Public Services Delivery
Scotland

NHS
SCOTLAND

Respiratory Protective Equipment (RPE)
Transmission Based Precautions Literature Review

Evidence Tables

Version 5.0

3 August 2026

Antimicrobial Resistance & Healthcare Associated Infection (ARHAI) Scotland
An NHS Scotland Assure Service, part of Public Services Delivery Scotland

Version history

This literature review will be updated in real time if any significant changes are found in the professional literature or from national guidance/policy.

Version	Date	Summary of changes
5.0	3 August 2026	A combined version of previous evidence updates and the current update of the surgical face mask review.

Contents

Introduction

All studies which are critically appraised as part of the literature review are assigned a grade of evidence based on the SIGN 50 methodology grading system (SIGN, 2004), which allows scientific studies to be assessed for quality using a number of reviewing forms (available from the SIGN website).

The main conclusions from the studies are summarized along with a brief description of the study quality in an Evidence Table. Studies, which have sufficient quality and specifically answer a defined research question are grouped together to enable formation of a “considered judgment” based on this information. This “considered judgment” is then used as the basis for formulation of recommendations.

This system allows formulation of recommendations supported by good quality observational studies in the case when RCTs are not available for practical or ethical reasons, as is generally found in infection control literature.

Levels of evidence

The following grades were given to the papers included in this evidence table:

Grade	Description
1++	High quality meta analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1+	Well conducted meta analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
1-	Meta analyses, systematic reviews of RCTs, or RCTs with a high risk of bias
2++	High quality systematic reviews of case-control or cohort studies. High quality case-control or cohort studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is causal
2+	Well conducted case control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal
2-	Case control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal
3	Non-analytic studies, for example case reports, case series

Grade	Description
4	Expert opinion

Research questions for evidence tables

Question 1: What is respiratory protective equipment?

Evidence added to 2024 update:

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Department of Health Infection Prevention and Control (IPC) National Clinical Guideline No. 30 Last updated: May 2023 Accessed: 03 February 2025	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence
Target audience: “This National Clinical Guideline applies to all health and social care workers because the control of healthcare associated infection is everyone’s responsibility. It is particularly relevant to Infection Prevention and Control (IPC) Practitioners. IPC

Assessment of evidence
Practitioners are those health and social care workers with specific training and expertise in the prevention and control of infection and who provide training, guidance and leadership to others on IPC." Recommendations: "FFP2 respirators are designed to help reduce exposure of the wearers airway to airborne contaminants such as particles, gases or vapours."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centre for Disease Control and Prevention (CDC) The National Institute for Occupational Safety and Health (NIOSH) Community Respirators and Masks – Types of Masks and Respirators Last updated: 16 May 2023	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Accessed: 07 January 2025					

Assessment of evidence

Target audience: Community, USA

“NIOSH Approved elastomeric half-mask respirator and elastomeric quarter-mask respirator

How Well It Protects You: NIOSH Approved elastomeric half-mask respirators (EHMRs) and elastomeric quarter-mask respirators (EQMRs) protect you against gases, vapors, and particles when equipped with the appropriate filter, cartridge, or canister.

How Well It Protects Others Around You: Some EHMRs and EQMRs, such as those without exhalation valves, filter the air you breathe out and you can use them to protect others around you.

Filtration: These are reusable respirators that, when equipped with particle filters, achieve a minimum of 95% filtration efficiency.

Fit: EHMRs and EQMRs cover the nose and mouth and are tight-fitting.”

“NIOSH Approved filtering facepiece respirator

How Well It Protects You: NIOSH Approved FFRs, such as N95 respirators, protect you against particles. They do not protect against gases or vapors.

How Well It Protects Others Around You: Some NIOSH Approved FFRs have exhalation valves that open to let air escape when you breathe out. This makes it easier to breathe and can make the respirator more comfortable to wear. An FFR with an exhalation valve may not protect others as well as one without a valve.

- Without exhalation valves: NIOSH Approved FFRs without exhalation valves filter the air you breathe out. You can use this type to protect others around you.

Assessment of evidence

- With exhalation valves: If the NIOSH Approved FFR has an exhalation valve, some of the air will come out of the exhalation valve and reduce the level of protection to others. Wearing one of these will provide similar levels of protection to others as BFCs and some disposable face masks and cloth masks.

Filtration: NIOSH Approved FFRs are a disposable respirator that achieve a minimum of 95% filtration efficiency.

Fit: NIOSH Approved FFRs seal against your face around the nose and mouth and are tight-fitting."

"International filtering facepiece respirator

How Well It Protects You: International FFRs, such as KN95s, protect you against particles. They do not protect against gases or vapors.

How Well It Protects Others Around You: Some international FFRs have exhalation valves that open to let air escape when you breathe out. This makes it easier to breathe and can make the respirator more comfortable to wear. An international FFR with an exhalation valve may not protect others as well as one without a valve.

- Without exhalation valves: International FFRs without exhalation valves filter the air you breathe out. You can wear this type to protect others around you.
- With exhalation valves: If the international FFR has exhalation valves, the level of protection to others is variable. You should not wear this type if your goal is to protect others around you.

Filtration: International FFRs are a disposable type of respirator that achieve a level of filtration efficiency based on the specified standard with a minimum of 80%.

Fit: International FFRs seal against your face around the nose and mouth and are tight-fitting. Since manufacturers designed these respirators for populations outside of the United States, they may not seal as well to your face as a NIOSH Approved respirator."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
European Centre for Disease Prevention and Control (ECDC) Considerations for infection prevention and control practices in relation to respiratory viral infections in healthcare settings Last updated: 6 February 2023 Accessed: 6 January 2025	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

"**Scope:** This document aims to support the development of guidance for healthcare facilities and healthcare providers in the European Union/European Economic Area (EU/EEA) on infection prevention and control (IPC) measures for the management of patients with respiratory tract viral infection in healthcare settings.

Target audience: National public health agencies, healthcare facility administrators, IPC and other professionals developing relevant IPC guidance and healthcare workers in EU/EEA countries."

"A respirator (also known as filtering face piece (FFP) mask or filtering half mask) is designed to protect the wearer from exposure to airborne contaminants (e.g. from inhaling infectious agents associated with inhaling small and large particle droplets) and is classified as

Assessment of evidence
personal protective equipment (PPE) [74]. FFP2 respirators have a filtering capacity of at least 94% for 0.3 µm particles. FFP3 respirators have a filtering capacity of at least 99% for 0.3 µm particles.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centres for Disease Control and Prevention (CDC) The National Personal Protective Technology Library (NPPTL) The Respiratory Protection Information Trusted Source. Healthcare Setting Specific FAQs. Last updated: 5 July 2022 Accessed: 6 January 2025	British Standard	Level 4	N/A	N/A	N/A

Assessment of evidence

“What is a surgical N95 respirator?

Surgical N95 filtering facepiece respirators are commonly used in healthcare settings. These respirators provide healthcare personnel protection from both airborne and fluid hazards (e.g., splashes, sprays). Therefore, use of these respirators outside of healthcare settings is not necessary.”

“What is the difference between a surgical mask and a N95 filtering facepiece respirator (FFR)?”

