on self-report

	Participants asked to wear face masks as much as possible in their residence hall during intervention period, encouraged to wear outside halls also. Daily change of masks was provided. **Control** No face mask or hand sanitiser provided Residence halls: n=2; Participants: n=552 **Duration of intervention** 6 weeks **Type of face mask** Standard medical procedure masks with ear loops (TECNOL procedure masks; Kimberly-Clark)			
Aiello 2012[15] **US** **Cluster RCT** **https://doi.org/10.1371/journal.pone.0029744**	**Population setting** *Included for analysis* 1,111 young adults living in 37 residence houses in 5 university residence halls during 2007–2008 influenza season included for analysis **Participant demographics** *Age:* Mean 18.95 years (SD 0.9) *Sex:* Male, 496 (45%); Female, 611 (55%) **Respiratory virus** Incident ILI (self-reported and or detailed in clinic visits) and throat swab detected influenza (laboratory-confirmed influenza A or B using RT-PCR) **Randomisation**	**ILI based on survey report or clinic visit** *Face mask alone group:* Adjusted rate ratio estimates showed no statistically significant reduction in ILI for any individual week or cumulatively over the study period (p threshold <0.05): RR 1.10 (95% CI: 0.88-1.38). *Face mask and hand hygiene group:* Significant reductions in ILI rates versus control group in each of weeks 3,4,5 and 6 of study: Week 3: RR 0.52 (95% CI: 0.30–0.88), Week 4: RR 0.40 (95% CI: 0.20–0.83), Week 5: RR 0.32 (95% CI: 0.12–0.84),	**Adherence/compliance** Mask compliance examined anonymously in residence halls by trained staff. Staff observed an average of 0.0007 participants properly wearing a mask for each hour of observation over the 6 week study period. The % of observational shifts in which participants were observed to be properly wearing face masks ranged from 0% to 41.7% of shifts across the 6 weeks. However not possible to gather observational data	Study not powered to detect small differences between the intervention groups. Largely based on self-report.

	Randomisation at residence hall/hall group level. N=37 residence halls randomised into 3 arms of study. **Intervention/s** *1. Face mask alone* Residence halls: n=13; Participants: n=392 *2. Face mask and hand hygiene (sanitiser)* Residence halls: n=12; Participants: n=349 Participants were asked to wear face masks for at least 6 hrs per day while in their residence hall during intervention period, and encouraged but not obliged to wear them outside residence halls. Daily change of masks was provided. **Control** No intervention Residence halls: n=12; Participants: n=370 **Duration of intervention** 6 weeks **Type of face mask** Standard medical procedure masks with ear loops (TECNOL™ procedure masks; Kimberly-Clark, Rosewell GA)	Week 6: RR 0.25 (95% CI: 0.07–0.87), adjusted for vaccination and other covariates. Statistically non-significant reduction in the rate of ILI cumulatively (over the entire 6 weeks: RR 0.78 (95% CI: 0.57-1.08) **Influenza (laboratory-confirmed)** *Face mask alone group:* No significant reduction in influenza rate over 6 weeks: RR 0.92 (95% CI 0.59-1.42), adjusted for vaccination and other covariates. *Face mask and hand hygiene group:* Statistically non-significant reduction in influenza rate over the 6 weeks: RR 0.57 (95% CI 0.26-1.24), adjusted for vaccination and other covariates.	on all participants at all time and venues. **Duration/frequency of mask wearing** (based on self-report) Face mask and hand hygiene group: average 5.08 hrs/day (SD, 2.23) compared with an average of 5.04 hrs/day (SD 2.20) in mask only group (intervention requested 6 hrs of use per day). No significant difference between groups throughout the study. **Harms** Not reported.	
Cheng 2020[31] **Hong Kong** **Observational study**	**Population setting** 961 patients diagnosed with COVID-19 in Hong Kong between 31 Dec 2019 and 8 Apr 2020. **Participant demographics** Not reported.	**Comparison of Hong Kong (universal mask wearing) with other countries (no universal mask wearing)** The incidence of COVID-19 in Hong Kong (129 per million population) was significantly lower ($p < 0.001$) than that in countries where face	**Adherence/compliance** The compliance of face mask usage by the general public was reported to be 96.6% (range: 95.7% to 97.2%).	This study excluded 15 family clusters. The authors conclude that community-wide mask wearing may

https://doi.org/10.1016/j.jinf.2020.04.024	**Respiratory virus** SARS-CoV-2 **Intervention/s:** N/A: non-interventional study **Type of face mask:** Not reported, although the public health advice was to 'wear a surgical mask' if an individual developed respiratory symptoms. The authors suggest that due to prior experience with SARS, the general public spontaneously adopted mask wearing soon after the first imported case of COVID-19 was reported.	mask usage was not (at the time) universally adopted in the community: Spain (2,983), Italy (2,250), Germany (1,242), France (1,152), US (1,103), U.K. (832), Singapore (260), and South Korea (201). Comparison countries were selected on the basis of having well-established health systems and over 100 confirmed cases on the day the pandemic was declared by the WHO. **Clusters of COVID-19 cases arising from mask-on vs. mask-off settings** Major clusters arising from mask-on (workplace) and mask-off (recreational) settings were analysed to evaluate the efficacy of wearing face masks. Among the 961 confirmed cases, there were 11 clusters comprising a total of 113 persons that were directly engaged in mask-off activities such as dining and drinking in a restaurant or bar, karaoke, and exercise in fitness clubs. This was compared to 3 clusters of 11 people in workplace 'mask-on' settings (p = 0.036).	Compliance was monitored by 67 staff members (residing in all 18 administrative districts) working in the Infection Control Unit, and Department of Microbiology, Queen Mary Hospital for 3 consecutive days from 6 Apr to 8 Apr 2020. Each staff member counted the number of persons not wearing a mask among the first 50 persons encountered in the street during their morning commute. A total of 10,050 persons were observed; only 337 (3.4%) persons did not wear a face mask.	contribute to the control of COVID-19 by reducing the amount of emission of infected saliva and respiratory droplets from individuals with subclinical or mild COVID-19.
Cowling 2009[16] **Hong Kong** **Cluster RCT** **https://doi.org/10.7326/0003-4819-151-**	**Population setting** *Included in analysis* 259 index patients presenting to 45 outpatient clinics in Hong Kong with ILIs (at least 2 of: temperature ≥37.8 °C, cough, headache, sore throat, myalgia) who were positive for influenza A or B virus by rapid testing. Participants and their household contacts were randomly assigned to 1 of 3 groups: control (lifestyle	**Influenza secondary attack ratio (SAR) at the individual level (the proportion of household contacts infected with influenza virus)** No significant difference in % of contact infections (RT-PCR confirmed influenza) between the 3 groups (p=0.22): *Face mask + hand hygiene:* 7% (95% CI: 4-11)	**Adherence/compliance** Face mask use: Index patients reported greater use of face masks than household contacts (see "duration of use" below)	Potential bias from recruiting symptomatic persons. Contamination between groups with face mask use also practiced in hand hygiene and control groups.

7-200910060-00142	measures), control plus enhanced hand hygiene only, and control plus face masks and enhanced hand hygiene. **Participant demographics** *Face mask plus hand hygiene:* Index cases (n=83): *Age:* Median 10 years (IQR 6-20) *Sex:* Men, 33 (40%); Female, 50 (60%) Contacts (n=258): *Age:* Median 38 years (IQR 27-48) *Sex:* Male, 98 (38%); Female, 160 (62%) *Hand hygiene only:* Index cases (n=85): *Age:* Median 11 years (IQR 8-28) *Sex:* Men, 41 (48%); Female, 44 (52%) Contacts (n=257): *Age:* Median 40 years (IQR 28-49) *Sex:* Male, 103 (40%); Female, 154 (60%) *Control:* Index cases (n=91): *Age:* Median 9 years (IQR 6-12) *Sex:* Men, 44 (48%); Female, 47 (52%) Contacts (n=279): *Age:* Median 38 years (IQR 26-45) *Sex:* Male, 105 (38%); Female, 174 (62%) **Respiratory virus** Influenza **Randomisation** Household level	*Hand hygiene only:* 5% (95% CI: 3-9) *Control:* 10% (95% CI: 6-14) Adjusted Odds Ratios (aOR) for the odds of RT-PCR-confirmed influenza did not show a significantly reduced odds of infection versus control: *Face mask + hand hygiene, versus control:* aOR 0.77 (95% CI: 0.38-1.55)[+] *Hand hygiene versus control:* aOR 0.57 (95% CI: 0.26-1.22)[+] [+]Adjusted for: intervention group; age, sex, vaccination history of contact; and index patient; age, sex, and antiviral use. *Subgroup analysis:* Analysis of risk of infection when intervention was applied within 36 hrs of index patient's symptom onset (n=462 contacts, n=154 households): *Face mask + hand hygiene versus control:* OR 0.33 (95% CI: 0.13-0.87) [+] *Hand hygiene versus control:* OR 0.46 (95% CI: 0.15-1.43) [+] [+]Adjusted for intervention group; age, sex, vaccination history of contact; and age, sex, and antiviral use of index patient No significant difference was found between the two intervention groups: OR 0.72 (95% CI: 0.21-2.48).	Adherence was similar in the subgroup of households in which the intervention was applied within 36 hrs of symptom onset in the index patient. **Duration/frequency of mask wearing** Face mask group: Proportion of individuals who reported wearing a surgical face mask often/always (rather than sometimes /never) during follow-up period: Index 49%, Contact 26% (within face mask group) Median number (IQR) of masks used: Index: 9 (3.0-16.3) Contact: 4 (0.0-9.0) **Harms** Not reported.	Proportion of individuals who reported wearing a surgical face mask often/always (rather than sometimes /never) during follow-up period: Hand hygiene group: Index, 31%, Contact 5%; Control group: Index 15%, Contact 7%

	Intervention/s 1. *Face masks + hand hygiene + lifestyle measures* Index cases: n=83, Contacts: n=258 Index patients and all household contacts were requested to wear masks as often as possible at home during 7-day follow-up period (except when eating or sleeping) and also when the index patient was with the household members outside of the household. Box of 50 masks provided for each member (or 75 per child). 2. *Hand hygiene + lifestyle measures* Index cases: n=85 Contacts: n=257 All household members (including the index patient) received education about the potential efficacy of proper hand hygiene in reducing transmission and were instructed when and how to use provided liquid soap and alcohol hand rub. **Control** Index cases: n=91; Contacts: n=279 Lifestyle measures only. Education about the importance of a healthy diet and lifestyle, both in terms of illness prevention (for household contacts) and symptom alleviation (for the index case). **Duration of intervention** Home visit up to 2 days post randomisation. Outcomes assessed up to 6 days after initial home visit (up to day 8 post randomisation).			

