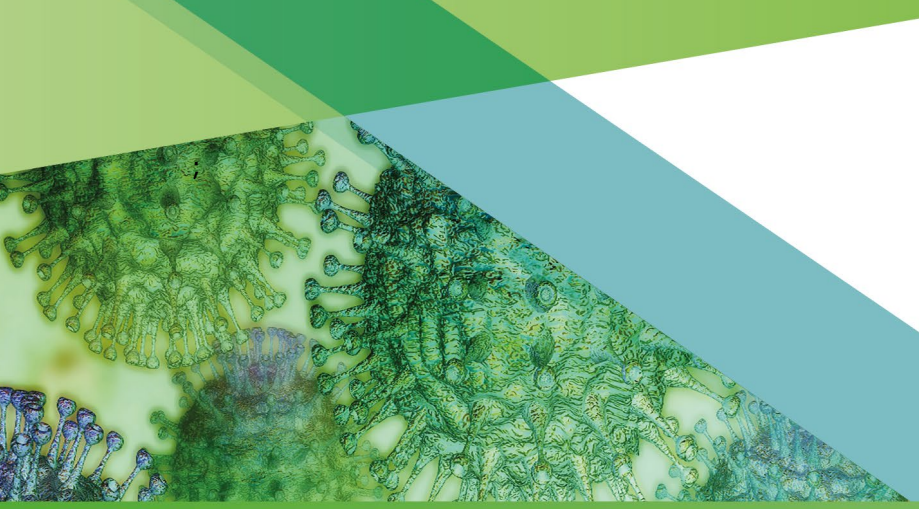

TECHNICAL REPORT

Using face masks in the community: first update

Effectiveness in reducing transmission of COVID-19

15 February 2021

Key messages

The role of face masks in the control and prevention of COVID-19 remains an issue of debate. Prior to COVID-19, most studies assessing the effectiveness of face masks as a protective measure in the community came from studies on influenza, which provided little evidence to support their use. This technical report reviews the evidence that has been accumulated since the emergence of COVID-19, in addition to what has existed on this topic prior to the pandemic, and updates the ECDC opinion on the suitability of using face masks in the community [1] published on 9 April 2020.

Assessment of the evidence

The evidence regarding the effectiveness of medical face masks for the prevention of COVID-19 in the community is compatible with a small to moderate protective effect, but there are still significant uncertainties about the size of this effect. Evidence for the effectiveness of non-medical face masks, face shields/visors and respirators in the community is scarce and of very low certainty.

Additional high-quality studies are needed to assess the relevance of the use of medical face masks in the COVID-19 pandemic.

Recommendations

Although the evidence for the use of medical face masks in the community to prevent COVID-19 is limited, face masks should be considered as a non-pharmaceutical intervention in combination with other measures as part of efforts to control the COVID-19 pandemic.

Taking into account the available evidence, the transmission characteristics of SARS-CoV-2, the feasibility and potential harms associated with the use of various types of face masks, the following options are proposed:

- In areas with community transmission of COVID-19, wearing a medical or non-medical face mask is recommended in confined public spaces and can be considered in crowded outdoor settings.
- For people vulnerable to severe COVID-19, such as the elderly or those with underlying medical conditions, the use of medical face masks is recommended as a means of personal protection in the above-mentioned settings.
- In households, the use of medical face masks is recommended for people with symptoms of COVID-19 or confirmed COVID-19 and for the people who share their household.

Suggested citation: European Centre for Disease Prevention and Control. Using face masks in the community: first update. 15 February 2021. ECDC: Stockholm; 2021.

- Based on the assessment of the available scientific evidence, no recommendation can be made on the preferred use of medical or non-medical face masks in the community.
- When non-medical face masks are used, it is advisable that masks that comply with available guidelines for filtration efficacy and breathability are preferred.

The very limited scientific evidence regarding the use of respirators in the community does not support their mandatory use in place of other types of face masks in the community. Although respirators would not be expected to be inferior to non-medical or medical face masks, the difficulties to ensure their appropriate fitting and use in community settings as well as potential adverse effects related to lower breathability should be taken into account.

The use of face masks in the community should complement and not replace other preventive measures such as physical distancing, staying home when ill, teleworking if possible, respiratory etiquette, meticulous hand hygiene and avoiding touching the face, nose, eyes and mouth.

The appropriate use of face masks and promoting compliance with their use when recommended as public health measures are key to the effectiveness of the measure and can be improved through education campaigns.

Scope of this document

This document provides an update to and replaces the ECDC opinion on the suitability of using face masks in the community [1] published on 9 April 2020. The aim was to review whether the scientific evidential basis has changed since April 2020. This document therefore builds on the evidence available in the literature and presents the main findings and recommendations for public health measures. The use of face masks by healthcare workers for the prevention of COVID-19 is out of the scope of this document and is covered in the latest update to the technical report Infection prevention and control and preparedness for COVID-19 in healthcare settings', published on 9 February 2021.

Target audience

Public health authorities and the public in Member States of the European Union (EU) and European Economic Area (EEA).

Figure 1. Types of face mask and shield

Medical face mask | Non-medical/'community' face mask | Respirator | Face shield/visor

Glossary

Face mask is an overarching term used for any device (i.e. a non-medical, medical face mask or a respirator) that is worn over the mouth and nose to prevent the inhalation of harmful substances such as infectious respiratory droplets or the release of infectious respiratory droplets produced by breathing, speaking, coughing or sneezing in the environment

Source control: When face masks are used to prevent the release of infectious respiratory particles such as droplets or aerosols by SARS-CoV-2-positive people into the environment to decrease the likelihood that these particles are inhaled by another healthy person or deposited on mucous membranes (i.e. protection of others).

Wearer protection: When face masks are intended to prevent SARS-CoV-2-containing infectious splashes and respiratory droplets, including aerosols from the environment to be inhaled or deposited on mucous membranes.

Non-medical face masks (also known as 'community' masks) include various forms of self-made and commercial masks, including re-usable face covers made of cloth, other textiles and other disposable materials

such as paper. They are not standardised and are not intended to be used in healthcare settings or by healthcare workers.

