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Short report

What face mask for what use in the context of the COVID-19 pandemic? The French guidelines

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ARTICLE INFO

Article history:

Received 6 April 2020

Accepted 23 April 2020

Available online 26 April 2020

Keywords:

COVID-19 pandemic

Respiratory protective equipment

Filtering facepiece (FFP) mask

N95 mask

Surgical mask



SUMMARY

In the context of the COVID-19 pandemic, wearing a face mask has become usual and ubiquitous, in both hospitals and community. However, the general public is consuming surgical or filtering facepiece (FFP) masks irrespective of their specificity, leading to a global supply shortage for the most exposed persons, who are healthcare workers. This underlines the urgent need to clarify the indications of the different categories of mask, in order to rationalize their use. This article specifies the French position for the rational use of respiratory protective equipment for healthcare workers.

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Introduction

In the context of the coronavirus disease 2019 (COVID-19) pandemic, healthcare workers' (HCWs) protection from contamination is based on the wearing of personal protective

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equipment (PPE) [1,2]. Transmission routes of severe acute respiratory syndrome coronavirus (SARS-CoV-2) include direct transmission (droplet, e.g. cough, sneeze) and contact transmission (contact with oral, nasal, and eye mucous membranes). The presence of SARS-CoV-2 in the environment of COVID-19 patients therefore reinforces the belief that fomites play a role in transmission of SARS-CoV-2; however, the relative importance of this route of transmission compared to direct exposure to respiratory droplets is still unclear. The wearing of face masks has become usual and ubiquitous, not only in hospitals but also in the community [3]. Without necessarily needing them, the general public is over-consuming surgical and filtering facepiece (FFP) masks irrespective of their specificity [4,5]. This may lead to supply shortages for HCWs in the frontline of patient care, as already reported in several countries [5]. In order to rationalize the use of masks and to prevent their shortage, we present the French guidelines on the indications for the use of anti-projection or surgical masks and FFP masks.

Rationalization of face mask distribution

The rational use of face masks is reinforced by the World Health Organization (WHO) update published on February 19th, 2020, which specifies indications for wearing masks as follows: in the context of stage 3 of an epidemic (active circulation of the virus) and during a period of difficulty in supplying masks, or even a shortage of masks, a prioritization of the distribution of respiratory masks (surgical masks in particular) may be envisaged in order to prioritize the protection of health professionals and other personnel, ensuring the continuity of patient care in health and social care facilities and in cities [1].

As defined in the 'influenza pandemic' plan by the European Centre for Disease Prevention and Control, this rationalization of mask distribution and use requires:

- definition of a strategy for the development and acquisition of health products and medical devices (definition of the doctrine of use)
- verification of availability
- preparation of the 'logistic scheme for the distribution of health products and equipment'
- preparation of mask stocks
- updating of protection and security plans for production and storage facilities for protective equipment and healthcare products

This provision encourages the temporary cancellation and postponement of all consultations and medico-surgical activities for non-urgent indications that do not require immediate patient care in order to rationalize the need for surgical masks and FFP2.

Categories of face mask

In France, the anti-projection mask or surgical mask is a medical device with an official EN 14683 standard description of 'a medical face mask' (Table I). It is indicated for the protection of the wearer's environment, as it is intended to avoid, when the wearer exhales, the projection of secretions from the upper airways or saliva that may contain infectious agents transmissible by 'droplet' or 'air' routes. A surgical mask is designed for a single use only. It should be changed as soon as it becomes wet and at least every 4 h at the most, taking into

Table I
Characteristics and effectiveness of face masks

Characteristics	Type of face mask ^a	
	Surgical masks	FFP respirators
Legal denomination and jurisdiction	Medical device of class 1 (EU directive 93/42/CEE and ANSM). EN 14683: March 2006. CE marking. Type of mask (types I, II, IIR).	PPE (French Ministry of Labour). EN 149 + A1: September 2009 CE marking. Efficiency class: - FFP1 masks filtering $\geq 80\%$ of aerosols (total inward leakage $< 22\%$); - FFP2 masks filtering at least 94% of aerosols (total inward leakage $< 8\%$); - FFP3 masks filtering at least 99% of aerosols (total inward leakage $< 2\%$).
Indicated person Protection	Patients, HCWs Protect persons in contact with the wearer and environment of the wearer by avoiding projection of secretions from the upper airways or saliva of the wearer. Do not protect the wearer from inhalation of aerosol and fine particles in suspension in the air.	HCWs. Protect the wearer from inhalation of droplets, aerosol, and fine particles in suspension in the air when in contact with patient.
Wearing duration	Less than 4 h. Must be changed as soon as it becomes wet.	Less than 8 h, in accordance with manufacturer's recommendations (NR: disposable; R: reusable).