	Type of face mask Surgical face mask (TECNOL-The Lite One; Kimberly-Clark). Paediatric masks for children (aged 3-7).			
Cowling 2008[17] **Hong Kong** **Cluster RCT** **https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2364646/pdf/pone.0002101.pdf**	**Population setting** *Included in analysis* 128 index patients aged 2+ years (and respective households) followed up and analysed post randomisation. Patients were identified from 30 outpatient clinics in Hong Kong having reported ILI (at least 2 of: temperature ≥37.8 °C, cough, headache, sore throat, myalgia) and who were positive for influenza A or B virus by rapid testing. Participants and their household contacts were randomly assigned to 1 of 3 groups: control (lifestyle measures), control plus enhanced hand hygiene only, and control plus face masks. **Participant demographics** *All index cases (n=128)* *Age:* • 2-15 years, 54 (42.2%) • 16-30, 19 (14.8%) • 31-50, 33 (25.8%) • 50+, 22 (17.2%) *Sex:* Male, 56 (43.8%); Female, 72 (56.3%) *All contacts (n=370)* *Age:* • 0-15 years, 57 (15.4%) • 16-30, 73 (19.7%)	**Influenza secondary attack ratio (SAR) at the individual level (the proportion of household contacts infected with influenza virus)** The overall laboratory-confirmed secondary attack ratio (SAR) was 6.0% (95% CI: 3.8%–9.0%) while the clinically diagnosed SARs were 18%, 11% and 5% according to 3 alternative definitions, with little difference between intervention arms. (Definition 1: fever≥38C or at least 2 of headache, runny nose, sore throat, aches or pains in muscles or joints, cough, or fatigue. Definition 2: at least 2 of fever≥38C, cough, headache, sore throat, aches or pains in muscles or joints. Definition 3: standard CDC classification of fever ≥38C plus cough or sore throat.) Laboratory-confirmed SARs by intervention group (proportion of household contacts infected with influenza virus): No difference between groups (p=0.99): *Face mask:* 7% (95% CI: 2-16) *Hand hygiene*: 6% (95% CI: 2-13) Control: 6% (95% CI: 3-10)	**Adherence/compliance** Face mask use: Generally low adherence with more than 1 in 4 household contacts in the face mask group not wearing a surgical mask at all during follow-up period. 45% of index subjects and 21% of household contacts in the face mask arm reported wearing a mask often/always during follow-up period. At the final home visits the index subjects had used a median of 12 masks (inter-quartile range, IQR: 6, 18) whereas household contacts had only used a median of 6 (IQR: 1, 20). **Duration/frequency of mask wearing** Not reported. **Harms** No allergic reactions reported nor other	Pilot & feasibility study that preceded study reported in Cowling 2009. Not powered to assess the relative efficacy of the interventions. Contamination observed as more than 1 in 4 index cases in the hand hygiene and control arms reported wearing masks at home of their own accord.

	• 31-50, 155 (41.9%) • 50+, 80 (21.6%) *Sex:* Men, 146 (39.5%); Female, 224 (60.5%) **Respiratory virus** Influenza. Index cases either tested positive for influenza A or B virus by rapid testing or tested negative by rapid testing but had fever ≥38^{0}C. **Intervention/s** 1. *Face mask (n=22 index cases, n=65 contacts)* Participants taught to wear masks as often as possible at home (except when eating and sleeping) and when the index was with the household members outside of the household. Box of 50 masks provided for each member (or 75 per child). 2. *Hand hygiene. (n=32 index cases, n=92 contacts)* All household members taught when and how to use the provided liquid soap (in place of their regular soap), hand sanitizer and hand gel. **Control (n=74 index cases; n=213 contacts)** Education about importance of healthy diet & lifestyle, illness prevention and symptom alleviation **Duration of intervention**	Similarly, no difference was found between the groups when each of the 3 clinical influenza definitions were applied.	conditions requiring medical attention.	

	Home visit within 36 hrs post randomisation. Outcomes assessed in home visits at 3, 6 and 9 days following baseline home visit. **Type of face mask** Surgical face mask (TECNOL-The Lite One; Kimberly-Clark) for adults. Paediatric masks for children (3-7 years).			
Doung-ngern 2020[28] (preprint) **Thailand** **Case-control study** **https://www.medrxiv.org/content/medrxiv/early/2020/06/19/2020.06.11.20128900.full.pdf**	**Population setting** *Included for analysis:* 1,050 contacts who had contact with or were in the same location as a symptomatic COVID-19 patient, and had no symptoms of COVID-19 on the first day of contact. Contacts were identified through contact tracing of 18 PCR-confirmed COVID-19 patients, from nightclub (n=374), boxing stadium (n=645) and state enterprise office (n=31) clusters, between 1 and 31 March 2020. *Cases* n=211 (contacts diagnosed with PCR-confirmed COVID-19 by 21 Apr 2020). *Controls* n=839 (contacts not diagnosed with PCR-confirmed COVID-19 by 21 Apr 2020. 719 controls (86%) were tested with PCR assays at least once). **Participant demographics** *All contacts* Age: Median 38 years (IQR: 28-51 years)	Wearing a mask all of the time was associated with a lower risk of infection: aOR 0.23 (95% CI: 0.09 – 0.60) Wearing a mask sometimes was not significantly associated with a lower risk of infection: aOR 0.87 (95% CI: 0.41 – 1.84) (Unclear which covariates are controlled for. Estimated with a random effect for location and a random effect for index patient nested within the same location). **Type of mask worn** *(worn sometimes and always during the contact period)* *Cases* Medical: 72/211 (34%) Non-medical: 25/211 (12%) Both medical and non-medical: 12/211 (6%) *Controls* Medical: 209/834 (25%)	**Frequency of mask wearing** **(medical/non-medical) during the contact period*** *Cases* Never: 102/210 (49%) Sometimes: 79/210 (38%) All the time: 29/210 (14%) *Controls* Never: 500/823 (61%) Sometimes: 125/823 (15%) All the time: 198/823 (24%) *Wearing masks incorrectly (i.e. not covering both nose and mouth) was considered as not wearing	The authors estimated that if everyone wore a mask all the time, washed hands often, did not share a dish, cup or cigarette, maintained distances >1 meter and spent ≤15 minutes with close contacts, cases would have been reduced by 84%. Study design precludes confirmation of causal relationship between variables. Estimated odds ratios are based on the assumption that contact with the index patient occurred. Not possible to identify every potential contact and

	Sex: Male, 580 (55%); Female, 470 (45%) *Cases* Sex: Male, 146 (69%); Female, 65 (31%) *Controls* Sex: Male, 434 (52%); Female, 405 (48%) **Respiratory virus** SARS-CoV-2 **Intervention/s:** N/A: Non-interventional study **Type of face mask:** Medical mask, non-medical mask	Non-medical: 77/834 (9%) Both medical and non-medical: 48/834 (6%) In unadjusted analysis, wearing a medical mask (compared with no mask) was associated with a significantly reduced risk of infection [OR (95% CI): 0.25 (0.12, 0.53), p=0.03]. Wearing non-medical masks [OR (95% CI): 0.78 (0.32, 1.90) or alternating medical and non-medical masks [OR (95% CI): 0.46 (0.13, 1.64)] were not associated with a reduced risk of infection compared with not wearing masks. Compliance with wearing masks was associated with lower risk of SARS-CoV-2 infection in multivariable models, while type of mask was not (ORs not reported). Due to collinearity between the two mask variables, type of mask was excluded from the final multivariable model.	**Factors associated with mask wearing** Compared with those who did not wear masks, those who wore masks all the time were more likely to: - have shortest distance of contact >1 meter (25% vs. 18%, pairwise p=0.03), - have duration of contact ≤15 minutes (26% vs 13%, pairwise p<0.001) and - wash their hands often (79% vs. 26%, pairwise p<0.001) Compared with those who did not wear masks, those who wore masks sometimes were more likely to: - wash their hands often (43% vs. 26%, pairwise p<0.001) However, compared to those who did not wear masks, they were also more likely to: - have physical contact (50% vs. 42%, pairwise p=0.03) and	some individuals may have been contacts to more than one COVID-19 patient. Findings are subject to memory recall, observer and information bias. While the authors 'strongly support' the wearing of non-medical masks in order to preserve supply of medical masks for healthcare workers, this does not seem to be supported by the data as presented in this paper.

