Guidelines for Personal Protective Equipment

A rapid review commissioned by RACS

11 August 2020

Royal Australasian College of Surgeons

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Version Number	Date Changed	Reason for Change
1	17 April 2020	Original version
2	11 August 2020	Latest WHO guidance on surgical masks added Comparison of surgical masks and P2/N95 respirators added Negative consequences of extended PPE use on healthcare workers added

Version Number	Date Changed	Reason for Change
		Methods of improving PPE education and monitoring added Peer-reviewed sequences for donning and doffing added Information on operative team checklists for higher-risk specialties (e.g. ENT) added Additional points on rationing and conserving PPE added

Recommendations

The extent of COVID-19 community spread is yet to be determined, and as such the recommendations offered in this report may be updated to reflect changes in practice as related to COVID-19 prevalence in the community over time.

The recommendations regarding appropriate PPE use are based on the available current literature:

1. Implement mandatory PPE donning and doffing training for all surgical staff

2. Implement mandatory infectious disease control training for all surgical staff

3. Consider contingency plans to extend the use of PPE specifically P2/N95 respirators

4. Patient to wear a surgical mask when transported to and from the operating theatre

5. PPE Composition:

    - **Non-Aerosol Generating Procedures (non-AGPs)**

    1. Surgical mask
    2. Disposable gown
    3. Double gloves
    4. Eye protection (safety glasses, goggles or full face shield)
    5. Head covering
    6. Shoe covering
    7. Perform hand hygiene

    - **Aerosol Generating Procedures (AGPs)** *disposable apron is a suggested additional PPE item*

    1. Surgical P2/N95 respirator
    2. Disposable gown
    3. Apron
    4. Double gloves
    5. Eye protection (safety glasses, goggles or full face shield)
    6. Head covering
    7. Shoe covering
    8. Perform hand hygiene

It is acknowledged that the decision for PPE use is situation and jurisdiction dependent; guidance provided below may be adapted by individual surgical teams.

- **Emergency surgery** (performed within 24 hours of presentation) where the patient is unconscious and unable to provide medical history and/or recent travel history; patient is conscious but the COVID-19 status and patient history are unknown; patient has no obvious symptoms (e.g., dry cough, fever, sore throat):
    - Decision**:** Surgical team to don appropriate level of PPE that is dependent on whether Aerosol Generating Procedures (AGPs) are performed. The rationale is to treat the patient as suspected COVID-19 positive until diagnostic tests indicate otherwise

- **Category 1 surgery** (surgery performed within 1 month of presentation)
    - Decision**:**
        - If patient is COVID-19 positive, surgical team to don appropriate level of PPE that is dependent on whether Aerosol Generating Procedures (AGPs) are performed
        - If patient is not COVID-19 positive, surgical team to don attire as stipulated by their surgical unit e.g., surgical mask, eye protection (shield or goggle protection), disposable gown, gloves

Executive summary

Although the pathogenic nature of COVID-19 is yet to be fully elucidated, health authorities in Australia and New Zealand have been afforded the rare opportunity to learn from the Northern Hemisphere experience as how best to maintain a healthy surgical and ancillary workforce during this pandemic.

Given that COVID-19 transmission occurs via droplets, aerosols and fomite contact, surgical teams exposed to asymptomatic COVID-19 positive patients are at greater risk during aerosol generating procedures (AGPs).

This has brought into focus the use of Personal Protective Equipment (PPE) as the last line of defence for surgical staff.

This guideline reinforces what is considered the minimum threshold for PPE use by healthcare workers (HCWs) in the treatment of COVID-19 patients.

These consist of P2/N95 filtering facepiece respirators (FFRs), eye protection, disposable gloves, gowns, aprons, head and foot covering as reported in the current peer-reviewed literature and guidance from the World Health Organization (WHO).

Formal training on donning and doffing PPE procedures, comprehensive infectious disease control education and good hand hygiene are equally important aspects for the prevention of COVID-19 infection in surgical staff.

Healthcare administrators are also encouraged to have contingency plans for extending the use of P2/N95 FFRs should PPE supply chains be interrupted.

