

Australian guidelines for SARS-CoV-2 infection prevention and control of COVID-19 in healthcare workers

NATIONAL
COVID-19
CLINICAL
EVIDENCE
TASKFORCE

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Disclaimer

The consortium is seeking NHMRC approval of the guideline under section 14A of the National Health and Medical Research Council Act 1992. As part of the approval process (and for the lifetime of the guidelines), public consultation is required. We welcome your feedback and suggestions. Comments can be submitted via the feedback function under each recommendation in Magic or by emailing guidelines@covid19evidence.net.au.

These clinical guidelines are a general guide to appropriate practice, to be followed subject to the clinician's judgement and the patient's preference in each individual case. The guidelines are not intended to be proscriptive. They are designed to provide information to assist decision making and have been informed by the highest quality evidence available at the time of compilation. Accordingly, the parties involved in the development of these guidelines shall have no liability to any users of the information contained in this publication for any loss or damage, cost or expense incurred or arising from reliance on the information contained in this publication.

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1. Reading Guide

Infection prevention and control of novel coronavirus disease 2019 (COVID-19) is a rapidly expanding area of research, with an unprecedented global effort underway to combat this disease. As a result, recommendations based on current evidence are likely to become outdated quickly as new primary studies are published. The living evidence approach facilitates rapid updating of recommendations. By frequently incorporating the most up-to-date evidence, these methods ensure that the currency of each recommendation remains high.

It is anticipated that these living recommendations will be updated weekly as and when new evidence is available. This will be reflected in the publication of a new version in which changes made to a specific recommendation or supporting information are highlighted to emphasise the update.

The guideline consists of two layers

1. The Recommendation

Recommendation for (Green)

A strong recommendation is given when there is high-certainty evidence showing that the overall benefits of the intervention are clearly greater than the disadvantages. This means that all, or nearly all, patients will want the recommended intervention.

Recommendation against (Red)

A strong recommendation against the intervention is given when there is high-certainty evidence showing that the overall disadvantages of the intervention are clearly greater than the benefits. A strong recommendation is also used when the examination of the evidence shows that an intervention is not safe.

Conditional Recommendation for (Yellow)

A conditional recommendation is given when it is considered that the benefits of the intervention are greater than the disadvantages, or the available evidence cannot rule out a significant benefit of the intervention while assessing that the adverse effects are few or absent. This recommendation is also used when patient preferences vary.

Conditional Recommendation against (Orange)

A conditional recommendation is given against the intervention when it is judged that the disadvantages of the intervention are greater than the benefits, but where this is not substantiated by strong evidence. This recommendation is also used where there is strong evidence of both beneficial and harmful effects, but where the balance between them is difficult to determine. Likewise, it is also used when patient preferences vary.

Consensus Recommendation (Bluish-Purple)

A consensus recommendation can be given for or against the intervention. This type of recommendation is used when there is not enough evidence to give an evidence-based recommendation, but the panel still regards it as important to give a recommendation.

2. Supporting information

Click on the recommendation to learn more about the basis of the recommendation. Note that early recommendations are primarily adapted from other guidelines and/or based on the consensus of the guideline panel, and supporting information will be limited. Additional information will be added as recommendations are updated in light of new evidence.

Evidence profile: The overall effect estimates and references to the studies.

Summary: Overview and brief review of the underlying evidence.

Certainty of the evidence:

High: We are very sure that the true effect is close to the estimated effect.

Moderate: We are moderately sure of the estimated effect. The true effect is probably close to this one, but there is a possibility that it is significantly different.

Low: We have limited confidence in the estimated effect. The true effect may be significantly different from the estimated effect.

Very low: We have very little confidence in the estimated effect. The true effect is likely to be significantly different from that estimated effect.

Evidence to decision: Brief description of beneficial and harmful effects, certainty of evidence and considerations of patient preferences.

Rationale: Description of how the above elements were weighted in relation to each other and resulted in the current recommendation

direction and strength.

Practical information: Practical information regarding the treatment and information on any special patient considerations.

Adaption: If the recommendation is adapted from another guideline you can find more information here.

Feedback: If you are logged in as a user, you can comment here on specific recommendations. See here for guidance on how to log in.

References: Reference list for the recommendation.

The gradation of evidence quality and recommendation strength used is based on the Grading of Recommendations Assessment, Development and Evaluation (GRADE). For a quick and informative introduction to GRADE, the article Understanding GRADE: an introduction by Goldet & Howick is recommended (J Evid Based Med 2013;6(1):50-4). See also <http://www.gradeworkinggroup.org>.

2. Introduction

Novel coronavirus disease 2019 (COVID-19) is an infectious disease caused by the newly discovered severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Since its identification in December 2019, COVID-19 has spread around the world and was declared a Public Health Emergency of International Concern by the World Health Organization (WHO) on 30 January 2020 [1].

As a consequence of their roles, healthcare workers are at particular risk of exposure to SARS-CoV-2. In order to protect the wellbeing of healthcare workers, to ensure the availability of this essential workforce, and to prevent further spread within the community, it is vital that the best available evidence is used to guide decision-making in the prevention of SARS-CoV-2 infection in healthcare workers.

Clinical guidelines are integral to ensuring that healthcare decisions are based on the best available evidence. With the support of the National Health and Medical Research Council (NHMRC), the National COVID-19 Clinical Evidence Taskforce was commissioned to develop (in partnership with the Infection Control Expert Group (ICEG) which advises the Australian Health Protection Principal Committee (AHPPC) and a range of national professional societies and organisations) living recommendations to guide decision-making in the prevention of SARS-CoV-2 infection in healthcare workers.

Recommendations within this guideline were developed in collaboration with ICEG and the organisations listed below. All member organisations are part of the steering committee and formally endorse the guideline. The Steering Committee is governed by a consensus based decision-making process, for more details on the methods and processes of the Taskforce please see the Methods and processes section of this guideline.