A medical face mask (also known as surgical or procedure mask) is a disposable medical device used by healthcare workers to prevent large respiratory droplets and splashes reaching the mouth and nose of the wearer, and as a means of source control to stop the spread of large respiratory droplets by the person wearing them [2]. Requirements for medical face masks, including the duration of use, are defined in the European Committee for Standardization's published standards [3]. Medical face masks are not defined as personal protective equipment in Regulation (EU) 2016/425 of 9 March 2016 or Directive 89/656/EEC on personal protective equipment [4]. However, for the purpose of this document and in accordance with guidance on infection prevention and control in the context of COVID-19 by the World Health Organization (WHO) [5] and on transmission-based precautions [6], medical face masks are considered to provide protection against infections transmitted by droplets.

A respirator (also known as a filtering face piece (FFP) mask or filtering half mask) is a device designed to protect the wearer from exposure to airborne contaminants (e.g. from inhaling dust or infectious particles). Requirements for respirators, including the intended duration of use, are specified in the European Committee for Standardization's published standards [7], and respirators are classified as personal protective equipment [2]. **An N95/N99 respirator** is the United States' equivalent of FFP2/FFP3 respirators as defined by U.S. standard NIOSH 42 CFR, part 84 [8].

FFP2 respirators have a filtering capacity of at least 94% for 0.3 µm particles, while FFP3 respirators have a filtering capacity of at least 99% for 0.3 µm particles. Respirators are mainly used by workplace users, including healthcare professionals, to protect themselves, especially during dust- and aerosol-generating procedures, and require a fitting test to ensure proper protection.

A face shield or visor is a device used to protect the face from hazards such as splashes. It is used by healthcare workers as part of droplet precautions for face and eye protection against large infectious droplets and splashes.

Background

In most instances, SARS-CoV-2 is believed to be transmitted from person to person primarily via large respiratory droplets and aerosols produced when breathing, talking or coughing, either by being inhaled or deposited on mucous membranes. People with mild or no symptoms at the pre-symptomatic and early stages of infection contribute to the spread of COVID-19 [9]. People with asymptomatic infection contribute to transmission, although to a lesser extent compared with symptomatic patients [9].

SARS-CoV-2 transmission has been mainly reported in crowded, confined indoor spaces such as workplaces (offices, factories), churches, restaurants, resorts, weddings, parties, shopping centres, worker dormitories, dance classes, cruise ships and vehicles [10]. Outdoor events, such as carnival celebrations [11] and football matches [12], have also been implicated in the spread of COVID-19, indicating a risk associated with crowding during outdoor events. However, such events are also linked to concurrent crowding in related indoor spaces, such as restaurants and bars, making it difficult to assess the contribution of outdoor spaces to transmission.

Medical face masks have been used in healthcare settings for both personal protection and source control. Prior to the COVID-19 pandemic, medical face masks have been recommended in the community as a mean of source control for people who are symptomatic for other diseases, in order to prevent the spread of respiratory droplets produced by coughing or sneezing. The use of medical face masks has been recommended for the reduction of transmission of other diseases, such as tuberculosis [13] and influenza [14].

A medical face mask may help reduce the spread of COVID-19 in the community by reducing the release of respiratory droplets *from* infected individuals who may not be aware they are infected (asymptomatic) and before they develop any symptoms (presymptomatic) or when they have mild non-specific symptoms.

Due to past shortages in the availability of medical face masks and the fact that they were prioritised for use in healthcare settings, non-medical face masks have also been extensively used in an attempt to reduce the spread of COVID-19 in the community. Non-medical face masks can be made from a range of materials, such as cotton or synthetics, and are either commercially available or home-made.

During the course of the pandemic and as of 12 February 2021, all EU/EEA countries have implemented various recommendations regarding the use of medical and non-medical face masks as a complementary non-pharmaceutical intervention in closed places (including retail and public transportation) as well as in public places where physical distancing is not always possible. In the vast majority of these countries, the use of medical or non-medical face masks has been or continues to be mandatory. For more details on the current national recommendations, please see the ECDC-Joint Research Centre response measures database [15] or ECDC's weekly Country Overview [16].

Methodological approach

This technical report draws upon evidence from a systematic literature search on the effectiveness of different types of face masks. Our primary question for the literature search was 'What is the effectiveness of face masks in preventing the spread of COVID-19 in the community?' We searched for different types of study designs (e.g. interventional and observational studies) that looked at the effectiveness of wearing face masks, either for personal protection or source control or both, for preventing the spread of COVID-19. Indirect evidence from other settings, such as households and healthcare settings, was also considered, as was evidence from other respiratory viral infections with similar modes of transmission to COVID-19 and potential for pandemic spread, such as influenza and SARS. We also searched for indirect evidence from experimental studies and for evidence on adverse effects of face mask use. Searches were run in the databases PubMed, Embase, Scopus, and CENTRAL on 10 November 2020, and re-run on 11 December 2020. Daily email search alerts for the above listed databases were established to keep the review team informed of any new studies published after 11 December 2020 and until 18 January 2021. The reference lists of identified reviews were searched for additional primary studies. Records were screened by two independent reviewers in two steps on the level of title and abstracts and on the level of full texts, using pre-defined selection criteria. Discrepancies between reviewers were resolved by consensus. Data were extracted using a pre-determined and tested extraction form. For the sake of time, the references were distributed between reviewers and each study was extracted and summarised by a single reviewer, together with the quality and risk of bias assessment. Details on the methodology of the systematic review can be found in the **supplementary material**.

The body of this document summarises the main findings. ECDC experts assessed the evidence according to the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) criteria [17], as well as the certainty/confidence of evidence (Table 1, Annex). Confidence in evidence was deemed to be lower where, for instance, inconsistencies in the findings were found or the literature only indirectly addressed the topic in question, i.e. other settings than community settings or other viral infections than COVID-19.

Table 1. GRADE definitions for the ratings of the overall confidence of evidence [17]

Rating	Definition
High	This research provides a very good indication of the likely effect. The likelihood that the effect will be substantially different is low.
Moderate	This research provides a good indication of the likely effect. The likelihood that the effect will be substantially different is moderate.
Low	This research provides some indication of the likely effect. However, the likelihood that it will be substantially different (a large enough difference that it might have an effect on a decision) is high.
Very low	This research does not provide a reliable indication of the likely effect. The likelihood that the effect will be substantially different (a large enough difference that it might have an effect on a decision) is very high.