Introduction

COVID-19 is a single stranded RNA spheroid shaped virus ranging from 40-140 nm in diameter, which is closely related to the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) group of viruses. The mechanism of human infection begins with airborne viral particles binding to the angiotensin-converting enzyme 2 (ACE 2) protein that is expressed on the surface of lung alveolar epithelial cells.[1] ACE 2 protein is widely distributed and is also present in a variety of human organs: oral and nasal mucosa, nasopharynx, lung, stomach, small intestine, colon, skin, lymph nodes, thymus, bone marrow, spleen, liver, kidney, and brain.[2]

Droplet, aerosol exposure and fomite contact are the main modes of transmission of COVID-19[3] and depending on the initial inoculum shed can remain viable and infectious in aerosols for hours, and depending on surface type for up to days.[4]

The highest priority for Australian State and Federal, and New Zealand health authorities must be that of preserving workforce capacity and capability by mitigating the risk of infection to healthcare workers (HCWs), specifically surgeons, anaesthetists and the theatre team. It is imperative that all surgical staff adhere to appropriate PPE precautions whilst there is evidence of community transmission to minimise spread of the virus.[7, 8] Surgical staff should practise physical distancing of at least one metre[9] within surgical departments, and wear surgical masks whenever possible if there is an adequate local supply.[10]

This document provides guidelines regarding the most appropriate use of Personal Protective Equipment (PPE) taking into consideration: i) the supply of and access to PPE and ii) the COVID-19 status of the patient.

Since the initial version of this document was produced on 17 April 2020, regular searches of the peer-reviewed literature have been conducted at weekly to fortnightly intervals to identify any guideline updates. Notable updates in the literature that have since been added to this document are outlined in the version control table on the title page.

Personal Protective Equipment (PPE)

PPE consists of disposable gowns, aprons, gloves, face shields, goggles, outer foot covering, head covering, surgical masks, filtering facepiece respirators (P2/N95) and PAPR (Powered Air Purifying Respirators). The properties and utility of surgical masks and filtering facepiece respirators (P2/N95) will be the focus of this guideline document.

Surgical Mask

Surgical masks are loose fitting, single-use items that cover the nose and mouth (Table 1). They are used as part of standard precautions to keep splashes or sprays from reaching the mouth and nose of the person wearing them. They also provide some protection from respiratory secretions and are worn when caring for patients who are on droplet precautions. Surgical masks can be placed on coughing patients to limit potential dissemination of infectious respiratory secretions from the patient to others - *NHMRC, Australian Guidelines for the Prevention and Control of Infection in Healthcare (2019)*[11]

Table 1. Surgical Masks - Level Barrier Protection

Characteristics	Level 1 Barrier	Level 2 Barrier	Level 3 Barrier	Test Method
Application	For procedures where the wearer is not at risk of blood or bodily substance splash or to protect staff and/or the patient from droplet exposure to microorganisms (e.g., patient with upper respiratory tract infection)	For procedures where the wearer is at risk of moderate exposure to blood and body substances (e.g., surgery, dentistry, general patient care areas; to protect staff and/or the patient from droplet exposure)	For procedures such as major trauma first aid or in any area where the health worker is at risk of substantial exposure to blood or bodily substance splash (e.g., orthopaedic, ENT, cardiovascular procedures)	N/A
Bacterial Filtration Efficiency (BFE)%	≥ 95%	≥ 98%	≥ 98%	ASTM F2101-14 or EN 14683:2014
Differential pressure (ΔP), mm H_2O/cm^2	< 4.0	< 5.0	< 5.0	EN 14683:2014
Resistance to penetration by synthetic blood (fluid resistance) minimum pressure in mmHg for pass result	80 mmHg	120 mmHg	160 mmHg	ASTM F1862 / F1862M-13 or ISO 22609

Source: *AS 4381: 2015 Standards Australia: Single-use face masks for use in health care*[12]

P2 and N95 filtering facepiece respirators

P2 and N95 respirators are disposable filtering facepiece respirators worn to protect both the patient and HCW from airborne microorganisms, bodily fluids and particulate matter (Table 2).

While the terms 'P2 respirator' and 'N95 respirator' are often used interchangeably in the healthcare setting, they are required to meet different standards. In Australia, the requirements for P2 respirators are stated in Standard AS/NZS 1716: 2012. The United States (US) National Institute of Occupational Safety and Health (NIOSH) specifies N95 respirator requirements. – NHMRC Australian Guidelines for the Prevention and Control of Infection in Healthcare (2019)[11]