- Australian Living Evidence Consortium (Coordinating Lead)
- Cochrane Australia (Secretariat)
- Allied Health Professions Australia
- Australasian Association of Academic Primary Care
- Australasian College for Emergency Medicine
- Australasian College for Infection Prevention and Control
- Australasian College of Paramedicine
- Australasian Sleep Association
- Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists
- Australasian Society for Infectious Diseases
- Australian Association of Gerontology
- Australian College of Critical Care Nurses
- Australian College of Midwives
- Australian College of Nursing
- Australian College of Rural and Remote Medicine
- Australian COVID-19 Palliative Care Working Group
- Australian and New Zealand College of Anaesthetists
- Australian and New Zealand Intensive Care Society
- Australian and New Zealand Society for Geriatric Medicine
- Australian Primary Health Care Nurses Association
- Australian Resuscitation Council
- Australian Society of Anaesthetists
- College of Emergency Nursing Australasia

- CRANApus
- National Aboriginal Community Controlled Health Organisation
- Royal Australasian College of Physicians
- Royal Australasian College of Surgeons
- Royal Australian College of General Practitioners
- Royal Australian and New Zealand College of Obstetricians and Gynaecologists
- Society of Hospital Pharmacists of Australia
- Thoracic Society of Australia and New Zealand
- Thrombosis and Haemostasis Society of Australia and New Zealand

Publication approval

The Taskforce will seek NHMRC approval of the guideline under section 14A of the National Health and Medical Research Council Act 1992 for an initial version of this guideline, and then on an ongoing basis as new recommendations are added or existing recommendations are changed.

This publication reflects the views of the authors and not necessarily the views of the Australian Government.

Updating and public consultation

A considerable volume of research related to SARS-COV-2 and COVID-19 is ongoing and will potentially impact clinical recommendations. To ensure these guidelines are updated rapidly in response to new and important evidence, the underpinning knowledge syntheses and recommendations will be reviewed and updated on an ongoing basis. It is anticipated that these living recommendations will be updated weekly as and when new evidence is available. This will be reflected in the publication of a new version in which changes made to a specific recommendation or supporting information are highlighted in order to emphasise the update.

The Taskforce will seek NHMRC approval of the guideline under section 14A of the National Health and Medical Research Council Act 1992 on an ongoing basis as new recommendations are added or existing recommendations are changed. As part of the approval process (and for the lifetime of the guidelines), public consultation is required. We welcome your feedback and suggestions. Comments can be submitted via the feedback function under each recommendation in MAGIC, see the reading guide in the above section for guidance, or by emailing guidelines@covid19evidence.net.au.

Purpose

The purpose of this guideline is to provide health professionals, organisations and policy-makers with up-to-date, evidence-based recommendations to guide decision-making in the prevention of SARS-COV-2 infection in healthcare workers. The guideline contains specific and actionable recommendations for selected, well-defined clinical problems (i.e. what needs to be done and who it is relevant to). It does not define the individuals responsible for providing or ensuring the relevant interventions, nor does it consider the economic implications of guideline adherence.

The Taskforce is also responsible for developing guidelines for clinical care of people with COVID-19, which are available [here](#).

Scope

This guideline aims to provide specific, evidence-based recommendations to guide decision-making in the prevention of SARS-COV-2 infection in healthcare workers in Australia.

Our primary interest is in preventing SARS-COV-2 infection in healthcare workers who are in direct patient/ resident / client-facing roles with individuals diagnosed or potentially infected with COVID19.

Our scope includes all Australian settings in which healthcare is provided. This includes:

- a. Primary care (including home-based care, medical and dental clinics)
- b. Hospital and inpatient care (including acute, sub-acute, rehabilitation and dental hospitals)
- c. Residential aged care facilities
- d. Transport/retrieval (including ambulance and emergency services)
- e. Managed quarantine

3. Methods, Processes and Definitions

Methods and processes

Information about the methods and processes used is described in the [technical report](#) and the [search methods document](#).

Information about our governance structure and members' details is available [here](#).

Our policy on the use of media statements, preprints and other non-peer-reviewed papers in formulating recommendations is available [here](#).

Scientific publications

Weekly updates of national living evidence-based guidelines: Methods for the Australian Living Guidelines for Care of People with COVID-19. Tendal et al. 2020 J Clin Epidemiol doi: [10.1016/j.jclinepi.2020.11.005](https://doi.org/10.1016/j.jclinepi.2020.11.005).

Conflicts of interest

The policy for management of conflicts of interest and the template used for collecting the declarations of interest can be found on the website at <https://covid19evidence.net.au/more-about-the-guidelines/>

A summary of the declarations of interests can be found [here](#).

Public consultation

We welcome feedback and suggestions. Comments can be submitted via the feedback function under each recommendation in MAGIC or by emailing guidelines@covid19evidence.net.au. When feedback is received, we will make responses to comments received available [here](#).

3.1. Terms used to define particle types

A variety of terms are used to describe the different types of aerosols/droplets that can carry matter in the air. Some of these terms are used interchangeably by some professional groups and very specifically by others, which can introduce confusion.

One important consideration in understanding the distance that particles travel, is the size range that those particles are likely to be. Particles less than 100 microns in size are able to be inhaled. The probability of inhalation depends on particle size, air movement and the breathing rate of the person.

The smaller the particles, the greater the likelihood that they will remain in the air for prolonged periods of time. Particles between 50 - 100 micron are typically deposited in the nose, throat and upper respiratory tract. Particles between 10 - 50 micron in size penetrate beyond the larynx, while those less than 10 micron allow deposition in the lower respiratory tract.

In this guideline, we usually talk about 'airborne particles'.

In using this term, we are referring to the full range of particle sizes that can carry matter in the air, and which include other more specific terms such as:

- 'droplets' or 'respiratory droplets' which are often used to describe larger particles
- smaller aerosols or 'droplet nuclei' which are often used to describe smaller particles.

Where we use terms other than 'airborne particles', we will define these in the text.

4. Personal Protective Equipment

When making decisions about ways to eliminate or minimise infection risks in the workplace, including when deciding on the type of personal protective equipment, there are additional factors to take into account. A good source of information is the [Model Code of Practice Work health and safety consultation, cooperation and coordination](#). Employers should also consult their relevant health and safety requirements in their state or territory.

4.1. Eye Protection

There is very limited research evidence available to evaluate the effectiveness of eye protection in preventing healthcare worker infection with SARS-CoV-2 or related viruses.

