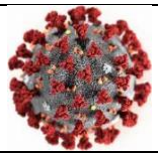
Swiss National COVID-19 Science Task Force (NCS-TF)



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Considerations regarding the mandatory use of FFP masks for the general population

Summary of request/problem

In January 2021, the state of Bavaria ordered the mandatory wearing of filtering facepiece 2 (FFP2) masks on public transport and in shops to reduce the transmission of SARS-CoV-2, especially the new variant B.1.1.7 (British variant). In most other countries, including Switzerland, the current recommendation is to wear surgical or tested community masks in public areas. This document seeks to answer the following question: “Should the wearing of FFP2 masks be made mandatory in Switzerland ?”.

Executive summary

FFP2 (or equivalent, e.g. N95 or KN95) masks are high-performance protective masks designed chiefly for working personnel. When worn properly they tend to outperform surgical or tested community masks, in terms of both protection of the wearer and, if and only if they have no valve, protection of her/his surroundings. FFP2 masks are, on the other hand, less comfortable, more expensive and more difficult to wear properly. Challenges exist in terms of achieving proper mask-fit, finding an individually fitting model, maintaining compliance with mask wearing for a yet unforeseeable timeperiod, and potential health hazards. There is furthermore an increasing body of evidence supporting the efficient protective effect of surgical masks.

In line with the statement[1] made by the “Deutsche Gesellschaft für Krankenhaushygiene (DGKH)” and the “Gesellschaft für Hygiene, Umweltmedizin und Präventivmedizin (GHUP)”, we therefore question the benefits of making the use of FFP2 masks mandatory for the general population in everyday settings such as public transport. We instead support promotion of the previously recommended measures to prevent transmission, emphasizing the importance of strict compliance.

While the considerations outlined above address recommendations for the mandatory use of FFP2 or equivalent masks for the general population in everyday settings, they also support maintaining the current recommendations published by Swissnoso emphazing the use of personal protective equipment with surgical masks even in the acute care settings, unless aerosol generating procedures are performed or expected.

Main text

Function of different mask types and requirements for proper use

The definition of the different types of masks (i.e. FFP masks, surgical masks and community masks), their specifications and their testing procedure are provided in the policy briefs "*Recommendations for minimal specifications for the community masks for Swiss manufacturers"* published on April 25th 2020 and updated on October 14th 2020 and *"Clarification on face mask types, architecture, quality, handling, test and certification procedures"* published on October 14th 2020. These definitions are outlined in the appendix of this document for direct reference. The role of wearing masks against the spread of SARS-CoV-2 has been addressed in the policy brief "*Role of masks"* published on April 20th 2020.

In brief, certified surgical masks type II/IIR must be able to filter 98% of particles with a diameter of 3µm according to Norm EN 14683. This already stops a large proportion of the droplets exhaled and most probably a major proportion of the particles responsible for transmission of SARS-CoV-2. FFP2 (or equivalent, e.g. N95 or KN95; we call all such masks FFP masks in what follows) masks, on the other hand, must be able to filter >94% of particles with a diameter of 0.45µm.

FFP masks are used primarily by professionals to prevent exposure to inhaled particles; they also serve as source control as long as they do not have an exhalation valve; however, this is not their primary function. In medical settings, their additional filtering capacity primarily plays a role in preventing transmission during aerosol-generating measures. FFP masks have different functions as compared to surgical masks: they are therefore classified as personal protective equipment. In contrast, surgical masks have been primarily developed for, and used in the present pandemic, for source control, thus to protect others from contamination from the wearer. This said, there is increasing evidence that surgical masks also protect their wearer as their filtration capacity acts both ways, providing a barrier for respiratory particles in both inward and outward airflow directions.