Surgical masks are loose fitting and provide only barrier protection against droplets, including large respiratory particles. Surgical masks do not require fit testing. N95 FFRs are tight-fitting respirators and require fit testing. These respirators filter out at least 95% of particles in the air, including large and small particles.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution (BSI) BS EN 143:2021 Respiratory protective devices – Particle filters – Requirements, testing, marking Accessed: 22 March 2023	British Standard	Level 4	N/A	N/A	N/A

Assessment of evidence

Overview:

BS EN 143 discusses respiratory protective devices (RPDs). BS EN 143 highlights the minimum requirements for particle filters in specifies particle filters for use as replaceable components in unassisted RPDs except for escape devices and filtering facepieces. Laboratory tests are included for the assessment of compliance with the requirements.

Some filters complying with BS EN 143 can also be suitable for use with other types of respiratory protective devices and/or escape devices. Note: BS EN 143 does not cover requirements concerning respiratory hygiene. Requirements for decrease of the microbiological hazards caused by the growth of bacteria and viruses on the filtration material is not determined."

Classification:

"Particle filters are classified according to their filtering efficiency. There are three classes of particle filters: P1, P2 and P3 in ascending order of the filtering efficiency. The protection provided by a P2 or P3 filter includes that provided by the filter of lower class or classes." (page 6)

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Australian Government National Health and Medical Research Council (NHMRC) Australian Guidelines for the Prevention and	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Control of Infection in Healthcare 2019 (revised 2024, v11.24) Accessed 11 October 2024					

Assessment of evidence

Funding: Guidance was co-funded by the NHMRC and Medical Research Council and Australian Commission on Safety and Quality in Health Care.

Aim of guidance (page 20): “By assisting healthcare workers to improve the quality of the care they deliver, these Guidelines aim to promote and facilitate the overall goal of infection prevention and control: the creation of safe healthcare environments through the implementation of evidence-based practices that minimise the risk of transmission of infectious agents.”

Target audience (page 20): “The Guidelines are for use by all those working in **acute** health care settings — this includes healthcare workers, management and support staff. As some of the principles and recommendations described in this guideline may be applicable to other health care settings, individuals working in other health care settings may also find the guidelines useful.”

The introduction states that all recommendations are based on systematic reviews, however there is insufficient evidence within the guidance to support this claim.

Note: P2 respirators meet the relevant Australian standard (AS/NZS 1716:2012 and 1715:2009) and differs to NIOSH, which specifies N95 respirators.

“P2 respirators are designed to help reduce the wearer’s respiratory exposure to airborne contaminants such as particles, gases or vapours.” (page 121, no citation provided)

Table 13 provides properties for P2 and N95 respirators. Relevant information relating to this RQ as are follows:

Assessment of evidence

P2 and N95 respirator characteristics [citation 170]:

- “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 minimise aerosol contamination of the mucous membranes of the nose and mouth”

Glossary states P2 respirator can filter particles 0.3 uM particles in size. Table 13 details particle size ranges in US/Aus legislation.

The information quoted is based on one citation [Citation 170] which is a non-systematic literature review that was published in 2010 (Gralton J, McLaws M-L Protecting healthcare workers from pandemic influenza: N95 or surgical masks?. Critical Care Medicine 2010;38 657-667).

Filtration efficiency requirements are provided within the table, however the filtration efficiencies quoted in the ARHAI Scotland review should be based upon relevant UK/European standards/legislation. The table quotes Australian and NIOSH requirements.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The National Institute for Occupational Safety and Health (NIOSH) Cichowicz J, Coffey C, Fries MP.	Guidance	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
A Guide to Air-Purifying Respirators. 2018. Accessed: 2 December 2022					

Assessment of evidence

Setting: USA

Target audience: Unclear – not healthcare specific

Air purifying respirators:

“Air-purifying respirators (APRs) work by removing gases, vapors, aerosols (airborne droplets and solid particles), or a combination of contaminants from the air through the use of filters, cartridges, or canisters. These respirators do not supply oxygen from other than the working atmosphere, and therefore cannot be used in an atmosphere that is oxygen-deficient1 or immediately dangerous to life or health[2] (IDLH). The appropriate respirator for a particular situation will depend on the environment and the contaminant(s).”

Filtering Facepiece respirators:

“Filtering facepiece respirators (FFRs) remove particles from the inhaled airstream of the wearer. They may be referred to as “N95 respirators”.

FFRs are divided into classes based on their filtration capabilities. “N95” is a term referring to the N95 filter class, which removes at least 95% of airborne particles using a “most-penetrating” sized particle during “worst case” NIOSH testing. The FFR classes include N (not resistant to oil), R (somewhat resistant to oil), and P (strongly resistant to oil) series, which are available at 95, 99, and 100 filtration efficiency levels.”

Assessment of evidence

“N95, N99, N100 – Filters at least 95%, 99%, 99.97% of airborne particles. Not resistant to oil.

R95, R99, R100 – Filters at least 95%, 99%, 99.97% of airborne particles. Somewhat resistant to oil.

P95, P99, P100 – Filters at least 95%, 99%, 99.97% of airborne particles. Strongly resistant to oil.”

“FFRs form a tight seal against the user’s face, covering the nose and mouth. As the user inhales air through the facepiece, particulate material collects on the fibrous material of the filter, which removes the particulate contaminant from the airstream. An FFR may have an exhalation valve located on the filter, which reduces breathing resistance during exhalation”

OSHA Assigned Protection Factor (APF) is 10.

Elastomeric Half Facepiece Respirators:

“Elastomeric half facepiece and quarter facepiece respirators are reusable devices with exchangeable cartridges or filters. The facepiece is made of rubber or silicone that forms a seal against the user’s face.”

“The attached filters and cartridges are replaceable and can be easily changed.”

“Elastomeric respirators can be used to protect against […] particles if equipped with the appropriate filters and/or cartridges.”

Elastomeric Full Facepiece Respirators:

“Like the elastomeric half facepiece respirator, the elastomeric full facepiece respirator is a reusable device. This type of respiratory protective device uses exchangeable cartridges, canisters, or filters. It is also made of rubber or silicone, but the elastomeric full facepiece has a clear plastic lens that covers the face and provides eye protection. The full facepiece covers roughly from the hairline to below the chin. These types of respirators tend to provide a more reliable face seal than FFRs or elastomeric half facepiece respirators. Since these respirators cover the user’s face and eyes, they can also be used to protect against liquid splashes and irritating vapours. […]. Elastomeric full facepiece respirators have an APF of 50”

Assessment of evidence

Powered Air-Purifying Respirator:

“Powered Air-Purifying Respirators (PAPRs) are battery-powered devices that use a blower to pull air through attached filters (for particles) or cartridges (for gases or vapours) to clean it before delivering it to the breathing zone of the wearer. High-efficiency (HE) filters are the only class of particulate filters available for powered air-purifying respirators. The benefits of PAPRs include a low breathing resistance with a high level of protection. PAPRs can be used to protect against particles, if equipped with the appropriate cartridge, canister, or filter. PAPRs are generally more protective than non-powered half mask respirators because the blower creates positive pressure inside the facepiece under most work conditions, which reduces inward leakage of potentially contaminated air. A half facepiece PAPR has an APF of 50, and a full facepiece PAPR has an APF of 1,000.”

“A PAPR may have a tight-fitting half or full facepiece or a loose-fitting facepiece, hood, or helmet.”

