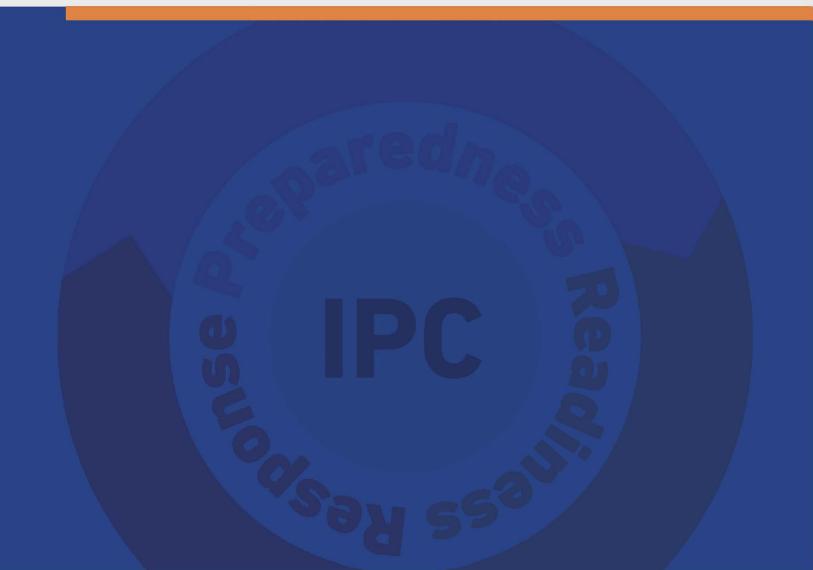
Infection prevention and control in the context of coronavirus disease (COVID-19): A living guideline

Updated Chapter: Mask use, Part 1: Health care settings

25 April 2022





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Infection prevention and control in the context of coronavirus disease (COVID-19): A living guideline - World Health Organization (WHO)

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Executive Summary

Updated

Version 3.0 Infection prevention and control in the context of coronavirus disease 2019 (COVID-19): a living guideline *Updated chapter: mask use. Part 1: health care settings*

About this guideline

The Infection prevention and control in the context of coronavirus disease 2019 (COVID-19): a living guideline consolidates infection prevention and control (IPC) technical guidance developed and published since the beginning of the COVID-19 pandemic. This document provides users with the latest evidence-informed recommendations for IPC in health care and community settings. It has two parts. Part 1 presents IPC recommendations in the context of health care settings, while Part 2 presents these recommendations in community settings. The methodology section discusses the methodological approach used to develop the guideline and a glossary is provided to support readers on specific definitions. An annex is included at the end of the document with evidence tables for mask use in the health care setting and mask use by children. The living guideline is written, disseminated, and updated on an online platform (MAGICapp). It has a user-friendly format and easy-to-navigate structure that accommodates dynamically updated evidence and recommendations, with a focus on what is new while keeping existing recommendations updated within the guideline.

This living guideline considers the current and evolving epidemiological situation for COVID-19 and the emergence of variants of concern, including Omicron and other factors such as population immunity, availability and uptake of vaccines, and other contextual factors of the COVID-19 pandemic.

The target audiences of these guidelines are policy- and decision-makers, public health professionals, IPC professionals at the national and facility levels, health care facility administrators, managers and other health workers.

Context

Each country is facing a different situation with the COVID-19 pandemic depending on a number of factors, including the intensity of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) circulation, the population-level immunity, capacity to respond and agility to adjust measures. As the pandemic continues and the virus evolves, changes in transmission intensity, the circulating variant of concern, and the capacity of health systems to respond to the situation will require policy adjustments related to IPC and public health and social measures. National policies should be informed by evidence and agile and should be adjusted as needed in view of these and other factors. Further information on Omicron can be found in the technical document *Enhancing response to Omicron SARS CoV-2 variant:* technical brief and priority actions for Member States, issued by the World Health Organization (WHO) on 21 January 2022 [1].

New recommendations

In this version of the guideline, the following recommendations are included: 1) a <u>strong recommendation</u> for universal masking in health facilities in areas of known or suspected community or cluster SARS-CoV-2 transmission; 2) a <u>conditional recommendation</u> to encourage health facilities to implement targeted continuous masking in areas of known or suspected sporadic SARS-CoV-2 transmission; 3) a <u>conditional recommendation</u> on the use of respirators or medical masks in settings when caring for patients with COVID-19; 4) upgrading of the strength of the existing conditional recommendation on respirator use for aerosol-generating procedures (AGP) to a <u>strong recommendation</u>. A good practice statement on mask fit is also included.

Understanding the new recommendations

When moving from evidence to recommendations, the Guideline Development Group (GDG) considered a combination of evidence assessing relative benefits and harms, values and preferences, resource implications, and availability and feasibility issues.

Updates to prior recommendations

Version 1.0 of the COVID-19 infection prevention and control living guideline: mask use in community settings was published in December 2021 [2], which provided new guidance on mask use in community settings. These updated guidelines published supersede existing advice in Mask use in the context of COVID-19, published in December 2020 [3].

Version 2.0 of the COVID-19 living guideline was jointly developed by WHO and the United Nations Children's Fund (UNICEF) and published on 7 March 2022 [4]. This version contained updated guidance on mask use in children. Advice on the use of masks for children in the context of COVID-19 was first published in August 2020 as an annex to the document *Mask use in the context of COVID-19* [3][5]. The guidance found in version 2.0 of the living guideline supersedes any previous advice on the use of masks for children in the context of COVID-19.

Guideline development

The GDGs included experts in IPC, epidemiology, infectious diseases, paediatrics, water, sanitation and hygiene, engineering, aerobiology, and health care providers. The groups were balanced according to geographical and gender representation. Different GDGs were convened to address specific settings or populations (see authorship, contributors, and acknowledgements section). A

methodologist with expertise in guideline development assisted the GDG in formulating the recommendations.

This guideline was developed in line with standards and methods for the development of trustworthy guidelines. While the GDG takes an individual patient perspective in making recommendations, it also considers resource implications, acceptability, feasibility, equity and human rights. Please see the methodology section for additional details on the GDG. The guideline was developed using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) processes and Evidence to Decision framework. The WHO Quality Assurance of Norms and Standards department helped identify published rapid systematic reviews for the review process. Where required, WHO staff or commissioned external experts conducted systematic reviews to address specific questions. Due to the rapidly evolving nature of the pandemic, preprints were included in the evidence synthesis. Additional details are described in the methodology section.

Updates and access

This guideline and its previous versions are available through the WHO website and MAGICapp (online and PDF outputs for readers with limited internet access).

Definitions

Adequately ventilated patient room or area	in health facilities where a mechanical ventilation system is available, the ventilation rate should be 6-12 air changes per hour (e.g., equivalent to 40-80 L/s/patient for a 4x2x3 m3 room), and ideally 12 air changes per hour for new constructions, with a recommended negative pressure differential of \geq 2.5Pa (0.01-inch water gauge) to ensure that air flows from the corridor into patient rooms" [6].
Aerosol generating procedures (AGP)	identified by the WHO as the following: 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 nebulised hypertonic saline, dentistry and autopsy procedures. In oral health care, the following are considered AGPSs: 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 nebuliser 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.
	is the spread of an infectious agent caused by the dissemination of droplet <i>nuclei</i> that remain infectious when suspended in air over long distances and time. Airborne transmission can be further categorized into obligate or preferential airborne transmission.
Airborne transmission*	 Obligate airborne transmission refers to pathogens that are transmitted only by deposition of droplet <i>nuclei</i> under natural conditions (e.g. pulmonary tuberculosis). Preferential airborne transmission refers to pathogens that can initiate infection by multiple routes, but are predominantly transmitted by droplet <i>nuclei</i> (e.g. measles and chickenpox). Opportunistic airborne transmission refers to agents that naturally cause disease through other routes, but under special circumstances may be transmitted via fine particle aerosols [7].
A child	is defined as any person under the age of 18 years [8].
Contact transmission	 is the spread of an infectious agent caused by physical contact of a susceptible host with people or objects. Direct contact transmission involves both a direct body-surface-to-body-surface contact and physical transfer of microorganisms between an infected or colonized person and a susceptible host. Indirect contact transmission involves contact of a susceptible host with a contaminated intermediate object

	(e.g. contaminated hands) that carries and transfers the microorganisms [7].
Droplet transmission	is the spread of an infectious agent caused by the dissemination of droplets. Droplets are primarily generated from an infected (source) person during coughing, sneezing and talking. Transmission occurs when these droplets that contain microorganisms are propelled (usually < 1 m) through the air and deposited on the conjunctivae, mouth, nasal, throat or pharynx mucosa of another person. Most of the volume (> 99%) comprises large droplets that travel short distances (< 1 m) and do not remain suspended in the air. Thus, special air handling and ventilation are not required to prevent droplet transmission [7].
Hand hygiene	is a general term that applies to handwashing, antiseptic handwashing, antiseptic hand rubbing or surgical hand antisepsis [7].
Health care facility	includes primary, secondary, tertiary care levels, outpatient care, and long-term care facilities.
Health workers	are all people primarily engaged in actions with the primary intent of enhancing health. This includes health service providers, such as doctors, nursing and midwifery professionals, public health professionals, technicians (laboratory, health, medical, and non-medical), personal care workers, healers, and practitioners of traditional medicine. It also includes health management and support workers, such as cleaners, drivers, hospital administrators, district health managers, social workers and other occupational groups in health-related activities. This group includes those who work in acute care facilities and long-term care, public health, community-based care and other occupations in the health and social care sectors [9].
Filtering facepiece respirators (FFR or respirators)	offer a balance of filtration, breathability and fit. Whereas medical masks filter 3-micrometre droplets, "N95" and "FFP2" rated FFRs must filter a more challenging 0.075-micrometre particles or particulates and do so across the entire surface of the respirator as a result of the fitted design. European "FFP2" FFRs, according to EN 149 standard, filter at least 94% Sodium Chloride (NaCl) salt particles and paraffin oil droplets. The United States of America "N95" FFRs, according to National Institute for Occupational Safety and Health (NIOSH) NIOSH 42 CFR Part 84, filter at least 95% NaCl salt particles. Certified FFRs must ensure unhindered breathing by meeting inhalation and exhalation breathing resistances below the maximum thresholds. Another important difference between FFRs and other masks is how filtration is tested. Medical mask filtration is assessed by testing filtration over a cross-section of the masks. In contrast, FFRs are tested for filtration across the entire surface. Most importantly, "FFP2" FFRs are fit-tested on a sample of human participants and the FFRs are measured for leaks as part of product certification. Similarly, for "N95" FFRs, individual workers are fit tested for specific FFRs at the workplace and typically on an annual basis. Therefore, in both cases, by ensuring the outer edges of the FFR seal around the wearer's face, the FFRs filtration is closer to the actual filtration of inhaled air. Other FFR performance requirements include being within specified parameters for maximum CO2 build-up [10].
Medical masks	are defined as surgical or procedure masks that are flat or pleated and are affixed to the head with straps around the ears, the head or both. Their <u>performance standards</u> are tested according to a set of standardised test methods (American Society for Testing Materials (ASTM) ASTM F2100, EN 14683, or equivalent) that aim to balance high filtration, adequate breathability and, optionally, fluid penetration resistance [10].
Non-medical masks	are a type of facial covering of the mouth and nose of the wearer used to mitigate the spread of respiratory infections which does not meet the performance standards of 'medical' or 'surgical' masks. Their primary purpose is for source control and to provide a degree of particulate filtration to reduce the amount of inhaled particulate matter. Essential parameters for the performance and safety of non-medical masks have been advocated during the COVID-19 Public Health Emergency of International Concern (PHEIC) through several existing international guidelines and one international standard for non-medical masks (ASTM F3502-21) [10][11][12][13][14]. Non-medical masks which are self-made or commercially produced and do not meet guideline supported essential parameters are permitted in areas which have not mandated minimum performance requirements for non-medical masks prior to sale and for use by the general public.
Standard precautions	are routine IPC precautions that should apply to all patients, in all settings. They are intended to minimize the spread of infection associated with health care and to avoid direct contact with patients blood, body fluids, secretions and, non-intact skin. These precautions include hand hygiene, use of PPE based on risk assessment, respiratory hygiene, environmental cleaning and disinfection, waste management, reprocessing of medical devices,

	linen and laundry, management, prevention of needle-stick or sharps injuries[15].
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 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.
Transmission based precautions	are used in addition to standard precautions for patients who may be infected or colonized with certain infectious agents. These precautions include contact, droplet, and airborne precautions and should be implemented to prevent infection transmission [15].

*Definition from the WHO Guidelines on "Infection prevention and control of epidemic-and pandemic-prone acute respiratory infections in health care" (2014) [7]. WHO will be hosting a global consultation in May 2022 to further review this definition. For the latest information on how COVID-19 is transmitted, please see "Coronavirus disease (COVID-19): How is it transmitted?".

Abbreviations

AGP	Aerosol generating procedure
ASTM	American Society for Testing Materials
aOR	Adjusted odds ratio
COVID-19	Coronavirus disease 2019
СІ	Confidence interval
СТ	Community transmission
DOI	Declaration of interest
EtD	Evidence to decision
FFP	Filtering facepiece respirator
GDG	Guideline Development Group
GPS	Good practice statement
GRADE	Grading of Recommendations, Assessment, Development and Evaluation
HAI	Healthcare associated infection
ILI	Influenza-like illness
IPA	International Paediatric Association
IPC	Infection prevention and control
NIOSH	National Institute for Occupational Safety and Health
MAGIC	Magic Evidence Ecosystem Foundation
OR	Odds ratio
PICO	Population, intervention, comparator, outcome
PHEIC	Public Health Emergency of International Concern
PHSM	Public health and social measures

PPE	Personal protective equipment
RCT	Randomized control trial
SARS-CoV-1	Severe acute respiratory syndrome coronavirus
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
UNICEF	United Nations Children's Fund
US CDC	United States Centers for Disease Control and Prevention
WHO	World Health Organization
VE	Vaccine effectiveness
VOC	Variant of concern

Methodology

Guideline Development Groups (GDG) and External Review Groups

The GDGs are convened to review the available evidence and determine the recommendations and good practice statements (GPS) found in this document. GDGs consist of individuals with broad expertise spanning multiple specialities, across all WHO regions and are genderbalanced. A consensus is sought for recommendations and good practice statements. When consensus is not achieved, approval of a recommendation or GPS requires a majority (> 70%) of the GDG voting members. The technical officer who leads the development of the guidelines collects the required declaration of interests (DOI) from GDG members and assesses them for any potential conflicts. If a conflict of interest is identified, appropriate actions are taken in accordance with the <u>WHO Handbook for guideline development</u> and <u>WHO Guidelines</u> <u>for DOI (for WHO Experts)</u> [16][17]. This includes removal from the GDG or recusal from voting or discussion for a particular recommendation or a decision to take no action. External review group members are also identified for specific technical areas and engaged for additional review of the guidelines. External review groups do not change the recommendations made by the GDG; however major concerns are brought back to the GDG for additional discussion. For more information on authorship, contributions, and DOI, please refer to this section.

