# Mask use in the context of COVID-19

# Interim guidance

# 1 December 2020



This document, which is an update of the guidance published on 5 June 2020, includes new scientific evidence relevant to the use of masks for reducing the spread of SARS-CoV-2, the virus that causes COVID-19, and practical considerations. It contains updated evidence and guidance on the following:

- mask management;
- SARS-CoV-2 transmission;
- masking in health facilities in areas with community, cluster and sporadic transmission;
- mask use by the public in areas with community and cluster transmission;
- alternatives to non-medical masks for the public;
- exhalation valves on respirators and non-medical masks;
- mask use during vigorous intensity physical activity;
- essential parameters to be considered when manufacturing non-medical masks (Annex).

# Key points

- The World Health Organization (WHO) advises the use of masks as part of a comprehensive package of prevention and control measures to limit the spread of SARS-CoV-2, the virus that causes COVID-19. A mask alone, even when it is used correctly, is insufficient to provide adequate protection or source control. Other infection prevention and control (IPC) measures include hand hygiene, physical distancing of at least 1 metre, avoidance of touching one's face, respiratory etiquette, adequate ventilation in indoor settings, testing, contact tracing, quarantine and isolation. Together these measures are critical to prevent human-to-human transmission of SARS-CoV-2.
- Depending on the type, masks can be used either for protection of healthy persons or to prevent onward transmission (source control).
- WHO continues to advise that anyone suspected or confirmed of having COVID-19 or awaiting viral laboratory test results should wear a medical mask when in the presence of others (this does not apply to those awaiting a test prior to travel).
- For any mask type, appropriate use, storage and cleaning or disposal are essential to ensure that they are as effective as possible and to avoid an increased transmission risk.

# Mask use in health care settings

• WHO continues to recommend that health workers (1) providing care to suspected or confirmed COVID-19

patients wear the following types of mask/respirator in addition to other personal protective equipment that are part of standard, droplet and contact precautions:

- medical mask in the absence of aerosol generating procedures (AGPs)
- respirator, N95 or FFP2 or FFP3 standards, or equivalent in care settings for COVID-19 patients where AGPs are performed; these may be used by health workers when providing care to COVID-19 patients in other settings if they are widely available and if costs is not an issue.
- In areas of known or suspected community or cluster SARS-CoV-2 transmission WHO advises the following:
  - universal masking for all persons (staff, patients, visitors, service providers and others) within the health facility (including primary, secondary and tertiary care levels; outpatient care; and long-term care facilities)
  - wearing of masks by inpatients when physical distancing of at least 1 metre cannot be maintained or when patients are outside of their care areas
- In areas of known or suspected sporadic SARS-CoV-2 transmission, health workers working in clinical areas where patients are present should continuously wear a medical mask. This is known as targeted continuous medical masking for health workers in clinical areas;
- Exhalation valves on respirators are discouraged as they bypass the filtration function for exhaled air by the wearer.

# Mask use in community settings

- Decision makers should apply a risk-based approach when considering the use of masks for the general public.
- In areas of known or suspected community or cluster SARS-CoV-2 transmission:
  - WHO advises that the general public should wear a non-medical mask in indoor (e.g. shops, shared workplaces, schools - see Table 2 for details) or outdoor settings where physical distancing of at least 1 metre cannot be maintained.
  - If indoors, unless ventilation has been be assessed to be adequate<sup>1</sup>, WHO advises that the general public should wear a non-medical mask, regardless of whether physical distancing of at least 1 metre can be maintained.

recommended ventilation rate of 10 l/s/person should be met (except healthcare facilities which have specific requirements). For more information consult "Coronavirus (COVID-19) response

<sup>&</sup>lt;sup>1</sup> For adequate ventilation refer to regional or national institutions or heating, refrigerating and air-conditioning societies enacting ventilation requirements. If not available or applicable, a

- Individuals/people with higher risk of severe complications from COVID-19 (individuals ≥ 60 years old and those with underlying conditions such as cardiovascular disease or diabetes mellitus, chronic lung disease, cancer, cerebrovascular disease or immunosuppression) should wear medical masks when physical distancing of at least 1 metre cannot be maintained.
- In any transmission scenarios:
  - Caregivers or those sharing living space with people with suspected or confirmed COVID-19, regardless of symptoms, should wear a medical mask when in the same room.

#### Mask use in children (2)

- Children aged up to five years should not wear masks for source control.
- For children between six and 11 years of age, a risk-based approach should be applied to the decision to use a mask; factors to be considered in the risk-based approach include intensity of SARS-CoV-2 transmission, child's capacity to comply with the appropriate use of masks and availability of appropriate adult supervision, local social and cultural environment, and specific settings such as households with elderly relatives, or schools.
- Mask use in children and adolescents 12 years or older should follow the same principles as for adults.
- Special considerations are required for immunocompromised children or for paediatric patients with cystic fibrosis or certain other diseases (e.g., cancer), as well as for children of any age with developmental disorders, disabilities or other specific health conditions that might interfere with mask wearing.

### Manufacturing of non-medical (fabric) masks (Annex)

- Homemade fabric masks of three-layer structure (based on the fabric used) are advised, with each layer providing a function: 1) an innermost layer of a hydrophilic material 2) an outermost layer made of hydrophobic material 3) a middle hydrophobic layer which has been shown to enhance filtration or retain droplets.
- Factory-made fabric masks should meet the minimum thresholds related to three essential parameters: filtration, breathability and fit.
- Exhalation valves are discouraged because they bypass the filtration function of the fabric mask rendering it unserviceable for source control.

# Methodology for developing the guidance

Guidance and recommendations included in this document are based on published WHO guidelines (in particular the WHO Guidelines on infection prevention and control of epidemic- and pandemic-prone acute respiratory infections in health care) (2) and ongoing evaluations of all available scientific evidence by the WHO ad hoc COVID-19 Infection Prevention and Control Guidance Development Group (COVID-19 IPC GDG) (see acknowledgement section for list of GDG members). During emergencies WHO publishes interim guidance, the development of which follows a

transparent and robust process of evaluation of the available evidence on benefits and harms. This evidence is evaluated through expedited systematic reviews and expert consensus-building through weekly GDG consultations, facilitated by a methodologist and, when necessary, followed up by surveys. This process also considers, as much as possible, potential resource implications, values and preferences, feasibility, equity, and ethics. Draft guidance documents are reviewed by an external review panel of experts prior to publication.

# Purpose of the guidance

This document provides guidance for decision makers, public health and IPC professionals, health care managers and health workers in health care settings (including long-term care and residential), for the public and for manufactures of non-medical masks (Annex). It will be revised as new evidence emerges.

WHO has also developed comprehensive guidance on IPC strategies for health care settings (3), long-term care facilities (LTCF) (4), and home care (5).

# Background

The use of masks is part of a comprehensive package of prevention and control measures that can limit the spread of certain respiratory viral diseases, including COVID-19. Masks can be used for protection of healthy persons (worn to protect oneself when in contact with an infected individual) or for source control (worn by an infected individual to prevent onward transmission) or both.