The existing research evidence is insufficient to develop evidence-based recommendations about eye protection. As a result, the Panel has developed consensus recommendations that reflect the combined expertise of the panel, the available evidence, and the underlying epidemiology and patterns of transmission of SARS-CoV-2.

These recommendations are developed in awareness of the balance of benefits and disadvantages or undesired effects, of eye protection including the implications of wearing eye protection on clinical practice and worker wellbeing, along with healthcare worker preferences and values. Additional information is available in the Eye Protection Practice Points. These recommendations will be updated to reflect new evidence as it emerges.

4.1.1. Recommendations

Consensus recommendation

All healthcare workers should follow standard and transmission-based precautions as described in the Australian Guidelines for the Prevention and Control of Infection in Healthcare (2019)

The Australian Guidelines for the Prevention and Control of Infection in Healthcare (2019) include a specific recommendation for eye protection:

30. It is suggested that face and eye protection should be worn during procedures that generate splashes or sprays of blood and body substances into the face and eyes.

The panel considers that for clinical examination or procedures involving close or extended face-to-face patient/client/resident exposure, eye protection is required in accord with standard precautions, for those patients/clients/residents with clinical features suggestive of a respiratory infection.

The risk of infection for healthcare workers who are in direct patient/ resident / client-facing roles with individuals who may be infected with COVID-19 varies with several factors, including:

- the individual patient's pre-existing likelihood of COVID-19,*
- current prevalence and transmission of COVID-19 in the population,*
- setting-specific factors such as the likelihood of increased generation of airborne particles and enclosed areas with low levels of ventilation, or where unexpected air movements may facilitate wider distribution of droplets in the air (eg; opening of doors between spaces of differential air pressure)*
- closeness and duration of contact, and*
- adherence to transmission-based precautions including safe use and removal of personal protective equipment*

The Australian Guidelines for the Prevention and Control of Infection in Healthcare provide a nationally accepted approach to infection prevention and control, outlining foundational principles and identifying priority areas which apply for all types of infections, including SARS-CoV-2/COVID-19.

These guidelines, the Australian Guidelines for Infection Prevention and Control of COVID-19 in Healthcare Workers, provide additional guidance specific to SARS-CoV-2/COVID-19, but do not replace, and should be read in conjunction with, the Australian Guidelines for the Prevention and Control of Infection in Healthcare.

Rationale

The Australian Guidelines for the Prevention and Control of Infection in Healthcare provide a nationally accepted approach to infection prevention and control, outlining foundational principles and identifying priority areas which apply for all types of infections, including SARS-CoV-2/COVID-19.

These guidelines, the Australian Guidelines for Infection Prevention and Control of COVID-19 in Healthcare Workers, provide additional guidance specific to SARS-CoV-2/COVID-19, but do not replace, and should be read in conjunction with the Australian Guidelines for the Prevention and Control of Infection in Healthcare

Consensus recommendation

Confirmed COVID-19

Healthcare workers who are providing direct care or working within the patient/client/resident zone with individuals diagnosed with COVID-19 should wear eye protection as part of a set of personal protective equipment.

Consensus recommendation

Suspected COVID-19

Healthcare workers who are providing direct care or working within the patient/client/resident zone with individuals who have symptoms consistent with COVID-19 should wear eye protection as part of a set of personal protective equipment.

Consensus recommendation

Asymptomatic individuals with epidemiological risk factors for COVID-19

Healthcare workers should wear eye protection if they are providing direct care or working within the patient/client/resident zone with individuals for whom there are reasons to suspect increased risk of COVID-19 due to:

- Close contact with a person with confirmed COVID-19 in the previous 14 days; OR
- Attendance at a currently designated COVID-19 exposure risk location in the previous 14 days; OR
- Return from international travel in the previous 14 days; OR
- Residence in, or travel through, a geographically localised area with elevated risk of community transmission in the previous 14 days

4.1.2. Practice Principles

The NC19CET practice principles for the use of eye protection can be found [here](#).

Info Box

The NC19CET practice principles for the use of eye protection can be found [here](#).

4.2. P2/N95 Respirators and Face (Surgical) Masks

There is limited epidemiological research evidence available to evaluate the effectiveness of different types of face masks in preventing healthcare worker infection with SARS-CoV-2 or related viruses.

The body of available epidemiological evidence consists of 1 randomised controlled trial and 11 observational studies. GRADE assessment of this evidence indicates that it is of low certainty, with high risk of bias, and substantial imprecision. The epidemiological evidence does not reliably demonstrate a significant difference in effectiveness between a surgical mask and a P2/N95 respirator, however the epidemiological evidence is of such low certainty that we can't currently exclude an effect. We are aware of at least one trial which is currently underway evaluating the effectiveness of P2/N95 respirators, and these recommendations will be updated to reflect the findings from that study and other new evidence as it emerges.

As a result, the Panel has developed consensus recommendations that reflect the combined expertise and experience of the panel, the standards of protection which P2/N95 respirators must meet, and the underlying epidemiology and patterns of transmission of SARS-CoV-2, including the variants of concern. Considerations of the impact of vaccination against SARS-CoV-2 of healthcare workers and the broader community have not been included at this stage of recommendation development.

Building on ICEG's previous recommendations, risk assessment remains central in the consideration of PPE requirements. These recommendations have been developed in the context of awareness of the balance of benefits, first principles, limitations and undesired effects of surgical masks and P2/N95 respirators, including the implications of wearing masks or respirators on clinical practice and worker wellbeing, along with the need for fit testing and checking, and healthcare worker preferences and values. Additional considerations that have informed these recommendations are described in the Background document.

Additional information on selection, use and maintenance of respiratory protective equipment is available in Australian Standard AS/NZS 1715-2009. Where a P2/N95 respirator is recommended for use, an assessment should be undertaken of the psychological

and physical suitability of this level of respiratory protection for each health care worker, and whether an increased level of protection is appropriate, as per the Standard.

4.2.1. Background to deliberations

Decisions about, and developing recommendations about, the choice of appropriate personal protective equipment (PPE) can be complex and challenging; and have both substantial organisational and personal implications for healthcare workers, along with implications for patient care. In developing these consensus recommendations, the Infection Prevention and Control Panel has brought together expertise in diverse fields including infection prevention and control, infectious disease, primary care, occupational hygiene, care of older people, women's health, paediatric and adolescent health, operative/perioperative care, emergency care, critical care, nursing care, occupational and environmental medicine, clinical engineering.

