13/04/2020

NERVTAG paper: face mask use in the community

Background

- This document summarises evidence o face mask use in the community on the transmission of SARS-CoV-2 to date and options for their use.

- This issue is considered in the context of the current control mechanisms of workplace closure and social distancing. Recommendations may change as the epidemic and control measures evolve.

Evidence summary

Indirect evidence

- Mechanistic studies of the effect of face mask use on viral shedding in symptomatic patients involve few patients but show that masks reduce expulsion of infectious particles and therefore may reduce transmission if worn by infected individuals.

- Modelling studies are theoretical and highly dependent on initial assumptions of mask effectiveness. They report a potential major benefit of universal face mask wearing, especially if masks are assumed to be highly effective. In the context of limited mask supply models suggest that it should be targeted at symptomatic infectious patients and those at high risk of severe disease.

Direct evidence

- There is weak evidence that use of face masks by symptomatic people may reduce transmission.

- Evidence from randomised trials do not show a protective effect of face masks in community settings but are often affected by low adherence.

- Evidence from observational studies tend to support a protective effect of wearing face masks in the community but results are heterogeneous and subject to major biases and residual confounding.

Table 1. Evidence summary by type and duration of exposure

Source isolation (worn by symptomatic person)	*Evidence of effectiveness*	
Personal protection (worn by uninfected person)		
	Duration of exposure	
Risk of exposure	Short	Prolonged
High (close contact with unwell individuals)	e.g. Health care setting. *Evidence of effectiveness* (training, good compliance, additional hygiene measures)	e.g. Household *Evidence of lack of effectiveness* (repeated exposure via multiple routes, challenges with compliance)
Low (contact with well individuals)	e.g. Contact in a shop *No evidence.*	e.g. Community *Evidence of lack of effectiveness* (repeated exposure via multiple routes, challenges with compliance)

1

Additional considerations for COVID-19

- In the COVID-19 pandemic, symptomatic individuals should be self-isolating rather than wearing masks in public.
- Recent estimates suggest that up to 40% infectiousness may occur prior to illness onset [1]. However, the effect of face masks for source control in asymptomatic individuals is unknown.
- Compliance with mask use may be better in this pandemic than in influenza studies.

Options

Table 2. Policy options

Policy option	Pros	Cons	Level of support
Face masks for the unwell	Evidence of effectiveness	These people should be self-isolating.	Recommended
Face masks for household members of the unwell.	May provide a small incremental increase in protection if compliance is good, combined with other hygiene measures, and is implemented early.	Evidence of lack of effectiveness in RCTs.	Permissive
Universal face masks in the community.	Given possibility of significant pre-symptomatic transmission, may provide a very small incremental increase in protection.	Evidence of lack of effectiveness. May result in decreased compliance with social distancing, hand hygiene etc. Unlikely to have a significant impact whilst social distancing in force. Supply issues.	Not recommended
Face masks in the community for all individuals only during short periods of unavoidable close contact.	Given possibility of significant pre-symptomatic transmission, may provide a small incremental increase in protection.	Evidence of effectiveness not available. May result in decreased compliance with social distancing, hand hygiene etc. Supply issues.	Permissive
Face masks in the community only for vulnerable individuals for short periods of unavoidable close contact.	Given possibility of significant pre-symptomatic transmission, may provide a small incremental increase in protection for most at-risk group.	Evidence of effectiveness not available. May result in decreased compliance with social distancing, hand hygiene etc.	Recommended