However, the use of a mask alone, even when correctly used (see below), is insufficient to provide an adequate level of protection for an uninfected individual or prevent onward transmission from an infected individual (source control). Hand hygiene, physical distancing of at least 1 metre, respiratory etiquette, adequate ventilation in indoor settings, testing, contact tracing, quarantine, isolation and other infection prevention and control (IPC) measures are critical to prevent human-to-human transmission of SARS-CoV-2, whether or not masks are used (6).

# Mask management

For any type of mask, appropriate use, storage and cleaning, or disposal are essential to ensure that they are as effective as possible and to avoid any increased risk of transmission. Adherence to correct mask management practices varies, reinforcing the need for appropriate messaging (7).

WHO provides the following guidance on the correct use of masks:

- Perform hand hygiene before putting on the mask.
- Inspect the mask for tears or holes, and do not use a damaged mask.
- Place the mask carefully, ensuring it covers the mouth and nose, adjust to the nose bridge and tie it securely to minimize any gaps between the face and the mask. If using ear loops, ensure these do not cross over as this widens the gap between the face and the mask.

- Avoid touching the mask while wearing it. If the mask is accidently touched, perform hand hygiene.
- Remove the mask using the appropriate technique. Do not touch the front of the mask, but rather until it from behind.
- Replace the mask as soon as it becomes damp with a new clean, dry mask.
- Either discard the mask or place it in a clean plastic resealable bag where it is kept until it can be washed and cleaned. Do not store the mask around the arm or wrist or pull it down to rest around the chin or neck.
- Perform hand hygiene immediately afterward discarding a mask.
- Do not re-use single-use mask.
- Discard single-use masks after each use and properly dispose of them immediately upon removal.
- Do not remove the mask to speak.
- Do not share your mask with others.
- Wash fabric masks in soap or detergent and preferably hot water (at least 60° Centigrade/140° Fahrenheit) at least once a day. If it is not possible to wash the masks in hot water, then wash the mask in soap/detergent and room temperature water, followed by boiling the mask for 1 minute.

# Scientific evidence

#### Transmission of the SARS-CoV-2 virus

Knowledge about transmission of the SARS-CoV-2 virus is evolving continuously as new evidence accumulates. COVID-19 is primarily a respiratory disease, and the clinical spectrum can range from no symptoms to severe acute respiratory illness, sepsis with organ dysfunction and death.

According to available evidence, SARS-CoV-2 mainly spreads between people when an infected person is in close contact with another person. Transmissibility of the virus depends on the amount of viable virus being shed and expelled by a person, the type of contact they have with others, the setting and what IPC measures are in place. The virus can spread from an infected person's mouth or nose in small liquid particles when the person coughs, sneezes, sings, breathes heavily or talks. These liquid particles are different sizes, ranging from larger 'respiratory droplets' to smaller 'aerosols.' Close-range contact (typically within 1 metre) can result in inhalation of, or inoculation with, the virus through the mouth, nose or eyes (8-13).

There is limited evidence of transmission through fomites (objects or materials that may be contaminated with viable virus, such as utensils and furniture or in health care settings a stethoscope or thermometer) in the immediate environment around the infected person (14-17). Nonetheless, fomite transmission is considered a possible mode of transmission for SARS-CoV-2, given consistent finding of environmental contamination in the vicinity of people infected with SARS-CoV-2 and the fact that other coronaviruses and respiratory viruses can be transmitted this way (12).

Aerosol transmission can occur in specific situations in which procedures that generate aerosols are performed. The scientific community has been actively researching whether the SARS-CoV-2 virus might also spread through aerosol transmission in the absence of aerosol generating procedures (AGPs) (18, 19). Some studies that performed air sampling in

clinical settings where AGPs were not performed found virus RNA, but others did not. The presence of viral RNA is not the same as replication- and infection-competent (viable) virus that could be transmissible and capable of sufficient inoculum to initiate invasive infection. A limited number of studies have isolated viable SARS-CoV-2 from air samples in the vicinity of COVID-19 patients (20, 21).

Outside of medical facilities, in addition to droplet and fomite transmission, aerosol transmission can occur in specific settings and circumstances, particularly in indoor, crowded and inadequately ventilated spaces, where infected persons spend long periods of time with others. Studies have suggested these can include restaurants, choir practices, fitness classes, nightclubs, offices and places of worship (12).

High quality research is required to address the knowledge gaps related to modes of transmission, infectious dose and settings in which transmission can be amplified. Currently, studies are underway to better understand the conditions in which aerosol transmission or superspreading events may occur.

Current evidence suggests that people infected with SARS-CoV-2 can transmit the virus whether they have symptoms or not. However, data from viral shedding studies suggest that infected individuals have highest viral loads just before or around the time they develop symptoms and during the first 5-7 days of illness (12). Among symptomatic patients, the duration of infectious virus shedding has been estimated at 8 days from the onset of symptoms (22-24) for patients with mild disease, and longer for severely ill patients (12). The period of infectiousness is shorter than the duration of detectable RNA shedding, which can last many weeks (17).

The incubation period for COVID-19, which is the time between exposure to the virus and symptom onset, is on average 5-6 days, but can be as long as 14 days (25, 26).

Pre-symptomatic transmission – from people who are infected and shedding virus but have not yet developed symptoms – can occur. Available data suggest that some people who have been exposed to the virus can test positive for SARS-CoV-2 via polymerase chain reaction (PCR) testing 1-3 days before they develop symptoms (27). People who develop symptoms appear to have high viral loads on or just prior to the day of symptom onset, relative to later on in their infection (28).

Asymptomatic transmission – transmission from people infected with SARS-CoV-2 who never develop symptoms – can occur. One systematic review of 79 studies found that 20% (17–25%) of people remained asymptomatic throughout the course of infection. (28). Another systematic review, which included 13 studies considered to be at low risk of bias, estimated that 17% of cases remain asymptomatic (14%–20%) (30). Viable virus has been isolated from specimens of presymptomatic and asymptomatic individuals, suggesting that people who do not have symptoms may be able to transmit the virus to others. (25, 29-37)

Studies suggest that asymptomatically infected individuals are less likely to transmit the virus than those who develop symptoms (29). A systematic review concluded that individuals who are asymptomatic are responsible for transmitting fewer infections than symptomatic and presymptomatic cases (38). One meta-analysis estimated that there is a 42% lower relative risk of asymptomatic transmission compared to symptomatic transmission (30).

# Guidance on mask use in health care settings

### Masks for use in health care settings

Medical masks are defined as surgical or procedure masks that are flat or pleated. They are affixed to the head with straps that go around the ears or head or both. Their performance characteristics are tested according to a set of standardized test methods (ASTM F2100, EN 14683, or equivalent) that aim to balance high filtration, adequate breathability and optionally, fluid penetration resistance (39, 40).

Filtering facepiece respirators (FFR), or respirators, offer a balance of filtration and breathability. However, whereas medical masks filter 3 micrometre droplets, respirators must filter more challenging 0.075 micrometre solid particles. European FFRs, according to standard EN 149, at FFP2 performance there is filtration of at least 94% solid NaCl particles and oil droplets. US N95 FFRs, according to NIOSH 42 CFR Part 84, filter at least 95% NaCl particles. Certified FFRs must also ensure unhindered breathing with maximum resistance during inhalation and exhalation. Another important difference between FFRs and other masks is the way filtration is tested. Medical mask filtration tests are performed on a cross-section of the masks, whereas FFRs are tested for filtration across the entire surface. Therefore, the layers of the filtration material and the FFR shape, which ensure the outer edges of the FFR seal around wearer's face, result in guaranteed filtration as claimed. Medical masks, by contrast, have an open shape and potentially leaking structure. Other FFR performance requirements include being within specified parameters for maximum CO2 build up, total inward leakage and tensile strength of straps (41, 42).