“Loose-fitting PAPRs have an APF of 25. Loose- fitting PAPRs with a helmet or hood can have an APF up to 1,000 if supported by manufacturer-supplied test evidence.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centers for Disease Control and Prevention (CDC). Infection Control Guidance: SARS-CoV-2 2023 Accessed: 30 October 2024	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence
Note: “This interim guidance has been updated based on currently available information about COVID-19 and the current situation in the United States. Updates were made to reflect the high levels of vaccine-and infection-induced immunity and the availability of effective treatments and prevention tools. This guidance provides a framework for facilities to implement select infection prevention and control practices (e.g., universal source control) based on their individual circumstances (e.g., levels of respiratory virus transmission in the community). This guidance is applicable to all U.S. settings where healthcare is delivered (including nursing homes and home health).” “**Respirator:** A respirator is a personal protective device that is worn on the face, covers at least the nose and mouth, and is used to reduce the wearer’s risk of inhaling hazardous airborne particles (including dust particles and infectious agents)”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centers for Disease Control and Prevention (CDC). Types of Respiratory Protection. 2019. Accessed: 11 November 2024	Infographic	Level 4	N/A	N/A	N/A

Assessment of evidence
Target audience: Healthcare workers (no definition provided – information found in ‘healthcare workers’ tab of website) “Elastomeric Half Facepiece Respirators are reusable and have replaceable cartridges or filters. They cover the nose and mouth and provide protection against gases, vapors, or particles when equipped with the appropriate cartridge or filter.”

Assessment of evidence
“Elastomeric Full Facepiece Respirators are reusable and have replaceable canisters, cartridges, or filters. The facepiece covers the face and eyes, which offers eye protection.” “Filtering Facepiece Respirators are disposable half facepiece respirators that filter out particles such as dusts, mists, and fumes. They do NOT provide protection against gases and vapours.” “Powered Air-Purifying Respirators (PAPRs) have a battery-powered blower that pulls air through attached filters, canisters, or cartridges. They provide protection against gases, vapours, or particles, when equipped with the appropriate cartridge, canister, or filter.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centers for Disease Control and Prevention (CDC). Understanding the difference, 2019. Accessed: 5 December 2022	Infographic	Level 4	N/A	N/A	N/A
Assessment of evidence					
“This information provides clarification regarding respirator and mask use in workplaces in which employees are exposed to respiratory hazards, it is not specific for the COVID-19 pandemic”					

Assessment of evidence
N95 respirator: • “Reduces wearer’s exposure to particles including small particle aerosols and large droplets (only non-oil aerosols) • Tight-fitting • Filters out at least 95% of airborne particles including large and small particles” Elastomeric Half Facepiece respirator: • “Reusable device made of synthetic or rubber material • Tight-fitting • May be equipped with filters that block 95%, 99%, or 100% of very small particulates.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
National Institute for Occupational Safety and Health (NIOSH) Respirator Exhalation Valve Research. 2020. Accessed 4 January 2023	Guidance	**Level 4**	N/A	N/A	N/A

Assessment of evidence
Information page with no references. The target audience is also unclear. “Some types of respirators include an exhalation valve that opens to allow exhaled air to escape through the valve and closes to force inhaled air through the filter. In filtering facepiece respirators (FFRs) and elastomeric half mask respirators (EHMRs), exhalation valves typically include a membrane composed of natural rubber, silicone, or neoprene. This membrane sits atop a support structure and lies beneath a plastic cover.” “The valve opens and closes based on the wearer’s breathing pattern. During inhalations, the membrane closes against the support structure and blocks the opening, thereby not allowing airflow through the valve opening and thus protecting the wearer. During exhalations, when sufficient positive air pressure is achieved, the membrane lifts and the wearer’s unfiltered breath exhausts (exits) from the valve, with only a portion of the exhaled breath from the wearer passing back through the filter media”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
National Institute for Occupational Safety and Health (NIOSH) Respiratory Protection Information Trusted Source. 2021. Accessed: 6 December 2022	Guidance	**Level 4**	N/A	N/A	N/A

Assessment of evidence
Target audience unclear: suggests any user of respirator

Assessment of evidence
Duplicate information from other CDC resources (e.g. types of respirator poster) not carried over into ET. “There are **two main types** of respiratory protection—air-purifying respirators (APRs) and atmosphere-supplying respirators (ASRs). Each respirator type provides a different level of protection based on its design. Therefore, it’s important to choose the right type of respirator for the specific exposure. To do that, you must identify all respiratory hazards in your environment and the amount of exposure. Additionally, each type of respirator has an assigned protection factor (APF). This indicates the level of protection you can expect to receive from that respirator” Air purifying respirators (filtering facepiece respirator, elastomeric half mask respirator, elastomeric full facepiece respirator and powered air purifying respirator): “APRs use filters, cartridges, or canisters to remove gases, vapors, aerosols, or a combination of contaminants from the air. Tight-fitting APRs require fit testing prior to use. Below are the different types of APRs.” “FFRs – disposable respirators that cover the nose and mouth Elastomeric half mask respirator (EHMR) – reusable respirators that cover the nose and mouth Elastomeric full facepiece respirator – reusable and cover the nose, mouth and eyes Powered air-purifying respirator – reusable and often have a hood or helmet that cover the nose, mouth, and eyes. A battery powered blower pulls air through filters or cartridges”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
World Health Organization (WHO). Infection prevention and control in the context of	Guidance	**Agree: Recommend**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
coronavirus disease (COVID-19): a living guideline. 2023. Accessed: 29 October 2024					

Assessment of evidence

Funding: "The development of the document was provided by the United States Center for Disease Control and Prevention (US CDC), in addition to WHO core funds"

Aim of guidance: "Provides users with the latest evidence-informed recommendations for IPC in health care and community settings." It "guides decision makers and IPC professionals to develop and implement policies on mask use in health care and settings".

Target audience: "Policy and decision-makers, public health professionals, IPC professionals at the national and facility levels, health care facility administrators, managers and other health workers."

Health workers in this document are defined as "people primarily engaged in actions with the primary intent of enhancing health. This includes health service providers, such as doctors, nursing and midwifery professionals, public health professionals, technicians (laboratory, health, medical, and non-medical), personal care workers, healers, and practitioners of traditional medicine. It also includes health management and support workers, such as cleaners, drivers, hospital administrators, district health managers, social workers and other occupational groups in health-related activities. This group includes those who work in acute care facilities and long-term care, public health, community-based care and other occupations in the health and social care sectors."

"Filtering facepiece respirators (FFR or respirators) offer a balance of filtration, breathability and fit. Whereas medical masks filter 3-micrometre droplets, "N95" and "FFP2" rated FFRs must filter a more challenging 0.075-micrometre particles or particulates and do so across the entire surface of the respirator as a result of the fitted design. European "FFP2" FFRs, according to EN 149 standard, filter at least 94% Sodium Chloride (NaCl) salt particles and paraffin oil droplets. The United States of America "N95" FFRs, according to National Institute for Occupational Safety and Health (NIOSH) NIOSH 42 CFR Part 84, filter at least 95% NaCl salt particles"

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
European Centre of Disease Prevention and Control (ECDC). Personal protective equipment (PPE) needs in healthcare settings for the care of patients with suspected or confirmed novel coronavirus (2019-nCoV) 2020. Accessed: 14 December 2022	Technical Report	**Level 4**	N/A	N/A	N/A
Assessment of evidence					
Setting: EU/EEA **Target audience:** “Public health authorities and hospital administrators in EU/EEA countries.” “The respirator protects from the inhalation of droplets and particles.”					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
European Centre of Disease Prevention and Control (ECDC). Guidance for wearing and removing personal protective equipment in healthcare settings for the care of patients with suspected or confirmed COVID, 2020. Accessed: 14 December 2022	Guidance	**Level 4**	N/A	N/A	N/A

Assessment of evidence

"**Scope of this document**

This document provides support to healthcare workers managing suspected or confirmed cases of novel coronavirus 2019 (COVID-19). The general objectives of the document are:

- to present the minimal set of personal protective equipment (PPE) required for managing suspected or
- confirmed COVID-19 cases;
- to make healthcare workers aware of the critical aspects of the donning and doffing of PPE; and

Assessment of evidence

- to strengthen occupational safety in healthcare workers for patients suspected of, or confirmed with, COVID19.