Evidence synthesis and assessment

Given the dynamic situation of the COVID-19 pandemic, this living guideline integrates existing guidance that was developed using streamlined processes. As noted in the Executive Summary, with support from the WHO Quality Assurance of Norms and Standards department, rapid systematic reviews of published literature are identified for review. Due to the time lag for peer-reviewed publication of relevant studies in the context of a dynamic pandemic, preprints are included in the evidence synthesis. In addition, for some topics, systematic reviews are commissioned to external groups (clinical effectiveness of mask use in health care and community settings) or conducted by WHO staff (ecological studies on the effectiveness of masks). These reviews have been published and detail a search strategy within the publication and are regularly updated to identify any emerging evidence that may inform deliberations by the GDG [18][19][20][21][22].

Evidence from randomized control trials (RCT) has been limited. Therefore, the reviews also include non-randomized studies. The review on clinical effectiveness focused on cohort and case-control studies. The review of ecological studies also included before-after studies. The systematic reviews are presented in GDG meetings are supplemented by other (non-systematically reviewed) data presented by WHO staff, Member States, or partner organizations. Such presentations inform considerations regarding contextual factors on mask recommendations, mask filtration properties and technical specifications on ventilation, including values/preferences, acceptability and feasibility, in the context of the changing epidemiology of COVID-19.

The literature for each identified topic is assessed using Grading of Recommendations, Assessment, Development and Evaluation (GRADE) to determine the certainty of the evidence (Table 1), based on the presence of risk of bias/study limitations, inconsistency, imprecision, indirectness and publication/reporting biases.

Table 1. Determining the Quality of Evidence in Grading of Recommendations, Assessment, Development and EvaluationGRADE

Quality level	Definition

High	The Group is very confident in the estimate of effect and considers that further research is very unlikely to change this confidence.	
Moderate	The Group has moderate confidence in the estimate of effect and considers that further research is likely to have an important impact on that confidence and may change the estimate.	
Low	The Group has low confidence in the estimate of effect and considers that further research is very likely to have an important impact on that confidence and is likely to change the estimate.	
Very low	The Group is very uncertain about the estimate of the effect.	

Process for developing recommendations

Once the certainty of the evidence is determined, the GDG, with the guidance of the Methodologist, determines if a recommendation (strong or conditional) or a GPS is warranted. GRADE evidence profiles contain an assessment of the certainty of the evidence and a summary of findings for each critical outcome and each key question. The GDG use these summaries as the basis for discussions and formulation of recommendations.

The Evidence to Decision (EtD) framework is used by the GDG to support the formulation of the recommendation or GPS. Core domains in the EtD framework are the balance of benefits and harms and the quality of the evidence, although other factors also influence the recommendations (Table 2). For some domains, there is insufficient published data to provide the GDG with informative systematic reviews or studies of health workers, patients or community members' perceptions or experiences with the implementation of IPC recommendations during the pandemic. In such cases, additional evidence/data is presented when available, supplemented by GDG members' (including community members) experiences and judgements. Strong recommendations are supported when benefits highly outweigh harms with high certainty, the recommendations are not sensitive to variability in preferences/values regarding outcomes, and the recommendations are widely feasible and acceptable, cost-savings or cost-effective, and would improve equity. When certainty is low or very low strong recommendations can be made but they require a strong rationale for potential net benefits and the other EtD domains. In these situations, GPS are considered (see the section on GPS). In some cases, after determining that the benefits of intervention do not outweigh the harms and considering EtD domains (Table 2), the GDG may make a recommendation against an intervention.

The GRADE tables used in this living guideline can be found in the Annex section of this living guidance.

The recommendations on mask use by children were additionally informed by five consultation sessions conducted by the United Nations Children's Fund (UNICEF) with members of the International Paediatric Association (IPA), and members from different geographical regions, in multiple languages, to synthesize paediatric health professionals'Children's field experiences with the implementation of the previous guidance.

Domain	Favours strong recommendations	Favours conditional recommendations
Balance of benefits and harms	Benefits highly outweigh harms	Benefits and harms more closely balanced
Quality of evidence	Higher certainty	Lower certainty
Values/preferences regarding outcomes	Benefits to harms assessment not impacted by variability in values/ preferences	Variability in values/preferences would impact benefits to harms assessment
Acceptability	Highly acceptable	Low or variable acceptability
Costs/resources	Cost saving/cost effective	Costly/cost ineffective

Table 2. Evidence to Decision (EtD) framework

Feasibility	Feasible in intended settings	Unfeasible or feasibility varies in intended settings
Equity	Increased equity	Decreased equity or effect on equity variable

Good practice statements and implementation considerations

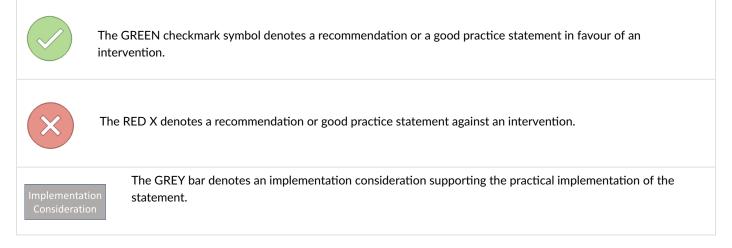
GPS are most suitable when benefits are large and harm very small; the certainty of benefits and harms are great; the values and preferences are clear; the intervention is cost saving; and the intervention is clearly acceptable, feasible, and promotes equity. GPS characteristically represent situations in which a large and compelling body of indirect evidence, made up of linked evidence including several indirect comparisons, strongly supports the net benefit of the recommended action. GPS are generally issued due to various reasons, including the process, priorities, timeline, resources or nature of the evidence being assessed but are rooted in the fact that answers are obvious. GPS are not GRADEd statements [23].

Implementation considerations are critical elements that facilitate the appropriate use of recommendations and GPS but are not assessed using the GRADE methodology. They may be actionable and relevant to implementing one of the intervention options and may include information to enhance the implementation of the intervention [24].

Readership cues for statements

Table 3 presents the readership cues used for the statements in this living guideline. The green checkmark and red X symbols reflect statements that are developed using the GRADE evidence assessment methodology and the use of the evidence to decision framework to inform a recommendation or a GPS. The grey bar refers to implementation considerations that support statements through practical advice and are the product of expert consensus.

Table 3. Readership cues used for statements in the living guideline



Periodicity of the guideline revision and updates

Ongoing reviews are being conducted by WHO staff, as is the external living systematic review that has been commissioned to continuously monitor emerging evidence on the use of masks in the context of the COVID-19 pandemic. New evidence identified in these reviews that could inform revised or new recommendations will trigger reconsideration of the evidence by the GDG. Furthermore, as the pandemic evolves, including changes in transmission intensity, circulation of new variants of concern, health systems capacity to respond to new epidemiological scenarios, the GDG will review the current evidence on IPC and PHSM.

Part 1: Health care settings

The document "Infection prevention and control in the context of coronavirus disease (COVID-19): A living guideline" brings together IPC technical guidance developed and published since the beginning of the COVID-19 pandemic. This consolidated document aims to provide

users with the latest evidence-informed recommendations, through the MAGICapp platform, as a way to easily navigate guidelines in the dynamic context of COVID-19. Many parts of the technical guidance related to *Part 1: Health care settings* are currently under review. Links to the most recent publication of the technical guidance are available in the sections that follow. Updated guidelines on health care settings will be available in this living guideline in the near future.

What is an IPC programme?

What is an Infection Prevention and Control Programme?

Infection prevention and control (IPC) is a practical, evidence informed approach to preventing patients and health workers from being harmed by avoidable infections. Healthcare-associated infections (HAI) are among the most common adverse events in care delivery and a major public health problem impacting morbidity, mortality and quality of life. On average, 7% of patients in developed and 15% in developing countries will acquire at least one HAI at any one time [25]. These infections also present a significant economic burden at the societal level. However, a large percentage are preventable through effective IPC measures.

Establishing an infection prevention and control programme at national and acute health care facility levels

The WHO Guidelines on core components of infection prevention and control programmes at national and acute health care facility levels [26] are the foundation of WHO strategies to prevent current and future threats from infection and antimicrobial resistance in health care. The core components constitute a framework of recommendations of good practices statement distributed into eight areas: 1) infection prevention and control programmes, 2) national and facility-level infection prevention and control guidelines, 3) infection prevention and control education and training, 4) healthcare-associated infections surveillance, 5): multimodal strategies for implementing infection prevention and control activities, 6) monitoring and evaluation and feedback, 7) workload, staffing and bed occupancy at the facility level and, 8) built environment, materials and equipment for infection prevention and control at the facility level. Ensuring adequate clinical staffing levels is recommended as a core component to prevent the transmission of HAI and multidrug-resistant organisms (MDRO), limit human-to-human transmission, reduce secondary infections, and prevent the transmission through amplification and super spreading events.

Considering that implementing an Infection Prevention and Control Programme requires a stepwise approach [27][28] to its full achievement, minimum requirements [29] have been identified to support it in countries where IPC is limited or nonexistent. In this regard, a facility level IPC programme with a dedicated and trained IPC team, or at minimum, an IPC focal point, should be in place and supported by the national and facility senior management. Achieving the IPC minimum requirements (and more robust and comprehensive IPC programmes in all countries is essential to sustain efforts to control the COVID-19 pandemic, other emerging and reemerging pathogens, and multi drug resistant organisms (MDRO). Finally, WHO has also developed guidance on the core competencies [30] required for infection prevention and control professional staff, which can be used for developing curricula for IPC specialists.

Environmental cleaning

The most up-to-date technical guidance for "<u>Cleaning and disinfection of environmental surfaces in the context of COVID-19: interim</u> guidance" was published 15 May 2020. This guidance is under review and is pending integration into "<u>Infection prevention and control</u> in the context of coronavirus disease (COVID-19): A living guideline".

Home care for patients

The most up-to-date guidance for "Home care for patients with suspected or confirmed COVID-19 and management of their contacts: interim guidance" was published 12 August 2020. This guidance is under review and is pending integration into "Infection prevention and control in the context of coronavirus disease (COVID-19): A living guideline".

IPC when COVID-19 is suspected or confirmed

The most up-to-date technical guidance for "Infection prevention and control during health care when coronavirus disease (COVID-19) is suspected or confirmed: interim guidance was published 12 July 2021. This guidance is under review and is pending integration into

"Infection prevention and control in the context of coronavirus disease (COVID-19): A living guideline".

IPC principles and procedures for COVID-19 vaccination activities

The most up-to-date technical guidance for "Aide-memoire: infection prevention and control (IPC) principles and procedures for COVID-19 vaccination activities" was published 15 January 2021. This guidance is under review and is pending integration into "Infection prevention and control in the context of coronavirus disease (COVID-19): A living guideline".

Long term care facilities

The most up-to-date guidance for "Infection prevention and control guidance for long-term care facilities in the context of COVID-19: interim guidance" was published 21 March 2020. This guidance is under review and is pending integration into "Infection prevention and control in the context of coronavirus disease (COVID-19): A living guideline".

Mask use

Background

The WHO continuously reviews available data on SARS-CoV-2 variants of concern. For this version, the global epidemiological situation of the COVID-19 pandemic as of 21 January 2022 – at a time when the Omicron VOC had been identified in 171 countries across all six WHO Regions and was rapidly replacing Delta worldwide – was considered [1].

Omicron has a substantial growth advantage, higher secondary attack rates and a higher observed reproduction number than Delta. There is now significant evidence that immune evasion contributes to the rapid spread of Omicron. Other factors may be a shorter serial interval (by about 0.8 to 1.2 days compared to Delta) and potential increased intrinsic transmission fitness [1]. There is growing evidence that with Omicron, there is lower vaccine effectiveness (VE) against infection and symptomatic disease soon after vaccination compared to Delta. There is also evidence of accelerated waning of VE over time of the primary series against infection and symptomatic disease for the studied vaccines. Further studies are required to better understand the drivers of transmission and declining incidence in various settings. These factors include the intrinsic transmission fitness properties of the virus, degree of immune evasion, vaccination coverage and level of vaccine-derived and post-infection immunity, levels of social mixing and degree of application of PHSMs.

Essential measures to prevent SARS-CoV-2 transmission in health care facilities remain valid in the context of Omicron and should be strengthened [1].

WHO recommends using face protection as part of a comprehensive package of prevention and control measures to limit the spread of SARS-CoV-2. National policies and health facilities must continue to achieve and maintain IPC measures, including having an IPC programme or at minimum a dedicated and trained IPC focal point in place. Other necessary measures include engineering, environmental and administrative controls, standard and transmission based-precautions, screening and triage for early identification of cases and COVID-19 surveillance and vaccination of health workers. This is particularly important considering the rapid spread of Omicron and the high proportion of individuals who may be infected but are asymptomatic [1].

This document guides decision makers and IPC professionals to develop and implement policies on mask use in health care settings.

Published 25 April 2022.

New

In areas of known or suspected community or cluster transmission

Strong recommendation for , Very low certainty evidence



In areas of known or suspected community or cluster SARS-CoV-2 transmission, universal masking is recommended in health care facilities:

• In settings where caring for non-COVID-19 patients, unless differently specified (e.g. AGP), all health workers, including community health workers and caregivers, other staff, visitors, outpatients and service providers, should wear a well-fitting medical mask at all times within the health facility and in any common area (e.g., cafeteria, staff rooms).

- Inpatients are not required to wear a medical mask unless physical distancing of at least 1 metre cannot be maintained (e.g., during examinations or bedside visits) or when outside of their care area (e.g., when being transported), provided the patient is able to tolerate the mask and there are no contraindications.
- <u>Click here</u> for the recommendation on the mask type for health workers when caring for a suspected or confirmed COVID-19 patient.

Published 25 April 2022.

Practical Info

When adopting universal masking within a health facility, it is essential health workers follow proper mask-wearing procedures and practices. For additional information review the implementation considerations on <u>mask management for health workers</u>.

The WHO recommendation on mask fitting should be followed, including the related considerations on this critical aspect.

Evidence To Decision

Benefits and harms

Substantial net benefits of the recommended alternative

Very low

The wearing of a medical mask is associated with a decreased risk of acquiring SARS-CoV-2 infection [19]. In areas where there is community transmission of COVID-19, universal masking has been adopted by most hospitals to reduce potential transmission between health workers and other staff, patients, and those entering the facility. Five studies found that implementing a universal masking policy in hospital systems was associated with decreased risk of healthcare-acquired SARS-CoV-2 infection [31][32][33][34][35]. However, these studies have limitations, as most originated in the United States of America, and used a before-after design. Other limitations include lack of or limited control for confounders, such as the use of other personal protective equipment and exposures [31][32][33][34][35]. Furthermore, potential sensitivity to time periods selected for analysis for pre-and post-universal masking was identified, but none of the studies included sensitivity analysis. Literature provides limited insight into the harms of universal masking; evidence on mask use, in general, indicates bothersome but non-serious harms. Therefore, despite the limitations in the evidence, the GDG judged that the benefits of implementing universal mask use in healthcare facilities outweigh potential harms.