# A. Guidance on the use of medical masks and respirators to provide care to suspected or confirmed COVID-19 cases

#### Evidence on the use of mask in health care settings

Systematic reviews have reported that the use of N95/P2 respirators compared with the use of medical masks (see mask definitions, above) is not associated with statistically significant differences for the outcomes of health workers acquiring clinical respiratory illness, influenza-like illness (risk ratio 0.83, 95%CI 0.63-1.08) or laboratory-confirmed influenza (risk ratio 1.02, 95%CI 0.73-1.43); harms were poorly reported and limited to discomfort associated with lower compliance (43, 44). In many settings, preserving the supply of N95 respirators for high-risk, aerosol-generating procedures is an important consideration (45).

A systematic review of observational studies on the betacoronaviruses that cause severe acute respiratory syndrome (SARS), Middle East respiratory syndrome (MERS) and COVID-19 found that the use of face protection (including respirators and medical masks) is associated with reduced risk of infection among health workers. These studies suggested that N95 or similar respirators might be associated with greater reduction in risk than medical or 12–16-layer cotton masks. However, these studies had important

<sup>2</sup> The WHO list of AGPs includes tracheal intubation, non-invasive ventilation, tracheotomy, cardiopulmonary resuscitation, manual

limitations (recall bias, limited information about the situations when respirators were used and limited ability to measure exposures), and very few studies included in the review evaluated the transmission risk of COVID-19 (46). Most of the studies were conducted in settings in which AGPs were performed or other high-risk settings (e.g., intensive care units or where there was exposure to infected patients and health workers were not wearing adequate PPE).

WHO continues to evaluate the evidence on the effectiveness of the use of different masks and their potential harms, risks and disadvantages, as well as their combination with hand hygiene, physical distancing of at least 1 metre and other IPC measures.

# Guidance

WHO's guidance on the type of respiratory protection to be worn by health workers providing care to COVID-19 patients is based on 1) WHO recommendations on IPC for epidemicand pandemic-prone acute respiratory infections in health care (47); 2) updated systematic reviews of randomized controlled trials on the effectiveness of medical masks compared to that of respirators for reducing the risk of clinical respiratory illness, influenza-like illness (ILI) and laboratory-confirmed influenza or viral infections. WHO guidance in this area is aligned with guidelines of other professional organizations, including the European Society of Intensive Care Medicine and the Society of Critical Care Medicine, and the Infectious Diseases Society of America (48, 49).

The WHO COVID-19 IPC GDG considered all available evidence on the modes of transmission of SARS-CoV-2 and on the effectiveness of medical mask versus respirator use to protect health workers from infection and the potential for harms such as skin conditions or breathing difficulties.

Other considerations included availability of medical masks versus respirators, cost and procurement implications and equity of access by health workers across different settings.

The majority (71%) of the GDG members confirmed their support for previous recommendations issued by WHO on 5 June 2020:

- 1. In the absence of aerosol generating procedures (AGPs)<sup>2</sup>, WHO recommends that health workers providing care to patients with suspected or confirmed COVID-19 should wear a medical mask (in addition to other PPE that are part of droplet and contact precautions).
- In care settings for COVID-19 patients where AGPs are performed, WHO recommends that health workers should wear a respirator (N95 or FFP2 or FFP3 standard, or equivalent) in addition to other PPE that are part of airborne and contact precautions.

In general, health workers have strong preferences about having the highest perceived protection possible to prevent COVID-19 infection and therefore may place high value on the potential benefits of respirators in settings without AGPs. WHO recommends respirators primarily for settings where AGPs are performed; however, if health workers prefer them and they are sufficiently available and cost is not an issue, they could also be used during care for COVID-19 patients in other settings. For additional guidance on PPE, including PPE

ventilation before intubation, bronchoscopy, sputum induction using nebulized hypertonic saline, and dentistry and autopsy procedures.

beyond mask use by health workers, see WHO IPC guidance during health care when COVID-19 infection is suspected (3) and also WHO guidance on the rational use of PPE (45).

Exhalation valves on respirators are discouraged as they bypass the filtration function for exhaled air.

# B. Guidance on the use of mask by health workers, caregivers and others based on transmission scenario

#### **Definitions**

Universal masking in health facilities is defined as the requirement for all persons (staff, patients, visitors, service providers and others) to wear a mask at all times except for when eating or drinking.

Targeted continuous medical mask use is defined as the practice of wearing a medical mask by all health workers and caregivers working in clinical areas during all routine activities throughout the entire shift.

Health workers are all people primarily engaged in actions with the primary intent of enhancing health. Examples are: nursing and midwifery professionals, doctors, cleaners, other staff who work in health facilities, social workers, and community health workers.

#### Evidence on universal masking in health care settings

In areas where there is community transmission or large-scale outbreaks of COVID-19, universal masking has been adopted in many hospitals to reduce the potential of transmission by health workers to patients, to other staff and anyone else entering the facility (50).

Two studies found that implementation of a universal masking policy in hospital systems was associated with decreased risk of healthcare-acquired SARS-CoV-2 infection. However, these studies had serious limitations: both were before-after studies describing a single example of a phenomenon before and after an event of interest, with no concurrent control group, and other infection control measures were not controlled for (51, 52). In addition, observed decreases in health worker infections occurred too quickly to be attributable to the universal masking policy.

# Guidance

Although more research on universal masking in heath settings is needed, it is the expert opinion of the majority (79%) of WHO COVID-19 IPC GDG members that universal masking is advisable in geographic settings where there is known or suspected community or cluster transmission of the SARS-CoV-2 virus.

- 1. In areas of known or suspected community or cluster SARS-CoV-2 transmission, universal masking should be advised in all health facilities (see Table 1).
- All health workers, including community health workers and caregivers, should wear a medical mask at all times, for any activity (care of COVID-19 or non-COVID-19 patients) and in any common area (e.g., cafeteria, staff rooms).

- Other staff, visitors, outpatients and service providers should also wear a mask (medical or non-medical) at all times
- Inpatients are not required to wear a mask (medical or non-medical) unless physical distancing of at least 1 metre cannot be maintained (e.g., when being examined or visited at the bedside) or when outside of their care area (e.g., when being transported).
- Masks should be changed when they become soiled, wet or damaged or if the health worker/caregiver removes the mask (e.g., for eating or drinking or caring for a patient who requires droplet/contact precautions for reasons other than COVID-19).
- 2. In the context of known or suspected sporadic SARS-CoV-2 virus transmission, WHO provides the following guidance:
- Health workers, including community health workers and caregivers who work in clinical areas, should continuously wear a medical mask during routine activities throughout the entire shift, apart from when eating and drinking and changing their medical masks after caring for a patient who requires droplet/contact precautions for other reasons. In all cases, medical masks must be changed when wet, soiled, or damaged; used medical masks should be properly disposed of at the end of the shift; and new clean ones should be used for the next shift or when medical masks are changed.
- It is particularly important to adopt the continuous use
  of masks in potentially high transmission risk settings
  including triage, family physician/general practitioner
  offices; outpatient departments; emergency rooms;
  COVID-19 designated units; haematology, oncology
  and transplant units; and long-term health and
  residential facilities.
- Staff who do not work in clinical areas (e.g., administrative staff) do not need to wear a medical mask during routine activities if they have no exposure to patients.