			- duration of contact >60 minutes (75% vs. 67%, pairwise p=0.04) **Harms** Not reported.	
Kim 2012[18] **South Korea** **Cross-sectional study** **https://doi.org/10.1111/j.1750-2659.2011.00318.x**	**Population setting** *Included in analysis* 7,448 school-aged children and adolescents (between 7 and 18 years old) in South Korea in 2009. Investigation of demographic and epidemiological factors, including anthropometric and behavioural patterns (including face mask use), related to influenza A (H1N1) infection in school-aged children. **Participant demographics** *Age:* Mean 12.97 years (SD 3.03) *Sex:* Male, 3149 (42%); Female, 4299 (58%) *Influenza group* (n=417; 5.6%) *Age:* Mean 13.24 years (SD 2.92) *Sex:* Male, 225 (54%); Female, 192 (46%) *No influenza group* (n=7,031; 94.4%) **Respiratory virus** Influenza A H1N1 infection (laboratory-confirmed by rRT-PCR, influenza rapid antigen test or viral culture test). **Intervention/s** (N/A: Non-interventional study)	**Association of face mask use with H1N1 influenza A:** In unadjusted analysis, face mask use was significantly associated (p=0.04) with risk of H1N1 infection; relative to non-use, continuous use was associated with a significant reduction in risk: Continuous user: OR 0.51 (95% CI: 0.30-0.88) Irregular user*: OR 1.02 (95% CI: 0.83-1.25) * including rare and usual users In stepwise (adjusted) logistic regression analysis, the use of face masks was independently associated with lower H1N1 infection: OR 0.44 (95% CI 0.23-0.49). Few details were provided regarding this analysis.	**Adherence/compliance** Not reported. **Duration/frequency of mask wearing** Face mask use was classified into 3 groups: 'non-user', 'irregular user' (including rare and usual users) and 'continuous user'. No further detail provided. Face mask use all participants, number (%): Non-user: 4,164 (56%) Irregular: 2,819 (38%) Continuous: 466 (6%) Face mask use H1N1 cases, number (%): Non-user: 239 (57%) Irregular: 164 (39%) Continuous: 14 (3%) **Harms** Not reported.	Study design precludes confirmation of causal relationship between variables. Data collected by self-reported questionnaire. Ascertainment bias possible – previous infection or asymptomatic infection may have been missed.

	Type of face mask Not reported.			
Larson 2010[19] **US** **Cluster RCT** **https://journals.sagepub.com/doi/10.1177/0033354912500206**	**Population setting** *Included in analysis* 443 households located in a predominantly immigrant Latino community in New York from November 2006 to July 2008. Mean household size: 4.5 people per one-bedroom apartment. **Participant demographics** *Age:* 0-5 years, 808 (29.2%) 6-11 years, 306 (11.1%) 12-17 years, 193 (7%) 18-40 years, 1,124 (40.7%) 41-64 years, 297 (10.7%) ≥ 65 years, 35 (1.3%) Missing age, 25 (0.9%) *Sex:* Male, 1,342 (48%); Female, 1,446 (52%) **Respiratory virus** Upper respiratory infections (URIs), influenza-like illness, and laboratory-confirmed influenza. **Intervention/s** 1. *Hand sanitiser plus education* (n=148 households) 2. *Face mask plus hand sanitiser plus education* (n=147 households) Masks were to be worn by both the carer and the ill person when an ILI occurred in any household member. The household carer was	There were minimal differences in incidence rates of URI, ILI or influenza among intervention groups in multivariable analysis (adjusted for vaccination status and other potentially important covariates). Specifically relating to secondary attacks, in multivariable analysis the face mask + hand sanitiser group was associated with lower odds of URI/ILI/influenza secondary attack compared with the control group (education only): OR 0.82 (95% CI 0.70-0.97).	**Adherence/Compliance** Compliance with mask use was poor - only half (22/44) of the households with an ILI reported using masks within 48 hrs of episode onset. **Duration/frequency of mask wearing** Those who used masks at all reported a mean of only two masks per day per ILI episode (range: 0–9). **Harms** Not reported.	Symptoms and compliance were based on self-report, although prompted at regular intervals. Reporting of symptoms was lowest in control groups (hence potentially understating the measurable impact of the interventions). Sample size was under-powered to detect differences in influenza cases. Households randomized to the education group reported at least occasional use of hand sanitizer resulting in some contamination bias. Due to community concern about MRSA hence potentially diluting the intervention's measurable impact

	instructed to wear a mask when he/she was within 3 feet of a person with an ILI for seven days or until symptoms disappeared, and to change the mask between interactions. If possible, the ill person was also encouraged to wear a mask within 3 feet of other household members. Training in appropriate mask use was provided and reminder phone calls re mask use were made to participants on days 1, 3 and 6 following symptom onset. A two-month supply of masks was provided, with supplies replenished at least once every two months. **Control** (n=148 households) Education only **Duration of intervention** Follow up for 19 months Mean duration of follow up 55.5 weeks **Type of face mask** Regular surgical mask: Procedure Face Masks for adults and children, Kimberly Clark, Roswell, Georgia.			Important differences existed among intervention groups (e.g. education status, immigration status) but were controlled for in multivariate analyses. Study is unable to separate the efficacy of face masks and hand sanitizer in terms of reduced secondary attack rates. Influenza vaccination and knowledge levels rates increased across all groups from the start to the finish of the trial.
Lau 2004[20] **Hong Kong** **Case control** **https://doi.org/10.3201/eid1004.030628**	**Population setting** 330 probable SARS cases with undefined sources of infection **Participant demographics** *Age:* Mean 47.1 years (SD: male-18.8, female-19.9) *Sex:* Male, 48%; female, 52% **Respiratory virus**	In univariate analysis, members of the case group were less likely than members of the control group to have frequently worn a face mask in public venues (27.9% vs. 58.7%, OR = 0.36, $p < 0.005$). Controlling for other significant risk and protective factors in multivariate analysis (including visiting affected areas or hospitals, frequent hand washing and disinfecting of living quarters), cases were significantly less	**Adherence/compliance** Not reported. **Duration/frequency of mask wearing** Not reported. **Harms** Not reported.	No demographic information reported for controls (but reported to be age and sex-matched).

	SARS **Type of face mask** Not reported.	likely than controls to have frequently worn a face mask in public [OR (95% CI): 0.36 (0.25 to 0.52)]. Repeating the analysis for the 118 cases with undefined sources (after 212 patients who had visited some particular places that were associated with risk for transmission were removed from the analysis), frequently wearing a mask in public places (adjusted OR = 0.36, p< 0.001) remained significantly protective.		
MacIntyre 2009[21] **Australia** **Cluster RCT** **https://www.nc.cdc.gov/eid/article/15/2/08-1167_article**	**Population setting** *Included in analysis* 143 households (of children, 0-15 years, seeking treatment at paediatric health services with fever and either cough or sore throat) in Sydney, Australia, during 2006 and 2007 winter influenza seasons (August to the end of October 2006 and June to the end of October 2007) **Participant demographics** Not reported. **Respiratory virus** Influenza A and B, respiratory syncytial virus (RSV), adenovirus, parainfluenza viruses (PIV) types 1–3, coronaviruses 229E and OC43, human metapneumovirus (hMPV), enteroviruses and rhinoviruses **Intervention/s (n= 93 families, 186 adults)**	Intention-to-treat analysis showed no difference between arms. By household, the RR (95%CI) of ILI in relation to control group: Surgical masks, 1.33 (0.70-2.54) P2 masks, 0.91 (0.43-1.89) All masks, 1.12 (0.62-2.03) By individual, the RR (95% CI) of ILI in relation to control group: Surgical masks, 1.29 (0.69-2.31) P2 masks, 0.95 (0.49-1.84) All masks, 1.11 (0.64-1.91) However, per-protocol analysis found that >3 day adherent mask users had a significant reduction in the risk for clinical infection compared with control group and non-adherent participants [RR, 0.42 (95% CI, 0.18-0.95)]	**Adherence/compliance** Fully adherent mask users, 30 (16.1%) Not fully adherent mask users, 156 (83.9%) Full compliance was defined as when parents reported wearing the mask "all" or "most" of the time (on a 5-point Likert scale) for the first consecutive 5 days Only 21% of household contacts in the face mask arms reported wearing the mask often or always. **Duration/frequency of mask wearing** On day 1 of mask use, (38%) 36/94 surgical mask users and (46%) 42/92 P2	Not sufficiently powered to detect a difference in the P2 arm. Some adults may have been incubating ILI at time of recruitment. Study required lab confirmation of ILI, which may have resulted in under-ascertainment of cases Adherence was determined by self-report

	1. Surgical mask intervention (plus pamphlets about infection control) (n=47 families, 94 adults) 2. P2 mask intervention (plus pamphlets about infection control) (n=46 families, 92 adults) Mask to be worn by both adults at all times when in the same room as the index child, regardless of the distance from the child **Control (n=50 families, 100 adults)** No mask (but received pamphlets about infection control) **Duration of intervention** One week for all participants and two weeks from symptom onset if any adult became symptomatic in the first week. **Type of face mask** Intervention 1 = 3M surgical mask (catalogue no. 1820; St. Paul, MN, US) Intervention 2 = P2 masks (3M flat-fold P2 mask, catalogue no. 9320; Bracknell, Berkshire, UK). P2 masks are almost identical specification to N95 masks.	Irrespective of the assumed value for the incubation period (1 or 2 days), the relative reduction in the daily risk of acquiring a respiratory infection associated with adherent mask use (P2 or surgical) was in the range of 60%–80% (HR, 0.26 (95% CI 0.09–0.77) and (HR, 0.32 (95% CI 0.11–0.98) for 1 day 2 days respectively)	mask users stated that they were wearing the mask "most or all" of the time. Adherence dropped to 29/94 (31%) and 23/92 (25%), respectively, by day 5 of mask use **Harms/Adverse outcomes** 50% or more of mask users reported concerns with mask use, the main one being that wearing a mask was uncomfortable, followed by forgetting to wear it, the child not liking it and a range of other (unspecified) concerns.	
Shin 2018[22] **Japan** **RCT** **https://www.ncbi.nlm.nih.gov/pmc/articl**	**Population setting** **Included for analysis** 265 healthy volunteers from Kyushu University of Health and Welfare **Participant demographics** *Treatment group (n=129)*	In the non-treatment group, incidence of common cold symptoms was 35.0% for those who reported wearing face masks, and 36.5% for those who did not report wearing masks. In the treatment group, the incidence of common cold symptoms was 31.4% in those	**Adherence/compliance** 35 (27.1%) participants in the treatment group reported wearing face masks. 40 (29.4%) participants in the non-	No intention to treat analysis. 34.9% of sample lost to follow-up.

