Role of Face masks as part of non-pharmaceutical interventions against coronavirus disease

1 REMASK

reMask is an expert group working to provide for Switzerland evidence-based information and propose innovative solutions around the use and production of face masks during the COVID-19 pandemic. Different work packages respectively address collection and reprocessing of used masks, establishing a state-of-the art network to test the efficacy of commercially available masks, setting standards to produce tissue masks, and summarizing the evidence-base to inform judicious use of masks in both healthcare and the public. This document summarizes the findings on face masks as a non-pharmaceutical intervention against infections due to respiratory viruses.

2 AUTHORSHIP

For reMask the following authors contributed to this literature review to the best of their knowledge: Jean-Romain Delaloye, Andreas Mortensen, Damien de Courten, Peter Wick, René Rossi, and Walter Zingg. The group also thanks Dr Michel Meisterhans for his contribution. The document has been further submitted to the expert group 8 of the National COVID-19 Science Task Force (NCS-TF) focusing on Infection prevention and control and accepted.

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3 CONTEXT

The spread of respiratory viral infections is known to occur through contact and by droplets (diameter >5um). New evidence suggests that severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) can also remain viable and infectious in aerosols (droplet diameter <5um), particularly on aerosol-generating procedures[1]. The use of face masks is an appropriate personal protective equipment (PPE) for the prevention of respiratory infections, and is part of both basic precaution measures and respiratory etiquette. [2] Any person who is in close contact (within 1-2 m) with someone who has respiratory symptoms (coughing, sneezing) is at risk of being exposed to potentially infective respiratory droplets (WHO, 3 May 2009). Mask can protect for droplets and aerosols; however, they also can control the source, meaning the spread of droplets from the bearer to others. There are, therefore, several mask types.

4 MASK TYPES

FFP Masks	**FFP Masks, particle Filtering FacePiece, or personal protection facemasks are masks meeting the criteria of the norm EN 149 (e.g. FFP1, FFP2, FFP3, N95, or equivalent)** FFP masks are personal protective equipments and have to comply with the EU directive (EU/2016/425, SR 930.115 – Verordnung über die

	Sicherheit von persönlichen Schutzausrüstungen (PSA-Verordnung)). They have to be tested according to the norm EN 149 and must be certified by an independent certification body. FFP masks are classified into FFP1, FFP2 and FFP3 depending on their filtration capacity. In the current situation of limited supply, FFP masks are to be strictly reserved for healthcare professionals directly exposed to aerosols by performing aerosol generating procedures (e.g. bronchoscopy, resuscitation, open suctioning, non-invasive ventilation) on individuals with laboratory-confirmed or clinically suspected COVID-19.
Surgical Masks	**Surgical Masks (preferred name in Switzerland), OP-Masks, or Medical masks are masks meeting the criteria of the norm EN 14683 (e.g. Type I, Type II, Type IIR, or equivalent)** Surgical masks have to comply with the regulation on medical products (EU/2017/745, SR 812.213 Medizinprodukteverordnung – MepV). They have to be tested according to the norm EN 14683 and certified. Surgical masks are classified into Type I, Type II and Type IIR. Only Type IIR protects against splashes.
Community masks	**"Community" mask is not an official term, but is been used here for masks that are certified neither by the norm EN 14683 nor by the norm EN 149.** The use of non-certified community masks is aimed at the general population, primarily for source control (respiratory etiquette) – thus, for protecting others from exhaled virus-containing droplets. Community masks is a wide concept that does not refer to any established standard. Still, research is presently being conducted to identify the best mask designs and to establish performance criteria on masks sufficiently blocking droplets while being comfortable to wear and allowing reprocessing at home. Not all mask designs and materials are suitable for barrier masks (e.g. based on current knowledge, the efficacy of cloth mask has been challenged[3]).

5 FUNCTION OF THE MASK

Masks in the context of the Covid-19 crisis thus serve one or both of two functions[4]:

- Source control: Mask used by an infectious person prevents onward transmission
- Personal protection: Mask used by healthy person prevents contamination by inhalation