FFP, filtering facepiece; PPE, personal protective equipment; ANSM, French National Agency for the Safety of Medicines and Health Products; CE, Conformité Européenne; HCWs, healthcare workers; Type I, IR, II, IIR, characteristic of the performances of bacterial filtration, differential pressure, and resistance pressure to splash, according to EN 146.

^a French authorities, in the COVID-19 period of extreme supply shortage, have allowed masks claiming non-European standards to be sold with equivalence table (https://www.preventioninfection.fr/?jet_download=9209).

account the conditions of use and integrity. Surgical masks must bear on their packaging: the CE (Conformité Européenne) marking, the dated reference of standard EN 14683, and the type of mask (type I, II, or IIR). This last information characterizes the performances of bacterial filtration, differential pressure, and resistance pressure to splash, according to EN 14683, the last being required only for IIR masks. A medical face mask with an appropriate microbial barrier can also be effective in reducing the emission of infective agents from the nose and mouth of an asymptomatic carrier or a patient with clinical symptoms.

On the other hand, respiratory protection devices (RPE) or FFP-type respiratory protection masks (or N95 respirator mask) are indicated for the protection of the wearer (Table I). They must bear the following indications on the masks and packaging: CE marking (CE symbol followed by the number of the notified body responsible for monitoring the quality of manufacture), the number and year of the standard corresponding to the type of equipment (EN 149), and the efficiency class (FFP1, FFP2, or FFP3) [6]. Wearing this type of mask is more restrictive (thermal discomfort, respiratory resistance) than wearing a surgical mask. There are three categories of FFP mask, according to their efficiency (estimated based on filter efficiency and leakage to the face). A distinction is made between:

- FFP1 masks, filtering $\geq 80\%$ of aerosols (total inward leakage $< 22\%$)
- FFP2 masks, filtering $\geq 94\%$ of aerosols (total inward leakage $< 8\%$)
- FFP3 masks, filtering $\geq 99\%$ of aerosols (total inward leakage $< 2\%$).

The wearing time must be in accordance with the instructions for use [7]. In any case, it should be < 8 h in a single day, subject to the conditions of use and type of respiratory protection equipment, and a removed FFP mask should not be reused.

FFP masks are subject to natural ageing and therefore have an expiry date beyond which their effectiveness cannot be guaranteed. From a legal point of view, once the expiry date has passed, respiratory protection masks cannot be resold, made available, sold or used, even free of charge. However, in the context of the COVID-19 pandemic, the French Ministry of Work changed the rule in the period of shortage to allow the use of FFP masks up to an expiry date of two years from the time of manufacture.

Indications for mask-wearing according to the French guidelines

The guidelines for mask-wearing by HCWs consider that:

- Wearing an anti-projection or surgical mask reduces the diffusion of potentially infectious particles and protects people and the environment. Furthermore, surgical masks limit the exposure of caregivers to potentially infectious droplets from patient. Transmission of fluid-borne agents from patients to staff may occur via splashes.
- Wearing an FFP mask protects caregivers from the airborne spread of very small infectious agents, provided that it fits snugly. This type of respiratory protection is usually

recommended for healthcare workers caring for patients with infection such as measles, tuberculosis, and pandemic flu. It may also be recommended in situations involving the management of other respiratory infectious diseases where there is a risk of aerosolization, such as when performing invasive procedures or airway manoeuvres that may generate an aerosol or provoke the patient to cough.

The use of any other kinds of barrier masks, such as tissue masks, is not recommended for HCWs during care duties [8].

Indications for the surgical mask

In the context of the COVID-19 pandemic, the wearing of a surgical mask must be reserved for (Table II):

- Persons with signs of respiratory infection suggestive and/or confirmed COVID-19
- HCWs, first-aid individuals, and medical transport persons in the event of contact with any of the above-mentioned persons
- HCWs in contact with a person with signs of respiratory infection, and in the absence of invasive procedures on the respiratory tract.

The non-ill population should not wear surgical masks, in order to preserve their use for the indications stated above in healthcare settings. Taking into account the pandemic evolution and an eventual exit from the period of people's confinement, the wearing of a face mask for the general public may complement the classical measures of physical distance, barrier measures, and hand hygiene. In this context a standard cloth mask is indicated and should be preferred.

Wearing masks by asymptomatic wearers, when used properly, greatly reduces virus transmission essentially by protecting the wearer's environment. However, this type of mask may not prevent a healthy person from becoming infected if s/he does not follow barrier precautions and if s/he is in close contact with a person with respiratory symptoms.

Indications for the FFP2 mask

The FFP2-type protective filtering masks must be reserved exclusively for HCWs when performing invasive medical procedures or manoeuvres on the respiratory tract that may generate an aerosol: intubation/extubation/laryngeal mask, invasive ventilation with open-expiratory circuit, non-invasive ventilation, endotracheal aspiration, bronchial fibroscopy, aerosol therapy, aerosol-generating chest physiotherapy (bronchial decongestion, induced sputum, etc.), nasopharyngeal sampling, functional respiratory explorations, dental surgery procedures, autopsy or other procedures at risk of aerosol (Table II).