Whether using masks for universal masking within health facilities or targeted continuous medical mask use throughout the entire shift, health workers should ensure the following:

- Medical mask use should be combined with other measures including frequent hand hygiene and physical distancing among health workers in shared and crowded places such as cafeterias, break rooms, and dressing rooms.
- The medical mask should be changed when wet, soiled, or damaged.
- The medical mask should not be touched to adjust it or if displaced from the face for any reason. If this happens, the mask should be safely removed and replaced, and hand hygiene performed.
- The medical mask (as well as other personal protective equipment) should be discarded and changed after caring for any patient who requires contact/droplet precautions for other pathogens, followed by hand hygiene.
- Under no circumstances should medical masks be shared between health workers or between others wearing them. Masks should be appropriately disposed of whenever removed and not reused.

• A particulate respirator at least as protective as a United States of America (US) National Institute for Occupational Safety and Health-certified N95, N99, US Food and Drug Administration surgical N95, European Union standard FFP2 or FFP3, or equivalent, should be worn in settings for COVID-19 patients where AGPs are performed (see WHO recommendations below). In these settings, this includes continuous use by health workers throughout the entire shift, when this policy is implemented.

Note: Decision makers may consider the transmission intensity in the catchment area of the health facility or community setting and the feasibility of implementing a universal masking policy compared to a policy based on assessed or presumed exposure risk. Decisions need to take into account procurement, sustainability and costs of the policy. When planning masks for all health workers, long-term availability of adequate medical masks (and when applicable, respirators) for all workers should be ensured, in particular for those providing care for patients with confirmed or suspected COVID-19. Proper use and adequate waste management should be ensured.

The potential harms and risks of mask and respirator use in the health facility setting include:

- contamination of the mask due to its manipulation by contaminated hands (53, 54);
- potential self-contamination that can occur if medical masks are not changed when wet, soiled or damaged; or by frequent touching/adjusting when worn for prolonged periods (55);
- possible development of facial skin lesions, irritant dermatitis or worsening acne, when used frequently for long hours (56-58);
- discomfort, facial temperature changes and headaches from mask wearing (44, 59, 60);
- false sense of security leading potentially to reduced adherence to well recognized preventive measures such as physical distancing and hand hygiene; and risk-taking behaviours (61-64);
- difficulty wearing a mask in hot and humid environments
- possible risk of stock depletion due to widespread use in the context of universal masking and targeted continuous mask use and consequent scarcity or unavailability for health workers caring for COVID 19 patients and during health care interactions with non-COVID-19 patients where medical masks or respirators might be required.

#### Alternatives to medical masks in health care settings

The WHO's disease commodity package (DCP) for COVID-19 recommends medical masks for health workers to be type II or higher (65). Type II medical masks provide a physical barrier to fluids and particulate materials and have bacterial filtration efficiency of ≥98% compared to Type I mask, which has bacterial filtration efficiency of ≥95% and lower fluid resistance (66) In case of stock outs of type II or higher medical masks, health workers should use a type I medical mask as an alternative. Other alternatives such as face shields or fabric masks should be carefully evaluated.

Face shields are designed to provide protection from splashes of biological fluid (particularly respiratory secretions), chemical agents and debris (67, 68) into the eyes. In the context of protection from SARS-CoV-2 transmission through respiratory droplets, face shields are used by health workers as personal protective equipment (PPE) for eye protection in combination with a medical mask or a respirator (69, 70) While a face shield may confer partial protection of the facial area against respiratory droplets, these and smaller droplets may come into contact with mucous membranes or with the eyes from the open gaps between the visor and the face (71,67).

Fabric masks are not regulated as protective masks or part of the PPE directive. They vary in quality and are not subject to mandatory testing or common standards and as such are not considered an appropriate alternative to medical masks for protection of health workers. One study that evaluated the use of cloth masks in a health care facility found that health care workers using 2 ply cotton cloth masks (a type of fabric mask) were at increased risk of influenza-like illness compared with those who wore medical masks (72).

In the context of severe medical mask shortage, face shields alone or in combination with fabric mask may be considered as a last resort (73). Ensure proper design of face shields to cover the sides of the face and below the chin.

As for other PPE items, if production of fabric masks for use in health care settings is proposed locally in situations of shortage or stock out, a local authority should assess the product according to specific minimum performance standards and required technical specifications (see Annex).

# Additional considerations for community care settings

Like other health workers, community health workers should apply standard precautions for all patients at all times, with particular emphasis regarding hand and respiratory hygiene, surface and environmental cleaning and disinfection and the appropriate use of PPE. When a patient is suspected or confirmed of having COVID-19, community health workers should always apply contact and droplet precautions. These include the use of a medical mask, gown, gloves and eye protection (74).

IPC measures that are needed will depend on the local COVID-19 transmission dynamics and the type of contact required by the health care activity (see Table 1). The community health workforce should ensure that patients and workforce members apply precautionary measures such as respiratory hygiene and physical distancing of at least 1 metre (3.3 feet). They also may support set-up and maintenance of hand hygiene stations and community education (74). In the context of known or suspected community or cluster transmission, community health workers should wear a medical mask when providing essential routine services (see Table 1).

Table 1. Mask use in health care settings depending on transmission scenario, target population, setting, activity and type\*

Transmission scenario	Target population (who)	Setting (where)	Activity (what)	Mask type (which one) *	
Known or suspected community or cluster transmission of SARS- CoV-2	Health workers and caregivers	Health facility (including primary, secondary, tertiary care levels, outpatient care, and long-term care	For any activity in patient-care areas (COVID-19 or non-COVID-19 patients) or in any common areas (e.g., cafeteria, staff rooms)	Medical mask (or respirator if aerosol generating procedures performed)	
	Other staff, patients, visitors, service suppliers	facilities)	For any activity or in any common area	Medical or fabric mask	
	Inpatients	In single or multiple- bed rooms	When physical distance of at least 1 metre cannot be maintained		
	Health workers and caregivers	Home visit (for example, for antenatal or postnatal care, or for a chronic condition)	When in direct contact with a patient or when a distance of at least 1 metre cannot be maintained.	Medical mask	
		Community	Community outreach programmes/essential routine services		
Known or suspected sporadic transmission of SARS- CoV-2 cases	Health workers and caregivers	Health facility (including primary, secondary, tertiary care	In patient care area- irrespective of whether patients have suspected/confirmed COVID-19	Medical mask	
	Other staff, patients, visitors, service suppliers and all others	levels, outpatient care, and long-term care facilities)	No routine activities in patient areas	Medical mask not required. Medical mask should be worn if in contact or within 1 metre of patients, or according to local risk assessment	
	Health workers and caregivers	Home visit (for example, for antenatal or postnatal care, or for a chronic condition)	When in direct contact or when a distance of at least 1metre cannot be maintained.	Medical mask	
		Community	Community outreach programs (e.g., bed net distribution)		
No documented SARS-CoV-2 transmission	Health workers and caregivers	Health facility (including primary, secondary, tertiary care levels, outpatient care, and long-term care facilities)	Providing any patient care	Medical mask use according to standard and transmission-based precautions	
		Community	Community outreach programs		
Any transmission scenario	Health workers	Health care facility (including primary, secondary, tertiary care levels, outpatient care, and long-term care facilities), in settings where aerosol generating procedures (AGP) are performed	Performing an AGP on a suspected or confirmed COVID-19 patient or providing care in a setting where AGPs are in place for COVID-19 patients	Respirator (N95 or N99 or FFP2 or FFP3)	

<sup>\*</sup>This table refers only to the use of medical masks and respirators. The use of medical masks and respirators may need to be combined with other personal protective equipment and other measures as appropriate, and always with hand hygiene.