In addition, the effect estimates of the studies were assessed to provide information on the magnitude of the effects observed in the studies. Due to the large heterogeneity in the methodologies and the reported effect estimates, it was not possible to perform a meta-analysis. We therefore summarised the effect estimates qualitatively based on the sample size, direction of effect (favourable or unfavourable), magnitude and statistical significance [18]. The summary of the effect estimates and certainty of the evidence from the interventional and observational studies is provided in the Annex.

It is important to note that this document was not developed as a formal GRADE process. However, given the rapidly growing evidence surrounding SARS-CoV-2 and COVID-19, it was deemed important to attempt to provide such an assessment of the available scientific evidence.

Scientific evidence for the use of face masks in the community

In this section, the scientific evidence for the effectiveness of face masks is presented. It is divided into four sections, namely medical face masks; non-medical face masks; visors and transparent face masks; and respirators. The key messages of each section are highlighted in a summary box.

Effectiveness of medical face masks for the prevention of COVID-19 in the community

Summary

There is evidence of low to moderate certainty for the use of medical face masks providing a small to moderate protective effect against COVID-19 in the community, both in terms of personal protection as well as source control (protection of others).

Most, but not all, studies show a favourable effect for medical face masks for protecting against COVID-19. However, this effect was not statistically significant in several studies, and the quality of the evidence was assessed as low in several studies, so the results should be interpreted with caution.

Looking at the evidence from studies in healthcare settings or other diseases than COVID-19 (i.e. influenza and other respiratory viral infections) did not improve the certainty of the evidence. Some of these studies show a statistically significant favourable effect and others a non-statistically significant favourable effect, while a few studies show an unfavourable effect for the use of medical face masks. In addition, these findings may not be directly extrapolated to COVID-19 and community settings, thus making it difficult to draw conclusions from these studies for the prevention of COVID-19 in the community.

The large heterogeneity in the methodology of the different studies makes it difficult to generalise results to all community settings as well as to compare different studies or settings. Additional high-quality studies are needed to investigate the relevance of medical face masks in the COVID-19 pandemic.

	Effect estimate	Certainty of evidence
Effectiveness of medical face masks for the prevention of COVID-19 in the community	Small to moderate	Low to moderate

Community settings: There is limited evidence on the effectiveness of medical face masks for the prevention of COVID-19 in the community. We identified only one randomised controlled trial (RCT), with around 3 000 participants in each of the intervention (medical face mask) and the control group [19]. The study showed an 18% decrease in the incidence of COVID-19 among people in the intervention group compared to the control group; however, this difference was not statistically significant. Although this study was conducted at a time of low incidence of COVID-19, leading to a relatively low number of events, the results support a relative reduction of risk lower than 50%. There was a risk of bias due to suboptimal compliance with the use of masks in the intervention group. No conclusion can be drawn from this study on the effectiveness of medical face mask use as source control (transmission to others), as the study was not designed to assess this. The evidence from this study is compatible with low or no effect of medical face masks for personal protection in the community, and the certainty of the evidence is moderate due to risk of bias.

Our search further identified one case-control [20] and four cross-sectional studies [21-24] that assessed the effectiveness of face masks for the prevention of COVID-19 in the community. These studies did not distinguish between medical face masks, non-medical face masks and respirators. With only one exception, these studies showed a very favourable statistically significant effect of face masks (OR range 0.16-0.3). The remaining study - a cross-sectional study -also showed a favourable effect, but it was not statistically significant. Despite the consistent favourable effect of face masks for the prevention of COVID-19, the certainty of evidence was considered low due to serious risk of bias and indirectness in some studies (one study was performed on a U.S. Navy ship and another in a school).

Furthermore, the literature search identified 11 ecological studies. These either compared various measures of the incidence of COVID-19 before and after the introduction of face mask use recommendations or mandates, or conducted comparisons between countries or regions with and without recommended or mandated face mask use in the community [25-35]. Nine studies showed a reduction in the number of COVID-19 cases after the introduction of the use of face masks, ranging from a reduction of 6% to 82% while one study resulted in a

significant reduction in the number of deaths due to COVID-19 ($p<0.001$). Finally, one study did not find a significant decrease in the number of new daily COVID-19 cases in the month before *vs.* after the mandatory use of face masks. Nevertheless, potential confounding factors associated with the evolution of the COVID-19 pandemic and the concurrent application of other control interventions limit the certainty of the evidence from these ecological studies. Furthermore, in these studies both medical and non-medical face masks were used in the community, making it difficult to distinguish the effect of each type of face mask.

Healthcare settings: Due to the limited evidence on the effectiveness of the use of medical face masks for personal protection from COVID-19 in the community, we also assessed evidence from studies performed in healthcare settings. Two case-control studies [36,37] and five cross-sectional studies [38-42] in healthcare settings assessed the protective effect of medical face masks against COVID-19 for healthcare workers. Both case-control studies showed a statistically significant favourable effect of medical face masks. However, both studies had a serious risk of bias due to selection bias, confounding and recall bias, which must be considered when interpreting the results. Four of the five cross-sectional studies showed a favourable effect, some statistically significant and some not. The remaining cross-sectional study found a higher risk of COVID-19 among healthcare workers wearing medical face masks than among healthcare workers wearing N95 respirators or no mask. Overall, there was large heterogeneity in the methodologies, the types of face mask used (medical face mask or respirator) and the study outcomes (seropositivity or PCR-confirmed infection). The risk of bias was also assessed as serious. The certainty of the evidence from these studies was assessed as low due to the risk of bias and indirectness, since these studies were performed in healthcare settings and the results may not be directly extrapolated to the community.

Use of medical face masks for the prevention of influenza, SARS and other respiratory viral infections

To complement the evidence from studies on COVID-19, our search also included evidence on the effectiveness of face masks in preventing influenza, SARS and other respiratory viral infections.

Community: Eight cluster randomised controlled trials (RCTs) studied the effectiveness of the use of medical face masks in preventing influenza and other respiratory tract infections in households when a member of the household is ill [43-49]. These RCTs showed inconsistent non-statistically significant results. In two of the RCTs, a statistically significant favourable effect was found in the subgroup that included use of a medical face mask within 36 hours from symptom onset [45,49]. In most of these RCTs, medical face masks were used both by the person that was ill and their contracts. It is therefore difficult to distinguish the part of the effect that is related to personal protection from that due to source control.