This document is based on current COVID-19 knowledge and PPE best practices.

ECDC will update this document based on the evolving situation and if new relevant information arises.

Target audience

Healthcare workers and infection prevention and control personnel in EU/EEA countries and in the United Kingdom."

"A respirator (also known as filtering face piece (FFP) mask or filtering half mask) is designed to protect the wearer from exposure to airborne contaminants (e.g. from inhaling infectious agents associated with inhaling small and large particle droplets) and is classified as personal protective equipment (PPE) [154]. FFP2 respirators have a filtering capacity of at least 94% for 0.3 μm particles. FFP3 respirators have a filtering capacity of at least 99% for 0.3 μm particles. Some valved respirators do not prevent the release of exhaled respiratory particles from the wearer into the environment and therefore may not be appropriate for use as a means of source control in the case of respiratory infections [155]."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Public Health Agency of Canada (PHAC). Routine Practices and Additional Precautions for Preventing the Transmission of Infection in	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Healthcare Settings, 2017. Accessed: 20 December 2022					

Assessment of evidence

Aim: To present evidence-based recommendations for monitoring, preventing and controlling healthcare associated infections.

Target audience: Infection prevention and control professionals and healthcare providers involved with developing policy and procedure for routine practices in healthcare settings (acute, long-term, ambulatory, home care or prehospital care settings)

Methods: These guidelines were produced by PHAC, advised by PHAC's Steering Committee on Infection Prevention and Control Guidelines Working Group, made up of professionals from different areas of healthcare who provided technical advice (list provided on page 2). They are described as "principles and recommendations" rather than strict standards.

Methods: A literature search was conducted for papers from 1999 (details of this search are available to request). Recommendations were graded based on the strength of evidence. This guidance is based on scientific evidence and expert opinion where evidence was lacking, but was graded as expert opinion due to limited methodological detail making it difficult to deduce how systematic methods were.

Relevant information:

"Respirator − A device that is tested and certified by procedures established by testing and certification agencies recognized by the authority having jurisdiction and is used to protect the user from inhaling a hazardous atmosphere. The most common respirator used in health care is a N95 half-face piece filtering respirator. It is a personal protective device that fits tightly around the nose and mouth of the wearer, and is used to reduce the risk of inhaling hazardous airborne particles and aerosols, including dust particles and infectious agents" (page 175)

this definition references Canadian Standards (233) and NIOSH (508)

Assessment of evidence

“A disposable, (Note: most respirators used for health care purposes are disposable filtering face pieces covering mouth, nose and chin) particulate respirator. Airborne particles are captured from the air on the filter media by interception, inertial impaction, diffusion and electrostatic attraction. The filter is certified to capture at least 95% of particles at a diameter of 0.3 microns; the most penetrating particle size. Particles of smaller and larger sizes are collected with greater efficiency. The “N” indicates a respirator that is not oil-resistant or oil-proof. N95 respirators are certified by the National Institute for Occupational Health and Safety (NIOSH - organization based in the United States) and must be so stamped on each respirator [National Institute for Occupational Health and Safety (NIOSH). NIOSH respirator selection logic 2004. 2004. Report No.: 2005- 100]” (page 173)

this definition references NIOSH (508)

In Part A, section B – “Role of organization to reduce exposure to and transmission of infectious agents” under the section on administrative controls (occupational health):

“Respiratory protection specifies the use of a respirator to prevent inhalation of aerosols containing infectious particles.” (page 37)

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Ministry of Health New Zealand. COVID-19: Infection prevention and control recommendations for health and disability care workers.	Guidance	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
2022. Last updated: 05 September 2024 Accessed: 04 November 2024					
Assessment of evidence					
“P2/N95 particulate respirators are worn to provide protection against exposure to airborne pathogens and procedures that can produce the generation of small particles. Particulate respirators work by filtering particles out of the air as you breathe.” No references provided.					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The British Standards Institution (BSI). EN 140:1998 Respiratory protective devices – Half masks and quarter masks – Requirements, testing, marking.	British standard	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Accessed: 11 July 2023.					

Assessment of evidence

Definitions:

“A half mask is a facepiece which covers the nose, mouth and chin. A quarter mask is a facepiece which covers the nose and mouth. They are intended to provide adequate sealing on the face of the wearer of a respiratory protective device against the ambient atmosphere, when the skin is dry or moist and when the head is moved.” (page 3)

Description:

“Air enters the facepiece and passes directly to the nose and mouth area of the facepiece. The exhaled air flows directly to the ambient atmosphere, via the exhalation valve(s) or by other appropriate means.” (page 3)

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The British Standards Institution (BSI). PD ISO/TS 16975-1:2016 Respiratory protective devices: selection, use and maintenance establishing and	International standard	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
implementing a respiratory protective device programme. Accessed: 11 July 2023.					

Assessment of evidence

“This part of ISO 16975 contains the essential requirements for establishing and implementing a complete respiratory protective device (RPD) programme for respiratory protective devices that meet the requirements of the performance standards. It contains information on risk assessment, selection procedure, training, use and maintenance. Informative Annexes provide additional guidance on how to implement such a programme.”

RPD: “personal protective equipment designed to protect the wearer’s respiratory tract against inhalation of hazardous atmospheres”

Annex A – types and components of Respiratory protective devices (RPDs) (page 32)

Modes of RPD:

“There are two modes of RPD — filtering RPD and supplied breathable gas RPD”

Filtering RPD: “Filtering RPD contains at least a respiratory interface and filter(s); these components can be integral or separate. Filtering RPD remove (by, e.g. filtration, adsorption or chemical reaction) hazardous substances present in the ambient air before being inhaled by the wearer. The air is drawn through the filter(s) either by the wearer’s inhalation action or with the assistance of a blower unit.”

Supplied breathable gas RPD: “Supplied breathable gas RPD contains at least a respiratory interface and a means for supplying uncontaminated breathable gas to the wearer. This can be achieved by a number of means. Self-contained RPD provides the highest independence for the wearer mobility by using pressurized breathable gas in valved cylinders or generated by a chemical reaction

Assessment of evidence

during use, as an integral part of the RPD. Other supplied breathable gas RPD use a gas source that is not part of the RPD nor carried by the wearer. The breathable gas can be supplied by a compressor located outside the hazardous area, from pressurized cylinders or from an uncontaminated area by a blower or drawn by the breathing action of the wearer."

Note: Schematic diagrams of respiratory interfaces with different types of filters are provided.

Main components:

Respiratory interfaces tight- and loose-fitting: "The primary purpose of the respiratory interface is to form a barrier between the wearer's respiratory tract and the contaminated environment. The respiratory interface may or may not be separable from the rest of the RPD; however, it is always part of the complete RPD. Some complete RPD includes respiratory interfaces and filters with standardized connectors according to ISO 17420-3 to allow interchangeability of filters between different RPD manufacturers.

There are two types of respiratory interface: tight-fitting and loose-fitting. a) Tight-fitting respiratory interfaces rely on a good seal between the RPD and the wearer. b) Loose-fitting respiratory interfaces rely on sufficient air being provided to prevent hazardous substances leaking into the area covering the face."