es/PMC6124826/	*Age:* Mean 27.2 years (SD 9.0) *Sex:* Male, 68 (52.7%); Female 61 (47.3%) *Control group (n=136)* *Age:* Mean 26.9 years (SD 9.5) *Sex: Male,* 62 (45.6%); Female, 74 (54.4%) **Respiratory virus** Common cold, gastrointestinal and influenza symptoms or diagnoses (self-reported). **Intervention** Sucking tablets containing lactoferrin (LF) and lactoperoxidase (LPO) to alleviate symptoms of the common cold and or influenza infection. Groups were further classified into subgroups habitually wearing a face mask, washing their hands, or gargling. **Control** No treatment **Duration of intervention** 8 weeks **Type of face mask** Not reported.	who reported wearing face masks, and 35.1% in those who did not.	treatment group reported face mask use. **Duration/frequency of mask wearing** Not reported. **Harms** Not reported.	
Simmerman 2011[23] **Thailand** **RCT** **https://doi.org/10.1111/j.1750-**	**Population setting** *Included for analysis* 348 households with a febrile, influenza positive child in Bangkok (total number of participants=1,233: n=348 index cases; n=885 contacts) **Participant demographics**	The overall secondary attack rate for laboratory-confirmed influenza was 21.5%. Secondary influenza infection was not significantly different between the groups: • Hand washing and face mask (23% SAR) (OR (95% CI): 1.16 (0.74, 1.82)	**Adherence/compliance** Not reported. **Duration/frequency of mask wearing** 289 subjects in the face mask arm used an average of 12 masks per person per	397 (89.8%) households reported that the index patient slept in the parents' bedroom. The authors suggest that as masks were not worn while sleeping,

2659.2011.00205.x	*Index cases* *Age:* Median 5.5 years, range 1 month to 15 years; 221 <6 years (50%) *Sex:* Male, 192 (55.2%); Female 156 (44.8%) *Household contacts* *Age:* Median 34 years (IQR 24–42) Sex: Male, 362 (40.9%); Female, 523 (59.1%) **Respiratory virus** Influenza (confirmed by rRT-PCR or serology) **Intervention/s** 1. Hand washing (HW) (n=119 index cases, n=292 contacts) 2. Hand washing plus surgical face masks (HW+FM) (n=110 index cases, n=291 contacts) It was not suggested that participants wear face masks while eating or sleeping as it was not deemed practical and could hinder breathing in a an ill child. **Control (n=119 index cases, n=302 contacts)** Neither intervention **Duration of intervention** 7 days **Type of face mask**	• Hand washing (23% SAR) (OR (95% CI): 1.20 (0.76, 1.88) compared with the control arm (19% SAR) In the subset of households where the intervention was applied within 48 hrs of index case illness onset, differences between the arms were not statistically significant when compared with the control arm: • Hand washing and face mask OR (95% CI): 1.15 (0.68, 1.93) • Hand washing OR (95% CI): 1.06 (0.62, 1.82) The SAR for ILI was 9% in the control arm, 17% in the hand washing arm, and 18% in the face mask plus hand washing arm. Relative to the control group, the ORs for ILI among household members in the hand washing arm (2.09; 95% CI 1.25, 3.50) and hand washing plus face mask arm (2.15; 95% CI: 1.27, 3.62) were twofold in the opposite direction from the hypothesized protective effect	week (median 11, IQR=7-16) and reported wearing a face mask a mean of 211 minutes/day (IQR=17–317 minutes/day). Parents wore their masks for a median of 153 (IQR=40–411) minutes per day, far more than other relations (median 59 minutes; IQR=9–266), the index patients themselves (median 35; IQR=4–197), or their siblings (median 17; IQR=6–107). **Harms** Not reported.	this prolonged and close exposure during periods of high viral shedding may have overcome any potential protective effects from the interventions. Time spent in close proximity (<1 m) from the index case was a strong predictor for a secondary influenza virus infection with an OR of 2.0 (95% CI 1.19, 3.37) in the group reporting the highest exposure. 65/370 (17.6%) control family members reported using used face masks during study week. The authors suggest that their results may be attributable to transmission that occurred before the intervention, poor face mask compliance, little difference in hand

	Standard surgical and paediatric face masks (Med-con company, Thailand #14IN-20AMB-30IN).			washing frequency between groups, and shared sleeping arrangements.
Suess 2011[24]$ **Germany** **Cluster RCT** **https://doi.org/10.1017/s0950268810003006**	**Population setting** *Included for analysis* 41 households with influenza index patients (147 participants) in Berlin **Participant demographics** *Index patients* *Age:* Mean age 7.9 years (SD 3.3) *Sex:* Male, 49% *Household contacts* *Age:* Mean age 30.0 years (SD 14.2). *Sex:* Male, 47% **Respiratory virus** Influenza (confirmed by qRT-PCR) **Intervention/s** 1. wearing a face mask and practicing intensified hand hygiene (n=17 index cases, n=40 contacts) (MH) 2. Face mask only (n=11 index cases, n=30 contacts) (M) Masks to be worn at all times except during the night when the index patient (or another member of the household with respiratory symptoms) was in the same room.	Primary outcome results reported by Suess 2012. **Adherence** Overall, 25 (89%) index patients and 62 (90%) household contacts from the combined MH and M groups reported wearing masks during the study period. After stratification of household contacts by age, 79% (11/14) of children and 93% (51/55) of adults wore masks. 81% (21/26) of index patients and 71% (49/69) of household members [64% (9/14) in child household contacts, 73% (40/55) in adult household contacts] wore a mask 'always' or 'most of the time' when in the same room with either a healthy or infected person, respectively. 62% (21/34) of healthy adult household members wore a mask when providing care for the infected person. **Reported harms** The majority (51/85, 60%) of all participants in the MH and M groups did not report any problems when wearing face masks. Of participants who reported having removed their masks in transmission-prone situations, 7/12 index patients (58%) and 5/22 household contacts (23%) reported 'feeling hot' as the	**Adherence/compliance** Daily wearing of face masks according to instructions was categorized as 'adherent' when the face mask was worn 'mostly' or 'always' during each day of the study period and otherwise as non-adherent. Analysis of daily adherence by age, irrespective of infection status, showed that the proportion of participants in the MH and M groups wearing a face mask after full implementation of the intervention reached about 60% by day 3 and remained above 50% until day 8 in children and above 45% in adults. **Duration/frequency of mask wearing** Participants of the MH group used a median of 15 masks (IQR: 7-20) per household member. Participants of the M group used a median of 13 masks	Face masks use peaked on day 4 after symptom onset of the index patient, at 73% for children and 65% for adults. Within the control group, 2/12 (17%) index patients and 3/32 (9%) household contacts wore face masks at some point during study period. The authors noted substantially increasing adherence after participants had received detailed instructions during a first household visit

	Control (n=13 index cases, n=36 contacts) Neither face mask nor intensified hand hygiene **Duration of intervention** 8 days, starting on the day of symptom onset of the index case. **Type of face mask** Surgical face masks (Aérokyn Masques, LCH Medical Products, France)	main reason (P=0.04). Other problems were pain [3 (25%) index patients, 2 (9%) household contacts], and shortness of breath [1 (8%) index patient, 2 (9%) household contacts].	(IQR: 7-20) per household member. **Harms/adverse outcomes** 60% of all participants did not report any problems when wearing face masks. 7 index patients and 5 contacts reported 'feeling hot' as the main reason why they removed their mask in transmission-prone situations. Other, less frequently reported problems included: pain when wearing the mask and shortness of breath.	
Suess 2012[(25)]$ **Germany** **Cluster RCT** **https://doi.org/10.1186/1471-2334-12-26**	**Population setting** *Included for analysis* 84 households with an influenza positive index case (either influenza A (H1N1) pdm09 or influenza B) (302 participants) in Berlin **Participant demographics** *Index cases* *Age:* Median 7 to 8 years Sex: Male, 50 (59.5%), Female, 34 (40.5%) *Household contacts* *Age:* Median 34 to 38 years *Sex:* Male, 106 (48.6%); Female, 112 (51.4%)	**Primary outcome** Laboratory-confirmed influenza in a household contact. The total secondary attack rate was 16% (35/218). For laboratory-confirmed cases, secondary attack rates were not significantly lower in the M (9% (6/69)) or MH group (15% (10/67)) compared with the control group (23% (19/82). Where index cases had influenza A (H1N1) pdm09, secondary attack rates were not significantly lower in the M (10% (6/58)) or MH group (8% (4/50)) compared with the control group (23% (13/56).	**Adherence/compliance** Daily adherence (defined as "always" or "mostly" wearing the mask as instructed), reached a plateau of over 50% in nearly all groups (M and MH groups; 2009/10 and 2010/11 influenza seasons). A gradual decline towards lower adherence began around the 6th day of the index patient's illness. **Duration/frequency of mask wearing**	The authors state that the main drawback of the study was that they did not reach the number of households aimed and planned for, one of the reasons being the at best moderate influenza season2010/11. There were also delays of up to 3 days between symptom onset of the index