Two cluster RCTs studied the effect of medical face masks for the prevention of influenza and other viral respiratory infections in other community settings; one during Hajj pilgrimage [50] and one in university residence halls [51]. The first RCT showed a non-statistically significant unfavourable effect of the use of medical face masks for the prevention of viral respiratory infections. Compliance was low in the intervention group and even several participants in the control group were using medical face masks. The RCT in university residence halls showed a non-statistically significant favourable effect of the use of medical face masks.

The cluster RCTs were characterised by large heterogeneity due to variable settings, studied outcomes and effect measures, making the synthesis and comparison of results challenging. Furthermore, deviations from interventions were very common in the included RCTs. Commonly, there was moderate compliance in the intervention group while in several studies individuals in the control group were also applying the intervention.

Two case-control studies of the transmission of SARS in the community showed a large statistically significant favourable effect for the use of face masks with a range of OR 0.3-0.36 [52,53]. A cross-sectional study showed a favourable but not statistically significant effect [54].

Healthcare settings: One small RCT in a healthcare setting did not identify any effect of wearing a medical face mask at work for the prevention of clinical respiratory infection [55]. The sample size was very small and the study did not adjust for exposure of the participants out of the workplace.

Five case-control studies [53,56-59] and two cross-sectional studies [60] investigated the role of medical face masks in preventing the transmission of SARS. Four out of the five case-control studies showed a very favourable statistically significant effect (range of aOR: 0.08-0.29) and one study showed a favourable but non-statistically significant effect (there were very few participants without any face mask in this study). One cross-sectional study also showed a large statistically significant favourable effect when comparing wearing any face mask (including N95 respirators and medical face masks) to not wearing any mask. However, when only comparing wearing a medical face mask to not wearing any mask, the effect was favourable but not statistically significant (the number of participants wearing a medical face mask was small and most of the exposure occurred during aerosol generating procedures). The second cross-sectional study showed favourable not significant effect for wearing either a medical face mask or a N95 respirator. The certainty of the evidence derived from these studies was assessed as low due to risk of bias and indirectness.

Medical face masks for source control

Only a few of the identified studies specifically examined the effectiveness of medical face masks as source control for the prevention of COVID-19 and other respiratory tract infections. We identified only one such retrospective study, which estimated a COVID-19 incidence of 8.1% among contacts of presymptomatic index cases who were wearing a face mask compared to 19% among contacts of presymptomatic index cases who were not wearing a face mask [23].

One of the clustered RCTs showed a small non-statistically significant decrease in clinical respiratory illness and laboratory-confirmed viral respiratory infection [61]. In the other identified cluster RCTs of the use of medical face masks for the prevention of influenza and other respiratory tract infections in households and other community settings, medical face masks were used both by index cases with infection and their contacts making it difficult to distinguish the effect of medical face masks when used for personal protection from the effect when used for source control. However, these studies, as described above, had inconsistent non-statistically significant results with the exception of a statistically significant favourable effect in the subgroup that only included early use (within 36 hours from the onset of symptoms) of a medical face mask. A prospective interventional before-after study that specifically assessed the effectiveness of medical face masks when used as source control by healthcare workers in an haematopoietic stem cell transplantation unit showed a decrease in the incidence of respiratory viral infections in patients, from 10.3% to 4.4%, after the introduction of a universal masking policy among healthcare workers [62].

Several experimental studies have shown that face masks decrease the amount or otherwise limit the release and spread of respiratory droplets during activities such as breathing, speaking and coughing [63-65]. These studies also show an additive effect when both the source and the exposed wear a face mask. An experimental study in an animal model (hamsters) showed a decrease of transmission from 66.7% (10/15) when a medical face mask partition was not used between the cages to 25% (6/24, P = .018) when a medical face mask partition was used as a protection of the naïve animals, and to 16.7% (2/12, P = .019) when a medical face mask partition was used as source control on the side of the partition of the infected index animals [66].

Effectiveness of non-medical face masks for the prevention of COVID-19 in the community

Summary

Evidence regarding the effectiveness of non-medical face masks for the prevention of COVID-19 is scarce. We did not identify any interventional or observational study directly comparing the effectiveness of non-medical face masks with that of medical face masks and no masks.

As non-medical masks can consist of different types of material and be constructed in different ways, the filtration effectiveness varies between types of non-medical face mask.

Experimental studies on non-medical face masks conducted in the laboratory show inconsistent results with large variability in their effectiveness.

Limited indirect evidence from experimental studies showed that non-medical face masks may decrease the release to the environment of respiratory droplets, although there was conflicting evidence about the relative efficiency of medical versus non-medical face masks.

	Effect estimate	Certainty of evidence
Effectiveness of non-medical face masks for the prevention of COVID-19 in the community	Small to moderate	Very low

We did not find any interventional or observational studies directly comparing the effectiveness of non-medical face masks with that of medical face masks for the prevention of COVID-19.

One cluster RCT compared cloth non-medical masks with medical face masks in healthcare workers and found a statistically significant increase in the incidence of clinical respiratory infection and of influenza-like illness among the healthcare workers in the wards randomised to cloth mask use. However, the results of this study have not been replicated and the cloth non-medical masks used were not representative of non-medical face masks [67].

Several ecological studies have either compared various measures of the incidence of COVID-19 before and after the introduction of recommendations or mandates on the use of face masks, or conducted comparisons between countries or regions with and without recommended or mandated use of face masks in the community [25-35]. As in most cases the requirements for face masks in the community have not distinguished between medical and non-medical face masks, these studies only provide indirect evidence of the effect of non-medical face masks.

The results of these ecological studies are summarised in the section on effectiveness of medical face masks (see above).

