Appendix 5 – Properties of PPE for use in healthcare

The hierarchy of control is a system for controlling risks in the workplace. The Australian Guidelines for the Prevention and Control of Infection in Healthcare (2019), available at https://app.magicapp.org/goto/guideline/Jn37kn/section/LkzVWj, has an overview of risk management in infection prevention and control. The use of PPE is the lowest in the hierarchy of control measures and is also considered the least reliable. All other measures should be taken to remove or control the risk to workers and patients where it is practicable to do so without the need for PPE. Healthcare workers must perform a local risk assessment prior to fitting PPE to inform their use and selection of PPE.

This risk assessment should consider the type of patient interaction, the risk of transmission of the infectious agent, and the risk of contamination of the healthcare worker skin/mucous membranes by patients' blood, body substances, secretions or excretions and how long the PPE is likely to be required to be worn.

Any examples included in this appendix are not exhaustive and are intended to illustrate potential uses for each type of protection.

The Therapeutic Goods Administration (TGA) provides advice for alternative use of PPE when supply levels reach *crisis supply levels.* This information can be found at https://www.tga.gov.au/media-release/advice-surgical-masks-and-gowns-during-covid-19. Items of PPE that are labelled or promoted for use in surgical or hospital environments require inclusion in the Australian Register of Therapeutic Goods (ARTG).

Standards Australia have published the relevant Australian or joint Australian/New Zealand standards that PPE must meet, including the applicable conformance test methods. This information is available at https://www.standards.org.au/summary-information-on-standards-and-conformance-for-ppe-products.

Masks

Surgical masks

Surgical masks are single use, fluid-resistant, disposable and loose fitting protection devices that create a physical barrier between the mouth and nose of the wearer and the immediate environment but do not achieve a close seal to the wearer's face. When used, surgical masks should cover both the mouth and the nose and be secured using the ear loops or ties at the back of the head. Surgical masks are graded as barrier level 1, 2 or 3 based on the level of protection provided and fluid resistance and are used for blocking splashes and large particle droplets or sprays which may occur (see below). They do not provide complete protection from pathogens and other small particle contaminants.

Australian Standard 4381:2015 Single use face masks for use in health care (AS 4381:2015) sets out the requirements for single use face masks which are used in healthcare. Masks intended by the manufacturer for use in an Australian hospital setting to reduce the transmission of pathogens should be included on the Australian Register of Therapeutic Goods (ARTG). These masks are used to minimise mucous membrane exposure to infectious microbial droplets.

Surgical masks are suitable for droplet precautions and are **not** suitable for use to protect the wearer from **airborne** infectious agents. Please see the section for respirators (P2/95 respirators) below for more information about respirators that are suitable for airborne precautions.

Face masks are categorised as level 1 barrier, level 2 barrier or level 3 barrier. The barrier protection levels refer to the characteristics of the masks based on three characteristics (see Table 1). The masks' resistance to penetration by synthetic blood at different pressures is the characteristic that is most relevant when considering whether a level 1, 2 or 3 barrier masks is used.

The COVID-19 pandemic has led to worldwide shortages of level 3 barrier protection masks. All three levels of surgical masks are fluid-resistant; however, the level of fluid resistance increases with each level of mask. Please refer to the Australian Standard 4381:2015 Single use face masks for use in health care for detailed information.

In the majority of situations where standard respiratory protection is needed, a single use surgical mask is appropriate (minimum level 1 barrier).

Considerations when using a surgical mask include:

- Masks should be changed when they become soiled or wet.
- Masks should never be reapplied after they have been removed.
- Masks should not be left dangling around the neck.
- Touching/adjusting the front of the mask while wearing it should be avoided.
- Hand hygiene should be performed upon touching or discarding a used mask.

Table 1. Characteristics of level 1, level 2, and level 3 surgical masks. Information adapted from AS 4381:2015

Characteristics	Level 1	Level 2	Level 3
Bacterial filtration efficiency %	≥95	≥98	≥98
Differential pressure (mm H_2O/cm^2)	<4.0	<5.0	<5.0
Resistance to penetration by synthetic blood (minimum pressure in mm Hg for pass)	80 mm Hg	120 mm Hg	160 mm Hg
Standard precautions	Yes	Yes	Yes
Droplet precautions	Yes	Yes	Yes
Suitable uses (as per AS 4381:2015)	For general purpose medical procedures where the wearer is not at risk of blood or body fluid splash or to protect staff and/or the patient from droplet exposure to microorganisms.	For use in emergency departments, dentistry, changing dressings on small wounds or healing wounds where minimal blood droplet exposure may possibly occur.	For all surgical procedures, major trauma first aid or in any area where the health care worker is at risk of blood or body fluid splash.
Examples of use	When the likelihood of exposure to body fluid is low, in routine care of suspected, probable, confirmed cases of COVID-19: suitable for the collection of nasopharyngeal swabs, interventions such as a patient interview, physiotherapy, nursing observations, administering most medications, assisting with most ADLs or encounters at a reception counter. Suitable to be provided to symptomatic patients or carer/s of those with respiratory symptoms. If only a level 1 mask is available and splash or spray of body fluid is anticipated, the level 1 mask may be used in combination with a full-face shield.	Use when there is a risk of blood or body fluid exposure/splash. Procedures where moderate to low blood or body fluid splash or spray or droplets are possible such as endoscopic procedures, IVC insertion, IDC emptying or phlebotomy.	These should be reserved for operating theatre use and trauma use where able. All interventions or situations where a blood or body fluid splash is more likely to occur such as during surgical procedures or obtaining an arterial blood specimen or there is or are likely to be large volumes of bodily fluids present.