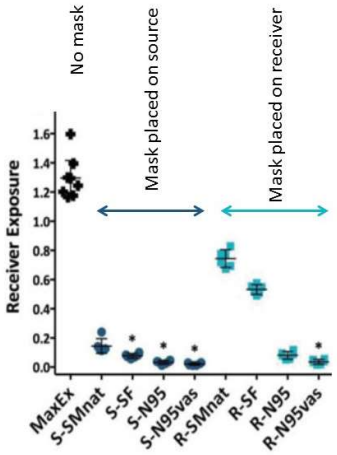
5.1 Source control

Wearing a mask blocks the forward momentum of the cough jet and its droplet content, although the loose fit of the mask that is required for comfort in wear can allow much of the air ejected by the cough to leak around the top, bottom and especially the sides of the mask. The air leaked on the sides has minimal momentum, and the resulting air jet towards other persons is much reduced; hence, even in the event of such leakage the mask can serve to mitigate virus propagation. [5]

Without Mask *With mask*

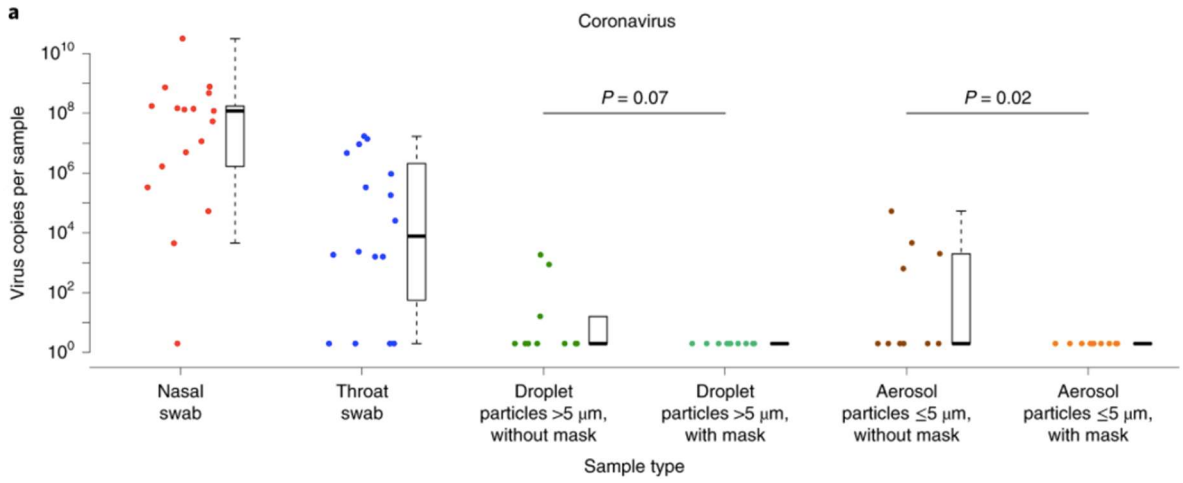
This protective effect has been demonstrated in vitro and in vivo:

- **In vitro study [4]**
  Results show that the mask more effectively captured the exhaled aerosols during coughing rather than protecting the exposed person – source control was clearly superior to masking the receiver (Personal protection)



Exposure data for cough, S = Source, R=Receiver, MaxEx=Maximum Exposure, SMnat=natural fit surgical mask, SF=SecureFit Ultra fitted surgical mask, N95=3M N95 respirator, N95vas = 3M N95 respirator with a Vaseline seal.

- **In vivo study[6]**
  This study published recently in *Nature Medicine* tested the efficacy of surgical masks in reducing respiratory virus shedding in respiratory droplets and aerosols of symptomatic individuals with coronavirus



Based on these results, authors suggested that surgical face masks could be used by ill people to reduce the onward transmission of COVID-19.

5.2 Personal protection

In vitro tests have demonstrated that surgical masks could reduce around 6 to 10-fold the exposure to infectious influenza virus present in bioaerosols. [7, 8] However, in vivo results showed that surgical masks will mitigate a mean reduction factor of around 2 against a simulated sneeze of inert airborne particles.[8] While surgical masks protect healthcare workers when exposed to patients with respiratory infections, there is limited evidence that wearing surgical masks by healthy individuals in the population is beneficial as a preventive measure during an epidemic, particularly when the attack rate is low.

Therefore, based on current knowledge, face masks are more effective as source control than as personal protection.