Table A.1. categorises interface by barrier lines, type and fitting

Examples of respiratory interfaces are provided with diagrams:

Tight-fitting respiratory interfaces covering the mouth, nose and chin area have been commonly known as "half masks". Tight-fitting respiratory interfaces covering the mouth and nose only have been known as "quarter masks" (not shown).

Respiratory interfaces covering the entire face can be either tight-fitting (see Figure A.7) or loose-fitting (see Figure A.8). When the respiratory interface is tight-fitting, it is commonly known as "full face mask" or "full facepiece". In both cases, the wearer's eyes are protected from the contaminated environment

Respiratory interfaces covering the entire head can be either loose-fitting or tight-fitting (see Figure A.9 and Figure A.10), and have been commonly known as "hoods" or "helmet". Hoods and helmets that are tight-fitting usually seal around the wearer's neck.

Assessment of evidence

Filters:

“Filtering RPDs have two methods of operation — particle filtration and gas/vapour filtration.

a) Particle filters are intended to remove solid and liquid particles (e.g. dusts, fibres, metal fumes and mists) – “trap and hold particles from the air flowing through them”

b) Gas filters are intended to remove gases and vapours.

Combination filters are intended to remove both particles and gases/vapours.”

Solely gas filters are outside the scope of the RPE review.

Combined RPD:

“Combined RPDs are RPDs that have both filtering and breathable gas supply modes. A combined RPD is a supplied breathable gas RPD with a filter attached to the RPD that

— provides protection in the event that the breathable gas supply fails, or

— permits the wearer to change the mode of operation to allow transit to and from a compressed breathable gas source. These RPDs are designed to be used in either a filtering or breathable gas supply mode but not both modes together.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The British Standards Institution (BSI). BS EN ISO 16972:2020	British standard	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Respiratory protective devices – Vocabulary and graphical symbols. Accessed: 11 July 2023.					

Assessment of evidence

Respiratory protective device (RPD) – “personal protective equipment designed to protect the wearer's (3.257) respiratory tract against the inhalation of hazardous atmospheres” (page 19)

Particle filter respiratory protective device – “divided particles (3.170) from the air to be inhaled by the wearer (3.257) Note 1 to entry: The filter medium may be replaceable or be an integral part of the construction” (page 16)

particle filter – “respiratory protective device particle filter RPD device consisting of a respiratory interface (3.202) with a particle filter (3.171) that removes finely divided particles (3.170) from the air to be inhaled by the wearer (3.257) Note 1 to entry: The filter medium may be replaceable or be an integral part of the construction” (page 17)

valved filtering half mask respiratory protective device - (3.203) fitted with exhalation valves (3.79) and inhalation valves (3.120) (page 24)

exhalation valve - non-return valve that allows the release of exhaled and excess breathable gas (3.29) from the respiratory protective device (3.203)

inhalation valve - valve that opens during inhalation and closes during exhalation

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). COSHH essentials: Respiratory protective equipment. UK Standard Assigned Protection Factor 4 (APF 4) Supplementary advice, 2006a. Accessed: 15 February 2023	Expert Opinion	Level 4	N/A	N/A	N/A

Assessment of evidence

This supplementary advice provided by HSE states “This information will help employers comply with the Control of Substances Hazardous to Health Regulations 2002 (COSHH), as amended, to control exposure to chemicals and protect workers’ health.”

“Selection of RPE with an APF of 4 or more

RPE is designed to help protect workers from dusts, fumes, vapours or gases. This sheet describes respirators (including 'dust masks') that filter contaminated air.”

“Types of RPE available are:

- filtering half-mask, EN 149;
- filtering half-mask with valve, EN 405;

Assessment of evidence
• filtering half-mask without inhalation valves EN 1827; • half mask EN 140 and filter; • full face mask EN136 and filter; and • any of the above devices incorporating a low efficiency P1 particulate filter.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). COSHH essentials: Respiratory protective equipment. UK Standard Assigned Protection Factor 10 (APF 10) Supplementary advice. 2006. Accessed: 15 February 2023	Expert Opinion	Level 4	N/A	N/A	N/A

Assessment of evidence

This supplementary advice provided by HSE states “This information will help employers comply with the Control of Substances Hazardous to Health Regulations 2002 (COSHH), as amended, to control exposure to chemicals and protect workers’ health.”

“Selection of RPE with an APF of 10 or more

- RPE is designed to help protect workers from dusts, fumes, vapours or gases. This sheet describes respirators (including ‘dust masks’) that filter contaminated air, and breathing apparatus (BA) that supplies clean air.”

“Types of RPE available are:

- filtering half-mask, EN 149;
- filtering half-mask with valve, EN 405;
- filtering half-mask without inhalation valves EN 1827;
- half mask EN 140 and filter;
- full face mask EN136 and filter;
- any of the above devices incorporating a medium efficiency P2 particulate filter, gas filter, or gas and P3 filter;
- powered hood model TH1 EN 146/EN 12941; and
- power-assisted mask model TM1 EN 147/EN 12942.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). COSHH essentials: Respiratory protective equipment. UK Standard Assigned Protection Factor 20 (APF 20) Supplementary advice. 2006. Accessed: 15 February 2023	Expert Opinion	Level 4	N/A	N/A	N/A

Assessment of evidence

This supplementary advice provided by HSE states “This information will help employers comply with the Control of Substances Hazardous to Health Regulations 2002 (COSHH), as amended, to control exposure to chemicals and protect workers’ health.”

“Selection of RPE with an APF of 20 or more

- RPE is designed to help protect workers from dusts, fumes, vapours or gases. This sheet describes respirators (including ‘dust masks’) that filter contaminated air”

“Types of RPE available are:

- filtering half-mask, EN 149;

Assessment of evidence
- filtering half-mask without inhalation valves EN 1827; - half mask EN 140 and filter; - any of the above devices incorporating a high efficiency P3 particulate filter; - full face mask EN136 and gas filter; - powered hood model TH2 EN 146 / EN 12941; and - power-assisted mask model TM2 EN 147/EN 12942. Caution: These are not suitable for use in confined spaces.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). COSHH essentials: Respiratory protective equipment. UK Standard Assigned Protection Factor 40 (APF 40) Supplementary advice. 2006.	Expert Opinion	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Accessed: 15 February 2023.					

Assessment of evidence

This supplementary advice provided by HSE states “This information will help employers comply with the Control of Substances Hazardous to Health Regulations 2002 (COSHH), as amended, to control exposure to chemicals and protect workers’ health.”

“Selection of RPE with an APF of 40 or more

- RPE is designed to help protect workers from dusts, fumes, vapours or gases. This sheet describes respirators that filter contaminated air.”

“Types of RPE available are:

- full face mask EN 136 and P3 filter;
- powered hood, helmet or blouse model TH3 EN 146/EN 12941; and
- power-assisted full face mask model TM3 EN 147/EN 12942.

  Caution: These are not suitable for use in confined spaces.”

Evidence from previous update(s):

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). Respiratory protective equipment at work: A practical guide. HSG53 (4th Ed.) 2013. ISBN: 978 0 7176 6454 2.	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

Setting: UK

About this guidance: This guide prepared by the HSE “in consultation with industry: employers, trade unions and trade associations”, is stated to support “the Approved Code of Practice (ACOP) to the Regulations that apply (see paragraphs 36–39)”.

“RPE is a particular type of personal protective equipment (PPE) designed to protect the wearer from breathing in harmful substances or from oxygen-deficient atmospheres when other controls are either not possible or insufficient on their own.”