To achieve protection by wearing FFP masks one must ensure adequate fitting of the mask to the face (according to Norm EN 149). This includes assuring that the design of the FFP mask provides a good seal with the face of its wearer, i.e. a low total inward leakage or a high fit factor. For FFP masks, the fit factor (defined as the ratio of the particle concentration outside of the mask to the concentration inside the mask) should be higher than 10. The fit factor value depends on the end-user of the mask and thus requires the selection of a well-fitting mask as well as training in its use.[2] Facial hair is not allowable: to achieve an adequate seal, both SUVA and the American Occupational Safety and Health Administration (OSHA)[3] state that "*The employer shall not permit respirators with tightfitting facepieces to be worn by employees who have facial hair that comes between the sealing surface of the facepiece and the face.* Furthermore, the OSHA (29 CFR 1910.134) requires an annual fit test to confirm the fit of any FFP mask before it is used at the workplace. This ensures that users are receiving the expected level of protection by minimizing any leakage of air (and thus, pathogen-containing particles) into the mask. Without proper selection of FFP masks and training of the wearer, protection factors were found to drop from an average of 20.5 to 3.3.[4] This is comparable to the fit factor value achieved by wearing a surgical mask, which ranges between 1.5 and 6 (mostly around 2), or by wearing a community mask.[4,5] Accordingly, most international and national health agencies recommend the user to perform a self-fit checking after each donning of an FFP mask to assure correct wearing and a good facial seal.

Considerations questioning making the use of FFP (or equivalent) masks mandatory for the general population

Proper wearing, fit and handling
As detailed above, a proper fit to the face of the user is required to achieve the expected protection provided by FFP masks. Achieving proper fit requires mask-fitting and training, which is challenging to fulfil on a population-wide level. The correct wearing of a mask, which includes coverage of nose and mouth and assuring that there are no gaps between the face of the wearer and the mask, is probably more important than its filtration capacity. Improper mask-fitting may not only result in a lower level of protection for the wearer, but also in impeded source-control, thus providing also lower protection for others. As the intrinsic resistance to airflow is higher across FFP masks than it is across surgical masks, this may potentially result in higher face seal leakage[6] and emission of infectious respiratory particles might be greater with an FFP mask that is not well fitted to the wearer's face compared with normally worn surgical masks.
Finally, proper handling of FFP masks may be further impeded by consumers potentially using them for extended time-periods, as they are approximately 10 times more expensive that surgical masks. This may consequently increase the risk of cross contamination. Prolonged wear may furthermore decrease the adequacy of fit and seal as the mask becomes looser after being repetitively donned and doffed.

If people with impaired lung function or elderly persons wear FFP masks, health effects cannot be ruled out as data beyond the targeted use for professionals are lacking. Public health authorities, such as the American OSHA require employers to medically evaluate professionals to determine the safety of wearing FFP masks.[3]

Compliance
Overall compliance with wearing and especially correctly wearing FFP masks may be low (44%) and may decrease over time.[7, 11] FFP masks have more breathing resistance and are heavier than surgical masks. Consequently, people may tend to remove their masks more often, exposing them and others to a higher infection risk.[11]
Compliance may be further impeded by unfavourable side effects associated with wearing FFP masks (this aspect is particularly relevant when considering that the duration of the mask obligation is not foreseeable at this point):

- Facial dermatitis caused by the tight fit of FFP2/N95 masks[8,9]
- Increased work of breathing due to greater breathing resistance of FFP2/N95 masks (resulting in elevated CO2-levels)[10,11]
- Increased fatigability[10,11]

Increasing evidence suggests that surgical masks provide protection from SARS-CoV-2 and other respiratory virus transmission
Several epidemiological studies have shown a decrease in transmission of SARS-CoV-2 after the introduction of a general mask requirement (not including FFP masks or equivalent).[12-16] Even after exposure to potentially aerosol-generating procedures performed on a patient with unrecognized COVID-19 in an intensive care unit, none (0/35) of the staff involved who were wearing surgical masks got infected by the patient.[17] Within "designated" COVID-19 medical wards at four acute care hospitals in Calgary, Canada, there have been an estimated 5544 person hours of continuous healthcare worker exposure to 132 COVID-19 inpatients, using personal protective equipment consisting of gowns, gloves, surgical masks, and face shields or goggles for routine care (excluding aerosol-generating procedures) with no nosocomial SARS-CoV-2 transmission events documented.[18]