In developing these recommendations, **the Panel's primary focus is on ensuring protection for health care workers from SARS-CoV-2 infection.**

The Panel acknowledges that there is little reliable, direct epidemiological evidence to underpin recommendations and so, in the absence of this evidence, makes consensus recommendations based on their combined experience and expertise, after consideration of a range of information and factors including those noted below.

These consensus recommendations carry less weight than a strong (or even conditional) evidence-based recommendation, but reflect our shared position on the most appropriate approach to these decisions.

In arriving at this shared position, we have undertaken a series of robust and respectful conversations in which we have all contributed our differing experiences, perspectives, and expertise.

Important notes

- *Personal protective equipment is a small but important part of an appropriate infection prevention and control response, and should be considered as the last line of defence. While choice of health care worker face mask or P2/N95 respirator and other PPE is critical, a broader response which includes minimisation of risk, implementation of administrative and engineering controls and other interventions is crucial to preventing healthcare worker infections.*
- *As living recommendations, these recommendations will be revised as new research evidence emerges and in light of other information which impacts on the Panel's consensus view. For example:*
 - *vaccination against SARS-CoV-2 of healthcare workers and the community may influence recommendations but further understanding of the impact of vaccination is required before an assessment of this can be made*
 - *recommendations were made in a time of low community prevalence and transmission, and may need to be adjusted as this changes.*

Issues considered

The issues we have considered in our deliberation include, but are not limited to:

- There is a hierarchy of health and safety hazard controls, in which PPE is last, not because it is least important, but because there is an expectation that all other preventative measures higher in the hierarchy (such as removal of the risk, administrative and engineering controls) have been explored and, where possible, instigated.
- Given the hierarchy of other controls, and variability across and within settings, and ability to implement other control measures, it is difficult to make hard and fast 'rules' about PPE and decision-making requires a nuanced approach, guided by evidence and important contextual factors.
- The standards of protection which P2/N95 respirators must meet to be certified (i.e. 94-95% removal of small airborne particles), including Australian Standard AS/NZS 1715-2009 and other background data on the utility of face masks and P2/N95 respirators, including studies in experimental settings. The Panel also notes that there is currently no Australian standard for eye protection in health care
- Emerging data on the underlying epidemiology and patterns of transmission of SARS-CoV-2, including the apparent increased transmissibility of recent SARS-CoV-2 variants of concern.
- Awareness that risk of transmission varies between contexts and timepoints, and is neither entirely predictable nor static

- Emerging evidence that SARS-CoV-2 can be detected (by PCR or culture) in small respiratory particles from infected patients in patient surrounds. These may be associated with close or more distant aerosol transmission.
- Data suggesting that there can be significant aerosol production from patients who are not undergoing procedures or displaying behaviours that would conventionally have been described as 'aerosol-generating'.
- Acknowledgement that no available direct human evidence can confirm the relative importance of airborne, droplet or contact spread.
- The responsibility of employers to ensure a safe workplace for their employees, and to consult with their employees to achieve this, including the Model Code of Practice Work health and safety consultation, cooperation and coordination and the relevant health and safety requirements in each jurisdiction.
- Awareness of extensive work undertaken to develop guidance at a jurisdictional level and that conflicting positions from these jurisdictions mean it is not possible for our recommendations to align with all existing recommendations.
- Whether, in the absence of evidence, it was useful to develop consensus recommendations, and the additional value a diverse, multidisciplinary panel like ours can or should contribute to guiding decision-making
- The balance of benefits and harms to healthcare workers of wearing P2/N95 respirators, acknowledging that the harms (e.g. skin injury, headache, increased work of breathing) are not infrequent but have a substantially lower impact than the significantly lower likelihood but much larger impact risk of COVID-19 infection.
- Potential difficulties in guideline implementation in some healthcare settings arising from many factors including training of workers, changes from existing protocols, etc
- Healthcare worker preferences and values for different forms of face masks and P2/N95 respirators
- Impact of choice of face mask or P2/N95 respirator on care of, communication with and comfort of patients/clients/residents
- Acknowledgement that health worker protection and patient care and safety demands equal consideration, supporting the risk assessment approach
- Awareness that given the substantial potential impact on healthcare workers, and the reasonably low cost of the intervention, while cost is a factor, particularly in settings like GP practices, this should not influence our recommendation on the more appropriate form of protection
- Insight that the risk assessment recommended by the Panel will usually be undertaken at an organisational/policy level and acknowledgement that individual healthcare workers may be best placed to make this assessment in some healthcare settings
- The need for balance between health worker risk assessment, professional flexibility and direct guidance
- Recognition that while there is currently no lack of P2/N95 respirators, in some settings it is not possible to source the full breadth of types of P2/N95 respirators required to ensure that every healthcare worker has access to the type of P2/N95 respirator that best fits them
- Possibility of leading to complacency with other infection prevention and control measures and other elements of the hierarchy of controls
- Concerns that recommendations to use P2/N95 respirators for certain individuals in the context of COVID-19 might lead to expectations that may not be justified, for example that:
 - P2/N95 respirators be used when caring for wider groups of individuals in the context of COVID-19
 - Other more complex infection prevention and control measures should also be applied when caring for individuals in the context of COVID-19
 - Other core elements of infection prevention and control are less important in the context of COVID-19
 - These recommendations be applied inappropriately to other communicable and non-communicable respiratory infections
 - These recommendations apply to community mask use more broadly and potential confusion with source control measures in the community
- Potential of need for guidance for other (non-healthcare) workers and possibility that recommendations would be extended to them. This might include other workers in a healthcare setting (e.g. reception, security, transport, hospitality staff) but also potentially staff in other settings not traditionally considered to be healthcare settings such as hotel quarantine.

Conclusion

Our consensus recommendations reflect the Panel's shared view after detailed discussion of these and other issues. We recognise that the issues are complex, multidimensional and interrelated, and that there is significant uncertainty. We welcome contributions and feedback and we seek to revise and update these recommendations as new evidence and other information becomes available.

