

Annex to

Infection prevention and control during health care when coronavirus disease (COVID-19) is suspected or confirmed

Interim guidance

1 October 2021



This document is an update of guidance published on 12 July 2021, after the review of new scientific evidence on transmission of SARS-CoV-2 variants of concern (VOC). The evidence was reviewed, and guidance issued using the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) process. It contains updated recommendations on the use of masks and respirators for health workers providing care to suspected or confirmed COVID-19.

Key Points

The World Health Organization (WHO) advises the following for health workers providing care to suspected or confirmed COVID-19, which was agreed upon using the GRADE process:

Recommendations:

- A medical mask should be worn along with other PPE as part of contact and droplet precautions before entering a room where there is a patient with suspected or confirmed COVID-19.
- For HWs performing aerosol-generating procedures (AGPs)¹ or in settings where AGPs are regularly performed among patients with suspected or confirmed COVID-19*, a particulate respirator should be worn.

Conditional recommendation, very low certainty evidence

- Based on health workers values and preferences about having the highest perceived protection possible to prevent SARS-CoV-2 infection and where widely available, respirators can also be used instead of medical masks in all settings when providing care to COVID-19 patients in other settings (even settings where AGPs are not performed).

Note

Good Practice Statement:

- Appropriate mask fitting should always be ensured (for respirators; through initial fit testing and seal check, and for medical masks; through methods to reduce air leakage around the mask) as well as compliance with appropriate use of PPE and other precautions.

* e.g., intensive care units, semi-intensive care units, emergency departments

¹ The current WHO list of these AGPs is tracheal intubation, non-invasive ventilation (e.g. BiLevel positive airway pressure, continuous positive airway pressure), tracheotomy, cardiopulmonary resuscitation, manual ventilation before intubation, bronchoscopy, sputum induction by using nebulized hypertonic saline, dentistry and autopsy procedures. In addition in oral health care the following are considered AGPs; all clinical procedures that use spray generating equipment such as three-way air/water spray, dental cleaning with ultrasonic scaler and polishing; periodontal treatment with ultrasonic scaler; any kind of dental preparation with high or low-speed hand-pieces; direct and indirect restoration and polishing; definitive cementation of crown or bridge; mechanical endodontic treatment; surgical tooth extraction and implant placement. It remains unclear whether aerosols generated by nebulizer therapy or high-flow oxygen delivery are infectious or whether other procedures (e.g. nasogastric tube insertion, suctioning for airway clearance, or swabbing procedures) involve the risk of aerosol generation, due to lack of evidence or low-quality evidence.

Purpose of this annex

This document provides guidance to decision makers and health professionals on masks and respirators that health workers should wear when providing care to individuals with suspected or confirmed COVID-19, in the context of the spread of variants of concern (VOC) that have demonstrated increased transmissibility (in particular, the Delta VOC). It does not address the use of masks by the public, including children. It will be revised and updated as new evidence becomes available, including emerging variants.

Background

The World Health Organization (WHO) continuously reviews available data on SARS-CoV-2 VOC to evaluate what, if any, adaptations and/or updates may be required with respect to Infection Prevention & Control (IPC) and Public Health and Social Measures (PHSM). The [Infection prevention and control during health care when COVID-19 is suspected or confirmed: interim guidance](#), published on 12 July 2021, took into account information known about circulating SARS-CoV-2 VOC at that time. Since publication, reports from around the world have however confirmed increased transmissibility of the Delta variant, which is rapidly spreading and causing new waves COVID-19, including some health care-associated outbreaks (1).

Earlier randomized controlled trials that compared respirators and medical masks for prevention of clinical influenza-like illness found no clear difference (2), although some observational studies found respirators associated with decreased risk of SARS-CoV-1 infection (3). Data on increased filtration efficacy of respirators and issues regarding the need for and availability of fit testing when using respirators have been described(4, 5).

In this context, the WHO Ad-hoc COVID-19 IPC Guidance Development Group (GDG) met three times during August and September 2021 to review the most recent evidence and WHO recommendations on the use of medical masks versus particulate respirators (N95 or FFP2 or FFP3 standard or equivalent) for the prevention of SARS-CoV-2 infection during the care of patients with suspected or confirmed COVID-19.

Methodology used by the WHO Ad-hoc COVID-19 IPC GDG for the discussion of the recommendation

The GDG members were asked to decide whether the current WHO guidance should be maintained (see Box 1 below), or whether a new recommendation should be made to give preference to respirators for use by all health workers providing care to suspected or confirmed COVID-19 patients, regardless of the setting and whether aerosol-generating procedures (AGPs) were performed.