Table 2. Properties of P2 and N95 respirators

Properties	P2 Respirators	N95 Respirators
Characteristics	• Raised dome or duckbill • 4-5 layers (outer polypropylene, central layers electret [charged polypropylene]) • Filtration through mechanical impaction and electrostatic capture • Designed to provide a good facial fit to minimize aerosol contamination of the mucous membranes of the nose and mouth P2 particulate filtering respirators/masks must have a filter efficiency of at least 94% when tested with sodium chloride aerosol at a flow rate of 95 L/min. Under the European Standard (EN) system, aerosol testing is similar to Standard AS/NZS 1716:2012 but have additional filter efficiency testing with paraffin oil aerosol that must also meet the minimum 94% filter efficiency to be classified as P2. The particle size of this aerosol has a mass median diameter of 0.3 to 0.6 microns with a range of particles in the 0.02 to 2 micron size range.	• Raised dome or duckbill • 4-5 layers (outer polypropylene, central layers electret [charged polypropylene]) • Filtration through mechanical impaction and electrostatic capture • Designed to provide a good facial fit to minimize aerosol contamination of the mucous membranes of the nose and mouth NIOSH classified N95 particulate filtering respirators/masks must have a filter efficiency of at least 95% when tested with sodium chloride aerosol at a flow rate of 85 L/min. N95 respirator masks can only be used for oil free aerosols. The particle size of this aerosol is ~0.3 micron.
Sealing	• Ties at crown and bottom of head, pliable metal nose bridge • Fit testing and fit checking recommended	• Ties at crown and bottom of head, pliable metal nose bridge • Fit testing and fit checking recommended
Standards	Standard AS/NZS 1715: 2009 Standard AS/NZS 1716: 2012	Set by the US NIOSH classification (NIOSH Guidelines – Procedure No. TEB-APR-STP-0059)

Intended use	• Routine care of patients on airborne precautions • High-risk procedures such as bronchoscopy when the patient's infectious status is unknown • Procedures that involve aerosolisation of particles that may contain specific known pathogens (AGPs)	• Routine care of patients on airborne precautions • High-risk procedures such as bronchoscopy when the patient's infectious status is unknown • Procedures that involve aerosolisation of particles that may contain specific known pathogens (AGPs)
Notes	Care must be taken if placing respirators on patients and must suit clinical need (i.e., if the patient has chronic obstructive airways disease, or is in respiratory distress, the respirator will exacerbate symptoms).	Care must be taken if placing respirators on patients and must suit clinical need (i.e., if the patient has chronic obstructive airways disease, or is in respiratory distress, the respirator will exacerbate symptoms).

Source: Table 13 - NHMRC, Australian Guidelines for the Prevention and Control of Infection in Healthcare (2019)[11]

Compared with surgical masks, N95 respirators display superior performance in laboratory testing, and may provide better protection in inpatient settings.[13] However it must be noted that urgent clinical situations requiring vigorous movement, such as during cardiopulmonary resuscitation, may result in inadequate protection.[14] Nevertheless, P2/N95 respirators are still the best available PPE in the healthcare context for reducing large scale COVID-19 transmission