4.2.2. Recommendations

Consensus recommendation

All healthcare workers should follow standard and transmission-based precautions as described in the Australian Guidelines for the Prevention and Control of Infection in Healthcare (2019)[40]

The Australian Guidelines for the Prevention and Control of Infection in Healthcare (2019)[40] include two specific recommendations for surgical masks and P2/N95 respirators:

24. It is suggested that a surgical mask should be worn when entering a patient-care environment to prevent droplet transmission. 27. It is suggested that a correctly fitted P2/N95 respirator is worn when entering the patient-care area when an airborne-transmissible infectious agent is known or suspected to be present.

The panel considers that for clinical examination or procedures involving close or extended face-to-face patient/client/resident exposure, surgical masks and eye protection are required in accord with standard precautions, for those patients/clients/residents assumed to have a respiratory infection, or who have not engaged in public health strategies such as social distancing, vaccination programs and therefore pose a potential increased risk to the HCW.

Consensus recommendation

Healthcare workers who are required to wear a P2/N95 respirator should complete fit testing before first use, and perform a fit (seal) check properly each time they are used.

Fit testing is a respiratory protection requirement specified by AS/NZS 1715:2009 "Selection, use and maintenance of respiratory protective equipment"[41] <https://covid19evidence.net.au/as-nzs-1715-2009/>.

Fit testing should be conducted annually on each healthcare worker who is required to wear a P2/N95 to identify the most appropriate type of P2/N95 respirator to be used by that worker, as fit varies between respirator types and different people. However, in situations where fit testing has not yet been carried out, and a P2/N95 respirator is recommended for use, a fit-checked P2/N95 respirator is preferred over a surgical mask.

Consensus recommendation

All healthcare workers providing direct patient care or working within the patient/client/resident zone for individuals with suspected or confirmed COVID-19 should have access to P2/N95 respirators.

Consensus recommendation

For healthcare workers providing direct patient care or working within the patient/client/resident zone for individuals with suspected or confirmed COVID-19, the choice between P2/N95 respirator or surgical mask should be based on an assessment of risk of transmission.

By 'suspected' we mean individuals who meet the definition of a 'suspected case' of COVID-19 according to the CDNA[42], based on presence of both clinical and epidemiological risk factors.

This recommendation also applies to individuals who have clear epidemiological risk factors and are either asymptomatic or have non-specific signs of infection, including individuals in managed quarantine. Institutions should ensure access to a range of respirators to provide suitable fit for different facial types.

Consensus recommendation

Assessment of risk of transmission of COVID-19 to healthcare workers should include consideration of:

- the individual patient/client/resident's pre-existing likelihood of COVID-19
- current prevalence and transmission of COVID-19 in the population
- setting-specific factors such as the likelihood of increased generation and dispersion of airborne particles and enclosed areas with low levels of ventilation
- closeness and duration of contact

The risk of infection for healthcare workers who are in direct patient/resident/client-facing roles with individuals who are confirmed with or suspected of COVID-19 varies with the combination of several factors, including:

Patient/client/resident pre-existing likelihood of COVID-19 based on:

- Close contact, or secondary close contact, with a person with confirmed COVID-19 in the previous 14 days; OR
- Return from international travel in the previous 14 days, particularly from countries with high prevalence of COVID-19; OR
- Attendance at a currently designated COVID-19 exposure risk site in the previous 14 days; OR
- Residence in, or travel through, a geographically localised area with elevated prevalence or community transmission of COVID-19 in the previous 14 days; OR
- Current prevalence and transmission of COVID-19 in the population; OR
- Symptoms consistent with COVID-19.

Patient/client/resident factors

- Potential for patient behaviours that increase the risk of SARS-CoV-2 transmission e.g. patients who have cognitive impairment, are unable to cooperate, or exhibit challenging behaviours; patients who are coughing or experiencing increased work of breathing
- Ability/appropriateness of the patient/client/resident to wear a surgical mask

Nature of the care episode

- Duration and proximity of contact between healthcare worker and individual
- Types of care that increase the risk of SARS-CoV-2 transmission e.g. airway management, respiratory treatments/procedures

Physical location

- Presence of multiple patients with suspected COVID-19 in an enclosed space
- Whether the environment has low levels of ventilation or unexpected air movements may facilitate wider distribution of droplets in the air (e.g. opening of doors between spaces of differential air pressure)
- Complex or less controlled care settings, including transport, home or community-based care

For detailed guidance and definitions on surveillance, laboratory testing and contact management for coronavirus disease 2019 (COVID-19) please consult Coronavirus Disease 2019 (COVID-19) CDNA National Guidelines for Public Health Units [42].

Consensus recommendation

Likely high-risk of SARS-CoV-2 transmission

Healthcare workers providing direct care or working within the patient/client/resident zone for individuals where assessment suggests a high-risk of transmission, should use P2/N95 respirators rather than surgical masks, along with the other PPE required.

Examples:

Direct care for a confirmed COVID-19 case while considered infectious.

Direct care for individuals with both epidemiological risk factors for, and clinical features of, COVID-19 prior to confirmation of COVID-19 status.

For example:

- *Care for a symptomatic close contact of a confirmed COVID-19 case*
- *Care for a symptomatic individual in managed quarantine*
- *Prolonged GP consultation in a poorly ventilated room with a distraught pregnant mother, an infant and two children under 4, one of whom has visible rhinorrhoea in an area of high community prevalence/ transmission.*

Direct care for individuals with epidemiological risk factors for COVID-19 but no current symptoms or atypical symptoms, especially where other factors increase risk.

For example:

- *Care for a close contact of a confirmed COVID-19 case, even in the absence of symptoms of COVID-19*
- *Nursing care for a patient with behavioural symptoms of dementia who has been transferred to a hospital from a residential aged care facility with a current COVID-19 outbreak, or from a facility in an area with high levels of community transmission*
- *Midwifery care for a woman in labour with an increased work of breathing, (including panting or accessorizing respiratory effort) or receiving inhalational analgesia, who has lived in a geographically localised area with elevated risk of community transmission in the previous 14 days*
- *Emergency department care of an unconscious/trauma patient from an area of community prevalence/ transmission*
- *Care of a patient requiring emergency surgery who has recently tested negative but is a close contact and has some symptoms suggestive of COVID-19 infection*

Clinical Question/ PICO

Population:	P2/N95 respirators versus surgical masks for protecting healthcare workers
Intervention:	Surgical mask
Comparator:	P2/N95 or equivalent

Summary

Summary

The evidence is uncertain as to whether P2/N95 respirators reduce the risk of SARS-CoV-2 infection in healthcare workers compared to surgical masks.