	Respiratory virus Influenza (either influenza A (H1N1) pdm09 or influenza B; confirmed by qRT-PCR) **Intervention/s** 1. Face mask plus practicing intensified hand hygiene (n=28 index cases, n=67 contacts) (MH) 2. Face mask only (n=26 index cases, n=69 contacts) (M) Masks to be worn at all times when the index patient and or any other household member with respiratory symptoms were together in one room with healthy household members. Not to be worn during the night or outside the house. Masks worn by both index cases and household contacts. **Control (n=30 index cases, n=82 contacts)** Neither face mask nor intensified hand hygiene **Duration of intervention** 8 days, starting on the day of symptom onset of the index case. Cases enrolled over two consecutive flu seasons (one of which also reported in Suess 2011) **Type of face mask** Surgical face masks in two sizes (Child's Face Mask, Kimberly-Clark, US; and Aérokyn Masques, LCH Medical Products, France)	In households where intervention was implemented within 36h after symptom onset of the index case, secondary infection in the pooled intervention groups was significantly lower compared with the control group (aOR 0.16, 95% CI, 0.03-0.92), adjusted for age, sex, timely antiviral therapy of the index case and vaccination of household contacts. Among households with index cases infected with A (H1N1)pdm09 (162 household contacts) secondary laboratory-confirmed infections were significantly lower in the mask plus hand hygiene group (aOR 0.27, 95% CI, 0.07-0.99) In a per-protocol analysis ORs were significantly reduced among participants in the face mask only group (aOR, 0.30, 95% CI, 0.10-0.94). Among households with index cases infected with A (H1N1)pdm09 (162 household contacts) secondary laboratory-confirmed infections were significantly lower in the face mask only (aOR 0.28, 95% CI, 0.08-0.97), and the face mask plus hand hygiene group (OR 0.26, 95% CI, 0.07-0.93)	Participants in the M group used a median of 12.9 face masks (IQR: 9.5-16) per individual. Participants in the MH group used a median of 12.6 face masks (IQR: 7.8-14) per individual. In 2010/2011 season only, participants in the M group used a mean of 1.8 face masks (SD: 1.8) per day. Participants in the MH group used a mean of 1.7 face masks (SD: 2.0) per day. **Reported harms** The majority of participants (107/172, 62%) did not report any problems with mask wearing. This was significantly higher in adults (71/100, 71%) compared with children (36/72, 50%) (p = 0.005). The main problem stated by participants (adults and children) was "heat/ humidity" (18/34, 53% of children; 10/29, 35% of adults), followed by "pain" and "shortness of breath".	patients and implementation of the intervention, which may have led to an underestimation of the true effect of the interventions.

Tuan 2007[30] **Vietnam** **Cross-sectional study** **https://doi.org/10.1017/S0950268806006996**	**Population setting** *Included for analysis* 212 eligible household and community contacts of 45 primary cases with SARS-CoV-1 confirmed by either PCR, serology or both, between 26 Feb and 28 Apr 2003. 9/180 contacts who provided a blood sample (5%) had serological evidence of SARS-CoV-1. Individuals were considered contacts if they lived in the same household; OR spent ≥2 hrs continuously engaged in face to face contact; OR physically cared for the person in the household setting, regardless of the time involved. **Participant demographics** (of 212 eligible contacts) Age: Median 32.7 years (range 2 months to 82 years) Sex: Male, 102 (48%); Female, 110 (52%) **Respiratory virus** SARS-CoV-1, coronavirus OC43 **Intervention/s:** N/A: Non-interventional study **Type of face mask:** Not reported. Masks were worn by contacts; mask wearing by patients was not reported.	All of the 9 secondary cases were adults who reported direct contact with a laboratory-confirmed SARS case whilst that case was sick. 9/156 non-cases (5.8%) reported wearing a mask sometimes or most times when in contact with the SARS patient, compared to 0 of 7 cases (0.0%). In bivariate analysis, wearing a mask during contact with a primary case was not associated with transmission of SARS-CoV-1: OR 0.0 (95% CI: 0.0 - 15.37).	**Adherence/compliance** 95% of contacts reported never wearing a mask during contact with the SARS case. 5% of contacts reported wearing a mask sometimes/most times. **Duration/frequency of mask wearing** Not reported. **Harms** Not reported.	Study design precludes confirmation of causal relationship between variables. Data collected by self-reported questionnaire. Mask use was self-reported. In this series of 45 laboratory-confirmed SARS cases there was limited community transmission despite unprotected contact; with each infectious case causing on average only 0.2 secondary infections.

Uchida 2017[26] **Japan** **Cross-sectional census** **http://dx.doi.org/10.1016/j.pmedr.2016.12.002**	**Population setting** *Included for analysis* 10,524 elementary school children in 29 public schools in Matsumoto City, Nagano **Participant demographics** *Age:* NR, grades 1–6 (7–12 years) *Sex:* Male, 5372 (51%), Female, 5152 (49%) N=5474 (52%) reported wearing masks (yes/no question) 2149 schoolchildren (20.4%) were considered to have had influenza (Report by guardian of a physician diagnosis) **Respiratory virus** Seasonal influenza **Type of face mask** Not reported.	Wearing masks was significantly protective [OR (95% CI): 0.859, (0.778, 0.949)] in multivariable analysis (controlling for sex, school grade, having a sibling, vaccination status, hand washing, frequency of going out, presence of underlying condition and influenza during previous season). The overall effectiveness of mask wearing was 8.6% in all children, 12.0% in children in grades 4–6 and 5.3% in children in grades 1–3. Effectiveness was calculated as [1 – (the proportion of children with influenza who wore a mask/the proportion of children with influenza who did not wear a mask)	**Adherence/compliance** Not reported. **Duration/frequency of mask wearing** Not reported.	Vaccination was protective [OR (95% CI): 0.87, (0.79, 0.95)]. Hand washing [OR (95% CI): 1.45 (1.27, 1.64)] and gargling [OR (95% CI): 1.32(1.18, 1.47)] were not associated with protection. The authors suggest that hand washing and gargling in schools may not have been performed appropriately, or may have led to transmission through faucets and knobs.
Wu 2004[27] **China** **Case control** **https://doi.org/10.3201/eid1002.030730**	**Population setting** *Included for analysis* 94 probable SARS patients and 281 controls in Beijing **Participant demographics** *Case patients* *Age:* Median 29 years (range 14-84) *Sex:* Male, 47 (50%), Female, 47 (50%) *Controls* Age: Median 31 years (range 14-82) *Sex:* Not reported.	The use of masks was strongly protective; always wearing a mask when going out was associated with a 70% reduction in risk compared with never wearing a mask [OR (95% CI): 0.3 (0.1 to 0.6)]. Wearing a mask intermittently was associated with a smaller yet significant reduction in risk [OR (95% CI): 0.4 (0.2 to 0.9)]. (based on multivariable analysis, although not clear which other variables are included in the model). The study did not evaluate the protective efficacy for different mask types.	**Adherence/compliance** Not reported. **Duration/frequency of mask wearing** Mask wearing for "a reference period corresponding to the 2 weeks before symptom onset for cases"	The authors suggest that due to the nonspecific clinical definition for SARS, a substantial portion of case-patients without contact with other SARS patients likely had pneumonia caused by pathogens other than SARS-CoV-1.

	Respiratory virus SARS. **Type of face mask** Not reported.			
Wang 2020[33] **China** **Retrospective cohort** **https://gh.bmj.com/content/5/5/e002794**	**Population setting** Self-report questionnaires completed by 335 people in 124 families with at least one laboratory confirmed COVID-19 case. Grouped by: • Families with transmission (n=41) • Families without transmission (n=83) **Participant demographics** *Primary cases* *Age:* Median 45 years (IQR 35.7-60.0) Sex: Male, 61 (49.2%), Female, 63 (50.8%) 96 had mild disease (77.4%), 20 severe disease (16.1%), 8 critical disease (6.5%). Time from illness onset to isolation 5 days (IQR 2-7). **Respiratory virus** SARS-CoV-2 **Duration of measurement** Families with secondary transmission were defined as those where some or all of the family members became infected within one incubation period (2 weeks) of symptom onset of the primary case. **Type of face mask**	The secondary attack rate in families was 23.0% (77/335). In unadjusted analyses, compared with no family members wearing masks, household transmission was reduced when all family members wore masks at home all the time after the primary case's illness onset date (OR 0.20, 95% CI 0.07, 0.60), but not if only some family members wore masks (OR 0.72, 9%% CI 0.30 to 1.73). In multivariable analysis, face mask use before the primary case's illness onset date by one or more persons in the household (primary case or household contact) was 79% effective in reducing transmission compared with no face mask use (OR=0.21, 95% CI 0.06 to 0.79). Wearing a mask after illness onset of the primary case was not significantly protective in multivariable analysis. The analysis appears to control for diarrhoea in the primary case, close contact at home with primary cases, and frequency of disinfectant use for house cleaning, although this is not clearly stated. The risk of household transmission was 18 times higher with frequent daily close contact with the primary case (unadjusted OR=18.26, 95% CI 3.93 to 84.79), and four times higher	**Adherence/compliance** Families (including primary cases and family members) wore masks at home after illness onset: Never: 41/124 (33.1%) Sometimes: 37 (29.8%) All the time: 46/124 (37.1%) **Duration/frequency of mask wearing** Not reported. **Harms** Not reported.	The authors state that this study is the first to confirm the effectiveness of mask use prior to symptom onset by family members, daily household disinfection and social distancing in the home. The authors suggest that this could inform precautionary guidelines for families to reduce intrafamilial transmission in areas where there is high community transmission or other risk factors for COVID-19. Retrospective questionnaire based study. Self-report method clearly high risk of bias. Definition of wearing a mask was