P2/N95 respirators (respirators)

Respirators are used to reduce the transmission of pathogens in healthcare and must comply with the Australian and New Zealand Standard 1715:2009 Respiratory protective devices. When intended or marketed for use in clinical settings they must be included on the ARTG. The TGA advises that AS/NZS 1716:2012 Respiratory protective devices, the standard for P2 respirators, can be used as a functional standard for both medical devices and for respirators that are not medical devices.

Devices that meet AS/NZS 1716:2012 may not be fluid resistant, particularly if they are not intended or marketed for use in clinical settings. Where devices are not fluid resistant, they should be used in conjunction with a full-face shield where there is a risk of exposure to droplets, splash or spray. Use of respirators that are not fluid resistant should be avoided for major trauma and surgical procedures.

Respirators are designed to form a very close seal around the nose and mouth to protect the wearer from exposure to airborne particles, including pathogenic biological airborne particulates such as viruses and bacteria. These respirators have been tested for particulate filtration to ensure they remove a minimum of 95% solid and liquid aerosols that do not contain oil. P2/N95 respirators are a single use item.

The wearer of these devices must be trained in their application and removal, be able to obtain a suitable fit and perform a fit check of the device. A fit check is required each time a P2/N95 respirator is put on to ensure it is applied properly. Fit checking is the minimum standard for each occasion of use of a P2/N95 respirator. Fit checks ensure the respirator is sealed over the bridge of the nose and mouth and that there are no gaps between the respirator and face creating an airtight protective seal. No clinical activity should be undertaken until a satisfactory fit has been achieved.

Surgical respirators are of a similar structure and design to standard respirators and therefore meet the same testing requirements to achieve a minimum 95% filtration against airborne particulates but have also been tested for fluid resistance against penetration by synthetic blood under different pressures, such as may occur during certain high-risk medical procedures. Correct selection of respirators is important to ensure optimal protection of staff while maintaining supply of respirators where PPE supplies are constrained.

Table 2. Respirators

Respirator type	Indication for use	Requirement of respirators
P2/N95 respirator	Aerosol-generating procedures on patients under droplet precautions where splash or spray of body fluids is not anticipated, OR in conjunction with a face shield if splash or spray of body fluids is anticipated.	Meet AS/NZS 1716:2012, AS/NZS 1715:2009
Surgical P2/N95 respirator	Aerosol-generating procedures in an operating theatre setting or setting where splash or spray of blood or body fluids is likely and fluid resistance is indicated.	Meet AS/NZS 1716:20012, AS/NZS 1715:2009 and fluid-resistant properties in accordance with 4381:2015 and ATSM F1862/F1862M-13 or ISO 22609

In circumstances when P2/N95 respirators included in the ARTG cannot be procured, it may be necessary to assess the suitability of respirators that meet international standards. Please refer to the Standards Australia Summary information on standards and conformance of PPE products for detailed information regarding the test method standards that PPE for use in Australian healthcare must meet https://www.standards.org.au/summary-information-on-standards-and-conformance-for-ppe-products. International standards that have similar specifications to AS/NZS 1715:2009 include:

- N95 (United States NIOSH-42CFR84)
- FFP2 (Europe EN 149-2001)
- Korea 1st class (Korea KMOEL - 2017-64)
- DS (Japan JMHLW-Notification 214, 2018).

Gowns

The purpose of a gown when used for droplet, airborne and contact precautions is to prevent direct contact between the healthcare worker's skin or clothing and the patient/care area, in order to prevent direct transfer of micro-organisms. A long-sleeved, preferably fluid-resistant, gown or apron are the current recommendations for contact precautions for COVID-19. A cloth gown or apron is adequate when direct physical contact is minimal and/or the risk of splash is low (e.g. specimen collection, observations, medication delivery).

Surgical gowns are single use items intended for use in the operating room to protect operating room personnel from the transfer of body, fluids, micro-organisms and particulate material. These are usually sterile.

Single use isolation gowns are intended to protect either the patient or healthcare providers and visitors from the transfer of infectious agents when they are in contact with each other. They must have long sleeves and cuffs or thumb loops so that they cover the wearer to the wrist.