Box 1. July 2021, WHO recommendation on the use of masks for health workers providing care to suspected or confirmed COVID-19

July 2021, WHO recommendation on the use of masks for health workers providing care to suspected or confirmed COVID-19

- **Use medical mask^{1,2}** along with other PPE as part of contact and droplet precautions before entering a room where there is a patient with suspected or confirmed COVID-19
- For health workers performing aerosol-generating procedures (AGPs) or in settings where AGPs are regularly performed among patients with suspected or confirmed COVID-19 (e.g. intensive care units, semi-intensive care units, emergency departments), **wear a particulate respirator²**

¹According to health workers' preferences about having the highest perceived protection possible to prevent SARS-CoV-2 infection, respirators could also be used by health workers instead of medical masks, when providing care to COVID-19 patients in other settings (even if aerosol-generating procedures are not performed) if they are widely available.

²High emphasis put on the importance of fitting (and initial fit testing and seal check for respirators) and compliance

The recommendations referenced above have been extracted from sections 3.3 (contact and droplet precautions) and 3.4 (airborne precautions) from "Infection prevention and control during health care when coronavirus disease (COVID-19) is suspected or confirmed Interim guidance 12 July 2021"

Data on a range of relevant aspects to inform the GDG discussion were presented (see below), in particular evidence on benefits and harms of medical masks versus respirators, the certainty of which was assessed using Grading of Recommendations, Assessment, Development and Evaluations (GRADE) methodology.

As consensus was not achieved during the first meeting, GDG members voted electronically and provide comments, including on the rationale behind their decisions. Consistent with previous methodology on guideline development, it was decided a priori that a vote of 70% or more constituted a majority position. The strength of the recommendation was decided in the second meeting. The third meeting was held to further refine the recommendation on fit.

Summary of the Evidence and Data Considered

The GDG was asked to review the latest evidence on benefits and harms of medical masks versus respirators among health workers and its level of certainty in order to discuss the current recommendation. A rapid, living review approach was conducted utilizing streamlined systematic review processes, the methodology has been described previously⁽⁶⁾ and reviews using this methodology have been updated regularly⁽⁷⁾.

As part of the background information provided to the GDG, data on the epidemiological situation and transmissibility of the delta variant were also presented, demonstrating higher transmissibility both for very close (household) and casual contacts, and higher viral loads, a decreased latent period and shorter serial interval^(1, 8-12). Similarly, unpublished data on health care-associated outbreaks

associated with the Delta variant reported to WHO and estimates of global forecasted needs for respirators and medical masks calculated by WHO were also presented to the GDG.

Update of the evidence on benefits and harms of medical masks versus respirators among health workers

Evidence comparing the effectiveness of respirators versus medical masks in health-care settings is limited to five observational studies (13-17) that had methodological limitations and reported inconsistent findings about whether respirators decreased the risk of SARS-CoV-2 infection. In addition, these studies were conducted prior to the emergence of the Delta and other variants of concerns and widespread implementation of vaccination in healthcare settings.

Five observational studies with methodological limitations reported inconsistent findings regarding the risk of SARS-CoV-2 infection comparing respirators and medical masks. One study showed reduction of risk with respirator use (15), while in another two studies the use of respirators was non-significantly associated with risk reduction (16, 17). One study showed no association (17), and another found respirators were associated with large increase risk (OR 7.1), likely related to confounding(14). Prior randomized controlled trials comparing respirators versus medical masks for prevention of clinical influenza-like illness found no difference(2, 18).

The following side effects have been reported with respirators: discomfort, headaches, possible development of facial skin lesions, irritant dermatitis, or worsening acne, when used frequently for long hours(19). Masks are typically associated with less discomfort or side effects given decreased thickness and reduced seal, although this has not been quantified.

Decision and remarks by the WHO Ad-hoc COVID-19 IPC GDG

GDG decision, recommendation, and its strength

Based on the above-mentioned evidence and using the GRADE process and evidence to decision making framework, the IPC GDG agreed that WHO should maintain its current recommendation but more clearly highlight the importance of mask fit and health worker values and preferences, with the following remarks.

Box 2. Updated WHO recommendation on the use of masks and respirators for health workers providing care to suspected or confirmed COVID-19

September 2021, updated WHO recommendation on the use of masks and respirators for health workers providing care to suspected or confirmed COVID-19

Recommendations:

- A medical mask should be worn along with other PPE as part of contact and droplet precautions before entering a room where there is a patient with suspected or confirmed COVID-19.
- For HWs performing aerosol-generating procedures (AGPs) or in settings where AGPs are regularly performed among patients with suspected or confirmed COVID-19*, a particulate respirator should be worn.