Certainty of the Evidence

Given the limited number and the type of evidence available (i.e., before-after studies) regarding the implementation of universal masking as an IPC procedure, the certainty of the evidence is rated as very low. However, despite the very low certainty of evidence pertaining to universal masking, the wearing of a medical mask is associated with a decreased risk of acquiring SARS-CoV-2 infection [19].

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Values and preferences

Given the protective effects associated with mask use, health workers, including community health workers and caregivers, would likely favour the implementation of universal masking [19][31][32][33][34][35][35]. In the context of universal masking, some health workers may prefer to wear respirators instead of a medical mask, based on their perception of what offers the better protection to prevent SARS-CoV-2 infection and emergent evidence that the use of respirators might be more effective in the control of transmission of some variants of concern such as Omicron. There are no substantial variabilities in values and preferences.

Resources and other considerations

Implementing universal masking is likely to have a low to moderate impact on resources.

Equity

No adverse impacts on equity to the individual have been identified, as long as masks are provided by health care facilities and are readily available for all health workers, staff, visitors and patients.

Acceptability

Universal mask use is likely to be easily accepted in health care facilities given the protective effects for health workers, other staff, visitors and patients [19][31][32][33][34][35][35].

Feasibility

The universal use of masks in health care facilities is likely feasible and is currently the standard in most countries, in the context of the COVID-19 pandemic.

Justification

Upon deliberations during the GDG meeting, the decision regarding this recommendation's strength was reached through online voting. Despite the very low certainty of the evidence for the implementation of universal masking, the evidence does indicate benefits without significant harms; in addition, the GDG members judged that universal masking could prevent potential serious harms of health care worker infections and transmission in health care. Of 28 members of the GDG, 78.6% (22) voted that this should be a strong recommendation. Members also felt that based on their own professional experience, or that of colleagues, universal masking in health settings is already routine in most countries; therefore, the acceptability and feasibility favoured a strong recommendation, as well. Furthermore, the utilization of a medical mask is associated with a decrease in SARS-CoV-2 transmission[20].

Additionally, the GDG reviewed the mask type to be used universally in health care facilities. In light of new VOCs with increased transmissibility and the subsequent need to better protect health workers and their patients, GDG members felt the exclusive use of medical masks was justified. Given the available evidence on mask effectiveness of medical masks and their requirement to adhere to strict standards, a majority of members felt the universal use of medical masks in the health care setting would provide better protection for staff, patients, visitors and the community.

No important issues with the recommended alternative

No substantial variability expected

No important issues with the recommended alternative

No important issues with the recommended alternative

In areas of known or suspected sporadic transmission

Conditional recommendation for, Very low certainty evidence

In areas of known or suspected sporadic SARS-CoV-2 transmission, targeted continuous medical mask use is recommended in health care facilities:

• In settings when caring for non-COVID-19 patients, health workers, including community health workers and caregivers who work in clinical areas, should continuously wear a well-fitting medical mask during routine activities throughout the entire shift, unless differently specified (e.g. when performing AGP) and apart from when eating and drinking.

- In non-patient areas, staff are not required to wear a medical mask during routine activities if they have no patient contact. •
- <u>Click here</u> for the recommendation on mask type for health workers when caring for a suspected or confirmed COVID-19 patient.

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Practical Info

When adopting targeted continuous masking within a health facility, it is essential health workers follow proper mask-wearing procedures and practices. For additional information review the implementation considerations on mask management for health workers.

The WHO recommendation on mask fitting should be followed, including the related considerations on this critical aspect.

Evidence To Decision

Benefits and harms

Given the protective effects of mask use, the benefits of implementing targeted continuous mask use in healthcare facilities outweigh potential harms [19]. Five studies found that consistent mask use in health care facilities was associated with a decreased risk of SARS-CoV-2 infections in health workers. However, it is essential to note that these studies only investigated universal masking, not targeted continuous masking. The effects found in these studies have been extrapolated for the aforementioned recommendation [31][32][33][34][35].

Certainty of the Evidence

Verv low

Updated

The evidence for targeted continuous masking has been extrapolated from evidence on universal masking; therefore, the certainty of the evidence is rated as very low. However, despite the very low certainty of evidence pertaining to targeted continuous masking, the wearing of a medical mask is associated with a decreased risk of acquiring SARS-CoV-2 infection [19].

Values and preferences

Given the protective effects of mask use, health workers, including community health workers and caregivers, would likely favour targeted continuous masking in health facilities [19][31][32][33][34][35]. There are no important variations in the values and preferences.

Resources and other considerations

The implementation of targeted continuous masking is likely to have a low to moderate impact on resources.

No substantial variability expected

No important issues with the recommended alternative

Substantial net benefits of the recommended alternative

Equity

No important issues with the recommended alternative

This intervention will likely cause no adverse impacts on equity, so long as masks are provided in health care settings and are readily available.

Acceptability

No important issues with the recommended alternative

The universal use of masks in healthcare facilities is the standard in most countries in the context of the COVID-19 pandemic and has been widely implemented.

Feasibility

No important issues with the recommended alternative

The use of targeted continuous mask use in health care facilities is likely feasible.

Justification

After GDG members discussed their perspectives on recommending the implementation of targeted continuous masking, the decision to formalise the above statement as a conditional recommendation was reached through online voting. GDG members felt a conditional recommendation was well suited for this guidance, given that the evidence for continuous masking was inferred from evidence on universal masking and the statement is written for an epidemiological situation with few COVID-19 cases.

Implementation consideration
 The following procedures and practices should be ensured when wearing a mask in health care settings [36] Medical masks should be combined with other measures including frequent hand hygiene and physical distancing of at least 1 metre among health workers in shared and crowded places such as cafeterias, break rooms and dressing rooms [37]. Medical masks must be changed when wet, soiled or damaged or if the health worker or caregiver removes the mask for any reason (e.g. for eating or drinking or caring for a patient who requires droplet/contact precautions for reasons other than COVID-19). Used medical masks should be disposed of properly. The medical mask should not be touched to adjust it or if it is 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 PPE) 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 a medical mask be shared between health workers. Medical masks can become displaced from their optimal placement, over the mouth and nose, during extended use, which creates gaps for respiratory particles to bypass the filtration layers on inhalation and exhalation [38]. The <u>WHO</u> recommendation on mask fitting should be followed, including the related considerations on this critical aspect.

Infection prevention and control in the context of coronavirus disease (COVID-19): A living guideline - World Health Organization (WHO)

In any transmission scenario

Good practice statement

Appropriate mask fitting should always be ensured (for respirators, through fit testing and a user seal check when a filtering facepiece respirator is donned; and for medical masks, through methods to reduce air leakage around the mask) as well as compliance with appropriate use of PPE and other standard and transmission-based precautions.

Updated

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Practical Info

Implementation consideration

Methods to improve the fit of respirators or medical masks

Respirators

- Filtering facepiece respirators (FFRs) vary for their measurement of fit, either through maximum allowable leak tightness or minimum fit factor. For European certified FFRs, the maximum leakage varies from:
 - FFP1 (maximum 22% leakage)
 - FFP2 (maximum 8% leakage) and
 - FFP3 (maximum 2% leakage)
 - European certified FFRs (EN 149) are subject to testing for leakage with human participants as part of the product's certification.
- For NIOSH, N-type FFRs (minimum fit factor of 100) are certified according to OSHA 29 CFR 1910.134 for each wearer prior to use.
- At a minimum, FFRs that meet FFP2 and N95 performance levels are recommended to be worn by health workers in areas where AGP are performed [10].
- Ensure a range of FFR sizes are available to accommodate different face shapes and sizes, especially for those with small faces.
- Qualitative or quantitative fit testing should be performed annually and for new staff at the employer's expense to ensure that the respirator model fits each health worker's unique facial features and provides a consistent seal [39].
- A seal check should be performed on FFRs whenever donned by a health worker to determine if the adequate fit is achieved by the specific FFR they have donned. See <u>WHO guidance on how to perform a particulate respirator seal check</u> for additional details.

Two methods can be used for fit testing FFRs

1) qualitative fit test (health worker reports taste of an ambient aerosol) and 2) quantitative fit test

	Qualitative Fit Testing	Quantitative Fit Testing
Standard test methods	OSHA 29 CFR 1910.134 Appendix A (for N95)	EN 149, Clause 7.9.1 (EN-type, e.g., FFP2) OSHA 29 CFR 1910.134 Appendix A (e.g., N95)
Equipment	Hood and sweet/bitter aerosol	Ambient aerosol condensation nuclei counter
Pass/Fail Criteria	Wearer report tasting aerosol	>8% leakage (for FFP2)

	<100 fit factor (for N95)

Medical masks

Improving the fit of medical masks may not always be possible in low resource settings, given the resource requirements. However, techniques such as the "tie-and-tuck" method may benefit low- and middle-income countries since they do not require additional materials. The "knot-and-tuck" and "linking-ear-loops-behind-the-head" techniques improve medical mask fit by reducing gaps on the sides of medical masks with ear loops. Such gaps allow air leakage (potentially containing infectious particles) to bypass the filtration layers of the medical mask when the wearer inhales or exhales.

Considerations on the use of linking-ear-loops-behind-the-head techniques to improve medical mask fit

- Always use a clean, unused rectangular pleated medical mask meeting the minimum performance standards (or equivalent)[10].
- Always clean hands thoroughly (per <u>WHO guidance</u>) prior to donning, doffing and/or manipulating a mask.
- Where connectors are used to link ear loops behind the head, ensure that these connectors are clean for use upon donning (either new, cleaned and disinfected or laundered, depending on the connector and local implementation strategy). When connectors are doffed, they should be treated as potentially contaminated. A local strategy should be in place to manage used connectors thorough cleaning and disinfection processes, laundering or discarding used connectors through standard waste management.



How to improve medical mask fit in health care settings When linking ear loops When using behind the head knot-and-tuck method Clean hands thoroughly before putting on and before and after taking off your mask Attach a clean connector Fold the mask horizontally to link ear loops together* Make a knot on both Place the medical mask ear loops as close colour-side facing outward, to the edge of the mask attach ear loops behind ears as possible Push the extra material Attach ear loops using under the mask inward to connector behind head ensure no gaps on both tightly sides

Ad the the

Adjust the wire at the bridge of the nose and ensure there are no gaps between the mask and your face at the sides of your nose, cheeks, and under your chin.

*Find a clean practical connector to link your ear loops, it can be:





silicone

**If a surface is used to fold and manipulate the mask, clean the surface first using a cloth wipe with soap and water, followed by disinfection using a cloth wipe soaked in 70-90% alcohol OR 0.1% sodium hypochlorite (or comparable hospital grade disinfectant) and allow for least 1 minute contact time before surface is used.

adjustable rope

When adopting a mask policy, it is essential health workers follow proper mask-wearing procedures and practices. For additional information review the implementation considerations on <u>mask management for health workers</u>.

Justification

GDG members were asked if WHO should consider developing practical advice on improving medical mask fit, where's the majority of GDG members agreed this would be useful. Five options to improve the fit of masks were presented: the "use of ear loops linked behind the head"; the "tie-and-tuck method"; the use of a brace/fitter; the use of masks with ties behind the head instead of ear loops; double masking.

Twenty-five GDG members (83.3%) agreed with the use of ear loops linked behind the head; 23 (76.7%) agreed with the use of the tie-and-tuck method; 19 (63.3%) agreed with the use of masks with ties behind the head instead of ear loops; 16 (53.3%) agreed with the use of a brace/fitter; 10 (33.3%) agreed with double masking. Therefore, the use of ear loops linked behind the head and of the tie-and-tuck method was retained as advisable methods to improve the fit of masks and additional details can be found in the practical information section.

GDG members reported that the evidence available on improving the fit of medical masks to reduce the transmission risk of SARS-CoV-2 is in the form of laboratory-based studies with limited field and clinical investigations.

Strong recommendation for , Very low certainty evidence

A respirator should always be worn along with other PPE* by health workers performing aerosol-generating procedures (AGP) and by health workers on duty in settings where AGP are regularly performed on patients with suspected or confirmed COVID-19, such as intensive care units, semi-intensive care units or emergency departments.

*PPE includes gown, gloves, eye protection.

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Practical Info

When adopting a mask policy within a health facility, it is essential health workers follow proper mask-wearing procedures and practices. For additional information review the section on <u>mask management for health workers</u>.

The WHO recommendation on mask fitting should be followed, including the related considerations on this critical aspect.

Evidence To Decision

Benefits and harms

Small net benefit, or little difference between alternatives

Among health care workers, exposure to an AGP such as tracheal intubation was associated with a higher risk of infection with SARS-CoV-1, the most closely related human coronavirus to SARS-CoV-2 [40]. Furthermore, a living rapid review showed that certain exposures such as involvement in intubations are significantly associated with SARS-CoV-2 infections [21][22]. However, no specific evidence assessing the effectiveness of different types of masks to prevent transmission of SARS-CoV-2 during AGP is available. Indirect evidence from laboratory simulation data provides insight on the plausibility and viability of aerosolised SARS-CoV-2 [41].

Respirators have higher filtration efficiency standards and demonstrate better fit with fewer air gaps allowing bypass of the filter media than the most commonly used rectangular medical masks, provided that they are appropriately fit tested and worn. Therefore, respirators are likely to be superior in preventing transmission of SARS-CoV-2 during AGP [21][22].

Certainty of the Evidence

Given the absence of direct evidence related to SARS-CoV-2 and the limitations of the indirect evidence, the certainty of the evidence for the utilization of particulate respirators for patients with suspected or confirmed COVID-19 during AGP was rated as very low.

Values and preferences

Health care workers would highly prefer to wear a respirator during AGP in order to benefit from the perception of a higher protective effect. Thus, no variability is expected in health care workers' preferences related to the use of respirators during AGP to prevent transmission risk in preventing transmission.

Resources and other considerations

Important issues, or potential issues not investigated

No substantial variability expected

Very low

Resource implications

The use of respirators requires an additional investment of financial and logistical resources, including the need for fit testing for all staff, requiring additional investments and expertise [39]. Some clinical and operational challenges may be experienced, in particular in low and middle income countries, and investments are needed in order to provide the best protection possible during AGP.

Knowledge gaps, research needs and comments

Additional research is needed to clarify which medical procedures produce aerosols and thus, potentially increase the transmission risk of SARS-CoV-2 and other respiratory pathogens thus, leading to the need for a higher level of respiratory protection. Conducting trials to compare the effectiveness of different types of masks to prevent infection during AGP would be unethical.

Equity

Important issues, or potential issues not investigated

Given the limited global supply of respirators and their high cost in particular for resource-limited settings, inequity issues likely exist.

Acceptability

No important issues with the recommended alternative

Stakeholders and policymakers' will likely accept the recommended use of respirators during procedures that produce aerosols as this is the policy currently in place in most countries and historically integrated into a conditional recommendation by the WHO for acute respiratory infections [7].

Feasibility

No important issues with the recommended alternative

The use of respirators during the performance of an AGP is feasible although some resources implications have been noted.