6 CLINICAL STUDIES

Based on the latest systematic reviews and meta-analysis we performed a rapid search of the literature on the wearing of masks by the general public or by healthcare professionals during epidemics or pandemics. We identified 23 studies (14 RCT, 1 cross-sectional study and 8 systematic-reviews including 6 meta-analyses) published between 2009 and 2020.[3, 9-30] Table 1 summarizes results of the 6 meta-analyses[21, 22, 26-28, 30]:

Recent meta-analyses about wear of mask +/- Hand Hygiene

	Title_Author_Year	Significant improvement	number of patients	Study population	Results	Limitations	Conclusion of the study	Our Analyse
2	Hand hygiene and risk of influenza virus infections in the community: A systematic review and meta-analysis_Wong2014	Yes with hand hygiene	not specificed, check individual studies	Community	**Hand hygiene alone not sufficient:** RR = 0.82 (95% CI = 0.66 to 1.02) **Significant reduction of 27% was reported for the hand hygiene and facemask group (RR = 0.73; 95% CI = 0.53-0.99).**	low statistical power, small number of RCTs that have been conducted to date on the efficacy of hand hygiene to control influenza, different settings and different hand hygiene interventions.	Hand hygiene alone not sufficient. The subgroup analysis from developed countries suggested that a combined intervention consisting of hand hygiene with facemasks is an effective strategy to prevent influenza, but they did not confirm the efficacy of hand hygiene alone for reducing influenza illness	Reliable metaanalysis. Hand hygiene alone doesn't provide any benefit. However mask and hand hygiene does.
3	Physical interventions to interrupt or reduce the spread ofrespiratory viruses_Jefferson_2011	Yes	not specificed, check individual studies	healthcare professionals and communities	hand washing: n=2825, OR 0.54 (95% CI= 0.44-0.67) Wearing mask: n=3216, OR 0.32 ((95% CI= 0.26-0.39) Wearing N95 respirator: n=817 OR0.17 (95% CI= 0.07-0.43) Wearing gloves: n= 1836 OR 0.32 (95% CI= 0.23-0.45)	studies were conducted over four decades and the settings were heterogeneous and included a variety of different populations from suburban schools to military to different hospital wards in low as well as in high-income countries. Variable quality of methods. Especially the before and after and the cohort studies showed missing randomisation. A commonly ignored confounder is the huge variability in viral incidence.	Simple and low-cost interventions would be useful for reducing transmission of epidemic respiratory viruses. N95 respirators were non-inferior to simple surgical masks but more expensive, uncomfortable and irritating to skin. Adding virucidals or antiseptics to normal handwashing to decrease respiratory disease transmission remains uncertain. limited evidence that social distancing was effective	Very extensive analysis. Case control studies for SARS coronavirus showed that the mask was the best performing intervention, even used as an isolated measure. Different studies showed that hand hygiene does reduced infection rates. A combination of mask and handhygiene is therefore benefical to reduce the Coronavirus infection rate.
8	Efficacy of face mask in preventing respiratory virus transmission: a systematic review and meta-analysis_Liang2020	Yes	not specificed, check individual studies	healthcare professionals and communities	Protective effect of masks: in general, OR = 0.35 (95% CI = 0.24-0.51); in healthcare workers, OR = 0.20 (95% CI = 0.11-0.37); in non-healthcare workers OR = 0.53, (95% CI = 0.36-0.79); 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 OR = 0.04 (95% CI =0.00-0.60).	Paper is not peer reviewed yet. A high amount of case control studies, which are generally inferior to RCTs. Low amount of RCTs.	evidence of the enhanced protective value of masks. The use masks serve as an adjunctive method regarding the COVID-19 outbreak.If masks are to be used, they should be combined with hand hygiene and other NPIs to prevent human-to-human mutual infection, and education of wearing masks properly and adherence to other NPIs would be needed.	Most recent metaanalysis containing case reports from the current COVID-19 outbreak. However case reports often have poor study settings and are inferior to RCTS.
4	Effectiveness of personal protective measures in reducing pandemic influenza transmission: A systematic review and meta-analysis_Saunders-Hastings_2017	No, mask alone	30'625	healthcare professionals and communities	2 analysis for masks: n=1371 OR 0.53 (95%CI 0.16-1.71); n=1736 OR=0.41 (95%CI 0.18-0.92) hand hygiene: n=3930, OR = 0.62 (95%CI 0.52-0.73)	No comparative studies included. No appropriate threshold for adequate, protective hand hygiene or facemask use. Big difference in studies stettings, moderate to high risk of bias in most of the included studies.	Hand hygiene is significantly effective in preventing infection. Facemask use demonstrated mixed results, but a randomized control trial suggests that it is effective in preventing infection. The results suggest that in situation of high risk of exposure, hand hygiene alongside facemasks are likely to contribute to preventing pandemic influenza infection.	Solid review and metaanalysis, however no comparative studies were included.
5	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_Jeffereson2020	No, mask alone	not specificed, check individual studies	healthcare professionals and communities	Masks: no significant reduction of influenza-like illness (ILI) cases (RR 0.93, 95%CI 0.83-1.05) or influenza (RR 0.84, 95%CI 0.61-1.17) in the general population, nor in healthcare workers (RR 0.37, 95%CI 0.05-2.50). No difference between surgical masks and N95 respirators: for ILI (Risk Ratio 0.83, 95%CI 0.63 to 1.08), for influenza (Risk Ratio 1.02, 95%CI 0.73 to 1.43). Harms were poorly reported and limited to discomfort with lower compliance.	Most included trials had poor design, reporting and sparse events. The paper is not peer-reviewed yet.	insufficient evidence to provide a recommendation on the use of facial barriers without other measures. Insufficient evidence for a difference between surgical masks and N95 respirators and limited evidence to support effectiveness of quarantine. Based on observational evidence from the previous SARS epidemic included in the previous version of our Cochrane review they recommend the use of masks combined with other measures.	Objective review, showing no evidence for recommendation on the use of face mask **alone** to reduce influenza-like illness (ILI) cases or infleunza in healthcare workers nor in the general population
6	Nonpharmaceutical Measures for Pandemic Influenza in Nonhealthcare Settings—Personal Protective and Environmental Measures_Xiao2020	No	>10'000	non-healthcare settings	The effect of hand hygiene combined with face masks on laboratory-confirmed influenza was not statistically significant (RR 0.91, 95% CI 0.73– 1.13; I2 = 35%, p = 0.39). No significant reduction in influenza trans-mission with the use of face masks alone (RR 0.78, 95% CI 0.51–1.20; I2 = 30%, p = 0.25)	Some studies reported being underpowered because of limited sample size, and low adherence to hand hygiene interventions was observed in some studies. Additional high-quality RCTs of efficacy of hand hygiene and face masks against laboratory-confimred influenza would be useful.	**No evidence to support a protective effect of hand hygiene or facial masks in reducing influenza transmission was found.** However, as with hand hygiene, face masks might be able to reduce the transmission of other infections and therefore have value in an influenza pandemic when healthcare resources are stretched.	Solid review and metaanalysis for non-healthcare settings. Results based exclusively on labor testing. Consider reported low adherence to hand hygiene or face mask in some studies.