2

Fuller evidence review

Table 3. Recent publications

Reviews and meta-analyses			
Article	**Inclusion**	**Result**	**Author's Conclusion**
Xiao et al. Nonpharmaceutical Measures for Pandemic Influenza in Nonhealthcare Settings—Personal Protective and Environmental Measures.[2]	10 RCts	no significant reduction in influenza transmission with the use of face masks (RR 0.78, 95% CI 0.51–1.20; I^2 = 30%, p = 0.25)	We did not find evidence that surgical-type face masks are effective in reducing laboratory-confirmed influenza transmission, either when worn by infected persons (source control) or by persons in the general community to reduce their susceptibility
Brainhard et al. Facemasks and similar barriers to prevent respiratory illness such as COVID-19: A rapid systematic review.[3]	31 eligible studies (including 12 RCTs)	Meta analyses of RCT evidence showed wearing a facemask may very slightly reduce the odds of developing ILI/respiratory symptoms, by around 6% (OR 0.94, 95% CI 0.75 to 1.19. (based on data from 3 RCTs) although the effect was not statistically significant. Wearing of a face mask by both infected people and their contacts may reduce ILI by 16% but the result was non-significant. Wearing of a mask by an exposed person alone reduced risk by 7% but the result was not significant. Evidence across six cohort studies showed a non -significant protective effect. This was mainly driven by one outlier study with the other five studies showing no evidence of protection. Evidence across case control studies and cross-sectional studies was inconsistent although overall they suggested a significant protective effect but had a high risk of bias. Meta-analyses by setting showed significant effects in healthcare settings but not other settings.	Wearing facemasks can be very slightly protective against primary infection from casual community contact and modestly protective against household infections when both infected and uninfected members wear facemasks. The evidence is not sufficiently strong to support widespread use of facemasks as a protective measure against COVID-19. However, there is enough evidence to support the use of facemasks for short periods of time by particularly vulnerable individuals when in transient higher risk situations.

		Meta-analyses by whether the mask was worn by the well person, ill person or both showed a non significant protective effect if the mask was worn by both. Metaanalyses of household studies whether the mask wearing was initiated within 36 hours of index case symptoms showed no significant protective effect.	
Jefferson et al. Physical interventions to interrupt or reduce the spread of respiratory viruses. Part 1 - Face masks, eye protection and person distancing: systematic review and meta-analysis.[4]	15 randomised trials investigating the effect of masks (14 trials) in healthcare workers and the general population	Compared to no masks there was no reduction of influenza-like illness (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) for masks in the general population, nor in healthcare workers (Risk Ratio 0.37, 95%CI 0.05 to 2.50)	There was insufficient evidence to provide a recommendation on the use of facial barriers without other measures.
Liang et al. Efficacy of face mask in preventing respiratory virus transmission: a systematic review and meta-analysis. [5]	21 studies	Use of masks by healthcare workers (HCWs) and non-healthcare workers (Non-HCWs) can reduce the risk of respiratory virus infection by 80% (OR = 0.20, 95% CI = 0.11-0.37) and 47% (OR = 0.53, 95% CI = 0.36-0.79).	Masks worn by non-infected people can effectively prevent the spread of respiratory viruses and reduce the overall risk of respiratory virus infection
Mechanistic data			
Leung et al. Respiratory virus shedding in exhaled breath and efficacy of face masks.[6]	Effect on mask wearing and virus detection in exhaled breath	Viral RNA was identified from respiratory droplets and aerosols produced by symptomatic patients over a 30 minute period who were randomised to measurement with or without face mask use. Most patients coughed repeatedly during this period. Surgical Face mask use led to significant reductions in the likelihood of identifying seasonal coronavirus in exhaled aerosols 4/10 without mask and 0/11 with mask p=0.04. No significant difference was seen for droplets. For influenza, face masks reduced identification of virus in respiratory droplets (6/23 vs 1/27 p= 0.04) but not in aerosols. For rhinovirus there were no significant differences. Influenza – respiratory droplets 6/23 vs 1/27 patients. and , including **30%**, 26% and 28% of respiratory droplets and **40%**, 35%	Surgical face masks could prevent transmission of human coronaviruses and influenza viruses from symptomatic individuals.