Limited evidence suggests that P2/N95 respirators may be associated with more pressure sores, difficulty breathing and rashes/dermatitis than surgical masks. The evidence is uncertain regarding whether P2/N95 respirators are associated with more or less headaches than surgical masks.

What is the evidence informing this recommendation?

The evidence regarding infection rate is derived from 16 observational studies (retrospective cohort studies, cross-sectional studies or case-control studies), and one randomised controlled trial (RCT). A further eight observational studies provided data on adverse events.

Study characteristics

Twelve of the observational studies reported on infection with SARS-CoV-2, and the remaining observational studies and the RCT reported on other coronaviruses (SARS-CoV-1 or less well-known viruses). Five of the studies (including the RCT) were from Canada, five were from the United States, two from Switzerland and individual studies were from China, Malaysia, Singapore, Japan, India, Spain, Italy and Morocco.

All the observational studies were considered to be at high risk of bias. All but one of the observational studies reporting on infection rates did not report what factors influenced which face coverings was chosen. The remaining observational study on infection rates reported that those healthcare workers who were working in intensive care or performing aerosol generating procedures involving a confirmed COVID-19 patient should wear a P2/N95 mask, whereas for general care of patients with COVID-19, surgical masks were recommended. Therefore, those wearing P2/N95 respirators may be at an increased risk of infection based on level of exposure, although it is unknown the extent to which other personal protective equipment, ventilation, appropriate donning and doffing etc may influence the rates of infection. Only one study assessed the differences in characteristics between those who FFP2 respirators and those who wore surgical masks (Haller et al. 2021). They reported that healthcare workers who wore FFP2 respirators were significantly more likely than those who wore surgical masks to work full time, perform aerosol generating procedures, work in the intensive care unit and care for over 20 COVID-19 patients (all of which would increase risk of infection). Conversely, they were also significantly more likely to wear other personal protective equipment (goggles, gloves and gown), and wear a mask outside of work (which would decrease risk of infection).

A single RCT was identified which reported on the rate of coronavirus infections (OC43, 229E, SARS, NL63, and HKU1) in those randomised to use either a fit-tested N95 respirator or surgical mask (Loeb et al. 2009). The primary outcome measure was to assess influenza infection rates (not reported here), and it was underpowered to detect differences in the rate of coronavirus infections. Furthermore, the study had to be stopped early after the Ontario Ministry of Health and Long-Term Care recommended the use of N95 respirators for all healthcare workers taking care of patients with febrile respiratory illness.

Eight studies provided comparative adverse event data comparing P2/N95 respirators and surgical masks in healthcare workers, working in direct contact with patients with COVID-19. These studies were at moderate to high risk of bias, due to the risk of recall bias, confounding and subjective outcome measures.

What are the main results for infection?

The randomised trial reported there was no significant difference between the rate of coronavirus infections (OC43, 229E, SARS, NL63, and HKU1) in those who wore N95 respirators (12/210; 5.7%) versus those who wore surgical masks (9/212; 4.2%; OR 0.73, 95%CI 0.30, 1.77) (Loeb et al. 2009)[32].

A total of 11 observational studies were identified which reported on SARS-CoV-2 infection rates in healthcare workers, who wore either surgical masks or N95 respirators (or equivalent) (Haller et al. 2021; Klompas et al. 2021[9]; Kumar et al. 2020[30]; Ng et al. 2020[34]; Niikura et al. 2021[35], Periyasamy et al. 2020, Martischang et al. 2021, Akinbami et al. 2020, Fletcher et al. 2021, Sims et al. 2020 and Venugopal et al. 2021). There was no significant difference between the rate of infection between mask/respirator groups (OR=1.23, 95%CI 0.99, 1.53).

When the studies were broadened to include other coronaviruses, the difference becomes statistically significant. Five observational studies reported on the rate of infection with the SARS-CoV-1 virus, and reported that there was a statistically significant difference between infection rates in those who wore N95 respirators and those who wore surgical masks (OR=4.75, 95%CI 1.96, 11.54) (Caputo et al. 2006[6]; Loeb et al. 2004[33]; Raboud et al. 2010[36]; Scales et al. 2003[38]; Seto et al. 2003[39]). The overall result for observational studies on SARS-CoV-1 or SARS-CoV-2 transmission was a statistically significant difference favouring N95 respirators over surgical masks (OR=1.34, 95%CI 1.06, 1.70).

What are the main results for adverse events?

The limited data available suggested that P2/N95 respirators may be associated with a higher rate of adverse events than surgical masks.

Pressure sores, redness and facial bruising were more frequent in healthcare workers wearing P2/N95 respirators than those wearing surgical masks (k=4; OR=3.58, 95%CI 2.08, 6.15) [25][50][46][48]. Similarly, rash and dermatitis were more commonly reported in those wearing P2/N95 respirators than those wearing surgical masks (k=2; OR=1.72, 95%CI 1.01, 2.94) [25][50]. Wearing a P2/N95 respirator was also associated with more difficulty breathing than surgical masks (k=3; OR=4.35, 95%CI 1.48, 12.76) [49][47][46]. Data on the rate of de novo headaches were more variable, with point estimates varying largely between studies, resulting in no statistically significant difference overall (k=4; OR=1.90, 95%CI 0.78, 4.63) [28][37][46][47].

Our confidence in the results

Certainty of the evidence is judged to be very low, due to a high risk of bias in the studies, and limited applicability of much of the evidence to COVID-19. We currently cannot determine whether P2/N95 respirators and surgical masks differ in their ability to protect healthcare workers from infection.