Conditional recommendation, very low certainty evidence

- Based on health workers values and preferences about having the highest perceived protection possible to prevent SARS-CoV-2 infection, and where widely available, particulate respirators can be used instead of medical masks in all settings when providing care to COVID-19 patients (even settings where AGPs are not performed).
(*Note*)

Good Practice Statement:

- Appropriate mask fitting should always be ensured (for respirators, through initial fit testing and seal check, and for medical masks; through methods to reduce air leakage around the mask) as well as compliance with appropriate use of PPE and other precautions.

* e.g., intensive care units, semi-intensive care units, emergency departments

Rationale for the recommendation on masks versus respirators

Given the methodological limitations of the evidence, notably inconsistency, and indirectness [studies conducted before the emergence of the Delta variant, evaluation of non-SARS-CoV-1 infection or assessment of non-clinical outcomes(20)], the certainty of evidence for particulate respirators versus medical masks was rated as very low. Given the significant data limitations described, the deliberations of the GDG and decision-making process were also informed by the perspectives and experience of experts represented in the panel.

The decision was based on the results of online voting, with 23 GDG members (70%) voting to maintain the current WHO recommendation and 10 members (30%) advising the following change: “Respirators (N95 or FFP2 or FFP3 standard, or equivalent) should be used by all health workers providing care to suspected or confirmed COVID-19 patients, regardless of the setting and whether AGPs performed or not”.

GDG members stated that the “Balance of Benefits and harm” and the “Certainty of evidence” were the two most important factors influencing their decision. The minority who were in favour of changing the recommendation also placed a high importance on equity. GDG members who advised maintaining the current recommendation considered factors related to resource implications, feasibility, acceptability and equity, also important.

The GDG unanimously agreed that the strength of this recommendation should be *conditional* however the specific wording and presentation of the recommendation was refined based on GDG discussions. This was based on the following factors (see GDG remarks):

- The benefits of using respirators instead of medical masks for providing care for patients with suspected or confirmed COVID-19 in the absence of AGPs) are limited, and the certainty of the evidence is very low. The balance of desirable and undesirable effects was rated as uncertain. It was deemed uncertain if respirators are more effective than medical masks in settings without exposure to AGPs.
- Some health workers may place strong values on and preferences for having the highest perceived protection possible and thus prefer using respirators in all COVID-19 settings. Feasibility, acceptability and equity considerations may vary.

GDG remarks

The following remarks were made by the IPC GDG members through the survey and were also used in the evidence to decision process.

Balance of desirable and undesirable outcomes

The balance of desirable and undesirable outcomes effects was rated as uncertain. It was deemed uncertain whether respirators are more effective than medical masks in settings without exposure to AGPs.

Respirators have higher standards of filtration efficiency and demonstrate better fit with less air gaps allowing bypass of the filter media than the most commonly used rectangular medical masks. Thus, some GDG members advised that respirators may be superior compared to medical masks based on fit allowing a higher level of effective filtration efficiency, and that they should be encouraged in particular when ventilation is inadequate. However, other GDG members noted that the fitting process for respirators is burdensome, and issues with achieving it have been well

described; moreover, it was noted that there are other factors that may influence the overall risk of transmission including general PPE use, ventilation, PPE training, fit testing, and behavioral factors (including compliance). Undesirable outcomes with prolonged use of respirators were noted, including general discomfort, headaches, and development of facial skin lesions, irritant dermatitis, or worsening acne(19).

Some GDG members saw relevance in the evidence showing that the Delta variant appears to be more transmissible and has higher viral loads. However, although some outbreaks have been reported in healthcare settings using standard PPE, these do not appear to be more frequent than previously reported. Several hospital clusters seem to be mostly linked to non-compliance with IPC measures and appropriate use of PPE, in both COVID-19 and non-COVID-19 wards. Some GDG members noted that increased vaccination rates among healthcare workers since the emergence of the Delta variant, may have resulted in less frequent healthcare-associated Delta variant outbreaks.

Values and preferences

Discussions with the IPC GDG indicated that there was variability in preferences related to the potential benefits of respirators in preventing healthcare-associated infections. In the context of the increased transmissibility of the Delta variant, some GDG members placed high value on wider use of respirators to potentially reduce health worker risk, despite the limited evidence, taking a precautionary approach. Other GDG members noted that health workers may not necessarily prefer wearing a respirator throughout their shift due to discomfort and potential side effects. Members expressed consensus that local values, preferences, and practicalities should play an important role in directing local choices on the use of respirators versus medical masks. Some GDG members suggested that in resource-limited settings where respirators might be less widely available, prioritization for certain high-risk health-care workers (for example, those in frequent close contact with COVID-19 patients,) could be considered, in addition to always making them available for AGPs.