4

		and 56% of aerosols collected while not wearing a face mask, from coronavirus, influenza virus and rhino- virus-infected participants, respectively	
Mathematical models or ecological data			
Modelling the Effectiveness of Respiratory Protective Devices in Reducing Influenza Outbreak [7]		It was found that a 50% compliance in donning the device resulted in a significant (at least 50% prevalence and 20% cumulative incidence) reduction in risk for fitted and unfitted N95 respirators, high-filtration surgical masks, and both low-filtration and high-filtration pediatric masks.	
Face mask use in the general population and optimal resource allocation during the COVID-19 pandemic.[8]		Assuming masks are effective at preventing infected people from spreading infection and uninfected people from acquiring infection, then the optimum strategy in the context of limited mask availability is to use masks in vulnerable groups and those with symptoms.	Distribution of relatively ineffective masks to 10% of the population could reduce mortality rates by 5%.
Widespread use of face masks in public may slow the spread of SARS CoV-2: an ecological study. [9]	Ecological study	Eight of the 49 countries with available data advocated wearing face masks in public: China, Czechia, Hong Kong, Japan, Singapore, South Korea, Thailand and Malaysia. In multivariate analysis controlling for age of the epidemic and testing intensity face mask use was negatively associated with number of diagnosed COVID-19 cases/inhabitant (coef. -326, 95% CI -601- -51, P=0.021).	Results "provide ecological level support to the individual level studies that found face mask usage to reduce the transmission and acquisition of respiratory viral infections.
Computational Science Research Center, Korea Institute of Science and Technology		The simulations suggest that social distancing, hand hygiene and face mask use have an additive effect on controlling the epidemic in Korea	
Impact assessment of non-pharmaceutical interventions against COVID-19 and influenza in Hong Kong: an observational study. [10]		The study showed that reductions in COVID transmission occurred following increases in a range of population behaviours including use of face masks in public, social distancing, staying at home and hand washing. The design did not enable the independent effects of these interventions to be distinguished.	Containment measures, social distancing measures and changes in population behaviour have successfully prevented spread of COVID-19.

5

Cloth face masks

Cloth face masks are not as effective as surgical face masks.[11]

1607 hospital HCWs aged ≥18 years working full-time in selected high-risk wards

"The rates of all infection outcomes were highest in the cloth mask arm, with the rate of ILI statistically significantly higher in the cloth mask arm (relative risk (RR)=13.00, 95% CI 1.69 to 100.07) compared with the medical mask arm"

Recent commentaries and recommendations

Greenhalgh et al.[12]

"We believe that, worn both in the home (particularly by the person showing symptoms) and also outside the home in situations where meeting others is likely (for example, shopping, public transport), they could have a substantial impact on transmission with a relatively small impact on social and economic life."

Feng et al.[13]

"Vulnerable populations, such as older adults and those with underlying medical conditions, should wear face masks if available. Universal use of face masks could be considered if supplies permit."

WHO position

"There is currently no evidence that wearing a mask (whether medical or other types) by healthy persons in the wider community setting, including universal community masking, can prevent them from infection with respiratory viruses, including COVID-19."

US CDC advice has changed on 4th April.

*We now know from recent studies that a significant portion of individuals with coronavirus lack symptoms ("asymptomatic") and that even those who eventually develop symptoms ("pre-symptomatic") can transmit the virus to others before showing symptoms. This means that the virus can spread between people interacting in close proximity—for example, speaking, coughing, or sneezing—even if those people are not exhibiting symptoms. In light of this new evidence, CDC recommends wearing cloth face coverings in public settings where other social distancing measures are difficult to maintain (e.g., grocery stores and pharmacies) **especially** in areas of significant community-based transmission.* https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/cloth-face-cover.html

Summary and conclusions:

1. A range of systematic reviews and meta-analyses have come to differing conclusions about the value of face masks in community settings. In general, the differing conclusions relate to whether or not the reviews combine randomised trials and

observational data or not and whether or not they combine trials in healthcare worker and community settings or not.

2. Evidence from randomised trials do not show a protective effect of face masks in community settings but are often affected by minimal adherence.

3. Evidence from observational studies tend to support a protective effect of wearing face masks in the community but results are heterogeneous and subject to major biases and residual confounding.