	Any mask type including N95 mask, disposable surgical mask, or a cloth mask	if the primary case had diarrhoea (OR=4.10, 95% CI 1.08 to 15.60). Household crowding was not significant.		categorised by household numbers as 'none' or 'one or more' Crowding defined as number of bedrooms per person being less than one
Xu 2020[29] (preprint) **China** **Cross-sectional study** **https://www.medrxiv.org/content/10.1101/2020.06.02.20120808v2.full.pdf**	**Population setting** 8,158 Chinese adults surveyed online between 22 Feb 2020 and 5 Mar 2020; 57 (0.73%) with COVID-19. Included for analysis: 5,054 for face masks **Participant demographics** *Age groups:* 18-39 years, 5,017 (61.5%) 40-59 years, 2,902 (35.6%) >=60 years, 239 (2.9%) *Sex:* Male, 3,030 (37%); Female, 5,128 (63%) **Respiratory virus** SARS-CoV-2 **Intervention/s:** N/A: Non-interventional study **Type of face mask:** Not reported.	**Mask wearing when going out** Not wearing a mask, compared with wearing a mask, was associated with a significant increased risk of COVID-19 infection: RR 12.38 (95% CI: 5.81–26.36), p<0.001 aOR 11.03 (95% CI: 4.53-26.84), p<0.001 Adjusted for unspecified socio-demographics variables aOR 7.20 (95% CI: 2.24-23.11), p<0.001 Adjusted for unspecified socio demographics variables, hand washing, coughing etiquette, social distancing and all 4 protective measures together. **Mask wearing combined with other protective measures** Wearing a mask, compared with not wearing a mask, was associated with a significant reduced risk of COVID-19 infection among those who practiced hand washing [RR (95% CI): 0.11 (0.04, 0.29)], proper coughing etiquette [RR (95% CI): 0.18 (0.05, 0.57)] and	**Adherence/compliance** 97.9% wore a mask when going out (self-report) **Duration/frequency of mask wearing** Not reported. **Harms** Not reported.	The authors concluded that mask wearing was the most effective protective measure against COVID-19 infection, with added preventive effect among those who practised all or part of the other 3 behaviours (hand washing, cough etiquette and physical distancing). Study design precludes confirmation of causal relationship between variables. Study sample was not randomly selected and has disproportionately more females and

		social distancing [RR (95% CI): 0.03 (0.01, 0.11)]. For those who practiced all 3 of hand washing, proper coughing etiquette and physical distancing, wearing a mask, compared with not wearing a mask, was associated with a significantly lower risk of COVID-19 infection: Infection Rate: 0.6% v 16.7%; p=0.035 For those who did not practice all 3 of hand washing, proper coughing and physical distancing, wearing a mask, compared with not wearing a mask, was still associated with a significantly lower risk of COVID-19 infection: Infection Rate: 0.6% v 6.9%; p<0.001 99.9% self-reported knowing how and why to wear a mask in public.		well educated persons and fewer smokers. Results are from a particular point in time during the outbreak, with most respondents from outside Hubei province, so the interpretation of results should be cautious and the generalisation of results to other settings and countries may be limited.
Zhang 2013[32] **Fuzhou, China** **Case-control study** **http://dx.doi.org/10.3201/eid1909.121765**	**Population setting** 9 case passengers with RT-PCR confirmed influenza A (H1N1)pdm09 infection and 32 non-infected control passengers who travelled on two flights from New York to Hong Kong and from Hong Kong to Fuzhou, China (of the 32 control passengers, 28 boarded in New York; 27 disembarked in Fuzhou and 1 disembarked in Hong Kong, and 4 boarded during a stopover in Vancouver and disembarked in Hong Kong). The analysis focused on the New York to Hong Kong journey. **Participant demographics** *Cases (n=9)* *Age groups:*	From New York to Vancouver, 11% (1/9) case-passengers wore a face mask compared with 57% (16/28) of control passengers. From Vancouver to Hong Kong, no case-passengers wore a face mask compared with 47% (15/32) of control-passengers. For the New York to Hong Kong journey (including the stopover), no case-passengers wore a face mask compared with 47% (15/32) of control-passengers. For the full journey from New York to Hong Kong, no case-passengers wore a face mask compared with 47% (15/32) of control-passengers.	**Adherence/compliance** Not reported. **Duration/frequency of mask wearing** Among control-passengers who used face masks, 4 did not use them during the New York to Vancouver trip, and 3 did not use them during the Vancouver to Hong Kong trip. **Harms** Not reported.	The authors suggest that during the outbreak, influenza A(H1N1)pdm09 virus appeared to have been transmitted on a New York to Hong Kong flight. No other common timeplace exposure could account for the point-source pattern. The authors concluded that wearing a face mask was associated with a

	<20 years, 4 (44%) 20-40 years, 4 (44%) > 40 years, 1 (11%) *Age range:* 6-46 years (median 20 years) *Sex:* Male, 5 (56%); Female, 4 (44%) *Controls (n=32)* *Age groups:* <20 years, 4 (12%) 20-40 years, 15 (47%) > 40 years, 13 (41%) *Sex:* Male, 15 (47%); Female, 17 (53%) **Respiratory virus** Influenza A(H1N1)pdm09. **Intervention** N/A: Non-interventional study. **Type of face masks:** Not reported (not known).			decreased risk for influenza acquisition during this long-duration flight. Study design precludes confirmation of causal relationship between variables. Complete information not provided for 43 other non-infected passengers. Seating and illness information was also lacking for 68% of the economy class passengers (seated in the same cabin) on the New York to Hong Kong flight

Appendix 2: Characteristics of systematic reviews

Author Study design DOI	Included studies	Primary outcome results	Other results/conclusions/ recommendations
Chou (2020)[44] **Living Rapid Review** **https://doi.org/10.7326/M20-3213**	**Included studies and designs** 39 studies, 18 RCTs and 21 observational studies of respirators, face masks or cloth masks in community and healthcare settings for the prevention of respiratory virus infections. **Number of relevant studies** 8 RCTs, 3 observational studies **Respiratory virus** SARS-CoV-2, SARS, MERS, influenza/ILI (studies relevant to this evidence summary considered SARS and influenza/ILI only). **Intervention** Respirators, face masks or cloth masks in community and healthcare settings	There was an absence of studies that evaluated the use of face masks for the prevention of SARS-CoV-2 infections in the community. Community mask use was associated with a potential decreased risk for SARS-CoV-1 infection in observational studies. Randomised trials in community settings did not indicate differences between N95 and surgical masks nor between surgical and no mask in risk for influenza or influenza-like illness, but compliance was low.	The authors note that evidence on SARS-CoV-2 was limited to 2 observational studies in healthcare settings with serious limitations. The authors concluded that evidence on mask effectiveness for respiratory infection prevention is stronger in healthcare than community settings. N95 respirators might reduce SARS-CoV-1 risk versus surgical masks in health care settings, but applicability to SARS-CoV-2 is uncertain.
Chu 2020[50] **Systematic review with meta-analysis** **https://www.sciencedirect.com/science/article/pii/S0140673620311429**	**Included studies and designs** 172 observational studies across 16 countries and 6 continents, of which: 30 studies on the association between use of various types of face masks and respirators by healthcare workers, patients, or both with virus transmission. *Note:* only 29 studies reported as included in meta-analysis	**Meta-analysis** **All settings (n=29)** The use of both N95/similar respirators or face masks (e.g. disposable surgical masks or similar reusable 12–16-layer cotton masks) by those exposed to infected individuals was associated with a reduction in risk of infection (unadjusted n=10,170, RR 0.34, 95% CI 0.26 to 0.45; adjusted n=2,647, aOR 0.15, 95% CI	The authors suggest that face mask use could result in a large reduction in risk of infection, with stronger associations in healthcare settings compared with non-healthcare settings. The findings support the idea that N95 or similar respirators might be associated with a larger degree of protection from viral infection than disposable medical masks or reusable

	Number of relevant studies N=3 observational studies on the association between use of face masks (type not reported) and virus transmission in a non-healthcare setting. **Respiratory virus** SARS-CoV-1 for non-healthcare settings SARS-CoV-1, SARS CoV-2, MERS for healthcare settings **Intervention** N95 or similar respirators, or face masks (surgical and other)	0.07 to 0.34; AR (absolute risk) 3.1% with face mask *vs* 17.4% with no face mask, RD –14.3%, 95% CI –15.9 to –10.7 (low certainty of evidence) across all settings, including healthcare. **Healthcare settings only (n=26)** RR 0.30, 95% CI 0.22 to 0.41 **Non-healthcare settings (n=3)** RR 0.56, 95% CI 0.40 to 0.79	multilayer (12–16-layer) cotton masks. However, the certainty of effect is low, and the majority of included studies were based in healthcare settings. Further high-quality research, including RCTs of the effectiveness of different types of masks in the general population and for health-care workers protection, is urgently needed.
MacIntyre 2020[51] **Rapid systematic review** **https://www.sciencedirect.com/science/article/pii/S0020748920301139**	**Included studies and designs** N=19 RCTs on use of respiratory protection by healthcare workers, sick patients and community members **Number of relevant studies** N=8 RCTs in community settings **Respiratory virus** Influenza A and B, respiratory syncytial virus (RSV), adenovirus, parainfluenza viruses (PIV) types 1–3, coronaviruses 229E and OC43, human metapneumovirus (hMPV), enteroviruses and rhinoviruses, incident influenza like illness, upper respiratory infections. **Intervention**	In the community, masks appear to be effective with and without hand hygiene, and both together are more protective (3/8 trials). In 2/8 trials, interventions had to be used within 36 hrs of exposure to be effective. 2/8 trials measured the effect of hand hygiene and masks, but didn't measure masks alone. The evidence suggested protection by masks in high transmission settings such as household and college settings, especially if used early, in some trials if combined with hand hygiene, and if wearers are compliant.	The authors conclude that community mask use by well people could be beneficial, particularly for COVID-19, where transmission may be pre-symptomatic. The studies of masks as source control also suggest a benefit, and may be important during the COVID-19 pandemic in universal community face mask use as well as in health care settings.