Justification

A majority of GDG members noted that despite the very low certainty of evidence, the acceptability and feasibility of implementation and the benefits of wearing a respirator during the performance of an AGP on a suspected or confirmed COVID-19 patient justified a strong recommendation. The GDG agreed to upgrade the strength of this recommendation from a conditional recommendation to a strong recommendation [7]. The decision was made in light of the increased widespread transmission of Omicron, its immune escape, and still limited vaccination coverage in health care workers worldwide.

Conditional recommendation for , Very low certainty evidence
Updated
A respirator or a medical mask should be worn by health workers along with other PPE- a gown, gloves and eye
protection – before entering a room where there is a patient with suspected or confirmed COVID-19.

Respirators should be worn in the following situations:

- In care settings where ventilation is known to be poor* or cannot be assessed, or the ventilation system is not properly maintained
- Based on health workers' values and preferences and on their perception of what offers the highest protection possible to prevent SARS-CoV-2 infection.

*Ventilation in a health care setting is considered to be poor when the requirements established for these settings are not in place (see "Definitions" section).

Note: This recommendation applies to any setting where regular care is provided to patients with suspected or confirmed COVID-19, including home care, long-term care facilities and community care settings. For settings where AGP are regularly performed on patients with suspected or confirmed COVID-19, see the strong recommendation above.

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Practical Info

When adopting a mask policy within a health facility, it is essential health workers follow proper mask-wearing procedures and practices. For additional information review the implementation considerations on <u>mask management for health workers</u>.

The <u>WHO recommendation on mask fitting</u> should be followed, including the related considerations on this critical aspect, like the type of FFR that should be used by health workers.

Evidence To Decision

Benefits and harms

Small net benefit, or little difference between alternatives

The recommendation noted above made no distinction between the use of medical masks and respirators when caring for a COVID-19 positive patient, except in situations where respirators are clearly needed (e.g., AGP). Respirators have higher filtration efficiency standards and demonstrate better fit with fewer air gaps allowing bypass of the filter media than the most commonly used rectangular medical masks, provided that the respirators are appropriately fit tested and properly worn [10][39]. Given the protective effects of respirators, several GDG members advised that respirators may be superior to medical masks in preventing SARS-CoV-2 infection and their use should be encouraged when the health care worker delivers care in close contact with the patient and/or when ventilation is inadequate.

Evidence comparing the effectiveness of respirators versus medical masks for SARS-CoV-2 in healthcare settings is limited to five observational studies [42][43][44][45][46], which were conducted prior to the emergence of the Delta, Omicron and other variants and before widespread vaccination in healthcare settings. These five observational studies had methodological limitations (for example, recall bias, low participation, limited measurement of exposures) and reported inconsistent findings regarding the risk of SARS-CoV-2 infection between the use of respirators versus medical masks. One study showed a reduction of risk with respirator use [43], while in another two studies the use of respirators was not significantly associated with risk reduction [45][46]. One study showed no association [46], and another found respirators were associated with increased risk (OR 7.1), likely related to confounding factors [44]. Prior randomised controlled trials comparing respirators versus medical masks for prevention of clinical influenza-like illness (ILI) found no difference [47][48][49][50][51]. Overall, the strength of this evidence was rated as insufficient to recommend one type of mask versus the other.

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]. Medical masks are typically associated with less discomfort or side effects than respirators given decreased thickness and reduced seal, although this has not been quantified. Undesirable outcomes from the prolonged use of respirators were noted, including general discomfort, headaches and the development of facial skin lesions, irritant dermatitis or worsening acne [19]. The fitting process for respirators is burdensome, and issues with achieving it have been well described. Furthermore, other factors may influence the overall risk of transmission, including general PPE use, PPE training, fit testing, ventilation, and and behavioural factors (including compliance) as well as the fact that transmission of SARS-CoV-2 among health workers appears to mostly occur in community settings [19]. The balance of desirable and undesirable outcome effects was rated as uncertain. It was deemed uncertain whether respirators are more effective than medical masks in settings without exposure to AGP.

Certainty of the Evidence

Given the methodological limitations of the evidence, notably inconsistency and indirectness (e.g. most studies conducted before the emergence of the Delta variant and none in the Omicron era), evaluation of non-SARS-CoV-2 infections or assessment of non-clinical outcomes, [19] the certainty of the evidence for particulate respirators versus medical masks was rated as very low.

Values and preferences

There is substantial variability in preferences related to the use of respirators in preventing HAI. In the context of the increased transmissibility of the Delta or Omicron variant, some health care workers may value the wider use of respirators to potentially reduce their risk, despite the limited evidence, as a precautionary approach. Others may not prefer to wear a respirator throughout their shifts because of discomfort and potential side effects. Local values, preferences and practicalities should play an important role in directing choices on the use of respirators versus medical masks.

Resources and other considerations

Important issues, or potential issues not investigated

Substantial variability is expected or uncertain

Resource implications

The use of respirators for the care of all patients with suspected or confirmed COVID-19 in health care facilities requires an additional investment of financial and logistical resources, which could be challenging, in particular, in low and middle income countries. There is also the need for fit testing for all staff, requiring additional investments and expertise; however, scaling up the market for respirators could lead to cost reduction.

Knowledge gaps, research needs and comments

Randomised controlled trials on respirators versus medical masks in health care settings are in progress. 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 Omicron and other variants are urgently needed. More research is also needed to investigate the risks associated with medical masks and respirators and adverse events (including self contamination) during extended and repeated use. Other gaps include studies on simpler, faster and less costly methods, or alternative methods, to determine respirator fit and seal. Further data is needed regarding compliance with appropriate PPE use, including masks, and in particular, appropriate donning and doffing practices in COVID-19 and non COVID-19 units.

Equity

Important issues, or potential issues not investigated

Given the limited global supply of respirators and their higher cost compared to medical masks, a recommendation to use respirators for all COVID-19 cases in health care settings could result in inequity in resource limited settings. However, it is also

Very low

expected that the widespread use of respirators (if available) will reduce inequities related to COVID-19 exposure risk. Unvaccinated health care workers worldwide are still at higher risk for infection, sometimes resulting in severe disease and death. There is an additional equity issue around medical masks, which may also not be available in sufficient quantities and of adequate quality in low resource settings.

Acceptability

No important issues with the recommended alternative

The current recommendation provides the option of using either respirators or medical masks, except for specific circumstances when a respirator is required. Given this flexibility, it should be acceptable for stakeholders' and policymakers'.

Feasibility

Important issues, or potential issues not investigated

Although WHO unpublished modelling data indicated an inadequate supply of respirators to replace medical masks in all COVID-19 health care settings, policies advising respirators in all COVID-19 settings would likely lead to increased investments and production. Furthermore, a strong supply distribution and logistics system is needed to ensure efficient procurement and reach across the whole health system. However, inefficiencies in the distribution of supplies and supply chain problems have been reported. The adequate fit of the device is correlated with the effectiveness of the FFP, but fit testing may not be feasible in all regions.

Justification

The GDG considered the very low certainty of the evidence for particulate respirators versus medical masks, and agreed that the strength of this evidence was insufficient to recommend one type of mask versus the other, except in some specific conditions. However, many GDG members saw relevance in the epidemiological evidence showing that the Omicron variant is spreading significantly faster than the Delta variant in countries with documented community transmission [1]. Serious concerns were expressed about the evidence of SARS-CoV-2 re-infection with Omicron, and the data showing a reduction in neutralising antibody titres against Omicron and a significant reduction in VE against infection and symptomatic disease for Omicron compared to Delta [1]. Some GDG members also highlighted the fact that as of November 2021, 65% of health workers in 135 countries were fully vaccinated, but the vaccination status was unknown for 77.7 million health workers (58% of the global health workforce)[53].

Following in-depth discussions, the GDG was asked to decide whether to maintain the recommendation on the type of mask to be used in COVID-19 settings included in the Annex to "Infection prevention and control during health care when coronavirus disease (COVID-19) is suspected or confirmed". Out of 33 IPC GDG members who voted, 24 (68%) would have preferred to maintain the previous recommendation on the type of mask to be used in COVID-19 settings. The previous recommendation took into strong consideration serious concerns about the limited availability of respirators in low and middle income countries and the resource implications of more widespread use of respirators. The GDG voting on this recommendation in light of Omicron was based on the very low certainty of the evidence for particulate respirators' availability. However, among GDG members who advised maintaining the previous recommendation, 48% also stated that they would consider it acceptable to recommend either respirators or medical masks; 33% of them even considered it acceptable to prioritise respirators; the remaining 19% of them stated that no other option but maintaining the previous recommendation; among these, 70% advised recommending either respirators or medical masks, whereas 30% recommended the sole use of respirators in all settings where COVID-19 patients are given care. Given the 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.

Following very careful interpretation of the GDG considerations and voting results which showed that 68% of GDG members would have preferred to maintain the recommendation included in the <u>Annex</u> issued on 1 October 2021, but also indicated what changes would have been acceptable to these GDG members, WHO decided to make this new conditional recommendation which was issued as <u>rapid guidelines on 22 December 2021</u>. Given the increased transmissibility and rapid spread of the Omicron VOC, WHO leadership felt it was necessary to take a precautionary approach, according to the hierarchy of controls, and add the option of respirators to the recommendation on masks to use when entering a room with a COVID-19 positive patient regardless of AGP

being performed, despite the limitations of the available evidence on respirators versus medical masks in health care facilities.

Updated

Transmission scenario	Target population	Setting	Activity	Mask type
Any transmission scenario	Health workers	Health care facility**	Performing an AGP or providing care in a setting where AGP are in place for suspected/confirmed COVID- 19 patient(s)	Respirator ***
			In settings where caring for suspected/confirmed COVID-19 patient(s)	Well-fitting respirator or a medical mask
	Other staff,			
Known or suspected community or cluster transmission of SARS-CoV-2	patients, visitors, service suppliers	Health care facility**	For any activity or in any common area	Well-fitting medical mask
	Inpatients		When physical distancing of at least 1 metre cannot be maintained or when outside of their care area	
		ers and or postnatal	In settings where caring for non-COVID-19 patients.	
	Health workers and caregivers			
	Community	Community	Community outreach programmes/essential routine services	
	Health		In settings when caring for	
Known or suspected sporadic transmission of SARS-CoV-2 cases	workers and caregivers		non-COVID-19 patient(s)	Well-fitting medical mask
	Other staff, patients, visitors, service suppliers and all others	Health care facility**	No routine activities in patient areas	A medical mask may not be required if no patient contac

No documented SARS-CoV-2 transmission	Health workers and caregivers	Health care facility**	Providing any patient care	Medical mask use according to standard and transmission- based precautions

*This table refers only to the use of medical masks and respirators. The use of medical masks and respirators should be combined with other personal protective equipment, standard and transmission-based precautions and other measures as appropriate, and always with hand hygiene.

** Health facility can include primary, secondary, tertiary care levels, outpatient care, and long-term care facilities.

*** N95 or N99 or FFP2 or FFP3

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PPE Technical Specifications

Pertinent sections of the technical guidance, "<u>Technical specifications of personal protective equipment for COVID-19</u>", published 13 November 2020, will soon be incorporated in this living guidance.

Updat echnical specifications for medical masks [10]				
Item	Characteristics	Performance standards (or alternative equivalent)		
Medical mask for a health care worker	Medical mask, good breathability, internal and external faces should be clearly identified, 98% droplet filtration, preferably fluid resistance.	 Always use a clean, unused rectangular pleated medical mask meeting the following minimum performance standards (or equivalent): EN 14683 (Type II or Type IIR); ASTM F2100 (Level 1, 2 or 3); or YY 0469 OR YY/T 0969 (with at least 98% bacterial filtration efficiency). 		
Medical mask for patient	Medical mask, good breathability, internal and external faces should be clearly identified	EN 14683 Type I YY 0469 or YY/T 0969, if bacteria droplet filtration is below 98% Or alternative equivalent standard		

Prevention, identification and management of health worker infection

The most up-to-date technical guidance for "Prevention, identification and management of health worker infection in the context of <u>COVID-19</u>: interim guidance" was published 30 October 2020. This guidance is under review and is pending integration into "Infection prevention and control in the context of coronavirus disease (COVID-19): A living guideline".

Rational use of PPE and considerations during severe shortages

The most up-to-date technical guidance for "Rational use of personal protective equipment for coronavirus disease (COVID-19) and considerations during severe shortages" was published on 23 December 2020. This guidance is under review and is pending integration into "Infection prevention and control in the context of coronavirus disease (COVID-19): A living guideline".

Risk assessment and management of exposure

The most up-to-date technical guidance for "Risk assessment and management of exposure of health care workers in the context of COVID-19: interim guidance" was published 19 March 2020. This guidance is under review and is pending integration into "Infection prevention and control in the context of coronavirus disease (COVID-19): A living guideline".

Safe dead body management

The most up-to-date guidance for "Infection prevention and control for the safe management of a dead body in the context of <u>COVID-19</u>: interim guidance" was published 4 September 2020. This guidance is under review and is pending integration into "Infection prevention and control in the context of coronavirus disease (COVID-19): A living guideline".

Water, sanitation, hygiene, and waste management

The most up-to-date technical guidance for "<u>Water, sanitation, hygiene, and waste management for SARS-CoV-2, the virus that causes</u> <u>COVID-19</u>" was published 29 July 2020. This guidance is under review and is pending integration into "<u>Infection prevention and control</u> in the context of coronavirus disease (COVID-19): A living guideline".

Part 2: Community settings

Many of the existing technical guidance documents that will be integrated into this section are under review. Updated versions will be available in future versions. This section includes updated guidelines for mask use by the general public in community settings and mask use by children. Sections that are pending updates have links to the most recent iteration of relevant IPC guidance published online.

Introduction to public health and social measures

What are public health and social measures?

Public health and social measures (PHSMs) are being implemented across the world to suppress SARS-CoV-2 transmission and reduce mortality and morbidity from COVID-19. PHSMs include personal protective measures (e.g. physical distancing, avoiding crowded settings, hand hygiene, respiratory etiquette, mask-wearing); environmental measures (e.g. cleaning, disinfection, ventilation); surveillance and response measures (e.g. testing, genetic sequencing, contact tracing, isolation, and quarantine); physical distancing measures (e.g. regulating the number and flow of people attending gatherings, maintaining distance in public or workplaces, domestic movement restrictions); and international travel-related measures. In this context, it does not include medical countermeasures such as drug administration or vaccination. PHSMs act in concert, and a combination of measures is required to ensure adequate control. Measures should be implemented by the lowest administrative level for which situational assessment is possible and tailored to local settings and conditions. For more information, please refer to the *Considerations for implementing and adjusting public health and social measures in the context of COVID-19* [125].

Who are these recommendations intended for?

These guidelines are intended for policy and decision-makers, public health professionals and infection prevention and control professionals at national and facility levels.

Safe dead body management

The most up-to-date guidance for "Infection prevention and control for the safe management of a dead body in the context of <u>COVID-19</u>: interim guidance" was published 4 September 2020. This guidance is under review and is pending integration into "Infection prevention and control in the context of coronavirus disease (COVID-19): A living guideline".