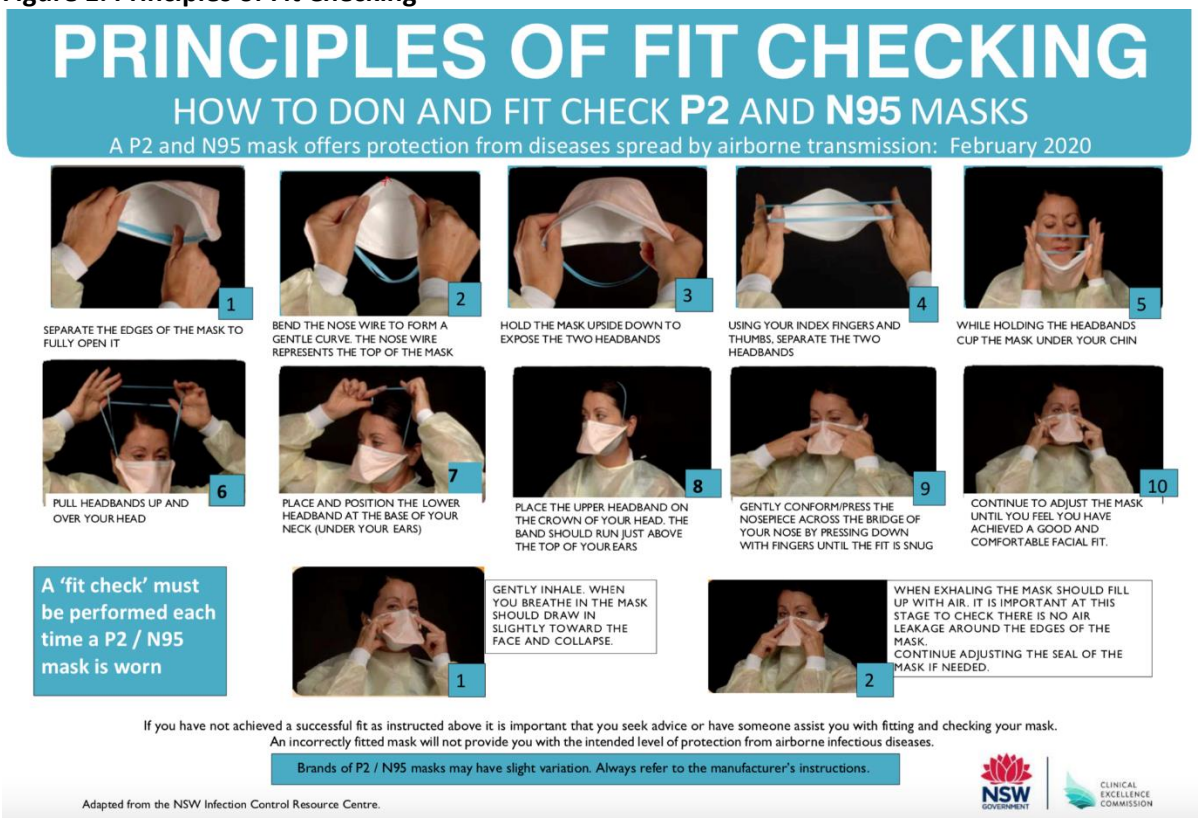
Fit testing

Fit testing is essential to ensure the expected level of protection (i.e., concentration of airborne contaminants inside the respirator is less than or equal to 10% of ambient levels).[15] The highest level of protection is provided by passing a fit-test with a N95 respirator model that has good-fitting characteristics; Figure 1.[16]

As most particle penetration occurs through face-seal leakage, which varies with breathing flow rate and particle size[17], manufacturers recommend the removal of facial hair for optimum sealing of a P2/N95 respirator around the wearer's face.

Pressure-related dermatological lesions have been associated with the tight facial fit required for optimal functioning of P2/N95 respirators.[18] Prophylactic and therapeutic measures (such as barrier creams[19] or other pressure-reducing methods) should be encouraged for the health of healthcare workers, but should not compromise respirator function. Similarly, headaches have also been associated with extended use of PPE during COVID-19.[20] The surgical staff should be afforded scheduled breaks during periods of extended PPE use, so that personal health, surgical performance, and patient outcome are not compromised.[21]

Figure 1. Principles of Fit Checking



Source: *Principles of fit checking: how to don and fit check P2 and N95 masks, adapted from the NSW Infection Control Resource Centre*

Importance of infectious disease education for HCW, including good hand hygiene

Good hand hygiene practice through the increased frequency of use of alcohol-based hand sanitisers (min 70% ethanol or isopropanol) is an economical and efficient method for reducing the risk of COVID-19 infection amongst HCWs.

A lesson learnt from the SARS outbreak was that inadequate (< 2 h) training on infection control procedures and inconsistent use of PPE were high risk factors for HCWs[22], as were HCWs being unsure of proper PPE donning and doffing procedures. Also, fatigue was a cited as a significant factor in poor decision making and breaches of PPE protocols.[23]

PPE donning and doffing training

It is imperative that formal training be provided to HCWs on donning and doffing PPE, given that improper doffing increases the risk of nosocomial COVID-19 spread.[24] During training, common breaches in biosafety during donning and doffing must be identified and explicitly outlined to all HCWs.[25] Simulation technologies could potentially be used as a tool to train staff on the use of PPE if available at local healthcare facilities.[26] Regular reinforcement of concepts and auditing of PPE competency should be conducted to ensure that the benefits of any formal PPE education are maintained.[27]