	Medical masks/masks with and without hand hygiene.		
Gupta 2020[45] **(preprint)** **Systematic review** **https://www.medrxiv.org/content/10.1101/2020.05.01.20087064v1.full.pdf**	**Included studies and designs** 14 studies of face masks in community settings (including laboratory and modelling studies): 7 RCTs, 3 non-RCTs, 2 observational studies, 2 mathematical models **Number of relevant studies** 9 studies: 7 RCTs, 2 observational studies **Respiratory virus** Influenza, influenza like illness, SARS **Intervention** Face masks: surgical or cloth	In the community, masks appear to be effective (3/7 RCTs, 2/2 observational studies).	The authors conclude that face mask use by the general population is vital in the prevention of a respiratory virus with unique transmission characteristics such as SARS-CoV-2. The benefit of mask usage by the community depends on the time of initiation of the usage of masks and the degree of adherence to it, with greater advantage when mask usage was started early.
Liang 2020[46] **Systematic review and meta-analysis** **https://www.sciencedirect.com/science/article/pii/S1477893920302301**	**Included studies and designs** 21 studies of face masks (all settings): 13 case-control studies, 6 cluster RCTs, 2 cohort studies **Number of relevant studies** N=6, 4 RCTs and 2 case-control studies~~5~~ **Respiratory virus** Laboratory-confirmed respiratory virus: influenza, influenza like illness, SARS-CoV-1, SARS-CoV-2 **Intervention** Surgical masks and respirators	In a subgroup analysis that included 8 studies (6 of which were in community settings), a protective effect for masks was found: OR 0.53 (95% CI 0.36–0.79). A more detailed analysis found significant effects in both the household subgroup (3 studies, OR 0.60, 95% CI 0.37–0.97), and the non-household subgroup (5 studies, OR 0.44, 95% CI 0.33–0.59).	In the subgroup of healthcare workers (n=12 studies, 4,751 participants), a more obvious protective effect was identified (OR 0.20, 95% CI 0.11–0.37). Across all 21 studies, masks had a protective effect against influenza viruses (OR 0.55, 95% CI 0.39–0.76), SARS (OR 0.26, 95% CI 0.18–0.37), and SARS-CoV-2 (studies in healthcare settings) (OR 0.04, 95% CI = 0.00–0.6). However, no significant protective effects against H1N1 was shown (OR 0.30, 95% CI 0.08–1.16).

			Well designed high-quality prospective studies and studies of mask wearing in the general public are still insufficient.
Wei 2020[49] **(preprint)** **Meta-analysis of RCTs** **https://doi.org/10.1101/2020.05.07.20094912.**	**Included studies and designs** 8 RCTs undertaken in community settings **Number of relevant studies** 5 RCTs **Respiratory virus** Influenza-like illness (ILI) (e.g. fever, cough, headache, sore throat, aches or pains in muscles or joints) irrespective of confirmatory testing for the causative virus. **Intervention** Face mask (no further detail provided)	**Meta-analysis** When all 8 studies were pooled, those wearing face masks had a significantly lower risk of developing ILI compared with those not wearing face masks: (pooled RR=0.81, 95% CI: 0.70-0.95). The decreased risk of developing ILI was more pronounced when everyone wore a face mask, irrespective of whether they were infected or not: (RR=0.77, 95% CI: 0.65-0.91) compared with only those infected wearing face masks (RR=0.95, 95% CI: 0.58-1.56) and only those uninfected wearing masks (RR=1.26, 95% CI: 0.69-2.31).	The authors conclude that wearing face masks, irrespective of infection status, is effective in preventing ILI spread in the community.
Marasinghe 2020[47] **(preprint)** **Systematic review and analysis of public health guidance** **https://doi.org/10.21203/rs.3.rs-16701/v3**	**Included studies and designs** 0 RCTs, 0 cohort studies, 0 retrospective or prospective studies. This is an 'empty' systematic review, last updated 10 Apr 2020. **Number of relevant studies** None. **Respiratory virus** SARS-CoV-2 **Intervention** Face masks worn by those who are not medically diagnosed with COVID-19.	None.	The authors suggest that the finding of the systematic review search, which was a lack of scientific evidence as of 10 Apr 2020, questions the basis of public health recommendations provided to the public at a very early, yet crucial stage of the outbreak and which were inconsistent with each other.

Stern (2020)[48] **Rapid Review (Spanish)** **http://www.saludpublica.mx/index.php/spm/article/view/11379**	**Included studies and designs** 21 studies: 8 systematic reviews, 7 RCTs, 3 observational studies and 3 modelling studies **Number of relevant studies** 6 studies: 5 RCTs, 1 cross-sectional study **Respiratory virus** Influenza and other respiratory viruses **Intervention** Face masks in community settings	**RCTs** 3/6 household based RCTs reported use of face masks reduced transmission, 1/6 found no association and 2/6 found that transmission was increased (not statistically significant). 1 RCT in university residences reported a non-statistically significant decrease in incidence of infection. 1 cross-sectional study in school children found a protective effect of face masks in influenza transmission.	The authors concluded the evidence is inconclusive to recommend or discourage the use of surgical masks at the population level. None of the studies included considered homemade masks.
Brainard 2020[36] **(preprint)** **Rapid systematic review** **https://doi.org/10.1101/2020.04.01.20049528**	**Included studies and designs** 31 studies, all designs, various community settings (including visits to healthcare providers, Hajj pilgrimage mass gatherings, and contact with animals e.g. veterinary students or poultry workers) **Number of relevant studies included** 13 (excluding Hajj pilgrimage mass gatherings, air travel and studies of animal contact) **Respiratory virus** Coronaviruses, rhinoviruses, influenza viruses or influenza like illness (ILI), tuberculosis. **Intervention** Face barrier (mask, goggles, shield, veil) - most often surgical face mask	In 3 RCTs, wearing a face mask 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 face masks 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 face mask (very low certainty evidence). **(Pooled analyses not statistically significant.)**	The authors noted that RCTs often suffered from poor compliance from intervention participants, while controls frequently used face masks. They suggest that the evidence does not support routine and widespread use of face masks in the community. However, they suggest that using a mask for short periods of time particularly by vulnerable individuals during transient exposure events may be justified.

		Among case-control (OR 0.39, 95%CI 0.18-0.84, I2 77%) and cross-sectional studies (OR 0.61, 95%CI 0.45-0.85, I2 95%), pooled data suggested that face mask wearing was protective, but effects were highly heterogeneous.	
Xiao 2020[42] **Systematic review** https://wwwnc.cdc.gov/eid/article/26/5/19-0994_article	**Included studies and designs** Overall number unclear, 10 RCTs of face masks **Number of relevant studies included** N=8 **Respiratory virus** Influenza **Intervention** Hand hygiene, respiratory etiquette, face masks, surface and object cleaning	No significant reduction in influenza transmission with the use of face masks in pooled analysis (RR 0.78, 95% CI 0.51–1.20; I^2=30%, p=0.25) Effect of face masks combined with hand hygiene on laboratory-confirmed influenza was not statistically significant (RR 0.91, 95% CI 0.73–1.13; I = 35%, p = 0.39). Effect of face masks with or without hand hygiene on laboratory-confirmed influenza was not statistically significant (RR 0.92, 95% CI 0.75–1.12; $I2$ = 30%, p = 0.40). None of the household studies reported a significant reduction in secondary laboratory-confirmed influenza virus infections in the face mask group.	The authors suggest several major knowledge gaps requiring further research, including an improved characterization of the modes of person-to-person transmission. The authors also note that most studies were underpowered because of limited sample size, and some studies reported suboptimal adherence in the face mask group.
Jefferson 2020[39] **(preprint)** **Systematic review (update of 2011 Cochrane review)** https://doi.org/10.1101/2020.03.30.20047217	**Included studies and designs** 15 RCTs investigating the effects of masks in healthcare workers and the general population (n=14), or person distancing (n=1). **Number of relevant studies included** N=7 trials of masks versus no masks, including 5 trials in the community setting	In a meta-analysis of 9 trials (2 of which were in the healthcare setting), there was no reduction of ILI cases (Risk Ratio 0.93, 95%CI 0.83 to 1.05) or influenza (Risk Ratio 0.84, 95%CI 0.61-1.17) with mask use compared with no masks.	Harms were poorly reported and limited to discomfort with lower compliance. Most included trials had poor design, reporting and few events. There was insufficient evidence to provide a recommendation on the use of facial barriers without other measures. Based on observational evidence from the previous SARS epidemic included in the