Fluid-resistant gowns can be further categorised based on the level of protection from fluid. The standards referring to fluid-resistant properties of gowns used in healthcare are ANSI/AAMI PB70:2012. These provide standards for liquid barrier performance. There are levels 1 to 4 for gowns in this standard.

All gowns meeting ANSI/AAMI PB70:2012 can be used for the care of COVID-19 patients. The level of fluid resistance should determine which gown should be used. The choice of gown should be made based on the level of risk of fluid contamination:

- If the risk of blood or body fluid exposure is low or minimal, gowns that claim minimal or low levels of barrier protection (ANSI/AAMI PB70 Level 1 or 2) can be used.
- If there is a medium to high risk of blood or body fluid exposure gowns that claim moderate to high barrier protection (ANSI/AAMI PB70 Level 3) can be used.
- For surgical procedures or a high risk of blood or body fluid exposure gowns that claim high level barrier protection (ANSI/AAMI PB70 Level 4) should be used.

A level 1 gown is suitable for contact and droplet precautions where the risk of blood or body fluid exposure is low or minimal. When choosing a gown, healthcare workers should undertake a risk-based assessment in line with standard precautions. If a gown is required to protect against anticipated splash or spray of blood or body fluids in line with standard precautions, in an environment outside of operating theatres, a level 3 gown or the addition of a plastic apron over a level 1 or level 2 gown may be required. Level 4 gowns are only required for surgical procedures or major trauma response, where large volumes of blood are anticipated.

Table 3. Possible use cases for barrier levels of gowns

Fluid barrier level (ANSI/AAMI PB70)	Examples of use
Cloth gown or apron (no ANSI/AAMI PB 70 rating)	Minimal contact with patients with COVID-19 where the risk of splash with blood or body fluid is low. For example, delivering medications, specimen collection or taking nursing observations.
Level 1 **OR** **Level 2**	Close contact with patients with COVID-19 including any routine care where the risk of spray or splash of blood or body fluid is minimal. For example: assisting with ADLs, dressing small wounds or insertion of a peripheral intravenous cannula.
Level 3	Suctioning, large dressings or dressings with high levels of exudate, emptying or inserting a urinary catheter or inserting an intravenous catheter. Aerosol-generating procedures outside of a major trauma or operating theatre setting.
Level 4	Surgery or major trauma

Table 4. Adapted from AAMI/ANSI PB70:2012

Test type	Level of protection	Notes
Impact penetration	1, 2, 3, 4	As measured using AATC 42
Hydrostatic pressure	2, 3 and 4	As measured using AATC 127
Resistance to penetration by blood-borne pathogens	4	As measured using ASTM F1671

Eye protection

Eye protection can consist of face shields, goggles, visors or wrap-around safety glasses. These may be single use or reusable devices. Their use is designed to prevent the mucous membranes of the wearer coming into contact with respiratory droplets. Where these devices are reusable, they must be reprocessed in accordance with manufacturer's instructions. If they require disinfection, a suitable TGA-listed medical device disinfectant or sterilant must be used as per AS/NZS 4187:2014. Further guidance about cleaning of protective eyewear can be found in the ICEG guidelines on cleaning and disinfection of protective eyewear in health and residential care facilities, available at https://www.health.gov.au/resources/publications/iceg-guidelines-on-cleaning-and-disinfection-of-protective-eyewear-in-health-and-residential-care-facilities.

As with other items that are intended for use in a health environment and make claims to protect the wearer or others from the transmission of diseases or micro-organisms, eye protection must be included in the ARTG as a Class I medical device. AS/NZS 1337.1:2010, particularly Appendix V, lists the required testing methods that determine the splash resistance of face or eye protection. Please note that if impact resistance is required, testing against other appendices of the standard may be required to be shown.

Gloves

All gloves used in the provision of healthcare should be disposable and include examination gloves, sterile gloves and medical gloves for handling chemotherapy.

The World Health Organization (WHO) recommends that examination gloves be powder free to avoid reactions with alcohol-based hand rubs used in healthcare facilities. If there are no other gloves available, powdered gloves may be used and healthcare workers should be instructed to perform hand hygiene using running water and liquid soap.

The wearing of gloves is not a substitute for hand hygiene. Gloves should be changed between episodes of care for different patients, and during the care of a single patient to prevent transmission of microorganisms from different body sites. Hand hygiene should be performed before putting gloves on and after removing gloves.

The standards applicable to medical gloves are AS/NZS 4011 and ISO 11193, and for sterile gloves AS/NZS 4179 and ISO 10282.

Version control – Appendix 5

Version	Date	Comments
V1.2	2 September 2020	• Clarification on use of P2/N95 respirators that are not fluid resistant
V1.1	31 May 2020	• Inclusion of Standards Australia Summary information on standards and conformance for PPE products • Minor revision to: Table 1 examples of use, fit checking of respirators and use of gowns. • Minor revision to Table 3 examples of use for non-fluid-resistant gowns or aprons.
V1.0	10 May 2020	• New Appendix