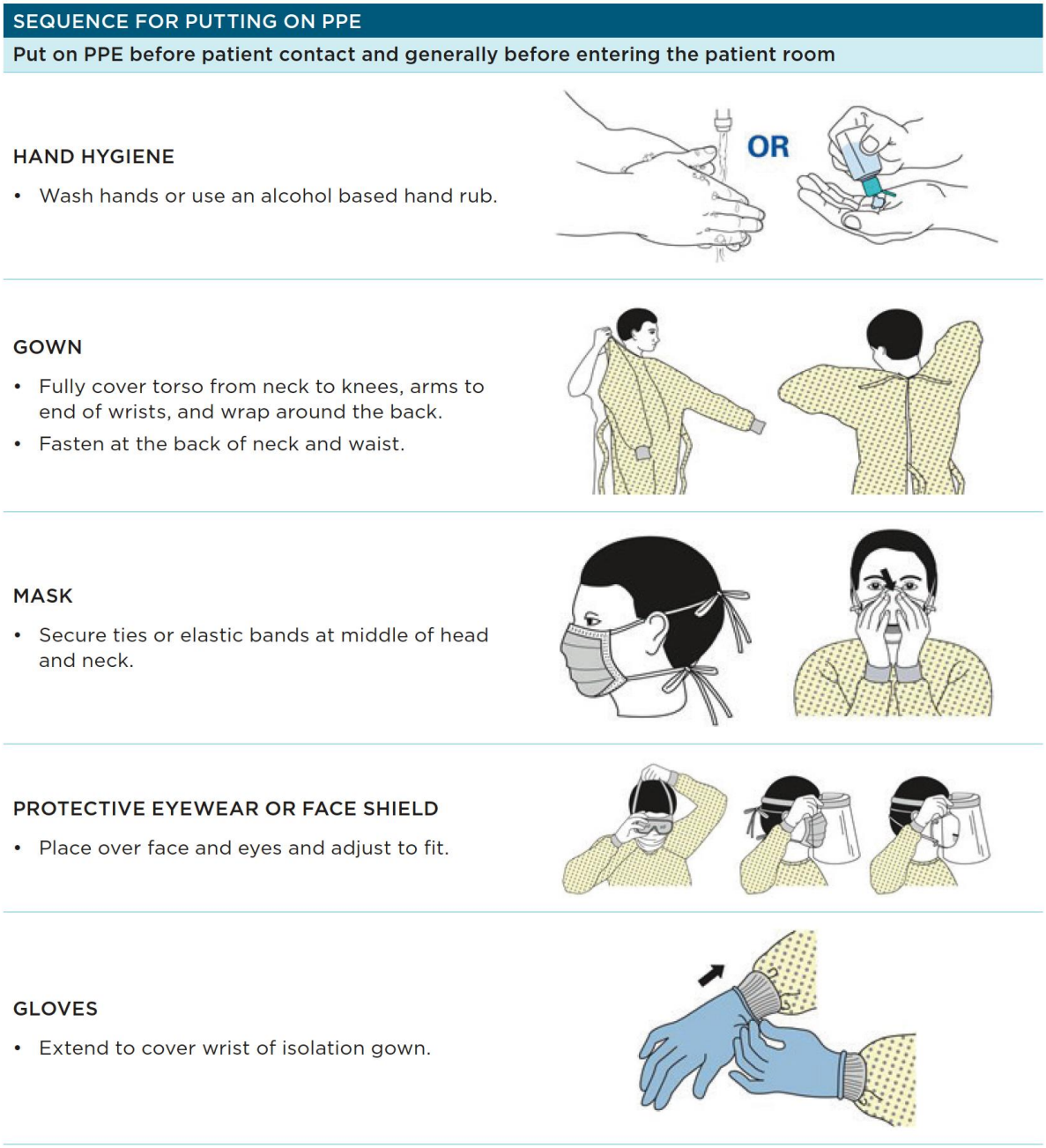
It should not be assumed that all HCWs have had adequate training in donning and doffing procedures.

Individual surgical units are strongly encouraged to:

- implement training programs for staff regardless of seniority or length of service
- use a buddy system where one person ("buddy") observes and gives step by step verbal instructions to the partner who follows as instructed. Remote audio visual surveillance of donning and doffing procedure has been suggested within the literature,[28] however further research is required before this can be definitively incorporated into the training regime.