“There are many different RPE types designed to:

protect the wearer from a variety of hazards;

suit a variety of work situations;

Assessment of evidence

match the specific requirements of the wearer."

"Respirators (filtering devices) use filters to remove contaminants from the air being breathed in. They can be either:

non-powered respirators – relying on the wearer's breathing to draw air through the filter; or

powered respirators – using a motor to pass air through the filter to give a supply of clean air."

"Respirators and BA are available in a range of styles, dividing into two main groups:

Tight-fitting facepieces (often referred to as masks) rely on having a good seal with the wearer's face. These are available as both non-powered and powered respirators and BA. A face fit test should be carried out to ensure the RPE can protect the wearer (see paragraphs 71 and 72).

Loose-fitting facepieces rely on enough clean air being provided to the wearer to prevent contaminant leaking in (only available as powered respirators or BA). Examples are hoods, helmets, visors, blouses and suits"

RPE filters

"A key component of any respirator is the filter. Filters are available for solid or liquid particles […] (see Table 1). They can be an intrinsic part of the device or come separately so they can be changed on a reusable respirator."

"As air is breathed in, it passes through the filter(s), removing the contaminants before they reach the lungs. The respirator can either:

be made of the filter material;

have a filter(s) fitted to it; or

use a motor to pass air through the filter(s) that may be separate from the facepiece."

"Some situations require a combination of filters suitable for the different substances or forms present."

Types of respirators available:

"Disposable half mask- particle filter (sometimes referred to as a filtering facepiece or orinasal respirator"

Assessment of evidence

“classification of RPE – FFP1 (protection factor 4), FFP2 (protection factor 10), FFP3 (protection factor 20)”

“effective against solid of liquid particles”

“Reusable half mask – particle filter”

“classification of RPE – Half mask + P1 filter (protection factor 4), Half mask + P2 filter (protection factor 10), Half mask + P3 filter (protection factor 20)”

“effective against solid or liquid particles”

“Full face mask – particle filter”

“classification of RPE – P1 (protection factor 4), P2 (protection factor 10), P3 (protection factor 40)”

“effective against solid or liquid particles only”

“Powered mask”

“classification of RPE – TM1 (protection factor 10), TM2 (protection factor 20), TM3 (protection factor 40)”

“effective against solid or liquid particles, gas or vapour depending on filter type”

“Powered goods/helmets”

“classification of RPE – TH1 (protection factor 10), TH2 (protection factor 20), TH3 (protection factor 40)”

“Effective against solid or liquid particles, gas or vapour depending on filter type”

Filters:

“Filters are classified in relation to the form of the hazardous substance(s) they can be used against – either particles gas/vapour, multi-gas or combined (particle and gas/vapour).”

“If the filter is also usable with powered respirators then they will also be marked ‘TH’ (turbo hood) for hood devices or ‘TM’ (turbo mask) for mask devices.”

Assessment of evidence

“Particle filters

6 Particle filters trap and hold particles (dust, mist, fume, smoke, micro-organisms) from the air flowing through them. Large particles are easier to trap than small ones. These filters can be used against both solid particles and liquid particles (mists, fine sprays and aerosols).

7 Particle filters are classified according to their efficiency. The filter (or the facepiece it is built into) will be marked with the letter P (for particle) and a number to indicate efficiency, or the level of protection provided:

P1 = Low efficiency.*

P2 = Medium efficiency.*

P3 = High efficiency.

“The APF is a number rating that indicates how much protection that RPE is capable of providing. For example, RPE with an APF of 10 will reduce the wearer’s exposure by at least a factor of 10 if used properly, or, to put it another way, the wearer will only breathe in one-tenth or less of the amount of substance present in the air.”

“Each RPE type and class is categorised by an assigned protection factor (APF). The APF is a number rating that indicates how much protection that RPE is capable of providing. For example, RPE with an APF of 10 will reduce the wearer’s exposure by at least a factor of 10 if used properly, or, to put it another way, the wearer will only breathe in one-tenth or less of the amount of substance present in the air”

“There are only a few number ratings used, so RPE APFs will be either: 4; 10; 20; 40; 200 or 2000. When calculating the protection factor, always choose an APF above the calculated value.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). Guidance on respiratory protective equipment (RPE) fit testing. INDG479 (rev1). 2019. ISBN: 9780717667062	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

Setting: UK

Examples of tight-fitting facepieces:

- Disposable mask
- Reusable mask
- Full-face mask

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Coia J.E., Ritchie L, Adisesh A, et al. Guidance on the use of respiratory and facial protection equipment. Journal of Hospital Infection, 2013; 85;170-182; doi: 10.1016/j.jhin.2013.06.020.	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

Setting: UK

"**Aim:** This article provides guidance (best practice guidelines) to support HCWs in hospital or community settings to select and wear the appropriate respiratory and facial protection to minimize the risk of acquisition of infection in the workplace."

Best practice guidance based on a non-systematic literature review published separately (Bunyan D, Ritchie L, Jenkins D, Coia JE. Respiratory and facial protection: a critical review of recent literature. J Hosp Infect 2013;85:165e169).

"The Scientific Development Committee of the Healthcare Infection Society established a short-life working group in May 2011 to develop appropriate guidance. The working group included representation from the Healthcare Infection Society, Public Health England, Health and Safety Executive (HSE), Association of National Health Occupational Physicians, Health Protection Scotland, Infection Prevention Society, Intensive Care Society, Clinical Virology Network and British Infection Association."

"Protection against aerosols requires filtration of inhaled contaminated air (i.e. the use of respirators)."

Assessment of evidence

Respirator definitions:

“A respirator is used by an individual to provide respiratory protection. In the healthcare setting, this most commonly relates to the filtering half face mask. The European standard for filtering face masks [EN 149 (currently 2009)] lists three classes of filtering face piece (FFP): FFP1, FFP2 (approximately equivalent to N95) and FFP3.5 These are classified by inward leakage in laboratory tests and simulated real-life use. Inward leakage can result from penetration through the material matrix of the face piece or through any gap between the face piece and the wearer’s face (see Appendix 1 ‘fit testing’). FFP3 offers the highest level of protection. Although most of the evidence base supporting the use of FFP respirators in the prevention of airborne transmission of infection is based upon N95/FFP2 devices, FFP3 is the only FFP class acceptable to HSE for use against infectious aerosols in health care in the UK (Appendix 3). In the USA, N95 (approximately equivalent to FFP2) is acceptable, as is the case in a number of other countries.”

“Protects mouth, nose and lower respiratory tract against splashes, droplets and aerosols”

Valved versus unvalved definition:

“FFP respirators are available with or without an exhalation valve. Valved FFPs, although slightly more expensive, are more comfortable to wear than non-valved FFPs as the valve reduces overall breathing resistance, and heat and humidity build up in the face piece.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Occupational Safety and Health Administration (OSHA). Guidance on Preparing Workplaces for an	Guidance	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Influenza Pandemic, 2009. Accessed 15th December 2022.					

Assessment of evidence

Guidance document produced by The Occupational Safety and Health Administration is an agency of the United States Department of Labor. Influenza pandemic guidance.