# Guidance on mask use in community settings

# Evidence on the protective effect of mask use in community settings

At present there is only limited and inconsistent scientific evidence to support the effectiveness of masking of healthy people in the community to prevent infection with respiratory viruses, including SARS-CoV-2 (75). A large randomized community-based trial in which 4862 healthy participants were divided into a group wearing medical/surgical masks and a control group found no difference in infection with SARS-CoV-2 (76). A recent systematic review found nine trials (of which eight were cluster-randomized controlled trials in which clusters of people, versus individuals, were randomized) comparing medical/surgical masks versus no masks to prevent the spread of viral respiratory illness. Two trials were with healthcare workers and seven in the community. The review concluded that wearing a mask may make little or no difference to the prevention of influenza-like illness (ILI) (RR 0.99, 95%CI 0.82 to 1.18) or laboratory confirmed illness (LCI) (RR 0.91, 95%CI 0.66-1.26) (44); the certainty of the evidence was low for ILI, moderate for LCI.

By contrast, a small retrospective cohort study from Beijing found that mask use by entire families before the first family member developed COVID-19 symptoms was 79% effective in reducing transmission (OR 0.21, 0.06-0.79) (77). A case-control study from Thailand found that wearing a medical or non-medical mask all the time during contact with a COVID-19 patient was associated with a 77% lower risk of infection (aOR 0.23; 95% CI 0.09–0.60) (78). Several small observational studies with epidemiological data have reported an association between mask use by an infected person and prevention of onward transmission of SARS-CoV-2 infection in public settings. (8, 79-81).

A number of studies, some peer reviewed (82-86) but most published as pre-prints (87-104), reported a decline in the COVID-19 cases associated with face mask usage by the public, using country- or region-level data. One study reported an association between community mask wearing policy adoption and increased movement (less time at home, increased visits to commercial locations) (105). These studies differed in setting, data sources and statistical methods and have important limitations to consider (106), notably the lack of information about actual exposure risk among individuals, adherence to mask wearing and the enforcement of other preventive measures (107, 108).

Studies of influenza, influenza-like illness and human coronaviruses (not including COVID-19) provide evidence that the use of a medical mask can prevent the spread of infectious droplets from a symptomatic infected person to someone else and potential contamination of the environment by these droplets (75). There is limited evidence that wearing a medical mask may be beneficial for preventing transmission between healthy individuals sharing households with a sick person or among attendees of mass gatherings (44, 109-114).

A meta-analysis of observational studies on infections due to betacoronaviruses, with the intrinsic biases of observational data, showed that the use of either disposable medical masks or reusable 12-16-layer cotton masks was associated with protection of healthy individuals within households and among contacts of cases (46). This could be considered to be indirect evidence for the use of masks (medical or other) by healthy individuals in the wider community; however, these studies suggest that such individuals would need to be in close proximity to an infected person in a household or at a mass gathering where physical distancing cannot be achieved to become infected with the virus. Results from cluster randomized controlled trials on the use of masks among young adults living in university residences in the United States of America indicate that face masks may reduce the rate of influenza-like illness but showed no impact on risk of laboratory-confirmed influenza (115, 116).

#### Guidance

The WHO COVID-19 IPC GDG considered all available evidence on the use of masks by the general public including effectiveness, level of certainty and other potential benefits and harms, with respect to transmission scenarios, indoor versus outdoor settings, physical distancing and ventilation. Despite the limited evidence of protective efficacy of mask wearing in community settings, in addition to all other recommended preventive measures, the GDG advised mask wearing in the following settings:

1. In areas with known or suspected community or cluster transmission of SARS-CoV-2, WHO advises mask use by the public in the following situations (see Table 2):

#### Indoor settings:

- in public indoor settings where ventilation is known to be poor regardless of physical distancing: limited or no opening of windows and doors for natural ventilation; ventilation system is not properly functioning or maintained; or cannot be assessed;
- in public indoor settings that have adequate<sup>3</sup> ventilation if physical distancing of at least 1 metre cannot be maintained;
- in household indoor settings: when there is a visitor who
  is not a household member and ventilation is known to
  be poor, with limited opening of windows and doors for
  natural ventilation, or the ventilation system cannot be
  assessed or is not properly functioning, regardless of
  whether physical distancing of at least 1 metre can be
  maintained:
- in household indoor settings that have adequate ventilation if physical distancing of at least 1 metre cannot be maintained.

resources from ASHRAE and others" https://www.ashrae.org/technical-resources/resources

<sup>&</sup>lt;sup>3</sup> For adequate ventilation refer to regional or national institutions or heating, refrigerating and air-conditioning societies enacting ventilation requirements. If not available or applicable, a recommended ventilation rate of 10 l/s/person should be met (except healthcare facilities which have specific requirements). For more information consult "Coronavirus (COVID-19) response

Table 2. Mask use in community settings depending on transmission scenario, setting, target population, purpose and type\*

Transmission scenario	Situations/settings (where)	Target Population (who)	Purpose of mask use (why)	Mask type (which one)
Known or suspected community or cluster transmission of SARS-CoV-2	Indoor settings, where ventilation is known to be poor or cannot be assessed or the ventilation system is not properly maintained, regardless of whether physical distancing of at least 1 meter can be maintained  Indoor settings that have adequate 4 ventilation if physical distancing of at least 1 metre cannot be maintained	General population in public* settings such as shops, shared workplaces, schools, churches, restaurants, gyms, etc. or in enclosed settings such as public transportation.  For households, in indoor settings, when there is a visitor who is not a member of the household	Potential benefit for source control	Fabric mask
	Outdoor settings where physical distancing cannot be maintained	General population in settings such as crowded open-air markets, lining up outside a building, during demonstrations, etc.		
	Settings where physical distancing cannot be maintained, and the individual is at increased risk of infection and/or negative outcomes	<ul> <li>Individuals/people with higher risk of severe complications from COVID-19:</li> <li>People aged ≥60 years</li> <li>People with underlying comorbidities, such as cardiovascular disease or diabetes mellitus, chronic lung disease, cancer, cerebrovascular disease, immunosuppression, obesity, asthma</li> </ul>	Protection	Medical mask
Known or suspected sporadic transmission, or no documented SARS- CoV-2 transmission	Risk-based approach	General population	Potential benefit for source control and/or protection	Depends on purpose (see details in the guidance content)
Any transmission scenario	Any setting in the community	Anyone suspected or confirmed of having COVID-19, regardless of whether they have symptoms or not, or anyone awaiting viral test results, when in the presence of others	Source control	Medical mask