Outcome Timeframe	Study results and measurements	Comparator P2/N95	Intervention Surgical mask	Certainty of the Evidence (Quality of evidence)	Plain text summary
Infection (from observational studies) SARS-CoV-1, and SARS-CoV-2 (clinically diagnosed or laboratory confirmed) 9 Critical	Odds Ratio 1.34 (CI 95% 1.06 – 1.7) Based on data from 32,468 patients in 17 studies. ¹ (Observational (non-randomized))	39 per 1000 Difference: 11 more per 1000 (CI 95% 0 fewer – 25 more)	50 per 1000	Very low Due to serious risk of bias, serious indirectness and serious imprecision ²	The evidence is uncertain as to whether P2/N95 respirators reduce the risk of SARS- CoV-2 infection in healthcare workers compared to surgical masks.
Infection (from randomised trial) Coronaviruses OC43, 229E, NL63, and HKU1 (laboratory confirmed) 9 Critical	Odds Ratio 0.73 (CI 95% 0.3 – 1.77) Based on data from 422 patients in 1 studies. ³ (Randomized controlled)	571 per 1000 Difference: 78 fewer per 1000 (CI 95% 286 fewer – 131 more)	493 per 1000	Low Due to serious indirectness and serious imprecision ⁴	There may be little or no difference between P2/N95 respirators and surgical masks in their ability to protect healthcare workers from SARS-CoV-2.
De novo headaches SARS-CoV-2 5 Important	Odds Ratio 1.9 (CI 95% 0.78 – 4.63) Based on data from 628 patients in 4 studies. ⁵ (Observational (non- randomized))	499 per 1000 Difference: 155 more per 1000 (CI 95% 62 fewer – 323 more)	654 per 1000	Very low Due to serious risk of bias, serious inconsistency and serious imprecision ⁶	The evidence is uncertain regarding whether P2/N95 respirators are associated with more or less headaches than surgical masks.
Pressure sores SARS-CoV-2 5 Important	Odds Ratio 3.58 (CI 95% 2.08 – 6.15) Based on data from 2,060 patients in 4 studies. ⁷ (Observational (non-randomized))	903 per 1000 Difference: 68 more per 1000 (CI 95% 48 more – 80 more)	971 per 1000	Very low Due to serious risk of bias and serious imprecision ⁸	Limited evidence suggests that P2/N95 respirators (or equivalent) may be associated with more pressure sores than surgical masks.

Outcome Timeframe	Study results and measurements	Comparator P2/N95	Intervention Surgical mask	Certainty of the Evidence (Quality of evidence)	Plain text summary
<p>Difficulty breathing / shortness of breath SARS-CoV-2</p> <p>5 Important</p>	<p>Odds Ratio 4.35 (CI 95% 1.48 – 12.76) Based on data from 374 patients in 3 studies.⁹ (Observational (non-randomized))</p>	<p>230 per 1000</p>	<p>565 per 1000</p>	<p>Very low Due to serious risk of bias and serious imprecision¹⁰</p>	<p>Limited evidence suggests that P2/N95 respirators (or equivalent) may be associated with more difficulty breathing/ shortness of breath than surgical masks.</p>
<p>Dermatitis SARS-CoV-2</p> <p>5 Important</p>	<p>Odds Ratio 1.72 (CI 95% 1.01 – 2.94) Based on data from 485 patients in 2 studies.¹¹ (Observational (non-randomized))</p>	<p>114 per 1000</p>	<p>181 per 1000</p>	<p>Very low Due to serious risk of bias and serious imprecision¹²</p>	<p>Limited evidence suggests that P2/N95 respirators (or equivalent) may be associated with more dermatitis than surgical masks.</p>
<p>Itching¹³ SARS-CoV-2</p> <p>5 Important</p>	<p>Odds Ratio 1.68 (CI 95% 1.11 – 2.54) Based on data from 697 patients in 4 studies.¹⁴ (Observational (non-randomized))</p>	<p>237 per 1000</p>	<p>343 per 1000</p>	<p>Very low Due to serious risk of bias and serious imprecision</p>	<p>Limited evidence suggests that P2/N95 respirators (or equivalent) may be associated with more facial itching than surgical masks.</p>

- Systematic review [58] with included studies: Haller 2021, Caputo 2006, Akinbami 2020, Fletcher 2021b, Fletcher 2021a, Raboud 2010, Periyasamy 2020, Niikura 2021, Ng 2020, Martischang 2021, Loeb 2004, Kumar 2020, Klompas 2021, Venugopal 2021, Sims 2020, Seto 2003, Scales 2003. **Baseline/comparator:** Control arm of reference used for intervention.
- Risk of Bias: Serious.** due to serious risk of confounding, risk of recall bias. **Inconsistency: No serious. Indirectness: Serious.** Differences between the population of interest and those studied in 6 studies (SARS-CoV-1 or other coronaviruses rather than SARS-CoV-2). **Imprecision: Serious.** Wide confidence intervals (small studies). **Publication bias: No serious.**
- Primary study[32]. **Baseline/comparator:** Primary study[32].
- Inconsistency: No serious. Indirectness: Serious.** Differences between the outcomes of interest (infection with SARS-coV-2) and outcomes reported (infection with other coronaviruses). **Imprecision: Serious.** Low number of patients, Only data from one study. Was powered to assess influenza infection rates, not coronaviruses.. **Publication bias: No serious.**
- Primary study[46], [47], [28], [37]. **Baseline/comparator:** Control arm of reference used for intervention.
- Risk of Bias: Serious.** due to serious risk of confounding, subjective outcome measures. **Inconsistency: No serious.** Point estimates vary widely. **Indirectness: No serious. Imprecision: Serious.** Low number of patients in surgical masks arms, Wide confidence intervals. **Publication bias: No serious.**
- Primary study[48], [46], [50], [25]. Battista - overall. Zaib - redness (general), Garra - Facial bruising, Jiang - injury (general). **Baseline/comparator:** Primary study.
- Risk of Bias: Serious.** due to serious risk of confounding (unknown how often healthcare workers wore other face protection such as eye protection, which could have contributed to adverse events). **Inconsistency: No serious.** Single study. **Indirectness: No serious. Imprecision: Serious.** Wide confidence intervals. **Publication bias: No serious.**
- Primary study[46], [47], [49]. Garra et al reported on "shortness of breath", Maniaci et al reported on "respiratory distress", and results for Ipek et al al were identical for "respiratory distress" and "difficulty breathing". **Baseline/comparator:** Control arm of reference used for intervention[49], [47], [46].
- Risk of Bias: Serious.** Due to high risk of bias. **Inconsistency: No serious. Indirectness: No serious. Imprecision:**

Serious. Low number of patients. **Publication bias:** No serious.