Mask use

Mask management

For any type of mask, appropriate use, storage, 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 [52]. WHO provides the following guidance on the correct use of masks:

- Wash hands thoroughly 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, wash hands thoroughly.
- Remove the mask using the appropriate technique. Do not touch the front of the mask; rather, untie it from behind.
- Replace the mask as soon as it becomes damp with a new, clean and 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.
- Wash hands immediately after discarding a mask.
- Do not reuse single-use masks.
- 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.

• A mask should be changed to a clean mask at least once daily.

For more information on mask technical specifications, review the following technical document - "<u>Technical specifications of personal</u> protective equipment for COVID-19", published 13 November 2020

Mask use in the community

Strong recommendation for , Moderate certainty evidence



In settings where there is community or cluster transmission of SARS-CoV-2, irrespective of vaccination status or history of prior infection, wearing a well-fitting mask* that covers the nose and mouth is recommended for the general public when interacting with individuals who are not members of their household:

- in 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 metre can be maintained¹;
- in indoor settings that have adequate ventilation if physical distancing of at least 1 metre cannot be maintained*; or
- in outdoor settings where physical distancing of at least 1 metre cannot be maintained*.

*Mask types include:

- reusable, non-medical masks that comply with the <u>ASTM F3502</u> standard or <u>CEN Working Agreement 17553</u>, or a nonmedical mask meeting WHO essential parameters (see practical info for more information).;
- disposable medical masks, complying with medical mask standards EN 14683 Type I, ASTM F2100 Level 1, YY/T 0969, YY 0469 (or equivalent) if the availability of medical masks meeting minimum performance criteria for health workers has been assured**;
- if the above options are not available, other types of well-fitting non-medical masks including homemade multilayered masks^{***} are an acceptable option (according to local policies).

¹Physical distance should be increased beyond 1 metre whenever feasible.

Published 22 December 2021.

Practical Info

For information on assessing and improving indoor ventilation, please see WHO's Roadmap to improve and ensure good indoor ventilation in the context of COVID-19.

Practical considerations for policy-makers:

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

- reduced spread of potentially infectious aerosols or droplets from exhaled breath, including from infected people before they develop symptoms [63];
- encouraging concurrent transmission prevention behaviours such as washing hands and not touching the eyes, nose and mouth [64][65][66]; and
- preventing transmission of other respiratory illnesses such as tuberculosis and influenza and reducing the burden of these diseases during the pandemic [67].

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

- headache and/or breathing difficulties, depending on the type of mask used [68];
- development of facial skin lesions, irritant dermatitis or worsening acne when used frequently for long hours [69][70];
- difficulty with communicating clearly, especially for persons who are deaf or have poor hearing or use lip reading [71][72];
- poor compliance with mask-wearing, in particular by young children [73][74][75][76];
- waste management issues; improper mask disposal leading to increased litter in public places and environmental hazards [77]; and
- further disadvantages for, or difficulty wearing masks by, certain members of the population, especially: children; developmentally challenged people; those with mental illness or cognitive impairment; those with asthma, chronic respiratory or breathing problems; those who have had facial trauma or recent oral maxillofacial surgery; and those living in hot and humid environments [68][74].

Evidence To Decision

Benefits and harms

Substantial net benefits of the recommended alternative

The utilization of masks in community settings is likely associated with a decreased risk of SARS-CoV-2 infections compared with no mask-wearing. SARS-CoV-2 B.1.617.2 (Delta) variant has been reported to have increased transmissibility [?][54][55][56][57]; most GDG members, therefore, agreed that, in the context of the Delta variant, the benefits of mask-wearing in the community setting outweigh potential harms. Ecological studies have identified an association with decreased number of confirmed cases of COVID-19 and policies requiring the use of masks [58][59][60]. A cluster randomized controlled trial evaluating mask promotion (as an indirect public health intervention) found that in a country with low mask use, mask promotion increased mask use and decreased symptomatic SARS-CoV-2 seroprevalence [61]. Conversely, another randomized controlled trial found no statistical significance associated with surgical mask use and a reduced risk of SARS-CoV-2 [62]. The study provided an imprecise estimate for mask utilization verse no utilization; however, the study was not designed to evaluate the effectiveness of mask use for source control.

Many GDG members note that, even though the certainty of the evidence is moderate, there is a substantial need for WHO to produce cohesive and robust recommendations, as the net benefits of mask use by the general public outweigh the potential harms.

Certainty of the Evidence

Balance of desirable and undesirable outcomes.

Values and preferences

Discussions with stakeholders and IPC GDG members have indicated a general preference to favour mask use in community settings. Many GDG members note that, in the context of the Delta variant and other variants of concern, masking is a vital SARS-CoV-2 mitigation measure. Members expressed a need to document a clear opinion on the use of masks in community settings, given the impact of local and national values and preferences on IPC policies. Given the availability of masks, community masking is likely feasible.

Resources and other considerations

No important issues with the recommended alternative

Moderate

No substantial variability expected

Many GDG members noted the global supply chain for mask manufacturing has improved and would not pose a severe obstacle to community masking. The cost of both medical masks and non-medical (fabric) masks are relatively low, and do not pose a substantial barrier for low- and middle-income countries.

Gaps in knowledge and research needs

Investigations on the utilization of masks in the community setting are ongoing; however, published work has identified the need for continued research. Well conducted observational studies and/or randomized controlled trials exploring the use of masks versus no masks in various settings (e.g. indoor, outdoor, ventilation status, etc.) would further clarify outstanding inquiries concerning mask use in community settings. In addition, research investigating the use of masks (including type of mask and transmission scenarios) in the context of the Delta variant would provide powerful evidence for future recommendations. However, GDG members discussed the challenges associated with obtaining compelling evidence from a randomized controlled trial on behavioural interventions. Furthermore, with the availability of a SARS-CoV-2 inoculation, further research will be needed to reinforce the impact of vaccination on mask utilization in community settings.

Justification

GDG members were asked to evaluate the strength of the proposed recommendation (strong recommendation versus conditional recommendation). Based on the available evidence, the GRADE process and the Evidence to Decision framework, the IPC GDG agreed on a strong recommendation. The opinion of the GDG was solidified via an online survey, in which 82.1% (23/28) of GDG members voted for a strong recommendation and 17.9% (5/28) voted for a conditional recommendation.

Good practice statement



In settings where there is community or cluster transmission of SARS-CoV-2, policies should be developed, strengthened and implemented to encourage appropriate adherence to a comprehensive package of preventive measures to reduce transmission (ventilation, physical distance, hand hygiene, and respiratory etiquette) including in particular, mask adherence by the general public.

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Justification

GDG members were initially asked if WHO should develop a statement on the importance of mask-wearing and/or interventions to improve adherence to mask-wearing guidance; however, many members thought it was essential to consider the "bundle" of public health social measures that pertain to the general public. The above good practice statement was determined by an online vote, where 27 GDG members responded, with 55.6% (15) voting for the statement as mentioned above, while the remaining 44.4% (12) voted for slightly different wording for the good practice statement.

Implementation consideration

In areas with known or suspected sporadic transmission, or no documented transmission, WHO advise that decision-makers should apply a risk-based approach focusing on the following criteria when considering the use of masks for the general public:

- purpose of mask use;
- risk of exposure to SARS-CoV-2;
- vulnerability of the mask wearer/population;
- setting in which the population lives;
- feasibility;
- type of mask;
- vaccination coverage; and
- circulating variants of concern.

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Justification

GDG members noted the importance of including vaccination coverage and circulating variants of concern to the implementation considerations given the availability of vaccination and the current landscape of SARS-CoV-2 transmission.

In any transmission scenario, persons with any symptoms suggestive of COVID-19 should wear a medical mask and 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 wash hands thoroughly [78];
- follow all additional measures, in particular, respiratory hygiene, frequent hand washing and maintaining a physical distance of at least 1 metre from other persons [79].
- If a medical mask is not available for individuals with suspected or confirmed COVID-19, a fabric mask with fit, filtration and breathability assessed to meet WHO's essential parameters for non-medical masks 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 particles from the user [80][81]

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.

Extracted from the guidance titled "Mask use in the context of COVID-19", published 1 December 2020.

Evidence To Decision

Certainty of the Evidence

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 healthy people

in the community to prevent infection with respiratory viruses, including SARS-CoV-2 [19]. A large randomized communitybased 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 [62]. 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 involved healthcare workers and seven had community-based participants. The review concluded that wearing a mask may make little or no difference to the prevention of ILI (RR: 0.99; 95% Cl: 0.82–1.18) or laboratory-confirmed influenza (LCI) (RR: 0.91; 95% Cl: 0.66–1.26) [47]; 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 (odds ratio (OR): 0.21; CI 0.06-0.79) [60]. 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 (adjusted odds ratio (aOR) 0.23; 95% CI 0.09-0.60). Several small observational studies with epidemiological data have reported an association between mask use by an infected person and the prevention of onwards transmission of SARS-CoV-2 infection in public settings [58][82][83][84][85].

A number of studies, some peer-reviewed but most published as pre-prints, reported a decline in the number of COVID-19 cases associated with face mask use by the public, using country- or region-level data [79][86][87][88][89][90] [91][92][93][94][31][95][168][96][97][98][99][100][101][102][103][104]. 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, ILI and human coronaviruses (not including COVID-19) provide evidence that the use of a medical mask can prevent the spread of infectious droplets from an asymptomatic infected person to someone else and potential contamination of the environment by these droplets [19]. 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 [47][109][110][111][112]. A meta-analysis of observational studies on infections due to beta coronaviruses, with the intrinsic biases of observational data, showed that the use of either disposable medical masks or reusable 12–16-layer cotton masks were associated with the protection of healthy individuals within households and among contacts of cases. 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 the risk of laboratory-confirmed influenza [113].

Values and preferences

In review

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.

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.

Extracted from the guidance titled "Mask use in the context of COVID-19", published 1 December 2020.

Practical Info

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 respiratory etiquette via coughing or sneezing into a bent elbow covering the mouth and nose, and then wash hands thoroughly).

Transmission scenario	Situations/settings (where)	Target population (who)	Mask type (which one)
	Indoor settings where ventilation is known to be poor or cannot be assessed or the ventilation system is not adequately maintained regardless of whether physical distancing of at least 1 metre can be maintained	The general population in public settings such as shops, shared workplaces, schools, churches, restaurants, gyms, etc. or in enclosed settings such as transportation	
In settings where there is known or suspected community or cluster transmission of SARS- CoV-2, irrespective of vaccination status	Indoor settings that have adequate ventilation** if physical distancing of at least 1 metre cannot be maintained	For households, in indoor settings, when there is a visitor who is not a member of the household	Non-medical mask
	Outdoor settings where physical distancing of at least 1 metre cannot be maintained	Individuals/people with a higher risk of severe complications from COVID-19	
	Settings where physical distancing of at least 1 metre cannot be maintained, and the individual is of increased risk of severe complications	Individuals/people with a higher risk of severe complications from COVID-19	Medical mask
Known or suspected poradic transmission or no documented SARS-CoV-2 transmission	Risk-based approach	General Population	Depends on purpose
Any transmission scenario	Any setting in the community	Anyone with suspected or confirmed COVID-19, regardless of whether they have symptoms or not. OR Anyone awaiting viral test results when in the presence of others	Medical mask

Mask use for those who are at higher risk of severe complications from COVID-19

Good practice statement



Individuals/people with a higher risk* of severe complications from COVID-19 should wear a medical mask where physical distancing of at least 1 metre cannot be maintained.

* High-risk populations are defined as: people aged \geq 60 years; or people with underlying comorbidities, such as cardiovascular disease or diabetes mellitus, chronic lung disease, cancer, cerebrovascular disease, immunosuppression, obesity or asthma.

Published 22 December 2021.

Justification

The decision to formalize the above statement as a good practice statement was reached through online voting. Thirty-one members responded; 19 (61.3%) voted to endorse the aforementioned statement as a good practice statement, and the remaining 12 (38.7%) members suggested that the statement should be considered an implementation consideration. Many GDG members noted that those at high risk of sequelae should use reputably manufactured masks, as there are discrepancies in the effective filtration, fit and breathability of non-medical masks, without quality control testing. GDG members thoroughly discussed advocating the use of medical masks for vulnerable populations, as they are intended for disposal after single use reducing both the risk of self-contamination and the eventual breakdown of effective filtration efficiency inherent with masks that are washed for reuse. GDG members indicated apprehension towards the statement, given concerns of excessive waste and environmental implications.

Type of mask used by the general public

Implementation consideration for policy-makers, when providing guidance, or setting standards for manufacturers on type of mask used by the general public

Implementation consideration

The following mask types are acceptable options for use by the general public:

- reusable non-medical masks that comply with standards*;
- disposable medical masks, if the availability of medical masks meeting minimum performance criteria for health workers has been assured^{**};
- if the above options are not available, other types of well-fitting non-medical masks*** are an acceptable option (according to local policies).

*Complying with the ASTM F3502 standard or CEN Working Agreement 17553, or a non-medical mask meeting WHO essential parameters (see practical info for more information).

**Complying with medical mask standards EN 14683 Type I, ASTM F2100 Level 1, YY/T 0969, YY 0469 (or equivalent).

***Including homemade multi-layered masks (see more info for more information).

Published 22 December 2021.

Practical Info

Table 2. Essential parameters (minimum and preferred thresholds) for manufactured non-medical mask

Essential Parameters	Minimum threshold	Preferred threshold
1. Filtration*		
1.1 Filtration efficiency	70% at 3 μm	>50% at 0.3 µm, without compromising breathability
1.2. Challenge particle	Solid: sodium chloride (NaCl), Talcum powder, Holi powder, dolomite, Polystyrene Latex spheres Liquid: DEHS Di-Ethyl-Hexyl-Sebacat, paraffin oil	Solid: sodium chloride (NaCl), Polystyrene Latex spheres
1.3. Particle size	Choose either size: 3 μ m, 1 μ m, or smaller	0.3 μm
2. Breathability		
2.1. Breathing resistance**	≤60 Pa/cm ²	Adult: ≤ 40 Pa/cm ² Children: ≤ 20 Pa/cm ²
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	Same as current requirements
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) OR Leakage ratio of ≥5
3.2. Sizing	Adult and child	Should cover from nose bridge to below the chin and cheeks on either side of the mouth Sizing for adults and children (6-9, 10-12, >12)
3.3 Strap strength		> 44.5 N

* Smaller particles may result in lower filtration.

** High resistance can cause bypass of the filtration layers of the mask. Unfiltered air will leak out the sides or around the nose on the path of least resistance.

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

Standards organizations' performance criteria

Manufacturers producing masks with consistent standardized performance can adhere to published, freely available guidance from several organizations including those from, ASTM International, 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.

Additional performance criteria:

- 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 workforce and adherence to UNICEF's Children's Rights and Business Principles are strongly encouraged.