Overall, experimental studies have shown inconsistent results with large variability in the efficiency of various non-medical face masks. Several experimental studies showed that non-medical face masks can have filtering properties comparable to that of medical face masks [63-66,68-104]. The filtration efficiency depends on the material and the construction of the face mask, including thickness and layering (from three to 16 layers [90]) and the combination of materials. However, results are often inconsistent, probably due to the large heterogeneity of applied experimental methodologies and conditions, and it is difficult to draw general conclusions from the results. To date, no interventional or observational study has directly evaluated the effect of non-medical face masks on the transmission of SARS-CoV-2. The European Committee for Standardization (CEN) and other standardisation agencies have established guidelines for the filtration characteristics and the breathability of non-medical face masks [105,106]. Factors such as the difficulty of breathing linked to various commonly available materials, especially when layered, must be taken into account when assessing the suitability of materials for non-medical face masks.

There is indirect evidence from experimental studies that non-medical face masks made from various materials may decrease the release to the environment of respiratory droplets produced by breathing, speaking and coughing, although there is conflicting evidence about the relative efficiency of medical versus non-medical face masks in this respect [64,65,107]. One of the advantages of non-medical face masks made of cloth or other textiles is that they can be easily made and can also be washed and reused.

Non-medical face masks with a transparent window are proposed to address communication impairment linked to face masks. We did not find any studies on the efficacy or effectiveness of such face masks to prevent exposure to respiratory droplets, but they would be expected to work similarly to other non-medical face masks if properly fit on the face of the wearer.

Effectiveness of face shields/visors for the prevention of COVID-19 in the community

Summary

There is a lack of scientific evidence on the effectiveness of face shields/visors and transparent face masks for the prevention of COVID-19.

One simulation study showed that face shields can reduce the short-term exposure to large respiratory droplets, although this was less effective for smaller droplets.

	Effect estimate	Certainty of evidence
Effectiveness of face shields/visors and transparent face masks for the prevention of COVID-19 in the community	Cannot be assessed	Very low

Face shields and visors have been proposed to be worn by the general public instead of face masks for the prevention of COVID-19 transmission. There is a lack of interventional and observational studies to address the question of their effectiveness. One experimental study using a coughing patient simulator and a breathing healthcare worker simulator showed that face shields can reduce the short-term exposure to large respiratory droplets by up to 96%, but are less effective against smaller droplets that tend to be suspended in the air (68–80% reduction) [108]. Other experimental studies have also shown that face shields block the jet cloud released in the forward direction through simulated sneezing [65]. In one observational study that examined the protective effect of face shields, the face shields were used in combination with medical face masks [109]. It is therefore difficult to determine the size of protective effect provided by the face shield alone.

Effectiveness of respirators for the prevention of COVID-19 in the community

Summary

Respirators, e.g. FFP2 masks, have a higher filtration efficacy than medical face masks as defined by standardised specifications.

Evidence regarding the effectiveness of respirators in community settings remains very limited. While two experimental studies have shown favourable results when compared to medical face masks, a household study did not find any difference between respirators and medical face masks.

The identified studies comparing medical face masks with respirators in healthcare settings showed conflicting results, some in favour and others not in favour of respirators.

Due to difficulties to ensure appropriate use and fitting of respirators when used in the community, any possible added value of respirators in preventing respiratory infections is expected to be lower in the community than in healthcare.

	Effect estimate	Certainty of evidence
Effectiveness of respirators for the prevention of COVID-19 in the community	Small to moderate	Low

Due to their better filtration efficiency, respirators have been considered for use in the community, in particular since the emergence of more transmissible new variants of SARS-CoV-2. We did not identify any RCT of the impact of respirators on community transmission of any respiratory infection in a pandemic.

One study in household settings, comparing respirators with medical face masks and with no mask for the prevention of influenza, did not show any difference in the incidence of infection between the groups using respirators and medical face masks [44].

Studies in healthcare settings comparing respirators with medical face masks have shown conflicting results. Two RCTs found small non-statistically significant differences in laboratory-confirmed influenza either in favour of or not in favour of respirators [110,111]. Two other RCTs found a statistically significant favourable difference for clinical respiratory infection, but the difference between healthcare workers wearing medical face masks and those using respirators was not statistically significant for influenza-like illness and for laboratory-confirmed influenza [112,113].

Respirators have a higher filtration efficacy than medical masks as defined by standardised specifications. An experimental study showed that, when coughing through the medical face mask or respirator at a distance of 20 cm from a Petri dish, respirators were more effective than medical face masks in limiting the release of infectious respiratory droplets containing SARS-CoV-2 from patients with COVID-19 [63]. Another experimental study applying a cough simulator also showed that respirators were more efficient than medical face masks when worn by the coughing mannequin and when worn by the exposed mannequin [64]. The efficacy was higher when the respirator was worn by the coughing mannequin and when the respirator was tightly fit. Efficacy was also dependent on distance and viral load.

The choice of suitable respirator for the shape of a user's face (type and size) and training to ensure that the user knows how carry out a pre-use seal check are crucial requirements for respirators to be effective [114]. The seal check should be repeated every time a user dons the respirator. Therefore, due to difficulties to ensure appropriate use and fitting of respirators when used in the community, any possible added value of respirators in preventing respiratory infections is expected to be lower in the community than in healthcare.

Considerations for implementation of face mask policies in the community

The proper use of face masks is key to their effectiveness and can be improved by clear guidance and appropriate communication and educational campaigns. ECDC has produced and published infographics and videos [115-117] on how to correctly put on and discard a face mask in the community. Concerns that the mandatory use of face masks would generate a false sense of security that could decrease adherence to other types of protective behaviour, such as physical distancing, have been both supported by some studies [118] and disputed by other studies [119,120]. The use of face masks has been associated with decreased face-touching [121]. The decision to introduce the mandatory

use of face masks in community settings should take into account the epidemiology, the local context, the availability of face masks for the public (which should not compromise the availability of medical face masks or respirators for health and social care workers) and the resources available to monitor implementation. When non-medical face masks are used, it is advisable that masks complying with available guidelines for filtration efficacy and breathability are preferred (CEN Workshop Agreement (CWA) guidelines CWA 17553) [122].

Compliance with the use of face masks is affected by several factors, such as availability, gender, age, and perceptions of one's own vulnerability and severity of COVID-19; women and the elderly are more willing to wear face masks than men and young people. [123]. Social acceptance and perceived pressure from the family, mass media and the government are also associated with the increased use of face masks in the community. In contrast, limited knowledge of COVID-19 is linked to lower compliance with wearing a face mask [123].