<sup>\*</sup>Public indoor setting includes any indoor setting outside of the household

<sup>&</sup>lt;sup>4</sup> For adequate ventilation refer to regional or national institutions or heating, refrigerating and air-conditioning societies enacting ventilation requirements. If not available or applicable, a recommended ventilation rate of 101/s/person should be met (except healthcare facilities which have specific requirements).). For more information consult "Coronavirus (COVID-19) response resources from ASHRAE and others" https://www.ashrae.org/technical-resources/resources

#### In outdoor settings:

- where physical distancing of at least 1 metre cannot be maintained;
- individuals/people with higher risk of severe complications from COVID-19 (individuals ≥ 60 years old and those with underlying conditions such as cardiovascular disease or diabetes mellitus, chronic lung disease, cancer, cerebrovascular disease or immunosuppression) should wear medical masks in any setting where physical distance cannot be maintained.
- 2. In areas with known or suspected sporadic transmission or no documented transmission, as in all transmission scenarios, WHO continues to advise that decision makers should apply a risk-based approach focusing on the following criteria when considering the use of masks for the public:
- **Purpose of mask use.** Is the intention source control (preventing an infected person from transmitting the virus to others) or protection (preventing a healthy wearer from the infection)?
- Risk of exposure to SARS-CoV-2. Based on the epidemiology and intensity of transmission in the population, is there transmission and limited or no capacity to implement other containment measures such as contact tracing, ability to carry out testing and isolate and care for suspected and confirmed cases? Is there risk to individuals working in close contact with the public (e.g., social workers, personal support workers, teachers, cashiers)?
- Vulnerability of the mask wearer/population. Is the mask wearer at risk of severe complications from COVID-19? Medical masks should be used by older people (≥ 60 years old), immunocompromised patients and people with comorbidities, such as cardiovascular disease or diabetes mellitus, chronic lung disease, cancer and cerebrovascular disease (117).
- Setting in which the population lives. Is there high population density (such as in refugee camps, camp-like settings, and among people living in cramped conditions) and settings where individuals are unable to keep a physical distance of at least 1 metre (for example, on public transportation)?
- Feasibility. Are masks available at an affordable cost?
   Do people have access to clean water to wash fabric masks, and can the targeted population tolerate possible adverse effects of wearing a mask?
- Type of mask. Does the use of medical masks in the community divert this critical resource from the health workers and others who need them the most? In settings where medical masks are in short supply, stocks should be prioritized for health workers and at-risk individuals.

The decision of governments and local jurisdictions whether to recommend or make mandatory the use of masks should be based on the above assessment as well as the local context, culture, availability of masks and resources required.

### 3. In any transmission scenario:

- Persons with any symptoms suggestive of COVID-19 should wear a medical mask and (5) additionally:
  - self-isolate and seek medical advice as soon as they start to feel unwell with potential symptoms of COVID-19, even if symptoms are mild);

- follow instructions on how to put on, take off, and dispose of medical masks and perform hand hygiene (118);
- follow all additional measures, in particular respiratory hygiene, frequent hand hygiene and maintaining physical distance of at least 1 metre from other persons (46). If a medical mask is not available for individuals with suspected or confirmed COVID-19, a fabric mask meeting the specifications in the Annex of this document should be worn by patients as a source control measure, pending access to a medical mask. The use of a non-medical mask can minimize the projection of respiratory droplets from the user (119, 120).
- Asymptomatic persons who test positive for SARS-CoV-2, should wear a medical mask when with others for a period of 10 days after testing positive.

#### Potential benefits/harms

The potential advantages of mask use by healthy people in the general public include:

- reduced spread of respiratory droplets containing infectious viral particles, including from infected persons before they develop symptoms (121);
- reduced potential for stigmatization and greater of acceptance of mask wearing, whether to prevent infecting others or by people caring for COVID-19 patients in non-clinical settings (122);
- making people feel they can play a role in contributing to stopping spread of the virus;
- encouraging concurrent transmission prevention behaviours such as hand hygiene and not touching the eyes, nose and mouth (123-125);
- preventing transmission of other respiratory illnesses like tuberculosis and influenza and reducing the burden of those diseases during the pandemic (126).

The potential disadvantages of mask use by healthy people in the general public include:

- headache and/or breathing difficulties, depending on type of mask used (55);
- development of facial skin lesions, irritant dermatitis or worsening acne, when used frequently for long hours (58, 59, 127);
- difficulty with communicating clearly, especially for persons who are deaf or have poor hearing or use lip reading (128, 129);
- discomfort (44, 55, 59)
- a false sense of security leading to potentially lower adherence to other critical preventive measures such as physical distancing and hand hygiene (105);
- poor compliance with mask wearing, in particular by young children (111, 130-132);
- waste management issues; improper mask disposal leading to increased litter in public places and environmental hazards (133);
- disadvantages for or difficulty wearing masks, especially for children, developmentally challenged persons, those with mental illness, persons with cognitive impairment, those with asthma or chronic respiratory or breathing problems, those who have had facial trauma or recent oral maxillofacial surgery and those living in hot and humid environments (55, 130).

#### **Considerations for implementation**

When implementing mask policies for the public, decision-makers should:

- clearly communicate the purpose of wearing a mask, including when, where, how and what type of mask should be worn; explain what wearing a mask may achieve and what it will not achieve; and communicate clearly that this is one part of a package of measures along with hand hygiene, physical distancing, respiratory etiquette, adequate ventilation in indoor settings and other measures that are all necessary and all reinforce each other;
- inform/train people on when and how to use masks appropriately and safely (see mask management and maintenance sections);
- consider the feasibility of use, supply/access issues (cleaning, storage), waste management, sustainability, social and psychological acceptance (of both wearing and not wearing different types of masks in different contexts):
- continue gathering scientific data and evidence on the effectiveness of mask use (including different types of masks) in non-health care settings;
- evaluate the impact (positive, neutral or negative) of using masks in the general population (including behavioural and social sciences) through good quality research.

# Mask use during physical activity

#### **Evidence**

There are limited studies on the benefits and harms of wearing medical masks, respirators and non-medical masks while exercising. Several studies have demonstrated statistically significant deleterious effects on various cardiopulmonary physiologic parameters during mild to moderate exercise in healthy subjects and in those with underlying respiratory diseases (134-140). The most significant impacts have been consistently associated with the use of respirators and in persons with underlying obstructive airway pulmonary diseases such as asthma and chronic obstructive pulmonary disease (COPD), especially when the condition is moderate to severe (136). Facial microclimate changes with increased temperature, humidity and perceptions of dyspnoea were also reported in some studies on the use of masks during exercise (134, 141). A recent review found negligeable evidence of negative effects of mask use during exercise but noted concern for individuals with severe cardiopulmonary disease (142).

#### Guidance

WHO advises that people should not wear masks during vigorous intensity physical activity (143) because masks may reduce the ability to breathe comfortably. The most important preventive measure is to maintain physical distancing of at least 1 meter and ensure good ventilation when exercising.