4. Mechanistic studies of the effect of face mask use on viral shedding in symptomatic patients involve very few patients but suggest masks may reduce expulsion of infectious particles and therefore may reduce transmission if worn by infected individuals.

5. Viral transmission via respiratory droplets and aerosols is likely to be substantially less in asymptomatic infected individuals than in symptomatic individuals.

6. Modelling studies are highly dependent on initial assumptions of mask effectiveness but suggest a potential major benefit of universal face mask wearing, especially if masks are assumed to be highly effective. Modelling suggests much lower, but potentially important benefit if masks are assumed to be less effective. In the context of limited mask supply models suggest that it should be targeted at symptomatic infectious patients and those at high risk of severe disease.

7. There is weak evidence that use of face masks by symptomatic people may reduce transmission but very limited evidence that wearing a surgical mask in the community reduces risk of acquiring infection unless accompanied by other interventions such as intensified hand washing.

8. In the COVID-19 pandemic symptomatic individuals should be self-isolating rather than wearing masks in public.

9. Widespread social distancing and hand hygiene may limit the potential additional value of mask use.

10. Overall there is insufficient evidence to recommend universal use of face masks in the community. In the short term, widespread community facemask use is likely to have a significant impact on the ability of the NHS to purchase sufficient masks for health care workers.

11. It is possible that widespread community mask use may lead to people being less stringent in social distancing and self isolation measures, although there is no direct evidence of this. However, it is also possible that if any such effect does exist it could be reduced or resolved through a proactive education / communications initiative.

12. The use of face masks in the community by vulnerable individuals for short periods of exposure combined with other control measures such as social distancing and hand hygiene, may be reasonable given that it may provide a small incremental increase in protection.

Detailed discussion of evidence

Review of trials and epidemiological studies on the use of face masks by the public and healthcare workers:

The review by Offeddu et al is restricted to HCW who wear the masks during work shifts and shows the benefit of N95 respirators; this shows evidence of benefit of both n95 respirators and medical face masks when used by trained healthcare workers in high exposure settings.[14]

A recently updated systematic review and metaanalysis of trials of face mask use (Jefferson et al) found that compared to no masks there was no reduction of influenza-like illness (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) for masks in the general population, nor in healthcare workers (Risk Ratio 0.37, 95%CI 0.05 to 2.50).[4]

A recent review (Brainard et al) of masks in community settings finds no significant evidence of protection in meta-analyses of community face mask use from randomised controlled trials or cohort studies.[3] The only significant protective findings were in case control studies, pre-post designs and cross-sectional designs where there is a high risk of bias. Meta-analyses by whether or not the ill person, the well person or both wore masks suggested no protective effect if only the well person or only the ill person wore a mask but a non-significant protective effect if both wore masks. However, this was based on a single case control study. Overall this review provides no evidence that community face mask use is effective.[3]

The review by Bin-Reza examines the issue more generally, including studies in household (HH) settings. Most of the trials showed no evidence of reduced risk in those individuals who were assigned to the mask wearing group (note that these were HH studies with an index case, where HH members were asked to wear a mask / respirator when in contact with the case).[15]

Specifically, the household index case trials by Cowling showed in subgroup analyses that early mask use combined with hand hygiene reduced risk of acquiring influenza but the main analysis showed no significant protection. Also, the trial could not distinguish between the effects of hand hygiene and the effects of mask use.[16]

The MacIntyre cluster randomised controlled trial comparing Respirator vs surgical mask vs no mask in households following an index case in child. There was no overall impact on ILI or laboratory confirmed influenza. Adherence was low and dropped to even lower levels several days in. Subgroup analysis showed those who were more adherent were less likely to develop ILI. This controlled for age of index case and number of adults and children in household but not for ethnicity (which showed some association with mask use). Also, the measures of adherence to hand hygiene and cleaning are not clearly reported so it is difficult to interpret if these may have a confounding effect.[17]

The cluster randomised trial of students in halls of residence over the flu season showed a protective effect of combined facemask and hand hygiene but non-significant effects of face masks alone. This is arguably the most directly relevant study as it encouraged wearing of

masks as much as possible in halls of residence and outside rather than using a HH design. Adherence is likely to have been lower than might be seen in pandemic COVID-19.