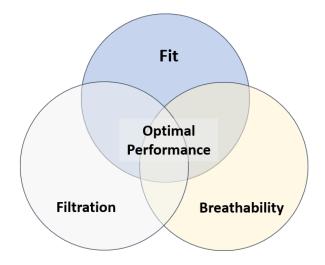


Figure 1. Illustration of the three essential parameters of filtration, breathability and fit.

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 2). Depending on the fabrics used, filtration and breathability can complement or work against each other. 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. 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 reuse. Additionally, elastic fabrics are sensitive to washing at high temperatures and may therefore degrade over time.

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

Fit: shape and sizing

Fit is the third essential parameter, and takes into consideration coverage, seal, sizing and strap strength. Fit of masks is currently 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). Ideally, the mask should not have contact with the lips, unless hydrophobic fabrics are used in at least one layer of the mask [81]. Leaks where unfiltered air moves in and out of the mask may be attributed to the size and shape of the mask [82].

Optional parameters for consideration

If reusable:

- the biodegradability;
- antimicrobial performance (where applicable); and
- chemical safety (see Practical Info section).

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 non-medical masks have antimicrobial performance. Antimicrobial performance may be the result of 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 not take full effect until after a contact time of 2–24 hours, depending on the standard. The standards have generally been used for athletic apparel and to 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 made, manufacturers should specify the standard that 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 United States Environmental Protection Agency (EPA), indicate that textile additives are safe and added at safe levels.

Justification

GDG members agreed with the notion of standardizing recommendations for the utilization and specifications of masks for the general public. Many GDG members expressed concern of being overly prescriptive while the current state of evidence on the quality and effectiveness of non-medical masks continues to evolve as this may limit the social enterprise of homemade mask production, a standard practice in many WHO member state countries. However, GDG members agreed with laboratory evidence confirming that non-medical masks without standardized quality control processes can have large variabilities in their key parameters (*see Practical info section for information on essential parameters for non-medical masks*). Members also conveyed the importance of specifying the use of well-fitting masks, as the fit is an essential parameter for effective source control and protection. In addition, GDG members spoke of the potential harms associated with limited resources and lack of personnel to test the essential parameters of masks in various low-income settings, along with expressing concerns regarding waste disposal.

Adaptation

Homemade non-medical masks made from 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) [83].

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 [81];

2. a middle hydrophobic layer of synthetic breathable non-woven material (spunbond polypropylene, polyester and polyaramid), which may enhance filtration, prevent permeation of droplets or retain droplets [81][84]; and

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 [81].

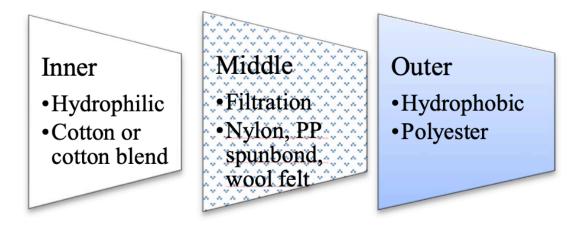
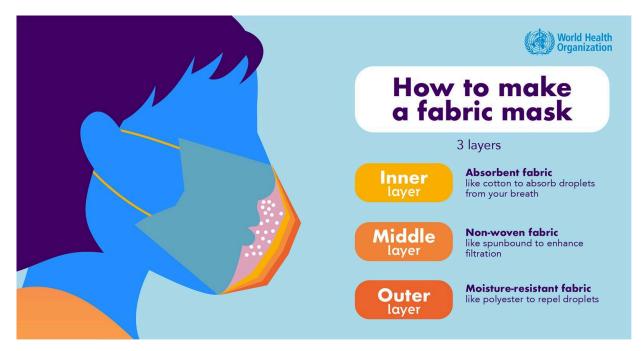


Figure 1. Non-medical mask construction using breathable fabrics such as cotton, cotton blends, polyesters, nylon and polypropylene spunbond that are breathable may impart adequate filtration performance when layered. Single- or double-layer combinations of advanced materials may be used if they meet performance requirements [85]



Although a minimum of three layers is recommended for non-medical masks for the most common fabric used, single, double or other layered combinations of advanced materials may be used if they meet performance requirements.

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 [86]. Fabrics with higher thread count offer improved filtration performance [87]. 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 [88].

Exhalation valves on respirators and non-medical masks are discouraged as they do not allow for adequate source control from the wearer. Exhalation valves permit bypass of the filtration layers when the wearer exhales, potentially allowing pass-through of infectious particles.

Extracted from the guidance titled "Mask use in the context of COVID-19", published 1 December 2020.

Use of face shields for respiratory protects and/or source control

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 protection and/or source control. Current laboratory testing standards only assess face shields for their ability to provide eye protection from chemical splashes [119].

Extracted from the guidance titled "Mask use in the context of COVID-19", published 1 December 2020.

Practical Info

In the context of non-availability or difficulties wearing a non-medical mask (e.g. on people with cognitive, respiratory or hearing impairments), face shields may be considered as an alternative, noting that they are inferior to masks with respect to

respiratory particle transmission and prevention. If face shields are to be used, ensure proper design to cover the sides of the face and below the chin.

Mask use during physical activity

WHO advises that people should not wear masks during vigorous-intensity physical activity [114] because masks may reduce the ability to breathe comfortably. The most important preventive measure is to maintain physical distancing of at least 1 metre and to ensure good ventilation when exercising.

Extracted from the guidance titled "Mask use in the context of COVID-19", published 1 December 2020.

Practical Info

When community or cluster transmission of SARS-CoV-2 is experienced in local context, particular attention should be paid to ensuring physical distancing of at least 1 metre between persons outside of their households and frequent cleaning and disinfection of any public environment in which exercise is performed, especially high-touch surfaces. As well, if the activity takes place indoors, adequate ventilation (e.g. 10 litres of air exchange per second, per person occupying an indoor space) should be ensured at all times through natural ventilation or a properly functioning and maintained ventilation system [118]. If all the above measures cannot be ensured, consider temporary closure of public indoor exercise facilities (e.g. gyms).



Wearing a mask during vigorous physical activity may reduce the ability to breathe comfortably, and wet or damp masks lose their effectiveness. Always follow the facility guidelines.

Evidence To Decision

Benefits and harms

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 [115][116][117][120][121][122]. The most significant impacts have been consistently associated with the use of respirators and in people with underlying obstructive airway pulmonary diseases such as asthma and chronic obstructive pulmonary disease (COPD), especially when the condition is moderate to severe [117]. Facial microclimate changes with increased temperature, humidity and perceptions of dyspnoea were also reported in some studies on the use of masks during exercise [116][123]. A recent review found negligible evidence of any negative effects of mask use during exercise but noted concern for individuals with severe cardiopulmonary disease [124].

Values and preferences

Mask use by children

Guiding Principles

Given the limited evidence on the use of masks by children in the context of COVID-19, including limited evidence on transmission of SARS-CoV-2 in children at specific ages, policy formulation by national authorities should be guided by the following overarching principles.:

- Do no harm: the best interest, health and well-being of the child should be prioritized.
- The application of these guidelines should not impact development or learning outcomes, including access to education.
- The guidelines should consider the feasibility of implementing recommendations in different social, cultural and geographic contexts, including limited resource and humanitarian settings, and among children with disabilities or specific health conditions.
- Any recommendation for mask use for children should encompass needed flexibility to enable children to maintain their rights to play, to education and ability to engage in everyday activities [8].
- National policies on the use of masks for children should be adapted based on social, cultural and environmental considerations, including in settings with limited resources and humanitarian settings.

Introduction

Introduction

WHO guidance on the use of masks for children in the community was first published in August 2020 as an annex to the document <u>Mask use in the context of COVID-19</u> [3][5]. In December 2021, it was incorporated into the online version 1.0 of the WHO IPC COVID-19 living guideline published using the MAGICapp platform [2]. This updated version includes new recommendations for mask use by children of different ages, accommodations for children living with disabilities and updated implementation considerations, including for school settings.

WHO and UNICEF jointly developed this guideline. A guideline development group, the WHO-UNICEF GDG for the use of masks by children in the context of COVID-19, was established. Details on the composition of the GDG and the retrieval, synthesis and assessment of evidence can be found in the methods and acknowledgements sections of the document.

When aiming to reduce community transmission and mitigate the impact of COVID-19 outbreaks on health and social services, policies developed for mask use should be included as one element of a comprehensive package of preventive measures to reduce transmission (ventilation, physical distance, hand hygiene, and respiratory etiquette). In any decision being made related to the use of masks by children, the guiding principles for the best interest of children and a "do no harm" approach should prevail.

Each country is facing a different situation in the pandemic depending on a number of factors including the intensity of SARS-CoV-2 circulation, amount of population level immunity, capacities to respond and agility to adjust measures. As the pandemic continues and the virus evolves, changes in transmission intensity, the circulating variant of concern, and the capacities for health systems to respond based on the situation will result in need for policy adjustments related to IPC and PHSM. National policies should be evidence based, agile and adjusted as needed taking into consideration these and other factors. Countries should conduct an assessment of the transmission scenario and the health system response capacity – and assign a situational level to a geographic area. The assessment should examine quantitative and qualitative information from available sources, and can refer to the situational and community transmission (CT) Levels CT1-CT4 as described in, *Considerations for implementing and adjusting public health and social measures in the context of COVID-19* [125]. Additional factors, including population level immunity, will need to be taken into account when setting national and sub-national policies, as outlined above.

This section of the guideline focuses on the use of masks in children in the context of COVID-19 in community settings, such as schools and recreational areas. Children spend a considerable portion of their time in schools, which may have indoor and outdoor areas, and there are existing specific guidance documents available that address school-related public health measures.

Recommendations on types of masks can be found in the mask use in community settings section of the document.

There are five statements for the use of masks by children, including three recommendations by <u>age group</u> (\leq 5, <u>6-11</u>, <u>12 and</u> <u>over</u>), and <u>two good practice statements</u>.

Evaluation

Monitoring and evaluation of the impact of mask use by children

When implementing policies for mask-wearing for children, key information should be collected on a regular basis and where possible utilized to inform future policy. Monitoring and evaluation should be established at the onset and include:

- indicators that measure the impact on the child's health, including mental health
- reduction in transmission of SARS-CoV-2 at community and health facility level
- motivators and barriers to mask-wearing
- impacts on children's development and learning and school attendance
- ability of children to express themselves
- impact on children with developmental delays, health conditions and disabilities or other vulnerabilities
- experiences of children, their needs, perspectives and expectations.

Data should be used to inform policy updates and strategies on:

• communication

- training and support to teachers, educators, parents and children
- distribution of materials that empower children to use masks appropriately
- indicators to lift mask requirements for children.

Analyses should include sex, age and physical, social and economic stratification to ensure that policy implementation reduces health and social inequities.

Research Needs

There are significant limitations in the available evidence on benefits and harms of mask use in children including a lack of evidence on important developmental and long-term outcomes. Future studies should consider evaluation of the effectiveness of mask use by children of different age groups in reducing transmission of SARS-CoV-2, impacts on learning and development, psychological health and quality of life. While RCTs would be ideal, well conducted observational studies that control for other infection control measures, exposures and other confounders would also be informative.

SARS-CoV-2 Transmission in Children

Disease severity and mortality due to COVID-19 including infections with VOCs increases with age, and children tend to present with a milder course of illness than older population groups [126][127][128]. The transmission characteristics among children need to be interpreted in light of new VOC's, in particular, Omicron; vaccination strategies and age-specific vaccination coverage and changes in mixing patterns as a result of the implementation of PHSM. Evidence early in the pandemic from household, serological and infection prevalence studies suggested that young children may be at lower risk of infection than adolescents and adults and potentially transmit SARS-CoV-2

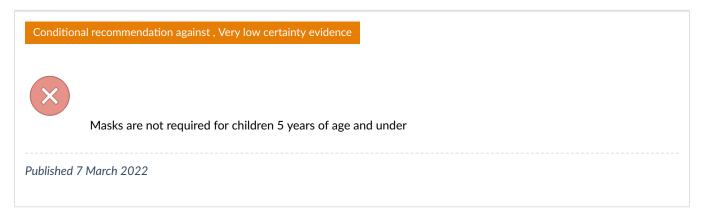
less [126][128][129][130][131][132][133][134][135][136][137][138][139]. However, more recent epidemiological trends seem to indicate that children contribute to transmission similarly to adults, due to their social mixing patterns in some settings and in light of emerging VOC's such as Omicron [1][140][141][142][143][144]. This has been well documented in settings where extensive community testing has been undertaken (e.g. the REACT study in the United Kingdom) [145]. The European Centre for Disease Prevention and Control (ECDC) reported the age distribution of COVID-19 among children, as of July 2021, in the European Union (EU), European Economic Area (EEA) and the United Kingdom. They found that children made up an increasing proportion of weekly case numbers, with the most noticeable increase among those aged 5-11 years. These findings should be interpreted in light of the proportion of vaccinated adolescents, social mixing patterns by age and adults in those countries at the time [128][140]

Studies from high-income countries have also shown that in some settings, children tend to have more extensive social mixing patterns than adults and consequently more contacts than adults [142]. Thus even though the propensity to transmit may be lower for children, in some settings, they may be contributors to transmission as a consequence of their social mixing patterns, especially if PHSMs have been relaxed [1][131][132][139][146][147][148][149].

The Omicron variant has resulted in very high levels of incidence in most countries, across all age groups, with higher incidence levels than observed earlier in the pandemic [149]. There is currently limited evidence to suggest a difference in transmission risk of Omicron according to age group, other than that modulated by vaccination, but more data are required. In the context of the Delta and Omicron VOC increased transmission and growth rates have been documented [149].

Age specific recommendations

Recommendation for children 5 years of age and under



Practical Info

Implementation considerations

As mask use is not recommended in this age group, IPC and public health and social measures should be prioritized to minimize the risk of SARS-CoV-2 transmission.

- Adults and staff working with children should follow national guidelines for vaccination against COVID-19.
- Adequate ventilation* should be in place and maintained in settings where children are congregating or cared for.
- Adults and staff working with children should wear masks (see WHO recommendations for mask use in adults).
- Adequate sanitation and hygiene requirements and a regimen for environmental cleaning and disinfection should be in place in settings where children congregate or are cared for.
- Children should be taught to perform frequent hand hygiene and respect respiratory etiquette using an age-appropriate approach and materials.

In the event that policymakers decide to adjust the age range for mask recommendations (i.e. children under the age of five years would utilize a mask), relevant settings should have adequate human resources to ensure safe mask use. Adoption of the mask recommendation should include appropriate and consistent supervision by an adult and the ability to ensure mask compliance and adherence, especially if mask-wearing is expected for an extended period. The guiding principles of the best interest of children and a "do no harm" approach should prevail.

*For adequate ventilation refer to regional or national institutions or heating, refrigerating and air-conditioning societies implementing ventilation requirements. If recommendations are not in place, a recommended ventilation rate of 10l/s/person should be met (except in healthcare facilities which have specific requirements). For more information, consult <u>Roadmap to improve and</u> ensure good indoor ventilation in the context of COVID-19 [6].