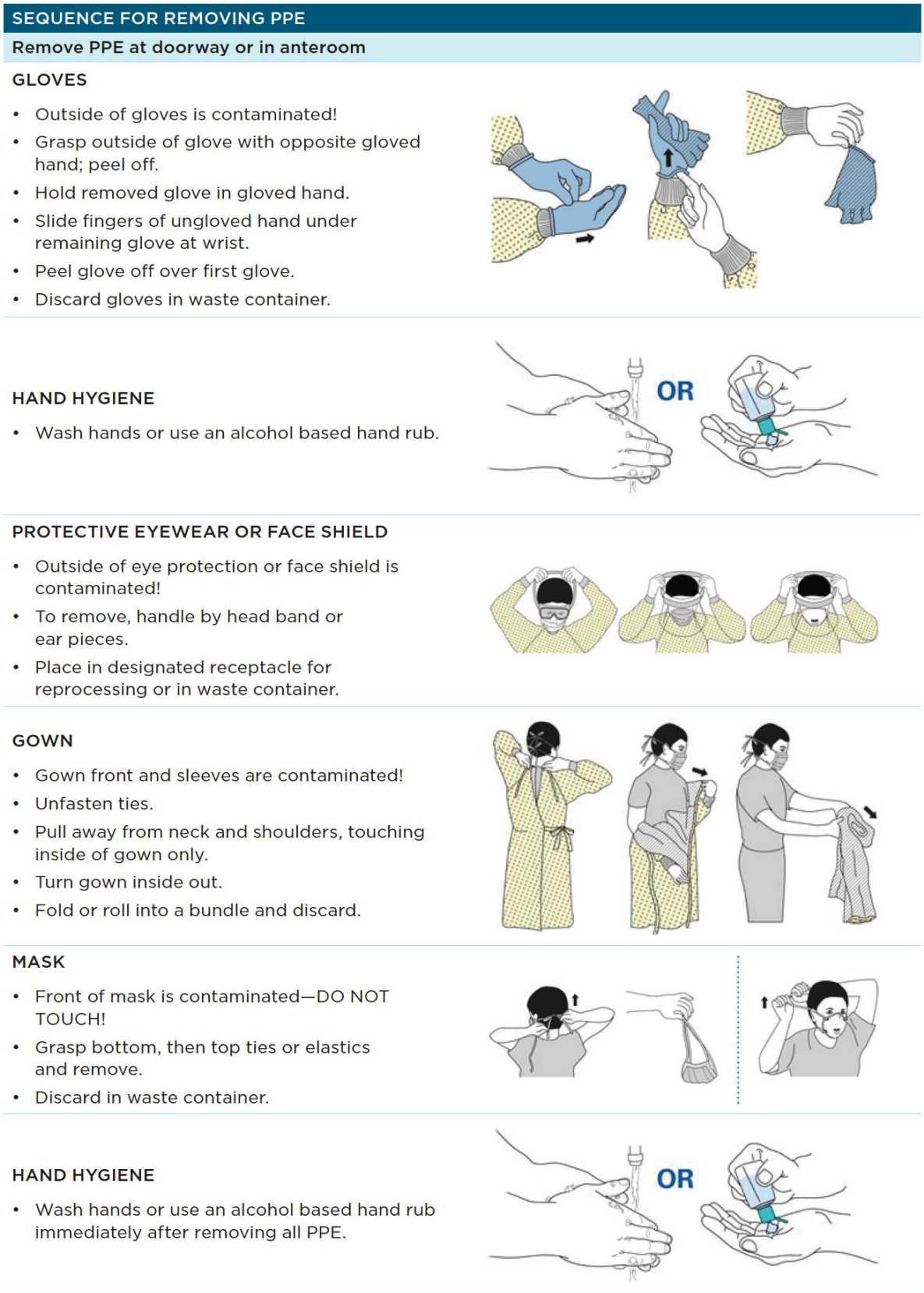
- fix laminated posters onto walls in ante rooms and/or theatre staff change rooms that demonstrate stepwise donning and doffing procedures (Figures 2a and b)
    - If possible, staff to doff in an ante room, practise hand hygiene before departing ante room
    - Staff to shower before resuming other duties[29]

Figure 2a. Donning PPE Prior to non-sterile Patient Encounters



Source: - *NHMRC, Australian Guidelines for the Prevention and Control of Infection in Healthcare (2019)*[11]

Figure 2b. Doffing PPE After non-sterile Patient Encounters



Source: - *NHMRC, Australian Guidelines for the Prevention and Control of Infection in Healthcare (2019)*[11]

As a method for increasing the protection of surgical teams during COVID-19, Evans et al have published a sequence for donning and doffing PPE before and after surgery in a peer-reviewed setting.[30] Similar protocols have also been published for non-surgical interventions, where the safety of the clinical team relies on appropriate donning and doffing around the respective procedure.[31]

As reported by Wong et al (2020) another measure to minimise COVID-19 infection employed in Singapore was to have the patient wear a surgical face mask whilst being transported to and from the operating theatre along a designated route with minimal contact with other HCWs.[32]

Patient status and PPE

The World Health Organization (WHO) has provided interim guidance which was issued against a backdrop of acute global PPE shortages: *Rational use of personal protective equipment for coronavirus disease (COVID-19) and considerations during severe shortages, Interim guidance, 6 April 2020* (Appendix 1). The guidance regarding the types of PPE to be worn when treating COVID-19 positive patients in AGP and non-AGP environments is in concordance with the Australian and New Zealand College of Anaesthetists (ANZCA) recently released *Statement on personal protection equipment during the SARS-CoV-pandemic, 9* April 2020 (Appendix 2).