Potential adverse effects of face mask use

Policies on the widespread use of face masks for the prevention of COVID-19 in the community should take into account potential barriers and adverse effects [124]. People wearing a face mask may perceive anxiety and difficulty in breathing [125]. This may be pronounced in people with underlying respiratory disease. However, there is no evidence that wearing a face mask exacerbates respiratory or other diseases [126]. Of note, several studies found that there are no substantial physiological effects on wearing a face mask even during vigorous exercise [127-130]. On the other hand, there are many reports of adverse skin reactions, such as erythema and pruritus due to the prolonged use of face masks [131-141]. It should also be highlighted that the tight fit of some face masks often results in limited tolerability, discomfort and headaches [142-145].

In addition, face masks may also impede communication, especially among people with hearing impairment, due to the presence of background noise and lack of speechreading cues [146-149]. As a result, the use of face masks can impair speech perception and therefore transparent masks can be considered for communication among people with hearing difficulties [150].

The availability of medical face masks may be limited during a pandemic. This can be a serious barrier for the implementation of face mask policies in the community and needs to be addressed. The costs incurred by individuals in complying with a face mask policy could be high and should be taken in consideration. This may hamper the successful implementation of the policy. Furthermore, individuals may choose to re-use face masks designed for single use, which could result in an increased risk of self-contamination [151].

The use of non-medical face masks is an option that has been adopted widely and may successfully address the issues of availability, cost and environmental impact. Although there is no direct evidence that non-medical face masks are effective in protecting the user from COVID-19, data from experimental studies show that certain non-medical face masks have filtration characteristics similar to that of medical face masks and that they are equally effective in reducing the release of respiratory droplets in the environment. Furthermore, non-medical face masks can easily be produced in large quantities and are reusable [152].

Finally, the potential environmental implications of the widespread use of face masks should be considered when developing a face mask policy. The production and disposal of large amounts of face masks made of synthetic materials may have a harmful impact on the environment if not appropriately managed [153].

The impact of using face masks depends on the prevalence of COVID-19 in the community and would be more pronounced in settings with widespread community transmission. In places without significant community transmission of COVID-19, the potential harms and costs may outweigh the benefits [121,153].

Recommendations for the use of face masks for the prevention of COVID-19 in the community

In areas with community transmission of COVID-19, wearing a medical or non-medical face mask is recommended in confined public spaces (such as stores, supermarkets and public transport).

The use of face masks can be considered in crowded outdoor settings.

For people vulnerable to severe COVID-19, such as the elderly or those with underlying medical conditions, the use of medical face masks is recommended as a means of personal protection in the above-mentioned settings.

In households, the use of medical face masks is recommended for people with symptoms of COVID-19 or confirmed COVID-19 and for the people who share their household, especially when isolation of the person with symptoms of or confirmed COVID-19 is not possible.

The use of face masks can be considered in certain workplaces and for certain professions that involve physical proximity to many other people (such as members of the police force, cashiers – if not behind a glass partition, etc.) as a complementary measure to technical measures (for example specific ventilation in areas with particular risk of transmission) and organisational measures (e.g. limiting the access of workers in such areas).[1]

When non-medical face masks are used, it is advisable that masks that comply with available guidelines for filtration efficacy and breathability are preferred.

The very limited scientific evidence on the use of respirators in the community does not support a recommendation for their mandatory use in place of other types of face masks in the community. Although respirators would not be expected to be inferior to non-medical or medical face masks, the difficulties to ensure their appropriate fitting and use when used in the community as well as potential harms related to lower breathability should be taken into account.

The use of face shields as a replacement for medical or non-medical face masks is not recommended, but can be considered when the impact of wearing a medical or non-medical face mask on communication is significant, such as for interaction with people with hearing impairment. A risk assessment should be made on individual cases. Non-medical face masks with a small transparent window but which still correctly fit the user's face can also be considered in these cases.

The use of face masks in the community should only complement and not replace other preventive measures that are recommended to reduce community transmission such as physical distancing, staying home when ill, respiratory etiquette, meticulous hand hygiene and avoiding touching the face, nose, eyes and mouth, teleworking if possible and appropriate ventilation of indoor spaces.

The appropriate use of face masks is important. The face mask should completely cover the face from the bridge of the nose down to the chin. The mask should be correctly adjusted on the bridge of the nose and to the face to minimise open space between the face and the mask. Hands should be cleaned with soap and water or alcohol-based hand sanitiser before putting on and taking off the face mask. The face mask should be removed from behind when taking it off; touching the front side should be avoided. Disposable face masks, e.g. medical face masks, should be safely disposed after use. Immediately after removing the face mask, hands should be washed or alcohol-based hand sanitiser applied. Washable, reusable face masks should be washed as soon as possible after each use, following the manufacturer's instructions. Common cotton face masks can be washed at 60˚C with a common detergent. Campaigns for the appropriate use of face masks can improve the effectiveness of the measure.

Promoting compliance is recommended to increase the effectiveness of the measure. Monitoring adherence and addressing potential factors that reduce compliance are recommended.

Justification for the recommendations

Although there is only low to moderate certainty of evidence for a small to moderate effect of the use of medical face masks in the community for the prevention of COVID-19, the balance of results towards a protective effect across the wide variety of studies reviewed, the very low risk of serious adverse effects and applying the precautionary principle leads us to conclude that face masks should be considered an appropriate non-pharmaceutical intervention in combination with other measures in the effort to control the COVID-19 pandemic.

For people vulnerable to severe COVID-19, the recommendation for the use of medical face masks for personal protection is based on the fact that most available evidence comes from studies on medical face masks and that they are standardised, as well as on the high impact of COVID-19 in these people.

The lack of definitively convincing evidence and of an accurate estimate of the effectiveness of face masks illustrates the challenges of the assessment of the effectiveness of public health measures at population level. RCTs are challenging to design and conduct in community settings while observational studies suffer from several forms of bias that are difficult to account for. Factors such as compliance and the large variability of transmission dynamics in different settings compound this assessment.