Evidence To Decision

Benefits and harms

Uncertain benefits and harms

The wearing of a well-fitted mask is associated with a decrease in SARS-CoV-2 transmission in the community and provides protective benefits to the individual [18][19][20]. A systematic review on the clinical effectiveness of masks included two RCT and three observational studies in adult populations, which provided some evidence that mask-wearing in the community is associated with decreased risk of COVID-19 infection [19][20][58][59][60][61][62]. The systematic review found inconsistent effects of masks on reducing the risk of influenza-like illness (ILI) in community settings, although a cluster RCT found that hand hygiene and face masks may prevent household transmission of influenza if applied early after symptom onset in an index case [73]. A systematic review evaluating 21 ecological studies in adults reports that mask use is associated with reducing mortality, the incidence of disease, and hospitalization in the

community in the context of COVID-19 [18]. Studies from the United States, Spain, Germany and the United Kingdom looked at the effectiveness of mask use in ages 4-18; and eleven studies reported an association between mask use and decreased COVID-19 incidence in children [150][151][152][153][154][155][156][157][158][159][160]., These studies were generally observational and ecological with important shortcomings including limited reporting of other infection control measures and exposures.

The systematic review did not find evidence of serious harms with masks in adults in community settings, although bothersome harms were common. Evidence on potential harms, specifically in children aged five years or younger, is limited. Parents who completed an online survey conducted in France reported behavioural and mood changes (e.g. anxiety, sadness, anguish), headaches, speaking difficulties and breathing discomfort attributed to mask-wearing [161]. There is currently no evidence on the long-term impact of mask use on the physical and mental health, development and wellbeing of children.

Given the lack of direct evidence in this age group, evidence was extrapolated from adults. The GDG found that evidence from adults is less applicable (more indirect) to children five and under compared to older children due to lower COVID-19 incidence and severity. Even if masks are associated with the same relative reduction in COVID-19 incidence in children five and under as in adults, the absolute benefits would be smaller due to lower incidence and severity. Furthermore, benefits in children five and under are likely further reduced due to suboptimal adherence.

Additionally, despite the limited/lack of evidence on harms in this age group, there were concerns regarding potential greater harms with regard to childhood development. The GDG, therefore, determined that given the above information, the benefits of mask-wearing in children aged five and under are trivial to none and do not outweigh potential harms.

Certainty of the Evidence

The evidence certainty is very low due to the limited evidence in this age group and lower applicability of evidence in adults to this age group compared to older children.

Values and preferences

The GDG determined that given the close balance of benefits and harms, different preferences (e.g. focusing on potential benefits in terms of reducing infection risk versus focusing on potential developmental harms) could change the decision. Therefore, variability in preferences/values could impact judgments about mask use in this population.

Resources and other considerations

Given that masks are not recommended for this age group, minimal resource implications are anticipated.

Equity

Effect on equity variable

Risk factors that increase the likelihood of contracting COVID-19 include race, ethnicity, and community-level socioeconomic status [162][163].

The GDG assessed effects on equity as uncertain or variable, because masks are not required in this age group, but would depend upon how mask use is implemented. If masks are widely available, using masks could improve equity by reducing the risk of transmission overall, including among socioeconomically disadvantaged groups more impacted by COVID-19. However, there is a need to ensure that lack of access to masks does not negatively impact children (which would decrease equity) and that certain populations (such as disabled individuals) are not adversely impacted.

Substantial variability is expected or uncertain

No important issues with the recommended alternative

Very low

Acceptability

There is a significant lack of evidence as to the acceptability of mask use for children in this age group across different contexts[164][150]. Additionally, despite limited evidence on harms in this age group, there are concerns regarding potential greater harms with regard to childhood development.

The GDG felt that the acceptability of mask use in children under five years of age is variable.

Feasibility

The GDG judged that use of masks is less feasible in this age group since it requires more supervision and children may have more difficulty wearing masks for prolonged periods and during certain activities.

Justification

The GDG determined that benefits of masks in children <5 years did not outweigh harms. This was based on the low certainty evidence and the lower incidence (and severity) of SARS-CoV-2 transmission in this age group relative to older children and adults. The GDG also considered the low acceptability and preference for mask use and agreed that a recommendation for the use of masks for this age group was not appropriate.

Decisions for children under the age of five years to wear masks may be informed by factors such as contact with high-risk individuals, local incidence of COVID-19, ability to adhere to and tolerate mask-wearing, local vaccination rates and parental preferences. There was agreement among the GDG members that in settings where children of this age group are congregating – for example, childcare settings – it is important to adhere to PHSM and IPC measures including adequate ventilation, hand hygiene and environmental hygiene measures, regardless of whether or not masks are used.

Recommendation for children 6 - 11 years of age

\checkmark

In areas where there is known or suspected community transmission* of SARS-CoV- 2, masks are recommended for use in children ages 6-11 years in the following settings:

- in 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 metre can be maintained,^{***}
- in indoor settings that have adequate ventilation** if physical distancing of at least 1 metre cannot be maintained***.

* Details on the levels of community transmission (CT1-CT4) can be found in <u>Considerations for implementing and adjusting</u> <u>public health and social measures in the context of COVID-19</u> [125].Countries should regularly assess the intensity of spread and health systems capacities at the most localized levels possible.

**For adequate ventilation refer to regional or national institutions or heating, refrigerating and air-conditioning societies implementing ventilation requirements. If regulations are not in place, a recommended ventilation rate of 10l/s/person should be met (except in healthcare facilities which have specific requirements). For more information, consult <u>Roadmap to improve and ensure good indoor ventilation in the context of COVID-1</u>9 [6].

***Physical distance should be increased beyond 1 metre whenever feasible.

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Implementation considerations

Countries should regularly assess the intensity of spread and health systems capacities at the most localized levels possible. The assessment should examine the quantitative and qualitative information from available sources and can refer to the situational level (S0-S4) and community transmission (CT) Levels CT1-CT4 as described in <u>Considerations for implementing and adjusting public health and social measures in the context of COVID-19</u> [125] Additional factors, including population level immunity, will need to be taken into account when setting national and sub-national policies.

Policy and decision-makers are encouraged to ensure the following considerations are addressed when implementing the use of masks in this age group.

- Factors that can influence the decision on implementing the use of masks include the age range in this group, the impact on education and development, routine activities, equity and the general health and wellbeing of children.
- Masks should be made accessible (free of charge) to children in schools, health care settings and any setting where they congregate (e.g. recreational areas), to ensure all children including those living in households or geographic areas with social vulnerabilities and limited resources have equitable access. No child should be denied access to these activities for not wearing a mask.
- Efforts should be made to accommodate children who do not have access to masks or are unable to tolerate a mask so they can participate in activities involving face-to-face gatherings. No child should be denied access to these activities for not wearing a mask.
- Routine mask breaks should be implemented when children are expected to wear masks for a longer duration.
- The child's capacity to adhere to correct mask use and availability of appropriate supervision should be addressed, especially in younger children within this age group.

- Age-appropriate communication should aim to help the child understand the purpose and proper use of mask-wearing.
- The design of masks for children should take into consideration the safety and overall quality of the material and ensure a proper fit without compromising breathability, comfort and child-friendliness (appropriate size, colours, patterns).
- Key stakeholders should develop and implement strategies for ensuring that each reusable mask is worn by one child and stored safely, for disposal of soiled masks (e.g. in dedicated bags or containers) and addressing the need for masks to be changed when soiled or wet.
- The use of masks is part of a comprehensive package of preventive measures to reduce transmission including ventilation, physical distance, hand hygiene and respiratory etiquette.

Evidence To Decision

Benefits and harms

Substantial net benefits of the recommended alternative

The wearing of a well-fitted mask is associated with a decrease in SARS-CoV-2 transmission in the community and provides protective benefits to the individual [18][19][20]. A systematic review on the clinical effectiveness of masks included two RCT and three observational studies in adult populations that provided some evidence that mask-wearing in the community is associated with decreased risk of COVID-19 infection [19][20]. The systematic review found inconsistent effects of masks on reducing the risk of ILI in community settings, though a cluster RCT found that hand hygiene and face masks may prevent household transmission of influenza if applied early after symptom onset in an index case [73]. A systematic review evaluating 21 ecological studies in adults report that mask use is associated with reducing mortality, the incidence of disease, and hospitalization in the community [18]. Studies from the United States, Spain, Germany and the United Kingdom looked at the effectiveness of mask use in ages 4-18. Ten studies reported an association between mask use and decreased COVID-19 incidence in children. However, these studies were generally observational and ecological with several limitations, including limited reporting of other control measures [151][152][153][154][155][156][157][158][159][160]. Furthermore, two studies of influenza (one RCT and one observational study) found a reduced incidence with mask-wearing in households and school settings [73][76].

The systematic review did not find evidence of serious harms with masks in adults in community settings, although bothersome harms were common. Evidence on potential harms, specifically in children aged 6-11, is limited. Parents who completed an online survey conducted in France - among whom only 9% had children over the age of 11-reported behavioural and mood changes (e.g. anxiety, sadness, anguish), headaches, speaking difficulties and breathing discomfort attributed with mask-wearing [161]. There is currently no evidence on the long-term impact of mask use on the physical and mental health, development and wellbeing of children.

The GDG previously determined that in adults, mask use in community settings is likely associated with a decreased risk of SARS-CoV-2 infections compared with no mask-wearing. The evidence is indirect since it is from adults. Emerging variants such as SARS-CoV-2 B.1.617.2 (Delta) and SARS-CoV-2 B.1.1.529 (Omicron) have been reported to have increased transmissibility [1]. The GDG judged that the benefits in this group are smaller than in adolescents 12 years and older, given lower incidence/severity and reduced adherence (at least in the younger children in this age range).

Evidence on the harms in this age group is also limited. An online survey conducted in France amongst parents of children in a wide age range (<6 years to >11 years) found that parents attributed behavioural change and mood changes (e.g. anxiety, sadness, anguish) headaches, speaking difficulties and breathing discomfort to mask-wearing [161]. However, another study in the United States of America found no apparent adverse biological effects (e.g. impacts on memory, heart rate, oxygen saturation, and emotional state) after mask wearing for at least 30 minutes in elementary school children [165]. There is currently no evidence on the long-term impact of mask use on the physical and mental health, development and wellbeing of children.

The evidence is indirect since it is from adults; the GDG judged that the benefits in this age group are smaller than in adolescents under 12, given lower incidence/severity and reduced adherence (at least in younger children in this age range). Therefore the GDG judged that the benefits of mask-wearing slightly outweigh the harms. Benefits are likely to be larger in situations in which the risk of infection are higher, e.g. poor ventilation and/or unable to physical distance.

Certainty of the Evidence

There is limited evidence on the benefits and harms of mask-wearing in this age group. Although ecological studies that include children aged 4-18 years have reported an association between mask mandates and a reduced incidence of infection these studies were judged to be low quality, with few studies available from low and middle-income countries [151][152][153][154][155][156][158][159][160][168][169]. Even though this evidence is largely indirect, it was judged by the GDG to have applicability, especially to older children in this group.

Values and preferences

Substantial variability is expected or uncertain

Low

Substantial variability in preferences, ideas and values is expected regarding the potential outcomes of mask use (prevention of SARS-CoV-2 infection, side effects). Such differences could have an impact on the decision to use masks in this age group.

The GDG determined that given the close balance of benefits and harms, different preferences (e.g., focusing on potential benefits in terms of reducing infection risk versus focusing on potential harms.) could change the decision. Consequently variability in preferences/values could impact judgments about mask use in this population.

Resources and other considerations

No important issues with the recommended alternative

There is no formal data available on costs. Given the widespread availability and relatively low costs of non-medical and medical masks, the GDG judged costs and resource availably to be low.

Equity

Effect on equity variable

Risk factors that increase the likelihood of contracting COVID-19 include race, ethnicity, and community-level socioeconomic status [162][163].

The GDG assessed effects on equity as uncertain or variable as it depends on mask use is implemented. If masks are widely available using masks could improve equity by reducing the risk of transmission overall, including among socioeconomically disadvantaged groups more impacted by COVID-19. However, there is a need to ensure that lack of access to masks does not negatively impact children (which would decrease equity) and that certain populations (disabled individuals) are not adversely impacted.

Acceptability

The limited evidence available indicates variability in the acceptance of masks in children aged 6 to 11. One online study found that parents were generally opposed to children between the ages of 6-10 wearing masks, especially in school settings. Other studies reported that children in this age group demonstrated good adherence to mask-wearing, in particular in school settings [150][158][166].

The GDG decided to make a conditional recommendation despite the low certainty evidence because the benefits of mask-wearing – reduction of SARS-CoV-2 transmission and access to schools – outweigh potential harms, and preferences and values and acceptability generally all favour mask-wearing.

Feasibility

Adherence is generally feasible in this age group, though there may be some issues in younger children within this

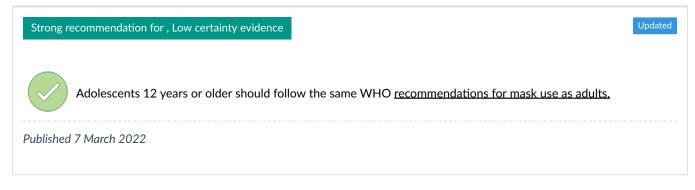
range [150][167].

Justification

Although there may be a net benefit in mask wearing, this was judged to be small. After reviewing the limited evidence available on the effectiveness of mask use in this age group, a survey was completed by GDG members, among whom 80% voted in favour of a conditional recommendation for mask use. Other factors informing the conditional recommendation were low certainty of evidence, variability in preferences and values that could impact decisions and some variability in acceptability and feasibility.

Settings in which the recommendation applies were also discussed, and members voted 70% in favour of applying the recommendation to indoor settings where ventilation is known to be poor or cannot be assessed or the ventilation system is not adequate and where a distance of at least 1 metre cannot be maintained. The GDG acknowledged the importance of the guiding principles noted earlier, including the right to play and the importance of children continuing to attend school in the context of the COVID-19 pandemic.

Recommendation for adolescents 12 years of age or older



Practical Info

Implementation consideration

Policy and decision-makers are encouraged to ensure the following considerations are addressed when implementing the use of masks in this age group, irrespective of vaccination status.

- Even where national guidelines apply, additional considerations and adaptations for special settings such as schools, during sports or for children with disabilities or underlying medical conditions will need to be specified.
- Masks should be made accessible free of charge to children in schools, health care settings and any setting where they
 congregate (such as recreational areas) to ensure all children including those living in households or geographic areas
 with social vulnerabilities and limited resources have equitable access. No child should be denied access to these
 activities for not wearing a mask.
- Efforts should be made to accommodate children who do not have access to masks or are unable to tolerate a mask so they can participate in activities involving face-to-face gatherings. No child should be denied access to these activities for not wearing a mask.
- Routine mask breaks should be implemented when children are expected to wear masks for a longer duration.
- Age-appropriate communication should aim to help the child understand the purpose and proper use of mask-wearing.
- Key stakeholders should develop and implement strategies for ensuring each reusable mask is worn by one child and stored safely, for disposal of soiled masks (e.g. in dedicated bags or containers) and for addressing the need for masks to be changed when soiled or wet.
- The use of masks is part of a comprehensive package of preventive measures to reduce transmission, including ventilation, physical distance, hand hygiene and respiratory etiquette.