HCWs with firsthand experience treating COVID-19 patients such as those in Italy[33] advised that PPE should include: helmets, covers or hoods, FFP3 or FFP2/N95 masks, goggles or face shields (if no helmets), hazmat suits or long sleeved fluid-resistant gowns, double gloves (possibly different colours), and overshoes. (*National Institute for Occupational Safety and Health (NIOSH)-approved FFRs require a minimum of 95 and 99.97% efficiencies for N95 and P100 FFR respectively. European Norms (EN)-certified 'Conformite European' (CE)-marked FFRs require 94 and 99% for class P2 (FFP2) and class P3 (FFP3) respectively*).

It is recommended that individual healthcare centres refer to advice issued by the Australian Government Department of Health: *Interim advice on non-inpatient care of persons with suspected or confirmed Coronavirus disease (COVID19), including use of personal protective equipment (PPE)* to define "low risk, suspected and confirmed COVID-19" status of patients.
New Zealand healthcare centres should refer to the Ministry of Health, NZ for guidance: *Case definition of COVID-19 infection 8 April 2020.*

Aerosol Generating Procedures (AGPs)

A major risk to HCWs is the exposure to viral particles during AGPs. The Australian and New Zealand College of Anaesthetists (ANZCA) recently released *Statement on personal protection equipment during the SARS-CoV-pandemic, 9* April 2020 (Appendix 2) indicated there is broad consensus that the following are classified as AGPs.

a. Bag and mask ventilation

b. Tracheal intubation

c. Tracheal extubation

d. Ventilation via supraglottic airways (including insertion and removal)

e. Non-invasive ventilation including Continuous Positive Airway Pressure (CPAP) and Bilevel Positive Airway Pressure (BiPAP) therapies

f. High flow nasal oxygen therapy

g. Use of nebulisers

h. Cardiopulmonary Resuscitation (CPR)

i. Anaesthesia procedures for women in late first stage labour and second or third stage labour and especially those who are distressed. Secretions from the respiratory tract and faeces are the principle risk to staff and others.

j. Anaesthesia procedures for highly symptomatic patients who are considered high risk for aerosol generation (e.g., coughing or other signs of respiratory distress)

High risk Procedural/Surgical AGPs

k. High Risk Procedural AGPs - Diagnostic and therapeutic instrumentation of the airway including bronchoscopy and tracheostomy

l. High Risk Surgical AGPs - Any surgical procedure involving the upper respiratory tract, such as ear, nose and throat, facio-maxillary or anterior pituitary surgical, procedures, where aerosolisation of tissue is likely; for example, the use of pulsed lavage, the use of high-speed drills and laser techniques. *The risk of transmission from non-respiratory tract blood aerosol, digestive tract aerosol, pulsed lavage and laser work is currently not accurately known but is thought to be lower.*

In addition to the above listed procedures, further examples are provided by the Australian Government Department of Health *Guidance on the use of personal protective equipment (PPE) in hospitals during the COVID-19 outbreak (version 4):*

i) Intentional or inadvertent disconnection/reconnection of closed ventilator circuit
ii) Intercostal catheter insertion for relief of pneumothorax
iii) Thoracic surgery that involves entering the lung
iv) Collection of induced sputum

Special attention is drawn to the high risk (k) procedural and (l) surgical AGPs, with respect to the final ANZCA statement regarding "*The transmission risk from non-respiratory tract blood aerosol etc*". We provide here more relevant information relating to COVID-19 presence in various bodily fluids. As the pandemic has progressed, operative team checklists have been published for surgical specialties at higher risk of aerosol generation (e.g. ENT surgery), in order to minimise the exposure of surgical staff to SARS-CoV-2.[34]

Evidence of COVID-19 in bodily fluids

Although rapid, Reverse Transcription-Polymerase Chain Reaction (RT-PCR) is an imperfect COVID-19 diagnostic test.[35] A review by Lippi et al (2020) found that due to patients being tested whilst in the early stages of disease progression and therefore carrying low viral loads, the RT-PCR test can report up to 30% false negative results. Other attributable factors include poor pre-analytical handling of patient samples and compromised quality of reagents and primers.[35]

- The highest COVID-19 RNA positive rates were detected in bronchoalveolar lavage fluid, then sputum, nasal swabs, fibrobronchoscope brush biopsy, pharyngeal swabs, faeces and blood but not urine samples of 205 patients screened by RT-PCR.[36] Four of the COVID-19 positive faecal specimens were cultured and viable viral particles detected by scanning electron microscopy (SEM).