Workplaces: not healthcare specific

Explanation provided on the spread of influenza:

“Influenza is thought to be primarily spread through large droplets (droplet transmission) that directly contact the nose, mouth or eyes. These droplets are produced when infected people cough, sneeze or talk, sending the relatively large infectious droplets and very small sprays (aerosols) into the nearby air and into contact with other people. Large droplets can only travel a limited range; therefore, people should limit close contact (within 6 feet) with others when possible. To a lesser degree, human influenza is spread by touching objects contaminated with influenza viruses and then transferring the infected material from the hands to the nose, mouth or eyes. Influenza may also be spread by very small infectious particles (aerosols) traveling in the air. The contribution of each route of exposure to influenza transmission is uncertain at this time and may vary based upon the characteristics of the influenza strain.”

“Respirators are designed to reduce an employee’s exposure to airborne contaminants. Respirators are designed to fit the face and to provide a tight seal between the respirator’s edge and the face. A proper seal between the user’s face and the respirator forces inhaled air to be pulled through the respirator’s filter material and not through gaps between the face and respirator. Respirators must be used in the context of a comprehensive respiratory protection program.” (pp 22).

Types of respirators:

Air-supplying

Assessment of evidence

Air purifying aka particulate respirators (do not protect against gas, vapour)

Air purifying respirator (particulate respirator) types:

Filtering facepiece respirators “where the entire respirator facepiece is comprised of filter material”, e.g. N95 respirator

Surgical respirators – combined properties of surgical face masks + N95 respirator. “Surgical N95 respirators are certified by NIOSH as respirators and also cleared by FDA as medical devices which have been designed and tested and shown to be equivalent to surgical masks in certain performance characteristics (resistance to blood penetration, biocompatibility) which are not examined by NIOSH during its certification of N95 respirators.”

Exhalation valves: “Some filtering facepiece respirators have an exhalation valve which can reduce breathing resistance, reduce moisture buildup inside the respirator and increase work tolerance and comfort for respirator users.”

Reusable/elastomeric respirator: can be used with different cartridges to offer appropriate protection for different hazards

Half mask – cover mouth + nose

Full mask – cover mouth, nose + eyes

Powered air purifying respirator (PAPR): “battery powered blower pulls contaminated air through filters, then moves the filtered air to the wearer’s facepiece”

Respirator classifications:

“An N95 respirator is one of nine types of particulate respirators. Respirator filters that remove at least 95 percent of airborne particles during “worst case” testing using the “most-penetrating” size of particle are given a 95 rating. Those that filter out at least 99 percent of the particles under the same conditions receive a 99 rating, and those that filter at least 99.97 percent (essentially 100 percent) receive a 100 rating. […] filters in this family are given a designation of N, R, or P to convey their ability to function in the presence of oils that are found in some work environments.” This classification is not relevant to health/care settings.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Occupational Safety and Health Administration (OSHA). Hospital Respiratory Protection Program Toolkit: Resources for Respirator and Program Administrators, 2015. Accessed: 23 December 2022	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence
“This toolkit was developed to assist hospitals in developing and implementing effective respiratory protection programs”. “This toolkit identifies existing public health guidance where available on the use of respiratory protection.” **Taken from their glossary:** “Filtering facepiece respirator—A type of disposable (single-use), negative-pressure, air purifying respirator where an integral part of the facepiece or the entire facepiece is made of filtering material.” “Powered air-purifying respirator (PAPR)—An air-purifying respirator that uses a blower to force air through filters or cartridges and into the breathing zone of the wearer. This creates a positive pressure inside the facepiece or hood, providing more protection than a non-powered or negative-pressure half mask APR.”

Assessment of evidence
“Respirator—A device worn over the nose and mouth to protect the wearer from hazardous materials in the breathing zone. Respirators must be certified by NIOSH for the purpose for which they are used.” “Hood—The portion of a respirator that completely covers the head and neck, and may also cover portions of the shoulders and torso, and through which clean air is distributed to the breathing zone.” “Loose-fitting facepiece—The portion of a respirator that forms a partial seal with the face but leaves the back of the neck exposed, is designed to form a partial seal with the face, and through which clean air is distributed to the breathing zone.” “Negative-pressure respirator—A tight-fitting respirator in which air is inhaled through an air-purifying filter, cartridge, or canister during inhalational efforts, generating negative pressure inside the facepiece relative to ambient air pressure outside the respirator.” **Limitations:** No references May not be applicable to UK health and care settings

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The British Standards Institution (BSI). EN 149:2001+A1:2009. Respiratory protective devices – Filtering half masks to protect against	European Standard	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
particles – Requirements, testing, marking. Accessed: 11 July 2023.					

Assessment of evidence
Re-usable particle filtering half mask is defined as “particle filtering half mask intended to be used for more than a single shift” (page 5) “A particle filtering half mask covers the nose and mouth and the chin and may have inhalation and/or exhalation valve(s). The half mask consists entirely or substantially of filter material or comprises a facepiece in which the main filter(s) form an inseparable part of the device. It is intended to provide adequate sealing on the face of the wearer against the ambient atmosphere, when the skin is dry or moist and when the head is moved. Air enters the particle filtering half mask and passes directly to the nose and mouth area of the facepiece or, via an inhalation valve(s) if fitted. The exhaled air flows through the filter material and/or an exhalation valve (if fitted) directly to the ambient atmosphere. These devices are designed to protect against both solid and liquid aerosols” (page 5) Three classes – FFP1, FFP2, FFP3

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The British Standards Institution (BSI). Standards Publication 529:2005. Respiratory protective devices Recommendations for selection, use, care and maintenance — Guidance document. Accessed 11 July 2023.	British Standard	Level 4	N/A	N/A	N/A

Assessment of evidence

Classification:

“There are two distinct types of respiratory protective devices:

a) Filtering devices: These purify the ambient air to be breathed using filters able to remove contaminants in the air.

b) Breathing apparatus: These supply the wearer with breathable air (e.g. compressed air), or breathable gas, (e.g. compressed oxygen) from an uncontaminated source.” (page 9)

Assessment of evidence

Components: “A respiratory protective device consists of two main components, a facepiece and filter(s) or a facepiece and a means of supplying uncontaminated breathable air or gas.” (page 9)

“Filtering devices purify the ambient air to be breathed by the wearer using filters able to remove contaminants in the air. They incorporate two major components – a filter for purifying the air and a facepiece to direct the purified air to the wearer’s nose and mouth area. A filtering device relying solely on the breathing action of the wearer is termed unassisted, also known as negative pressure devices. Filtering devices employing a mechanical method for pulling the air through the filter and to deliver the air to the breathing zone of the wearer are termed powered and power assisted filtering devices.” (page 24)

“The facepiece directs the uncontaminated breathable air or gas to the wearer’s nose and mouth area. Filtering devices and breathing apparatus are available with a range of different facepieces but there are some important limitations.

Tight-fitting facepieces (filtering facepieces, quarter masks, half masks and full face masks) rely heavily on a good seal between the mask and the wearer’s face. Full face masks, half masks and quarter masks may be used for both types of devices as described in 4.1.

Loose-fitting facepieces (e.g. hoods, helmets, visors, blouses, suits) rely on enough air being provided to prevent contaminants leaking into the facepiece as the wearer breathes and moves about. They are only used on powered filtering devices or with suitable breathing apparatus. In other words, loose-fitting facepieces are not suitable for devices which rely on the breathing action of the wearer to draw air. These include unpowered filtering devices and some breathing apparatus.

Mouthpieces are used with certain devices. They make any form of verbal communication impossible. They are used in conjunction with a nose clip.” (page 9)

“Half mask without inhalation valves and with separable filters to protect against gases or gases and particles and particles only (EN 1827) This device is a lightweight half mask without inhalation valves covering the nose, mouth and the chin. The mask may or may not have exhalation valves. The filter(s) is separable from the mask and replaceable. Filters are intended to be used for a maximum of a single shift. The half mask itself is intended for replacement after a relatively small number of uses.