If the activity takes place indoors, adequate ventilation should be ensured at all times through natural ventilation or a properly functioning or maintained ventilation system (144). Particular attention should be paid to cleaning and disinfection of the environment, especially high-touch surfaces. If all the above measures cannot be ensured, consider temporary closure of public indoor exercise facilities (e.g., gyms).

# Face shields for the general public

At present, face shields are considered to provide a level of eye protection only and should not be considered as an equivalent to masks with respect to respiratory droplet protection and/or source control. Current laboratory testing standards only assess face shields for their ability to provide eye protection from chemical splashes (145).

In the context of non-availability or difficulties wearing a non-medical mask (in persons with cognitive, respiratory or hearing impairments, for example), face shields may be considered as an alternative, noting that they are inferior to masks with respect to droplet transmission and prevention. If face shields are to be used, ensure proper design to cover the sides of the face and below the chin.

# Medical masks for the care of COVID-19 patients at home

WHO provides guidance on how to care for patients with confirmed and suspected COVID-19 at home when care in a health facility or other residential setting is not possible (5).

- Persons with suspected COVID-19 or mild COVID-19 symptoms should wear a medical mask as much as possible, especially when there is no alternative to being in the same room with other people. The mask should be changed at least once daily. Persons who cannot tolerate a medical mask should rigorously apply respiratory hygiene (i.e., cover mouth and nose with a disposable paper tissue when coughing or sneezing and dispose of it immediately after use or use a bent elbow procedure and then perform hand hygiene).
- Caregivers of or those sharing living space with people with suspected COVID-19 or with mild COVID-19 symptoms should wear a medical mask when in the same room as the affected person.

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WHO continues to monitor the situation closely for any changes that may affect this interim guidance. Should any factors change, WHO will issue a further update. Otherwise, this interim guidance document will expire 1 year after the date of publication.

# Annex: Updated guidance on non-medical (fabric) masks

#### **Background**

A non-medical mask, also called fabric mask, community mask or face covering, is neither a medical device nor personal protective equipment. Non-medical masks are aimed at the general population, primarily for protecting others from exhaled virus-containing droplets emitted by the mask wearer. They are not regulated by local health authorities or occupational health associations, nor is it required for manufacturers to comply with guidelines established by standards organizations. Non-medical masks may be homemade or manufactured. The essential performance parameters include good breathability, filtration of droplets originating from the wearer, and a snug fit covering the nose and mouth. Exhalation valves on masks are discouraged as they bypass the filtration function of the mask.

Non-medical masks are made from a variety of woven and non-woven fabrics, such as woven cotton, cotton/synthetic blends, polyesters and breathable spunbond polypropylene, for example. They may be made of different combinations of fabrics, layering sequences and available in diverse shapes. Currently, more is known about common household fabrics and combinations to make non-medical masks with target filtration efficiency and breathability (119, 146-150). Few of these fabrics and combinations have been systematically evaluated and there is no single design, choice of material, layering or shape among available non-medical masks that are considered optimal. While studies have focussed on single fabrics and combinations, few have looked at the shape and universal fit to the wearer. The unlimited combination of available fabrics and materials results in variable filtration and breathability.

In the context of the global shortage of medical masks and PPE, encouraging the public to create their own fabric masks may promote individual enterprise and community integration. Moreover, the production of non-medical masks may offer a source of income for those able to manufacture masks within their communities. Fabric masks can also be a form of cultural expression, encouraging public acceptance of protection measures in general. The safe re-use of fabric masks will also reduce costs and waste and contribute to sustainability (151-156).

This Annex is destined intended for two types of readers: homemade mask makers and factory-made masks manufacturers. Decision makers and managers (national/subnational level) advising on a type of non-medical mask are also the focus of this guidance and should take into consideration the following features of non-medical masks: breathability, filtration efficiency (FE), or filtration, number and combination of fabric layers material used, shape, coating and maintenance.

# Evidence on the effectiveness of non-medical (fabric) masks

A number of reviews have been identified on the effectiveness of non-medical masks (151-156). One systematic review (155) identified 12 studies and evaluated study quality. Ten were laboratory studies (157-166), and two reports were from a single randomized trial (72, 167). The majority of studies were conducted before COVID-19 emerged or used laboratory generated particles to assess filtration efficacy. Overall, the reviews concluded that

cloth face masks have limited efficacy in combating viral infection transmission.

#### Homemade non-medical masks

Homemade non-medical masks made of household fabrics (e.g., cotton, cotton blends and polyesters) should ideally have a three-layer structure, with each layer providing a function (see Figure 1) (168). It should include:

- 1. an innermost layer (that will be in contact with the face) of a hydrophilic material (e.g., cotton or cotton blends of terry cloth towel, quilting cotton and flannel) that is non-irritating against the skin and can contain droplets (148)
- 2. a middle hydrophobic layer of synthetic breathable nonwoven material (spunbond polypropylene, polyester and polyaramid), which may enhance filtration, prevent permeation of droplets or retain droplets (148, 150)
- 3. an outermost layer made of hydrophobic material (e.g. spunbond polypropylene, polyester or their blends), which may limit external contamination from penetrating through the layers to the wearer's nose and mouth and maintains and prevents water accumulation from blocking the pores of the fabric (148).

Although a minimum of three layers is recommended for non-medical masks for the most common fabric used, single, double or other layer combinations of advanced materials may be used if they meet performance requirements. It is important to note that with more tightly woven materials, breathability may be reduced as the number of layers increases. A quick check may be performed by attempting to breathe, through the mouth, through the multiple layers.

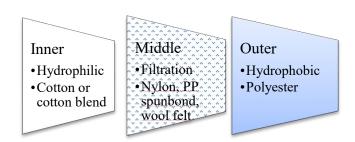


Figure 1. Non-medical mask construction using breathable fabrics such as cotton, cotton blends, polyesters, nylon and polypropylene spunbond that are breathable may impart adequate filtration performance when layered. Single- or double-layer combinations of advanced materials may be used if they meet performance requirements (72).

Assumptions regarding homemade masks are that individual makers only have access to common household fabrics and do not have access to test equipment to confirm target performance (filtration and breathability). Figure 1 illustrates a multi-layer mask construction with examples of fabric options. Very porous materials, such as gauze, even with multiple layers, may provide very low filtration efficiency (147). Higher thread count fabrics offer improved filtration performance (169). Coffee filters, vacuum bags and materials not meant for clothing should be avoided as they may contain injurious content when breathed in. Microporous films such as Gore-Tex are not recommended (170).

# Factory-made non-medical masks: general considerations for manufacturers

The non-medical mask, including all components and packaging, must be non-hazardous, non-toxic and child-friendly (no exposed sharp edges, protruding hardware or rough materials). Factory-made non-medical masks must be made using a process that is certified to a quality management system (e.g., ISO 9001). Social accountability standards (e.g., SAI SA8000) for multiple aspects of fair labour practices, health and safety of the work force and adherence to UNICEF's Children's Rights and Business Principles are strongly encouraged.

### Standards organizations' performance criteria

Manufacturers producing masks with consistent standardized performance can adhere to published, freely available guidance from several organizations including those from: the French Standardization Association (AFNOR Group), The European Committee for Standardization (CEN), Swiss National COVID-19 Task Force, the American Association of Textile Chemists and Colorists (AATCC), the South Korean Ministry of Food and Drug Safety (MFDS), the Italian Standardization Body (UNI) and the Government of Bangladesh.