Conditions for prolonged usage

Both surgical and FFP masks are single-use devices, intended to be worn while caring for one patient and to be changed between patients. However, in the context of a supply shortage, prolonged use may be envisaged albeit with strict adherence to the following conditions: tolerance and accessibility

Table II
Type of face mask recommended by clinical indication or professional category

Category of professional	Indication for wearing a mask		Type of mask		
			Patients	Professionals	
			Surgical	Surgical	FFP2
	Situation of care	Infectious status of patient			
HCWs ^a	Simple procedures including consultations but excluding AGPs and invasive care ^b	Asymptomatic patients who present a risk of severe form of COVID-19 ^c	✓	✓	
	AGPs and invasive care ^b	Symptomatic patients ^d regardless of infectious status	✓	✓	
	AGPs and invasive care ^b	COVID-19 patients	✓	✓	
HCWs who present a risk of severe form of COVID-19 ^c	All procedures including consultations but excluding AGPs and invasive care ^b	All patients regardless of infectious status			✓
	AGPs and invasive care ^b	All patients regardless of infectious status		✓	
		Patients who present a risk of severe form of COVID-19 ^c	✓	✓	
		Symptomatic patients ^d regardless of infectious status	✓	✓	
		COVID-19 patients	✓	✓	
Pharmacists and pharmacy dispensers	Contact with:	All patients regardless of infectious status			✓
Home carer	Contact with:	Patients who present a risk of severe form of COVID-19 ^c	✓	✓	
		All symptomatic patients ^d regardless of infectious status	✓	✓	
Medical transport personnel	Contact with:	Patients who present a risk of severe form of COVID-19 ^c	✓	✓	
		All symptomatic patients ^d regardless of infectious status	✓	✓	
Prison administration personnel	Contact with:	Patients who present a risk of severe form of COVID-19 ^c	✓	✓	
		All symptomatic patients ^d regardless of infectious status	✓	✓	
Fire brigade	Contact with:	Patients who present a risk of severe form of COVID-19 ^c	✓	✓	
		All symptomatic patients ^d regardless of infectious status		✓	
Nursery	Contact with:	All children		✓	

FFP, filtering facepiece; HCWs, healthcare workers; AGPs, aerosol-generating procedures; COVID-19, coronavirus disease 2019.

^a Medical doctors, nurses, dentists, masseur-physiotherapists (only for chest physiotherapy), midwives, in healthcare settings, medico-social establishments, and ambulatory medicine.

^b Intubation/extubation/laryngeal mask, invasive ventilation with open-expiratory circuit, non-invasive ventilation, endotracheal aspiration, bronchial fibroscopy, aerosol therapy, aerosol-generating chest physiotherapy (bronchial decongestion, induced sputum, etc.), nasopharyngeal sampling, functional respiratory explorations, dental surgery procedures, autopsy, or other procedures at risk of aerosol generation.

^c Immunocompromised patients, diabetic, hypertensive, etc.

^d Symptoms of respiratory infections: cough, sneeze, fever, etc.

for HCWs according to the duration of wearing; sealing and integrity during the wearing, especially in case of proven exposure to infective droplets; no re-use of mask since it has been manipulated or removed with increased risk of contamination for HCWs and their environment [9].

It is important to note that, even when considering the stipulations above, the duration of wearing may not exceed 4 h for surgical masks and 8 h for FFP masks, according to the supplier's recommendations.

Conclusion

Simple barrier measures of hand hygiene and respiratory measures through the use of anti-projection or surgical masks are effective measures for preventing the transmission of SARS-CoV-2. Wearing FFP masks is strictly reserved for HCWs exposed to aerosol during invasive or specific procedures for patients suspected or confirmed as having COVID-19, although airborne transmission cannot completely be excluded. Hand hygiene is a key additional barrier measure to control the SARS-CoV-2.

WHO continues to recommend droplet and contact precautions for those people caring for COVID-19 patients, and airborne precautions for circumstances and settings in which aerosol-generating procedures and support treatment are performed, according to risk assessment [10]. Applying this strategy aims to mitigate the effects of the epidemic wave and limit its health impact on the population by acting upon the transmissibility and clinical effect of SARS-CoV-2, the vulnerability of the population (the immunocompromised, the elderly, etc.), the morbidity (number of sick people in the population), the mortality (number of deaths in the population), and the disorganization of the health system due to saturation of the healthcare system.

Acknowledgements

We thank the members of the scientific committee of the French Society for Hospital Hygiene and the members of the Coronavirus Permanent Committee of the French High Council for Public Health.

Conflict of interest statement

None declared.

Funding sources

None.

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