	(all RCTs or cluster RCTs). All were conducted in non-pandemic settings. **Respiratory virus** Acute respiratory illness, defined as ILI, influenza, or other respiratory infections **Intervention** Surgical or medical mask		previous version of our Cochrane review the authors recommend the use of masks combined with other measures.
Jefferson 2011[38] **Cochrane systematic review** https://doi.org/10.1002/14651858.CD006207.pub4	**Included studies and designs** 67 studies including RCTs and observational studies (includes both healthcare and community settings) **Number of relevant studies included** Overall review: N=5 studies of mask use and community transmission were included (3 RCTs of influenza transmission, 2 Case Control studies of SARS transmission) **Respiratory virus** Mixed **Intervention** Physical interventions (screening at entry ports, isolation, quarantine, social distancing, barriers, personal protection, hand hygiene)	**Meta-analysis** Simple mask-wearing was found to be highly effective, based on meta-analysis of 7 case control studies set in either the healthcare or community setting: OR 0.32 (95% CI 0.26-0.39) Overall, in a pooled analysis 7 of case-control studies of mask use in both healthcare and community settings, masks were the best performing intervention across populations, settings and threats.	The most common problem in all of these studies was a lack of reporting of viral circulation in the reference population, making interpretation and generalisability of their conclusions questionable.
Cowling 2010[37] **Systematic review**	**Included studies and designs** 12 studies, including healthcare and community settings	There is some evidence to support the wearing of masks or respirators during illness to protect others, and public health emphasis on mask wearing during	The authors suggest that it is important to consider the potential for leakage around the sides of the mask in addition to direct penetration of infectious viral particles through the

https://doi.org/10.1017/S0950268809991658	**Number of relevant studies** N=4 RCTs 3 included studies used case-ascertained designs, where ill index cases were recruited from outpatient clinics and households were followed up for 7–10 days to observe secondary transmission **Respiratory virus** Influenza **Intervention** Face masks	illness may help to reduce influenza virus transmission. There is little evidence to support the effectiveness of face masks to reduce the risk of infection. Current research has several limitations including underpowered samples, limited generalizability, narrow intervention targeting and inconsistent testing protocols, different laboratory methods, and case definitions.	mask, if the results are to have practical implications for reduction of transmission in community and other settings
Bin-Reza 2012[35] **Systematic review** https://doi.org/10.1111/j.1750-2659.2011.00307.x	**Included studies and designs** 17 RCTs, quasi experimental and observational studies, healthcare and community settings **Number of relevant studies** N=7 (5 RCTs, 2 case control) **Respiratory virus** Influenza and other viral respiratory infections **Intervention** Surgical masks and respirators	6 of 8 RCTs (5 of which were conducted in community settings) found no significant differences between control and intervention groups (masks with or without hand hygiene; N95/P2 respirators). One household trial found that mask wearing coupled with hand sanitiser use reduced secondary transmission of upper respiratory infection/ILI/laboratory-confirmed influenza compared with education. 8 of 9 retrospective observational studies (of which 2 were community based) found that mask and/or respirator use was independently associated with a reduced risk of severe acute respiratory syndrome (SARS).	The authors concluded that community studies do not provide conclusive evidence that face masks are effective in primary intention to treat analyses, although statistical power was limited. The authors note that the included studies were poorly designed, had many weaknesses and so were very difficult to interpret. Most studies were too small to reliably detect what would be anticipated to be moderate effects.
MacIntyre 2015[40] **State of the art review**	**Included studies and designs** 13 RCTs, 3 unpublished RCTs, 9 systematic reviews	Overall, findings indicated that face masks and face masks plus hand hygiene may prevent infection in community	Compliance in the household setting decreases with each day of mask use, which makes long term use over weeks or months a challenge

https://www.jstor.org/stable/10.2307/26520626	**Number of relevant studies** 8 RCTs and cluster RCTs **Respiratory virus** Mixed, mainly influenza and ILI **Intervention** Face masks	settings, subject to early use and compliance. Of the nine trials of face masks identified in community settings, in all but one, face masks were used for respiratory protection of well people.	The use of reusable cloth masks is widespread globally, but there is no clinical research to inform their use, with most studies conducted before the development of disposable masks. The statistical power of each individual RCT may have been too low to determine efficacy by intention to treat, and larger trials may be needed. A meta-analysis of the existing community trials would be difficult because of the diverse settings, interventions, outcomes, and measurements.
Saunders-Hastings 2017[41] **Systematic review** http://dx.doi.org/10.1016/j.epidem.2017.04.003	**Included studies and designs** 16 RCTs, case-control and cohort studies (6 studies focus on healthcare workers, 8 studies include hand hygiene interventions only) **Number of relevant studies** N=2, 1 cross-sectional survey, 1 cluster RCT **Respiratory virus** Influenza (predominantly (H1N1) pdm09) **Intervention** Personal protective measures including any form of hand hygiene, use of face masks or respiratory etiquette (covering mouth during coughing and sneezing).	The primary finding was that regular hand hygiene was significantly protective in protecting from pandemic influenza infection, while face mask use was not significantly protective. 2/8 studies on face mask use were conducted in community settings. Both found a statistically significant protective effect of mask use.	Little non-pharmaceutical intervention research that has been conducted in pandemic settings. The authors noted that most studies included had a moderate-to-high risk of bias, due to a lack of blinding and reliance of subject self-reporting. The authors also note performance, detection and reporting biases, suggest that cases and controls may misjudge their adoption of PPMs in order to rationalize their infection status.

Aledort 2007[34] **Evidence review combined with expert opinion** http://dx.doi.org/10.1186/1471-2458-7-208	**Included studies and designs** N=168 (9 systematic reviews (SRs), 49 narrative reviews, 3 RCTs, 29 observational studies, 12 mathematical models, 30 case reports/series, 9 evidence based guidelines, 27 expert opinions/editorials & commentaries) **Number of relevant studies** N=12 (9 SRs, 3 RCTs although individual relevance unclear as references not consistently reported) **Respiratory virus** Influenza **Intervention** Non-pharmaceutical interventions	The authors suggest that the published literature revealed scant confirmatory evidence on efficacy and overall effectiveness of non-pharmaceutical public health interventions in an influenza pandemic. The experts consulted for this review endorsed hand hygiene and respiratory etiquette, surveillance and case reporting, and rapid viral diagnosis in all settings and during all pandemic phases. They also encouraged patient and provider use of masks and other personal protective equipment as well as voluntary self-isolation of patients during all pandemic phases.	Other non-pharmaceutical interventions including mask-use and other personal protective equipment for the general public, school and workplace closures early in an epidemic, and mandatory travel restrictions were rejected as likely to be ineffective, infeasible, or unacceptable to the public.
Wong 2014[43] **Systematic review** https://doi.org/10.1017/S0950268814000003X	**Included studies and designs** N=10 RCTs of hand hygiene interventions **Number of relevant studies** N=5 RCTs of interventions combining hand hygiene with face masks **Respiratory virus** Influenza (laboratory-confirmed); ILI **Intervention** Hand hygiene (with or without face masks)	Analysis for interventions conducted in developed countries: significant reduction in laboratory-confirmed influenza of 27% reported for the hand hygiene and face mask group (RR = 0.73; 95% CI = 0.53 to 0.99; I2 = 0%; p = 0.05); the hand hygiene only comparison was not statistically significant. For ILI, a significant reduction of 27% (RR = 0.73; 95% CI = 0.60 to 0.89; I2 = 0%; p = 0.002) was noted for the combined comparison of hand hygiene and face mask use, while the result from hand hygiene alone was not statistically significant.	For the two studies conducted in less developed countries, the efficacy of hand hygiene was not significant in the pooled analysis for the laboratory-confirmed influenza outcome. For the ILI outcome, a non-significant relative increase was observed for the efficacy of combined comparison of hand hygiene and mask use.

Appendix 3: Risk of bias summary of RCTs

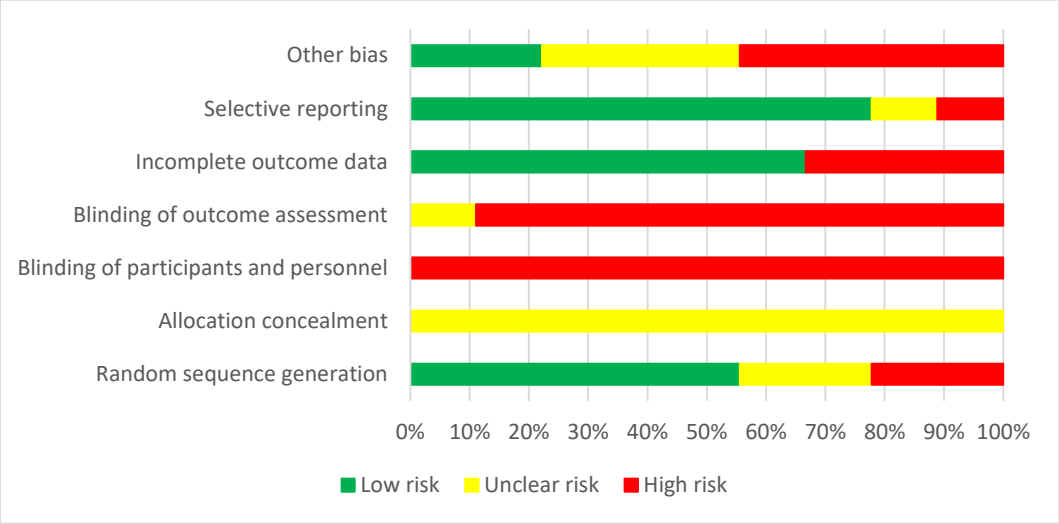

Figure 1. Risk of bias summary of RCTs

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