### **Essential parameters**

The essential parameters presented in this section are the synthesis of the abovementioned regional and national guidance. They include filtration, breathability and fit. Good performance is achieved when the three essential parameters are optimized at the preferred threshold (Figure 2).

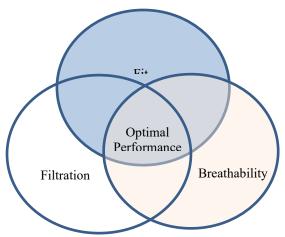


Figure 2. Illustration of the three essential parameters of filtration, breathability and fit.

The summary of the three essential parameters can be found in Table 1 and the additional performance considerations in Table 2. The minimum threshold is the minimum acceptable parameter, while the preferred threshold is the optimum.

#### Filtration and breathability

Filtration depends on the filtration efficiency (in %), the type of challenge particle (oils, solids, droplets containing bacteria) and the particle size (see Table 1). Depending on the fabrics used, filtration and breathability can complement or work against one another. The selection of material for droplet filtration (barrier) is as important as breathability. Filtration is dependent on the tightness of the weave, fibre or thread diameter. Non-woven materials used for disposable masks are manufactured using processes to create polymer fibres that are thinner than natural fibres such as cotton and that are held together by partial melting.

Breathability is the difference in pressure across the mask and is typically reported in millibars (mbar) or Pascals (Pa) or, normalized to the cm² in mbar/cm² or Pa/cm². Acceptable breathability of a medical mask should be below 49 Pa/cm². For non-medical masks, an acceptable pressure difference, over the whole mask, should be below 60 Pa/cm², with lower values indicating better breathability.

Non-medical fabric masks consisting of two layers of polypropylene spunbond and two layers of cotton have been shown to meet the minimum requirements for droplet filtration and breathability of the CEN CWA 17553 guidance. It is preferable not to select elastic material to make masks as the mask material may be stretched over the face, resulting in increased pore size and lower filtration through multiple usage. Additionally, elastic fabrics are sensitive to washing at high temperatures thus may degrade over time.

Coating the fabric with compounds like wax may increase the barrier and render the mask fluid resistant; however, such coatings may inadvertently completely block the pores and make the mask difficult to breathe through. In addition to decreased breathability unfiltered air may more likely escape the sides of the mask on exhalation. Coating is therefore not recommended.

Valves that let unfiltered air escape the mask are discouraged and are an inappropriate feature for masks used for the purpose of preventing transmission.

Table 1. Essential parameters (minimum and preferred thresholds) for manufactured non-medical mask

Essential Parameters	Minimum threshold	Preferred threshold	
1. Filtration*			
1.1. filtration efficiency	70% @ 3 micron	> 70%, without compromising breathability	
1.2. Challenge particle	Solid: sodium chloride (NaCl), Talcum powder, Holi powder, dolomite, Polystyrene Latex spheres	Based on availability	
	Liquid: DEHS Di-Ethyl-Hexyl-Sebacat, paraffin oil		
1.3. Particle size	Choose either sizes:	Range of particle sizes	
	3 μm, 1 μm, or smaller		
2. Breathability			
2.1. Breathing	≤60 Pa/cm <sup>2</sup>	Adult: ≤ 40 Pa/cm <sup>2</sup>	
resistance**		Paediatric: ≤ 20 Pa/cm <sup>2</sup>	
2.2 Exhalation valves	Not recommended	N/A	
3. Fit			
3.1. Coverage  Full coverage of nose and mouth, consistent snug perimeter fit at the nose bridge, cheeks chin and lateral sides of the face; adequate surface area to minimize breathing resistance and minimize side leakage			
3.2 Face seal	Not currently required	Seal as good as FFR (respirator):	
		Fit factor of 100 for N95	
		Maximum Total Inward Leakage of 25% (FFP1 requirement)	
3.2. Sizing	Adult and child	Should cover from the bridge of the nose to below the chin and cheeks on either side of the mouth	
		Sizing for adults and children (3-5, 6-9, 10-12, >12)	
3.3Strap strength		> 44.5 N	

<sup>\*</sup> Smaller particle may result in lower filtration.

<sup>\*\*</sup> High resistance can cause bypass of the mask. Unfiltered air will leak out the sides or around the nose if that is the easier path.

### Fit: shape and sizing

Fit is the third essential parameter, and takes into consideration coverage, seal, sizing, and strap strength. Fit of masks currently is not defined by any standard except for the anthropometric considerations of facial dimensions (ISO/TS 16976-2) or simplified to height mask (South Korean standard for KF-AD). It is important to ensure that the mask can be held in place comfortably with as little adjustment of the elastic bands or ties as possible.

Mask shapes typically include flat-fold or duckbill and are designed to fit closely over the nose, cheeks and chin of the wearer. Snug fitting designs are suggested as they limit leaks of unfiltered air escaping from the mask (148). Ideally the mask should not have contact with the lips, unless hydrophobic fabrics are used in at least one layer of the mask (148). Leaks where unfiltered air moves in and out of the mask may be attributed to the size and shape of the mask (171).

#### **Additional considerations**

Optional parameters to consider in addition to the essential performance parameters include if reusable, biodegradability for disposal masks, antimicrobial performance where applicable and chemical safety (see Table 2).

Non-medical masks intended to be reusable should include instructions for washing and must be washed a minimum of five cycles, implying initial performance is maintained after each wash cycle.

Advanced fabrics may be biodegradable or compostable at the end of service life, according to a recognized standard process (e.g., UNI EN 13432, UNI EN 14995 and UNI / PdR 79).

Manufacturers sometimes claim their NM masks have antimicrobial performance. Antimicrobial performance may be due to coatings or additives to the fabric fibres. Treated fabrics must not come into direct contact with mucous membranes; the innermost fabric should not be treated with

antimicrobial additives, only the outermost layer. In addition, antimicrobial fabric standards (e.g., ISO 18184, ISO 20743, AATCC TM100, AATCC 100) are generally slow acting. The inhibition on microbial growth may take full effect after 2- or 24-hour contact time depending on the standard. The standards have generally been used for athletic apparel and substantiate claims of odour control performance. These standards are not appropriate for non-medical cloth masks and may provide a false sense of protection from infectious agents. If claims are maid, manufacturers should specify which standard supports antimicrobial performance, the challenge organism and the contact time.

Volatile additives are discouraged as these may pose a health risk when inhaled repeatedly during wear. Certification according to organizations including OEKO-TEX (Europe) or SEK (Japan), and additives complying with REACH (Europe) or the Environmental Protection Agency (EPA, United States of America) indicate that textile additives are safe and added at safe levels.

Table 2. Additional parameters for manufactured nonmedical masks

Additional parameters	Minimum thresholds	
If reusable, number of wash cycles	5 cycles	
Disposal	Reusable	
	If biodegradable (CFC-BIO), according to UNI EN 13432, UNI EN 14995	
Antimicrobial (bacteria, virus, fungus) performance	ISO 18184 (virus) ISO 20743 (bacteria) ISO 13629 (fungus) AATCC TM100 (bacteria)	
Chemical safety	Comply with REACH regulation, including inhalation safety	

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