The Larson study in urban households found no evidence of benefit of mask use.[18]

Observational case control studies in China show some evidence that frequent wearing of a mask outside the household may reduce risk of SARS but may be subject to bias because of observational design.

An ecological study by Kenyon et al (https://doi.org/10.1101/2020.03.31.20048652) found an association between whether or not countries advocated face mask use and the number of diagnosed cases of COVID (p=0.02). This was controlled for stage of the epidemic and testing intensity but not for the intensity of other control measures or population structures. This study is subject to major biases and considerable residual confounding.[9]

A further ecological study by Cowling et al found that reductions in COVID transmission in Hong Kong occurred following increases in a range of population behaviours including use of face masks in public, social distancing, staying at home and hand washing. The design did not enable the independent effects of these interventions to be distinguished, so it is not possible to infer whether face mask use contributed to this decline in transmissibility.[10]

Summary of epidemiological evidence – Although there is evidence of effectiveness of face mask use in highly exposed health care workers there is no convincing evidence of the effectiveness of face mask use in community settings. Meta-analyses of randomised controlled trials and cohort studies show no significant effects. Subgroup analyses of trials suggest that the minority of people who are highly adherent to mask use in household studies may be protected but it should be emphasised that these subgroup analyses are potentially subject to bias. Some research suggests that effectiveness may be greater if both the ill person and the well person wear masks, but this finding was not statistically significant and was from a case control study. Observational studies tend to show a greater effect than trials (e.g. significant effects were seen in cross sectional, before and after, case control and ecological studies). However these studies are all subject to significant bias and confounding.

Mechanistic studies.

Leung et al - Viral RNA was identified from respiratory droplets and aerosols produced by symptomatic patients over a 30 minute period who were randomised to measurement with or without face mask use. Most patients coughed repeatedly during this period. Surgical Face mask use led to significant reductions in the likelihood of identifying seasonal coronavirus in exhaled aerosols 4/10 without mask and 0/11 with mask p=0.04. No significant difference was seen for droplets. For influenza, face masks reduced identification of virus in respiratory droplets (6/23 vs 1/27 p= 0.04) but not in aerosols. For rhinovirus there were no significant differences. Despite very small numbers and marginal significance, the study suggests face masks worn on symptomatic patients may reduce transmission of coronavirus and influenza. Detection of virus appeared markedly less in the subset of patients who were not coughing, so the impact on transmission from asymptomatic patients may be marginal.[6]

9

Modelling studies

Yan et al [7]- The study relies on extrapolating from a variety of experimental studies on the efficacy of different face masks is preventing expulsion and inhalation of respiratory particles produced by tidal breathing. Filtration efficacies achieved in experimental settings are unlikely to be replicated in public use for example where masks are poorly fitted and worn for prolonged periods. These filtration efficacy values are combined with measures of the likely concentration and size distribution of particles in exhaled breath, estimates of the concentration of infectious particles in the breath, the breathing rate and volume, estimates of the distance over which particles will spread through the air, estimates of the contact rate within a time and distance sufficient to breath in an exhaled infectious particle, estimates of the likelihood that an inspired particle will establish an infection. These are in addition to the range of parameters used in standard SEIR models. The model also ignores the role of transmission through contact and surface/fomite transmission which is likely to play an important role in transmission. Given the degree of uncertainty in very many of these measures the output of the model needs to be treated with considerable caution especially as it seems to imply a substantially greater protective effect than experimental studies of community mask use. The plausibility also needs to be questioned as the impact seems to be of a greater scale than can be achieved through influenza vaccination which is likely to have a greater protective effect than public face mask use. Thus, although the model is valuable as a thought experiment it should not form the basis of policy decisions in this area.