Resource implications

Many GDG members indicated that availability of respirators would be an obstacle in low-income countries and use of respirators for the care of all patients with suspected or confirmed COVID-19 in health-care facilities would require additional investment of financial and logistical resources. In addition, this would also entail the need for fit testing for all staff, which would require resource investments and expertise. Indeed, some GDG members considered the cost of respirators and their fit testing to be prohibitive if there is a recommendation of replacing medical masks with respirators for management of all COVID-19 cases. Other GDG members noted that scaling up the market for respirators could lead to cost reduction.

Feasibility

Data and modeling demonstrated an inadequate supply of respirators to fully replace medical masks in all healthcare settings. However, some GDG members noted that policies advising use of respirators in all COVID-19 settings would likely lead to increased investments and production and thus, access. Other GDG members noted that in addition to cost, a recommendation for the universal use of respirators in all health care settings would likely prompt a demand for their universal use in the community. This would entail major challenges to fit test respirators and train people to use them appropriately. Feasibility is already challenged by suboptimal adherence to existing masks guidance. Furthermore, inefficiencies in distribution of supplies have also been reported in some countries. Consequently, feasibility is also linked to the existence of strong supply distribution and logistics systems to ensure efficient procurement and reach across the whole health system. Feasibility of wearing respirators may also be an issue in warm climates.

Finally, feasibility of using respiratory protection appropriately is influenced by adequate fit of the device. When filtering facepiece respirators (FFR) are used, fit may be improved by selecting models with elastic or adjustable ties or straps worn tightly behind the head instead of ear loop designs, since this allows for a tighter and more consistent fit and for the face seal to be maintained(21). Qualitative or quantitative fit testing should be performed annually at the employer's expense to ensure that the respirator model fits to each individual health worker's unique facial features and will allow for a consistent seal. However, limited selection of available filtering facepiece respirators and the high cost of implementing a fit testing programme may make fit testing less feasible and equitable. A self-seal check should be performed by a user after donning and adjusting an FFR to determine if there are gaps allowing unfiltered air passage on inhalation and exhalation. Fit of medical masks may be improved by selecting models with tie straps worn tightly behind the head rather than ear loops, as tying a mask behind the head allows for a tighter and more consistent fit to the wearers face. Medical masks that use an adjustable wire at the bridge of the nose to minimize air gaps will also improve the fit. A reusable mask brace (also known as a fitter) worn on top of the outer frame of a mask to enhance fit may minimize gaps in the perimeter frame of medical masks during extended use.

As a follow up to GDG remarks on the importance of fit, a focused meeting was held followed by a survey to address this important issue. 73% of GDG members voted that medical mask fit should be explicitly advised through a good practice statement. 83% of members voted that the WHO should develop practical advice on how to improve the fit of medical masks for use in health care settings.

Acceptability

Acceptability for stakeholders and policymakers about maintaining the current guidance may vary depending on the severity of Delta outbreaks, the availability of respirators and other factors. Some GDG members noted that acceptability of universal masking is challenging.

Equity

Given that the global supply of respirators is limited, and respirators are more costly than medical masks, a recommendation to use respirators for all COVID-19 cases in healthcare settings could result in inequity in resource-limited settings. However, it is also possible that the widespread use of respirators (if available) might reduce inequities related to COVID-19 exposure risk. In addition, an equity issue also exists for medical masks which may also not be available in sufficient quantities and of adequate quality in low-resource settings. Unvaccinated health-care workers worldwide are still at high risk for infection, including infection resulting in severe disease and death.

Gaps, research needs and comments

Randomized control trials on respirators versus medical masks in healthcare settings are in progress, although with significant challenges. Most recruitment occurred before the emergence of the Delta variant. Well-conducted observational studies on respirators versus medical masks and the risk of SARS-CoV-2 infection in healthcare settings in the context of the Delta variant are urgently needed. More research is needed to investigate risks associated with medical masks and respirators and adverse events (including self-contamination), including during extended and repeated use.

Further research is also needed on simpler, faster, and less costly methods or alternative methods to determine respirator fit and seal. Further data are needed on compliance with appropriate PPE use, in particular appropriate donning and doffing practices in COVID-19 units and non-COVID-19 units.

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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 2 years after the date of publication.

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