- Detection of COVID-19 RNA in sputum from convalescing patients that tested negative in their throat and anal swabs[37]; further confirming that COVID-19 virions attach to alveolar epithelium in the lower lungs.

- Lacrimal secretions from another cohort of COVID-19 positive patients screened by RT-PCR and viral isolation (inoculation of lacrimal sample into Vero-E6 cells and examined for signs of cytopathic effect) returned negative results at the time their nasopharyngeal swab tested positive for COVID-19.[38] *However*, a **COVID-19 infected patient with conjunctivitis** tested positive for COVID-19 RNA in tear and conjunctival secretions.[39]

Aerosolisation of infectious viruses by excimer laser

For context, COVID-19 virions are elliptical/spheroid particles with a diameter of 40-140 nm.

- *Live virus production following excimer laser*

Excimer laser photoablation of the A549 adenocarcinoma cell line infected with Herpes Simplex Virus (155–240 nm diameter) and adenovirus (90-100 nm diameter) produced live virus that was detected in sentinel dishes of uninoculated A549 monolayer placed at adjacent sites.[40]

- *Smaller viruses can survive excimer laser ablation*
  The captured phototherapeutic ablation plumes from fibroblasts previously inoculated with oral polio virus (30 nm diameter) caused a cytopathic effect when seeded on untreated human embryonic lung fibroblasts.[41] The authors suggested that laser plumes generated during corneal photorefractive keratectomy were to be treated as biohazardous material. They advised wearing surgical masks that filter out small particles and evacuating the laser plume where possible.

- *Generation of 0.13-0.42 µm diameter respirable particles during ablation*
  Excimer laser plume of eye-bank corneas set for phototherapeutic ablation produced respirable particles.[42] The authors commented that particles of 5.0 µm or larger are generally deposited on mucosa of nasopharynx, trachea and bronchial bifurcation whereas particles smaller than 2.0 µm lodged in the respiratory bronchioles and alveoli.

Conserving and extending P2/N95 respirator use

The critical worldwide shortage of P2/N95 respirators is posing a challenge to health department administrators as how best to manage current stocks in hospitals. Strategies for ethical rationing have been discussed,[43] however every proposed system has inherent flaws.

Strategies for conserving and extending P2/N95 respirator use may include:

1. mandating the use of full face shields over the P2/N95 respirator to reduce the contamination of the outer respirator surface. The protection from droplets and aerosols afforded by the face shield allows extended use of the respirator,[44] and potentially for safe reuse on subsequent patients in situations of low resource supply (unless suspected or confirmed COVID-19 positive).[45]
2. covering respirators with surgical masks or similar disposable covers over the top of respirators can potentially extend the life of the respirator without significant adverse effects. A study trialling 30 NIOSH-approved N95 FFR models, with and without a surgical mask cover, found that at the lower levels of energy expenditure, placement of a surgical mask cover over the FFR produced clinically small changes in inhaled breathing gases and pressure and minimal effect on physical work performance.[46]
3. disinfection of P2/N95 respirators by Ultraviolet Germicidal Irradiation (UVGI). MS2 coliphage (single stranded RNA virus of 27 nm diameter) viral droplets aerosolised onto N95 FFRs (model N1105; Willson, Santa Ana, CA) then subjected to UV irradiation resulted in approximately 3-log reduction in the level of MS2 virus at a dose of 4.32 J/cm^2 (3 h of contact time with a UV intensity of 0.4 mW/cm^2).
   At higher doses of ≥7.20 J/cm^2; UV intensity, 0.4 mW/cm^2 and contact times ≥5 h, all MS2 was inactivated.[47] The UV doses used are significantly higher than that required to inactivate single-stranded RNA viruses, such as SARS-CoV-2 which are generally inactivated by UVGI exposure of 2-5 mJ/cm^2 .[48]
4. the use of industrial-style elastomeric half-mask respirators has also been reported as a method of reducing dependence on N95 respirators in clinical settings of significantly high demand.[49]

Conclusions

Correct use of PPE, infectious disease control training and good hand hygiene are fundamental to reducing the risk of HCWs contracting COVID-19.

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