There is a limited evidence base to support the use of masks in healthcare or community settings. However, three of the six meta-analyses identified a significant decrease of respiratory viral infection risk while the other three reported a positive but non-significant trend towards the benefit of masking. No study reported that wearing a mask significantly or non-significantly increased the risk for infection by a respiratory virus. This situation is similar to hand hygiene, which demonstrated a decrease in the risk of respiratory infection, but with the caveat that the difference with the control group was not always significant. [21, 22]

Despite discrepancies between results, all authors of the reported meta-analyses recommended the use of masks as part of a package of personal protection, particularly including hand hygiene, in an event of pandemics. Those recommendations are supported by the WHO in their"Non-pharmaceutical public health measures for mitigating the risk and impact of the epidemic and pandemic influenza" document published last year.

According to randomized controlled trials included in our review of literature, wearing a mask is safe.[3, 9, 15, 17, 19, 20] The only adverse events reported in the literature are discomfort because of heat, humidity and breathing difficulties. No study demonstrated a diminution of hand-washing induced by a false safety feeling conferred by the wearing of a mask.[10, 11, 13, 14, 25] Moreover, a study performed in Honk Hong showed that a self-reported significant increase in compliance wearing mask was correlated with concomitant self-reported significant increase in compliance following hand hygiene.[31]

Finally, wearing mask and hand hygiene together are part of non-pharmaceutical interventions including, in particular, restrictions on the circulation of people, quarantine and isolation, together with social distancing. Altogether those measures have already shown, in Japan and Hong Kong, an association with a decrease in the transmission of respiratory viruses, including COVID-19.[31, 32]

7 CONCLUSION

In the face of the COVID-19 pandemic, risk-benefit is largely in favor of generalized mask wearing in association with hand hygiene wherever social distancing cannot be maintained. Although no study demonstrated that hand hygiene was reduced by mask wearing, focusing on masks alone may, on common grounds, reduce the perceived importance of hand hygiene. The generalized wearing of masks must therefore be implemented together with equally generalized hand hygiene and social distancing, and must be communicated as part of a broader, coherent, package of preventive measures for the entire community.

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