Worby et al modelled a range of mask effectiveness scenarios (75% 50% 25% effectiveness in containing COVID-19 in those infected and 75% 50% and 25% effectiveness in preventing COVID-19 infection in those exposed).[8] This was also modelled according to mask scarcity. When masks were scarce the optimum approach was to target mask use to those at higher risk of death and to those with symptoms of infection. Healthcare workers were not explicitly modelled. They inferred that even with minimal distribution (10% of population) of relatively ineffective masks this could reduce overall mortality rates by 5%. They also inferred that more widespread distribution of highly effective masks could have a major impact on mortality.[8]

A simulation study from Korea found additive effects of social distancing, mask use and handwashing but insufficient methodological detail was provide to assess validity.

References
1.   He X, Lau E, Wu P, et al. Temporal dynamics in viral shedding and transmissibility of COVID-19. 2020.
2.   Xiao J, Shiu EYC, Gao H, et al. Nonpharmaceutical Measures for Pandemic Influenza in Nonhealthcare Settings-Personal Protective and Environmental Measures. Emerg Infect Dis 2020;26.
3.   Brainard JS, Jones N, Lake I, Hooper L, Hunter P. Facemasks and similar barriers to prevent respiratory illness such as COVID-19: A rapid systematic review. 2020.
4.   Jefferson T, Jones M, Ansari A, et al. Physical interventions to interrupt or reduce the spread of respiratory viruses. Part 1 - Face masks, eye protection and person distancing: systematic review and meta-analysis. 2020.

5.   Liang M, Gao L, Cheng C, et al. Efficacy of face mask in preventing respiratory virus transmission: a systematic review and meta-analysis. 2020.

6.   Leung N, Chu K, Shiu EYC, et al. Respiratory virus shedding in exhaled breath and efficacy of face masks. Nature Medicine 2020.

7.   Yan J, Guha S, Hariharan P, Myers M. Modeling the Effectiveness of Respiratory Protective Devices in Reducing Influenza Outbreak. Risk Anal 2019;39:647-61.

8.   Worby CJ, Chang H. Face mask use in the general population and optimal resource allocation during the COVID-19 pandemic. 2020.

9.   Kenyon C. Widespread use of face masks in public may slow the spread of SARS CoV-2: an ecological study. 2020.

10.   Cowling BJ, Ali ST, Ng TWY, et al. Impact assessment of non-pharmaceutical interventions against COVID-19 and influenza in Hong Kong: an observational study. 2020.

11.   MacIntyre CR, Seale H, Dung TC, et al. A cluster randomised trial of cloth masks compared with medical masks in healthcare workers. BMJ Open 2015;5:e006577.

12.   Greenhalgh T, Schmid MB, Czypionka T, Bassler D, Gruer L. Face masks for the public during the covid-19 crisis. BMJ 2020;369:m1435.

13.   Feng S, Shen C, Xia N, Song W, Fan M, Cowling BJ. Rational use of face masks in the COVID-19 pandemic. Lancet Respir Med 2020.

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

15.   Bin-Reza F, Lopez Chavarrias V, Nicoll A, Chamberland ME. The use of masks and respirators to prevent transmission of influenza: a systematic review of the scientific evidence. Influenza Other Respir Viruses 2012;6:257-67.

16.   Cowling BJ, Chan KH, Fang VJ, et al. Facemasks and hand hygiene to prevent influenza transmission in households: a cluster randomized trial. Ann Intern Med 2009;151:437-46.

17.   MacIntyre CR, Cauchemez S, Dwyer DE, et al. Face mask use and control of respiratory virus transmission in households. Emerg Infect Dis 2009;15:233-41.

18.   Larson EL, Ferng YH, Wong-McLoughlin J, Wang S, Haber M, Morse SS. Impact of non-pharmaceutical interventions on URIs and influenza in crowded, urban households. Public Health Rep 2010;125:178-91.