Evidence To Decision

Benefits and harms

Small net benefit, or little difference between alternatives

The wearing of a well-fitted mask is associated with a decrease in SARS-CoV-2 transmission in the community and provides protective benefits to the individual [18][19][20]. A systematic review on the clinical effectiveness of masks included two RCT and three observational studies in adult populations that provided some evidence that mask-wearing in the community is associated with decreased risk of COVID-19 infection [19][20]. The systematic review found inconsistent effects of masks on reducing the risk of ILI in community settings, though a cluster RCT found that hand hygiene and face masks may prevent household transmission of influenza if applied early after symptom onset in an index case [73].

A systematic review evaluating 21 ecological studies reports that mask use is associated with reducing mortality, the incidence of disease, and hospitalization in the community [18]. Studies from the United States, Spain, Germany and the United Kingdom looked at the effectiveness of mask use in ages 4-18; twelve studies reported an association between mask use and decreased COVID-19 incidence [151][152][153][154][155][156][157][158][159][160][168][169]. However, these studies were generally observational and ecological with important shortcomings including limited reporting of other infection control measures and exposures.

The systematic review did not find evidence of serious harms with masks in adults in community settings, although bothersome harms were common. Evidence on potential harms specifically in adolescents 12-18 years of age is limited. Parents who completed an online survey conducted in France-among whom only 9% had children over the age of 11-reported behavioural and mood changes (e.g. anxiety, sadness, anguish), headaches, speaking difficulties and breathing discomfort attributed with mask-wearing [161].

The GDG previously determined that in adults, the use of masks in community settings is likely associated with a decreased risk of SARS-CoV-2 infections compared with no mask-wearing. The GDG found that evidence on the use of masks in community settings in adults is likely applicable to adolescents 12 and older due to the similarity in the incidence of SARS-CoV-2 infection (compared with young adults) and ability to adhere to mask-wearing. Emerging variants such as SARS-CoV-2 B.1.617.2 (Delta) and SARS-CoV-2 B.1.1.529 (Omicron) have been reported to have increased transmissibility [1].

The GDG judged the benefits, such as reduced transmission and facilitating increased access to schools/in-person learning, in adolescents to be small but agreed that in the context of the Delta and Omicron variants, the benefits of mask-wearing in the community setting outweigh potential harms.

Certainty of the Evidence

There is limited evidence on the benefits and harms of mask-wearing in this age group. Although ecological studies that include children aged 4-18 years have reported an association between mask mandates and a reduced incidence of infection these studies were judged to be low quality with few studies available from low and middle-income countries [151][152][153][154][155][156][157][158][159][160][168][169]. Evidence on the effectiveness of masks in adolescents can also be extrapolated from adults. Even though this evidence is indirect, it was judged by the GDG to be more applicable to this age group due to the similarity in incidence and severity of SARS-CoV-2 infection in young adults and adolescents.

Values and preferences

No substantial variability expected

Low

There is limited data available on adolescents' perception of the value and benefits or harms of wearing masks. Some studies conducted in European settings looking at parental perceptions, showing mixed results but generally favouring mask use in children over the age of 12 [166][170][171]. Given the potential benefits of masks for preventing infections and considering the presence of bothersome but non-serious harms, the GDG determined that differences in values/ preference regarding outcomes would not impact the decision to wear masks. This supports a strong recommendation,

despite the low certainty of evidence.

Resources and other considerations

No important issues with the recommended alternative

There is no formal data available on costs. Given the widespread availability and relatively low costs non-medical and medical masks, the GDG judged the impact of costs and resource availably to be low.

Equity

Important issues, or potential issues not investigated

Risk factors that increase the likelihood of contracting COVID-19 include race, ethnicity, and community-level low socioeconomic status [162][163].

The GDG assessed effects on equity as uncertain or variable as it depends on how mask use is implemented. If masks are widely available using masks could improve equity by reducing the risk of transmission overall, including among socioeconomically disadvantaged groups more impacted by COVID-19. However, there is a need to ensure that lack of access to masks does not negatively impact children (which would decrease equity) and that certain populations (such as disabled individuals) are not adversely impacted.

Acceptability

No important issues with the recommended alternative

This recommendation was assessed by the GDG as likely acceptable in this age group. Studies on the perception of the effectiveness of mask use are limited and generally focused on European countries for children over the age of 10. The GDG considered the limited evidence and discussed knowledge of practice in their respective countries, including the evolution of acceptance of mask use as the pandemic has continued and the emergence of VOC. The GDG agreed that for children over the age of 10mask-wearing was generally regarded as useful [166][170][171].

Feasibility

No important issues with the recommended alternative

GDG members noted that masks are widely recommended and used in many contexts throughout the world in this age group. The feasibility of implementing this recommendation was judged to be acceptable and feasible given low concerns about tolerance and likely higher adherence to mask-wearing in older age groups [150].

Justification

The GDG considered the low certainty of evidence and, although the majority of the evidence was in the adult population, felt it was reasonable to extrapolate from (young) adults. The GDG noted that the benefits of mask use, such as potential reduction in transmission and ability to keep schools functioning, outweighed any potential bothersome harms and considered other factors (not preference-sensitive, low costs, acceptability, feasibility) and believed that this supported a strong recommendation.

Special populations

Good practice statement



Children with cognitive or respiratory impairments, developmental disorders, disabilities^{*} or other specific health conditions who experience difficulties wearing a mask or have health conditions that interfere with mask-wearing should not be required to wear a mask.

* According to the Convention on the Rights of persons with disabilities, children with disabilities "include those who have long-term physical, mental, intellectual or sensory impairments which in interaction with various barriers may hinder their full and effective participation in society on an equal basis" [172].

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Practical Info

Implementation consideration

- The individual decision for a child to wear a mask should be discussed in consultation with the child's medical provider when possible.
- A safe environment should be created for children who are not able to tolerate a mask, including requirements for caregivers, teachers or other adults interacting with the child to wear a mask when interacting with the child and to be vaccinated against COVID-19 according to national vaccination policies.
- The use of masks with a transparent component may be considered for children with hearing impairment and people who interact with them, where available. These masks should meet approved regulatory standards, if available.

Justification

The GDG acknowledged that children with several health conditions may experience difficulties or harm while wearing a mask. Despite little direct evidence but considering equity and ethical issues, the GDG determined that a good practice statement was justified.

Good practice statement

The use of a medical mask is recommended for children with a higher risk* of severe complication from COVID-19 but should be assessed in consultation with the child's medical provider.

* This includes paediatric patients with underlying non-communicable diseases (for example, diabetes, cardiac disease, chronic lung disease, chronic kidney disease, immunosuppression, obesity, mental disorders and cancer) and those living with HIV [173].

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Justification

The GDG noted that in some low-resource settings there may be challenges for families to access medical masks or have access to a health care provider. It was proposed that in some circumstances it may be more appropriate for caregivers to wear a mask when interacting with the child. In conclusion, the GDG agreed that while there is no direct evidence, a good practice statement was justified due to this population's higher risk of COVID-19 complications.

Implementation considerations for use of masks in schools

Implementation consideration

Policy and decision-makers are encouraged to consider the following when implementing mask-wearing by children in school settings.

Updated

- Policies should be evidence based, agile and adjusted as needed taking into consideration factors such as changes in transmission intensity, the circulating variant of concern and the capacities for health systems to respond based on the situation.
- No child should be denied access to education because of mask-wearing or the lack of a mask due to low resources or unavailability.
- The views of teachers and educators on risks and time burden required to ensure mask adherence by children should be considered while ensuring that national policies are followed.
- Situations where wearing a mask can significantly interfere with the learning process or have a negative impact on critical school activities such as physical education, or sports and recreation (during which they may reduce ability to breathe comfortably) and meal programmes, require special consideration.
- Specific instructions and supplies should be provided for the availability, safe handling and storage of masks.
- A sufficient supply of appropriate masks should be ensured.
- Masks should not increase social inequalities in access to schools, especially for marginalized communities. No child should be denied access to these activities for not wearing a mask
- Basic water, sanitation, hygiene, ventilation, and space requirements should be met in the school building so that IPC and PHSMs can be implemented.
- If disposable masks are used, a system for waste management of used masks needs to be established to reduce the risk of contaminated masks being disposed of in the classroom and recreational or sports settings.

The recommendations for wearing masks in the different age groups of children in this document supersede those existing in other WHO documents published prior to this update. The following guidance documents can be used to inform policy making and programming for a comprehensive school safety strategy when re-opening or during normal operations in the context of COVID-19:

- WHO considerations for school-related public health measures in the context of COVID-19
- WB/WFP/UNESCO/UNICEF framework for school reopening
- WHO/UNICEF/IFRC Interim Guidance for COVID-19 Prevention and Control in Schools

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Justification

GDG members agreed that the recommendations on mask-wearing in this document should be implemented in the context of school settings. They also noted the importance of applying existing public health and social measures and infection prevention and control measures in schools, in addition to mask-wearing.

Home care for patients

The most up-to-date guidance for "Home care for patients with suspected or confirmed COVID-19 and management of their contacts: interim guidance" was published 12 August 2020. This guidance is under review and is pending integration into "Infection prevention and control in the context of coronavirus disease (COVID-19): A living guideline".

Water, sanitation, hygiene, and waste management

The most up-to-date technical guidance for "<u>Water, sanitation, hygiene, and waste management for SARS-CoV-2, the virus that causes</u> <u>COVID-12</u>" was published 29 July 2020. This guidance is under review and is pending integration into "<u>Infection prevention and control</u> in the context of coronavirus disease (COVID-19): A living guideline".

Authorship, contributors and acknowledgements

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Authorship, contributions, acknowledgements

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Declaration of conflicts of interest

R. Chou is an author on some of the evidence used to inform some recommendations. However, as a methodologist, he provided guidance to the GDG on methodologic issues and is not a voting member of the GDG. In some meetings, he presented evidence and provided clarification on methods to guide discussions regarding the EtD tables; however, all decisions were made by voting members of the GDG.

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Declaration of conflicts of interest

Dr F. Lessa is an employee of the United States CDC which has provided funding towards the development of this guideline. After consulting with the WHO Ethics Committee, it was determined Dr Lessa would contribute to discussions as she brings significant technical and field expertise to the discussions; however, be recused from voting on recommendations.

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Declarations of interest of external reviewers were collected and assessed, and no conflict of interest was identified.

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Annexes

Annex 1. Evidence tables for mask use in the health care setting

This section contains three tables highlighting the application of GRADE to available literature reviewed for mask use in the health care setting.

Table 1.1 GRADE table for assessment of respirators versus medica	I mask use in health care settings
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Outcome	SARS-CoV-2 infection
Number and type of studies	5 observational studies
Consistently	Inconsistent
Precision	No imprecision
Directness	No indirectness
Strength of evidence	Very low
Main findings	Inconsistent findings for N95 vs surgical masks and risk of SARS-Cov-2 infection in health workers. Study 1: OR 1.25 (0.55-2.85) and OR 1.18 (0.86-1.62) Study 2: aOR 7.1(3.6-13.9)

Study 3: OR 0.76 (0.63 - 0.92)
Study 4: OR 0.60 (0.31 - 1.15)
Study 5^: PCR+aOR 0.80 (0.64 to 1.00) , seroconversion aOR 0.73 (0.53 - 1.00)

*All studies were conducted in the pre-delta area except for study 5, which was based on data from June 2020 to February 2021.

^Non-peer-reviewed study

Table 1.2 GRADE table for universal masking versus no universal masking

Outcome	SARS-CoV-2 infection in health workers
Number and type of studies	4 before-after studies
Risk of Bias	High
Inconsistently	Not serious
Imprecision	Not serious
Indirectness	Not serious
Quality	Very low
Main findings	Implementation of universal masking temporally associated with reduced incidence of SARS- CoV-2 infection in HCWs

Table 1.3 GRADE table for consistent/always mask use versus inconsistent mask use

Outcome	SARS-CoV-2 infection in health workers
Number and type of studies	6 studies (2 SARS-CoV-2, 4 SARS-CoV-1 or MERS-CoV)
Risk of Bias	High
Inconsistently	Not serious
Imprecision	Not serious
Indirectness	Serious*
Quality	Very low
Main findings	Consistent/always mask use associated with decreased risk of infection in HCWs vs. inconsistent mask use

*Most studies were on non-SARS-CoV-2 coronavirus infections; there was insufficient direct evidence from studies of SARS-CoV-2 to determine effects on risk of infection

Annex 2. Evidence tables for mask use by children.

This section contains two tables highlighting the application of GRADE to available literature reviewed for mask use by children.

Table 2.1. GRADE table for assessment of masks versus no mask use in community settings

Outcome	SARS-CoV-2 infection
Number and type of studies	2 RCT and 3 observational studies[20][58][59][60][61][62]
Consistently	Moderate
Precision	Some imprecision*
Directness	Some indirectness*
Strength of evidence	Moderate
	RCT1 (cluster): Mask promotion intervention associated with increased mask use and decreased risk of symptomatic SARS-CoV-2 seroprevalence; adjusted prevalence ratio of 0.91, 95% CI 0.82 to 1.00 [61]
	RCT 2: OR 0.82, 95% CI 0.52 to 1.23 [62]
Main findings	Two observational studies reported inconsistent and imprecise estimates for mask use vs no mask use in community settings outside the home [59][60]. One observational study found mask use by all members of a household or prior to index case illness onset associated with decreased risk of secondary infection vs no mask use [58].

Note: All studies were conducted in settings without widespread delta variant. Also, ecological studies were not included in this table but consistently found policies requiring masks were associated with decreased risk of SARS-CoV-2 infection.

*Of 2 RCTs, one reported an imprecise estimate while the other evaluated an indirect intervention (mask promotion)

Table 2.2 GRADE assessment of observational and ecological studies on Mask effectiveness

	Adult Studies	Ecological Studies	Influenza Studies
Outcome	SAR-CoV-2 infection	SARS-CoV-2 infection	SARS-CoV-2 infection
Number of studies	2 RCTs and 3 observational studies [58][59][60][61][62]	13 [151][152][153][154][155][156][157][158][159][160][166][168][169].	1 RCT [73]and 1 observational study [76].
Risk of bias	Moderate	High ²	Moderate
Consistency	Consistent	Consistent	Consistent
Precision	Some imprecision	Some imprecision	Some imprecision
Directness	Serious indirectness ¹	Serious indirectness ³	Serious indirectness ⁵
Strength of evidence	Low	Very low	Very Low

1 Different population, adult evidence strength rated as moderate. Rated down 1 for children.

2 Studies did not control for the effect of concurrent interventions.

3 Different interventions. Studies did not assess actual mask-wearing or adherence to the intervention

4 RCT outcomes had wide confidence intervals (0.31 - 0.087)

5 Different outcomes were measured. Different population. RCT was a cluster household trial including adults and children. Differences in the intervention: RCT randomized households to facemasks plus 'enhanced hand hygiene' (educational materials provided).

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