[1] *At workplaces with risk of transmission of COVID-19, workplace risk assessments in accordance with occupational safety and health legislation will need to be revised and the occupational health and safety measures adapted in agreement with occupational safety and health services and workers, taking into account all types of risk (also taking into account the additional physical load when wearing personal protective equipment). The prevention measures should be set in a certain order of priority: technical and organisational measures have priority over personal protective measures. Where there is a safety and health committee in place, it should be consulted. More information on occupational safety and health is available at the following links:*
Overview: https://osha.europa.eu/en/themes/covid-19-resources-workplace
COVID-19: guidance for the workplace: https://oshwiki.eu/wiki/COVID-19:_guidance_for_the_workplace
COVID-19: Back to the workplace - Adapting workplaces and protecting workers
https://osha.europa.eu/en/publications/covid-19-back-workplace-adapting-workplaces-and-protecting-workers/view

There is very limited evidence from interventional or observational studies on the use of non-medical face masks, respirators and face shields in the community. Most studies on face masks in the community have assessed medical face masks. Experimental studies indicate that several types of non-medical face masks have filtration characteristics comparable to that of medical face masks.

Regarding respirators, experimental studies have confirmed that they have a better filtration efficiency than that of medical and other types of face mask. However, the effectiveness of respirators depends on their appropriate fitting and use, and decreases if fitting is not optimal. Moreover, breathability and comfort are reduced and potential skin problems more frequent with respirators, e.g. FFP2 masks, especially if used for longer duration than recommended. Some respirators with an unprotected valve to facilitate exhalation do not prevent the release of exhaled respiratory particles from the wearer into the environment and therefore may not be appropriate for use as a means of source control in the case of respiratory infections. Finally, the cost of respirators is significantly higher than that of face masks. Altogether, the anticipated added value of the universal use of respirators in the community is currently considered very low. Taking into account the potential costs and harms, a recommendation for the use of respirators in place of other types of face masks in the community is not considered currently justifiable.

Based on experimental studies, options to maximise the fitting of medical face masks have been proposed, e.g. making knots close to the mask on each of the mask's ear-loops, applying a mask fitter or wearing a non-medical cloth mask over a medical face mask [102,154]. However, the results of such experimental studies cannot be directly extrapolated to real-life situations as these options have not been shown to decrease the transmission of respiratory viral infections, nor are the face masks and other products used in such experiments representative of what is used in real life. Considerations about breathability when increasing the number of filtering layers also apply.

We did not provide recommendations for use of face masks in children. Considerations for the use of face masks in children have been published by the World Health Organization [155].

Limitations

This assessment is undertaken based on facts known to ECDC at the time of publication. There are some limitations related to the methodological approach used for the literature review, e.g. search limitations, and quality and risk of bias assessment performed by one reviewer for each study among a team of 10 reviewers. The data extraction table and the risk of bias assessment were agreed and piloted within the review team. Other limitations relate to the identified evidence, such as: small number of studies addressing the primary review question; small number of randomised studies; and large heterogeneity. Although we included all studies on adverse effects identified through our search, we did not perform a systematic review of these studies nor did we include knowledge, attitude and perception (KAP) studies and surveys, so some information on adverse effects may have been missed. We did not apply a GRADE evidence-to-decision framework for the development of the recommendations.

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Annex

Table. Certainty assessment and summary of findings from interventional and observational studies included in the systematic review (GRADE) [1]

Certainty assessment								Summary of findings			
Number of studies	**Design**	**Setting**	**Risk of bias**	**Indirectness**	**Inconsistency**	**Imprecision**	**Other considerations**	**Number of persons intervention/ no of cases (for observational studies)**	**Number of persons comparison / no of controls (for observational studies)**	**Effect estimate**	**Certainty**
Question: Effectiveness of medical face masks for the prevention of COVID-19 in the community										Small Moderate	Moderate Low
One [2]	RCT, SARS-CoV-2	Community	Serious, intervention bias due to participants in intervention group not consistently wearing face masks	No	N/A	No	Low community transmission at the time of the study	3 030	2 994	OR: 0.82 (0.53-1.23) p 0.33	Moderate
One [3]	Case-control SARS-CoV-2	Community	Serious	No	N/A	No	No	211	839	OR: 0.16 (0.07-0.36) p < 0.001	Low
Four [4-7]	Cross-sectional SARS-CoV-2	Community	Very serious Two studies not providing adjusted estimates of the effect	Serious One study in US Navy ship, one study in school	No	No	No	174	1 082	One study with favourable non-statistically significant effect (OR 0.58) Three studies with very favourable statistically significant effect (OR 0.21-0.3)	Low

Certainty assessment								Summary of findings			
Number of studies	**Design**	**Setting**	**Risk of bias**	**Indirectness**	**Inconsistency**	**Imprecision**	**Other considerations**	**Number of persons intervention/ no of cases (for observational studies)**	**Number of persons comparison / no of controls (for observational studies)**	**Effect estimate**	**Certainty**
11 [8-18]	Ecological SARS-CoV-2	Community	Very serious	No	No. All studies except one (No 214) indicated effect of use of mask as the COVID-19 cases were reduced during the period of study.	No	No	Not possible to measure. Multiple countries and regions included	Not possible to measure. Multiple countries and regions included	Nine studies indicated reduction in the number of COVID-19 cases ranging from 6% to 82% or with p value ranging from p<0.000 to p<0.021 and one study showed a significant reduction in the number of deaths due to COVID-19 (p<0.001). One study did not find a significant decrease in the number of new daily COVID-19 cases in the month before vs. after introduction of mandatory use of face masks.	Very low
Eight [19-26]	Clustered RCT, other viruses	Community, Household	Serious	Yes influenza, household	Yes	Yes Multiple endpoints with conflicting results	No	2 237	3 745	One study with unfavourable statistically significant effect for one outcome but non-significant effect for second outcome Three studies with unfavourable non-statistically significant effect Four studies with favourable non-statistically significant effect (Two studies with statistically significant effect in subgroup analysis including only early mask use)	Low