As already mentioned, technical characteristics of FFP masks, including filtering capacity and fitting, are superior to those of Type II or IIR surgical masks. In *in vitro* studies, this higher performance of FFP masks demonstrated a higher source control efficacy and a higher effectiveness in preventing transmission of respiratory virus compared to surgical masks. Similar results were found in a recent study using mannequin heads[28]. However, this difference was so far not confirmed in clinical studies.[19,20] Observational studies and some randomized trials showed no increased protection against transmission of respiratory viruses by FFP2/N95 masks in direct comparison with surgical masks.[21-23] These findings were supported by a recent meta-analysis[24], yet results from randomized trials in the setting of SARS-CoV-2 are still lacking.
The intrinsic performance of properly worn and used (valve-free) FFP masks can, in short, surpass that of surgical masks in terms of filtration efficiency; however, FFP masks also have drawbacks (e.g. reduced air permeability resulting in an increased respiratory effort and a higher bypass-rate when the fit of the mask is not good). Those drawbacks make their mandated collective use by the general public likely less beneficial than what can be expected by mandating surgical masks or community masks fullfilling the recommendation of the science task force. Furthermore, transmission of respiratory viruses may occur despite the use of FFP masks, especially under specific circumstances or inadequate compliance with infection prevention and control measures. This has been reported for SARS-CoV-1[25-27] and has been reported in the context of SARS-CoV-2.[1]

Considerations for people belonging to high-risk populations
We agree with the recommendations made by the "Deutsche Gesellschaft für Krankenhaushygiene (DGKH)" and the "Gesellschaft für Hygiene, Umweltmedizin und Präventivmedizin (GHUP)". The use of FFP masks for people belonging to high-risk populations should only be considered after carefully balancing potential benefits and risks within the setting of professional medical consultation and education on how to wear and handle such masks according to the principles detailed above in terms of achieving adequate fit.[1]

Conclusions

Based on concerns regarding the challenges in terms of (i) consistently achieving proper mask-fit, (ii) compliance with mask-wearing overall for a yet unforeseeable time period, (iii) potential side-effects and (iv) an increasing body of evidence supporting the protective effect of surgical masks, we question the benefits of mandating a compulsory use of FFP masks by the general population. At this point, there is currently no evidence that transmission routes, as opposed to infectivity, of the new SARS-CoV-2 variants differ from those reported so far. We therefore support maintaining and promoting current mandatory measures that are enforced to prevent transmission, emphasizing the importance of strict compliance. We acknowledge that emerging evidence needs to be continuously re-assessed and recommendations may need to be adapted accordingly.

While the considerations outlined above focus on recommendations for the use of FFP masks for the general population, they also support maintaining the current recommendations published by Swissnoso emphazing the use of personal protective equipment with surgical masks even in acute care settings, unless aerosol generating procedures are performed or expected.

Appendix
Mask terminology

FFP masks
FFP masks, Filtering Facepiece Particles facemasks, 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 equipment and have to comply with the PPE-directive (EU/2016/425, SR 930.115 – Verordnung über die Sicherheit von persönlichen Schutzausrüstungen (PSA-Verordnung)). They have to be tested according to EN 149 and certified. FFP masks are classified into FFP1, FFP2 and FFP3 depending on their filtration efficiency, and they are available in various designs (e.g. with exhalation valve or without).

Surgical Masks
Surgical Masks, 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 EN 14683 and certified. Surgical masks are classified into Type I, Type II and Type IIR. Only Type IIR offers a protection against liquid splashes.

Community masks
"Community" mask is not an official term; it is 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 or aerosols emitted by the mask wearer. Since not all mask designs and materials are suitable for community masks, further research is being conducted to identify the best mask designs and the recommendation of the Swiss National Science Task Force for community masks and especially their testing should be followed.

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Complementary Policy Briefs:

Policy Brief: Role of masks, 20.4.2020

Policy Brief: Benefits of wearing mask in community settings where social distancing cannot be reliably achieved from 1.7.2020

Policy Brief: Recommendations for minimal specifications for the community masks for Swiss manufacturers from 14.10.2020

Policy Brief: Clarification on face mask types, architecture, quality, handling, test and certification procedures from 14.10.2020