11. Primary study[25], [50]. Battista - Rash/dermatitis, Zaib - contact dermatitis. **Baseline/comparator:** Control arm of reference used for intervention.

12. **Risk of Bias: Serious.** Due to serious risk of confounding. **Inconsistency: No serious.** **Indirectness: No serious.**

Imprecision: Serious. Low number of patients. **Publication bias: No serious.**

13. Itching associated with mask use

14. Primary study[47], [25], [46], [50]. Battista - skin itch in general, not itchy nose. Intervention = N95. **Baseline/comparator:** Control arm of reference used for intervention.

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58. P2/N95 vs surgical masks for protecting healthcare workers.

Consensus recommendation

Likely low-risk of SARS-CoV-2 transmission

Healthcare workers providing direct patient care or working within the patient/client /resident zone for individuals where assessment suggests a low risk of transmission, should use PPE in accord with existing guidance for Standard, Contact and Droplet Precautions as specified in the Australian Guidelines for the Prevention and Control of Infection in Healthcare[40].

Examples:

Direct care for individuals with symptoms without epidemiological risk factors, where other factors do not increase risk.

For example:

- *Care of a patient admitted to hospital with acute respiratory symptoms pending confirmation of COVID-19 status in the context of no community transmission*
- *Care of a child presenting to a general practice with symptoms of an upper respiratory tract infection in the context of no community transmission*
- *Care for a patient with a fever and other symptoms consistent with a provisionally diagnosed infective process – e.g. appendicitis or a urinary tract infection in the context of no community transmission*
- *Care of a patient in a community setting who has respiratory symptoms, in the context of no community transmission*
- *Care of a patient with chronic respiratory symptoms in the context of no community transmission*

Direct care for individuals without symptoms and without epidemiological risk factors, even in the context of other factors that increase risk and no other communicable respiratory infection is suspected.

For example:

- *Intubation of a patient without clinical features of COVID-19 in the setting of no community transmission*
- *Performing endoscopy on a patient without clinical features of COVID-19 in the setting of no community transmission*
- *Care for a patient with behavioural symptoms of dementia in a facility without an COVID-19 outbreak in the setting of no community transmission*

Direct care that involves very brief and controlled contact, regardless of symptoms or epidemiological risk factors:

For example:

- *Healthcare workers in a drive-through COVID-19 testing centre who have very brief controlled contact with suspected COVID-19 cases (and where those suspected cases are wearing a surgical mask for most of the time) in the context of no community transmission.*

4.3. Research Recommendations

Our searches for evidence to underpin recommendations on face masks, respirators and eye protection have identified that there is very limited reliable research evidence available to evaluate the effectiveness of these interventions in preventing healthcare worker infection with SARS-CoV-2 or related viruses.

In the absence of definitive evidence, the Panel has developed consensus recommendations that reflect the combined expertise of the panel, the available evidence, and the underlying epidemiology and patterns of transmission of SARS-CoV-2. These recommendations will be updated to reflect new evidence as it emerges.

Given the absence of evidence, the Panel recommends future research be conducted to inform these recommendations, and to ensure research systems are in place that will enable Australia to be better prepared for future pandemics.

Implications for research

Rigorous comparative research studies (including implementation and operations research) should be conducted to evaluate the relative effectiveness, adverse effects, acceptability/tolerability, and impact on patients of different forms of face masks, respirators and eye protection in reducing workplace acquisition of COVID-19 (or similar respiratory viruses) in healthcare workers.

These studies should appropriately control and/or adjust for potential confounders arising from considerations such as:

- Other infection control measures in place
- Vaccination status of workers and patients
- Risk factors relating to the type of care provided
 - Closeness and duration of contact
 - Types of care that increase the risk of transmission (e.g. airway management)
- Risk factors for transmission related to the patient population including:
 - Prevalence of COVID-19 in the patient population
 - Likelihood of COVID in the patient population given epidemiological risk and symptoms
 - Patient behaviours (e.g. coughing, dementia)
- Risk factors for transmission in the healthcare setting including
 - Levels of ventilation

Where epidemiological studies of effectiveness are not feasible or inconclusive, experimental studies should be conducted.

To best inform recommendations of the Australian National COVID-19 Clinical Evidence Taskforce, this research should:

- *Implement rigorous study designs (whether RCT or observational) which minimise potential for bias and confounding*
- *Be relevant to the Australian context*
- *Address the variety of healthcare settings that form the scope of the Taskforce guidelines*
- *Consider the complexities of differing healthcare worker cadres/levels of training*

This research should be aligned with the Behavioural, Environmental, Social and Systems Interventions (BESSI) Principles <https://www.bessi-collab.net/> and ensure minimal safety requirements are met so that healthcare workers are protected.

Generation of evidence evaluating the effectiveness of face masks, respirators and eye protection requires seed funding, so that preparations can be made to ensure research is ready to commence when the epidemiology of a respiratory pathogen such as COVID-19 makes a study viable.

5. Abbreviations

AHPPC: Australian Health Protection Principal Committee

AS/NZS 1715-2009: Standard 'Selection, use and maintenance of respiratory protection equipment'

BESSI: Behavioural, Environmental, Social and Systems Interventions

CDNA: Communicable Diseases Network Australia

COVID-19: Novel Coronavirus Disease 2019

GRADE: Grading of Recommendations Assessment, Development and Evaluation

GP: General Practice/Practitioner

HCW: Healthcare Worker

ICEG: Infection Control Expert Group

MAGIC: Making GRADE the Irresistible Choice

NHMRC: National Health and Medical Research Council

P2/N95: Particulate respirator

PCR: Polymerase Chain Reaction

PPE: Personal Protective Equipment

RCT: Randomised Controlled Trial

SARS-COV-2: Severe acute respiratory syndrome coronavirus 2

WHO: World Health Organization

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