Certainty assessment								Summary of findings			
Number of studies	**Design**	**Setting**	**Risk of bias**	**Indirectness**	**Inconsistency**	**Imprecision**	**Other considerations**	**Number of persons intervention/ no of cases (for observational studies)**	**Number of persons comparison / no of controls (for observational studies)**	**Effect estimate**	**Certainty**
Two [27,28]	Clustered RCT, other viruses	Community, Other settings (university residence halls, Hadj tents)	Serious	Yes influenza, special community settings	Yes	Yes	No	4 609	4 375	One study with favourable non-statistically significant effect (One study with statistically significant difference in subgroup analysis) One study with unfavourable non-statistically significant effect	Low
Two [29,30]	Case-control other viruses	Community	Serious	Serious	No	No	No	424	941	Two studies with very favourable statistically significant effect OR 0.3-0.36	Low
One [31]	Clustered RCT other viruses	Healthcare	Serious (relatively small studies and several type of biases present)	Very serious, (healthcare setting, other viruses)	Not applicable	Yes	Small study	17	15	One study with non-significant favourable effect The study did not demonstrate a benefit of mask use in healthcare workers in terms of cold symptoms or getting colds. In fact, subjects in mask group significantly more likely to experience headache.	Very low
Two [32,33]	Case-control SARS-CoV-2	Healthcare	Serious	Serious, healthcare setting	No	No	No	425	507	Two studies with very favourable statistically significant effect. One study with OR 0.35 $p < 0.001$	Low

Certainty assessment								Summary of findings			
Number of studies	**Design**	**Setting**	**Risk of bias**	**Indirectness**	**Inconsistency**	**Imprecision**	**Other considerations**	**Number of persons intervention/ no of cases (for observational studies)**	**Number of persons comparison / no of controls (for observational studies)**	**Effect estimate**	**Certainty**
										One study with aOR 0.13 p 0.04 for not staying in the same personnel break room with other colleagues without a mask for >15 min	
Five [34-38]	Cross-sectional SARS-CoV-2	Healthcare	Serious, several types of bias	Serious, healthcare setting	No/Serious: Multiple studies found a descriptive effect of mask use on seroprevalence, but another study also had higher infections among those using masks compared to those using face masks	Serious, no extensive analysis for multiple studies, more descriptive, rather small studies	Not necessarily applicable to community settings. Some studies compared to "incorrect mask use" and not "no mask use" due to requirements for HCW	>46	>96	Four studies with favourable results; mask use/consistent mask use group had lower proportion/rate of infection/seropositivity, patients more frequently did not wear a mask One study with unfavourable effect (higher % of healthcare workers wearing a face mask got infected compared to no mask use - no infection in FFP2 group) - no effect measure	Low
One [39]	Cross-sectional other viruses	Community	Serious	Serious	No	Serious	No	9	147	One study with favourable not statistically significant effect OR 0 (0.00-20.93) p 1	Very low

Certainty assessment								Summary of findings			
Number of studies	**Design**	**Setting**	**Risk of bias**	**Indirectness**	**Inconsistency**	**Imprecision**	**Other considerations**	**Number of persons intervention/ no of cases (for observational studies)**	**Number of persons comparison / no of controls (for observational studies)**	**Effect estimate**	**Certainty**
Four [40-43]	Case-control other viruses	Healthcare	Serious	Very serious healthcare setting, different virus	No	No	No	394	260	Four studies with very favourable statistically significant effect (aOR: 0.08-0.29) One study with favourable but non-statistically significant effect (very few participants without face mask)	Low
Two [44,45]	Cross-sectional other viruses	Healthcare	Serious	Very serious, healthcare setting, other viruses, only involvement in aerosol generating procedures in one study	Yes	No	No	1 598	101	One study with very favourable direction of effect and significant difference when comparing always wearing any mask vs not wearing any mask and non-significant difference when comparing always wearing a surgical mask vs not wearing any mask One study with favourable not significant direction of effect for wearing either a medical face masks or a N95 respirator and for wearing a N95 respirator and unfavourable not significant effect for wearing a medical face mask	Very low
Question: Effectiveness of face masks as source control (protection of others)										Small	Low

Certainty assessment								Summary of findings			
Number of studies	**Design**	**Setting**	**Risk of bias**	**Indirectness**	**Inconsistency**	**Imprecision**	**Other considerations**	**Number of persons intervention/ no of cases (for observational studies)**	**Number of persons comparison / no of controls (for observational studies)**	**Effect estimate**	**Certainty**
One [6]	Cross-sectional SARS-CoV-2	Community	Serious	No	N/A	No	No	24	197	One study with favourable direction of effect and statistically significant result	Very low
One [46]	Before-after, other viruses	Healthcare	Serious	Yes	N/A	No	No	911	920	One study with favourable direction of effect and statistically significant result	Low
One [21]	Clustered RCT , other viruses	Household	Serious	Yes	N/A	Yes	Small number of outcomes Intervention bias due to patients in control group also wearing face masks	123	122	The study did not find a significant benefit of medical masks as source control, but rates of clinical respiratory infection and influenza-like illness in household members were consistently lower in the mask arm compared with the control arm.	Low
Question: Effectiveness of non-medical face masks for the prevention of COVID-19 in the community											
One [47]	Clustered RCT	Healthcare	Serious	Yes	N/A	Yes	No	569	580	One study with unfavourable direction of effect for cloth masks and statistically significant result for clinical respiratory disease and influenza-like illness	Very low
Question: Effectiveness of respirators for the prevention of COVID-19 in the community											

Certainty assessment								Summary of findings			
Number of studies	**Design**	**Setting**	**Risk of bias**	**Indirectness**	**Inconsistency**	**Imprecision**	**Other considerations**	**Number of persons intervention/ no of cases (for observational studies)**	**Number of persons comparison / no of controls (for observational studies)**	**Effect estimate**	**Certainty**
One [20]	Clustered RCT	Household	No	Yes	N/A	Yes	No	538	296	One study found small non-statistically significant favourable effect of respirators compared to no mask and a small non-statistically significant unfavourable effect of medical face masks compared to no mask	Low
Four [48-51]	RCT other viruses	Healthcare	Serious	Yes	Yes	Yes	No	4 260	3 347	Two studies found small non-statistically significant differences in laboratory confirmed influenza both favourable and unfavourable for respirators Two studies with statistically significant favourable difference in clinical respiratory infection, but not statistically significant difference in influenza-like illness and laboratory-confirmed influenza infection.	Low
One [43]	Case-control other viruses	Healthcare	Serious	Yes	Yes	No	No	13	241	One study with no difference between respirators and medical mask (zero infections in both groups)	Low

N/A: not applicable

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