Assessment of evidence

The filter/mask combination is ‘dedicated’. This means that the mask should only be used with filters specified by the manufacturer. Since the mask has no inhalation valve and reduced strength requirements it should not be confused with half masks meeting EN 140. Complete devices are designated according to the filter type and class used and will have the prefix FM.” (page 21)

Half masks and quarter masks (EN 136)

“A half mask is a facepiece which covers the nose, mouth and the chin of the wearer and is held in place with adjustable straps. Similarly, a quarter mask is a facepiece which covers the nose and mouth. When used with a- filtering device air is drawn through an appropriate filter(s) by the wearer’s lung-power or from a power assisted filtering device (see A.1.3). The exhaled air is discharged through an exhalation valve(s), or by other appropriate means. Filters are available for particulates, gases/vapours or as a combined filter (see A.2). Half masks may also be used with breathing apparatus.” (page 21)

Full face masks (EN 136)

“A full face mask covers the eyes, nose, mouth and the chin. It seals against the face of the wearer and is held in place with adjustable straps. When used in a filtering device air is drawn into the mask either through an appropriate filter(s) by the wearer’s lung-power or from a power assisted filtering device. This mask may also be used with breathing apparatus. Exhaled air is discharged through an exhalation valve(s). Most masks have an inner mask which can reduce the re-inhalation of exhaled carbon dioxide, reduce visor misting and assist comfort. Some devices are fitted with a speech diaphragm to improve the clarity of communication and others may have facilities for fitting special spectacles within the mask. The visor provides protection against particulates and gases. In some cases special grade visors are needed for protection against chemical splashes or impact.

Particle filters or gas/vapour filters or combined filters can be used with this mask. See A.2.3. There are three classes of masks. Class 1 is of light-duty construction intended in the main for filtering devices and (light-duty) continuous flow compressed air line breathing apparatus.” Classes 2 and 3 outside scope of IPC. (page 21)

Filter

“Filtering devices should have the correct type of filter(s) matched to the substance(s) from which the wearer needs protection. The filters can only protect against limited concentration ranges of contaminants as specified by the manufacturers. The filter can be for

Assessment of evidence

protection against particles (particle filters), gases/vapours (gas filters) and for protection against particles and gases/vapours (combined filters)."

Filtering half masks against particles (EN 149)

"These masks are designed for particle filtration. Filtering half masks cover the nose, mouth and the chin. The mask consists entirely or substantially of filter material or comprises a facepiece in which the main filter(s) form an inseparable part of the device. Air enters the particle filtering half mask and passes directly to the nose and mouth area of the wearer or via, an inhalation valve(s) if fitted. The exhaled air flows through the filter material and/or an exhalation valve (if fitted) directly to the ambient atmosphere. These devices are designed to protect against both solid and liquid aerosols and are classified according to their filtering efficiency and their maximum total inward leakage. There are three classes of devices: FFP1, FFP2 and FFP3. […] Particle filters used against micro-organisms and enzymes should be discarded after the first use and disposed according to national regulations or work practices. These organisms may grow and pass through the material of particle filters" (pages 22-23)

Valved filtering masks (EN 405)

"A valved filtering half mask covers the nose, mouth and the chin. The device consists either entirely or substantially of filter material. These devices are for use essentially against gases and vapours. In addition these devices can be designed to protect against solid and liquid aerosols. Any gas/vapour filter forms an inseparable part of the device. The particle filter, if present, may be integral or separable. These devices should have both inhalation and exhalation valves." (page 25)

"**Power assisted filtering devices incorporating full face masks or half masks (EN 12942)**

A complete power assisted filtering device consists at least of a turbo unit, a battery as a power supply for the turbo unit, one or more particle-, gas- or combination filter(s) and a full face mask or a half mask. The power operated turbo unit pulls the ambient air through the filter(s) and then directs the purified air to the facepiece directly or by means of a breathing hose. The turbo unit usually is worn on a waist belt or attached to the mask. The battery power supply for the turbo unit may also be attached to a waist belt carried by the device wearer or held elsewhere." (page 25)

Assessment of evidence

Powered filtering devices incorporating a helmet or a hood (EN 12941)

A complete powered filtering device consists at least of a turbo unit, a battery as a power supply for the turbo unit, one or more particle, gas, or combination filter(s) and a facepiece having no tight fit to the wearers face, e.g. a hood, visor, helmet, blouse or even a full suit. The power operated turbo unit pulls the ambient air through the filter(s) and then directs the purified air to the facepiece directly or by means of a breathing hose. The turbo unit usually is worn on a waist belt or attached to the facepiece. The battery power supply for the turbo unit may also be attached to a waist belt carried by the device wearer or held elsewhere. (page 26)

Breathable air or gas supply source for breathing apparatus – "A source (e.g. chemical oxygen generator or compressed air line) or a vessel (e.g. a gas cylinder) which is capable of supplying uncontaminated breathable air or gas to a breathing apparatus. The quality of the compressed air for breathing apparatus should be in accordance with EN 12021." (page 9)

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Siegel J.D., Rhinehart E., Jackson M., et al. 2007 guideline for isolation precautions: preventing transmission of infectious agents in health care settings. AJIC. 2007;35(10); PP:65-164.	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Last updated: September 2024 Accessed: 28 October 2024					

Assessment of evidence

Aim: To provide recommendations for healthcare settings embedded with infection prevention principles that can be sensibly modified depending on the setting.

Target audience: Infection control staff, health care epidemiologists, healthcare administrators, nurses, other health care providers and persons involved in infection control programs (developing, implementing and evaluating) for healthcare settings.

Methodology: Expert opinion by CDC and HIPAC (members listed). This guidance presents narrative synthesis summary of literature and how it contributes to IPC guidance. New emerging pathogens, rising concern for known pathogens, new therapy development and rising concern for bioterrorism prompt updates. Little detail is provided on the methodology for literature search and review process.

Consistent with the TBP review, this was AGREE Not Recommend based on lack of detail on review methods.

The reference list was screened for papers/guidance which may be relevant for RPE review. Unless otherwise stated, CDC guidance is cited to support these deadlines.

“Respirator. A personal protective device worn by health care personnel over the nose and mouth to protect them from acquiring airborne infectious diseases due to inhalation of infectious airborne particles , 5 mm in size. These include infectious droplet nuclei from patients with Mycobacterium tuberculosis, variola virus [smallpox], or severe acute respiratory syndrome and dust particles that contain infectious particles, such as spores of environmental fungi (eg, Aspergillus spp). The Centers for Disease Control and Prevention’s National Institute for Occupational Safety and Health (NIOSH) certifies respirators used in health care settings (see http://www.cdc.gov/niosh/topics/respirators/). The N95 disposable particulate, air-purifying respirator is the type used most commonly by

Assessment of evidence
health care personnel. Other respirators used include N-99 and N-100 particulate respirators, powered air-purifying respirators with high-efficiency filters, and nonpowered full facepiece elastomeric negative pressure respirators.” (page 1396)

Question 2: Are there any legislative requirements for the use of RPE for infection control purposes and what standards (BS/EN) should RPE adhere to?

Evidence added to 2024 update:

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Government UK Statutory Instrument No. 8 Health and Safety The Personal Protective Equipment at Work (Amendment) Regulations. 2022. Came into force 6 April 2022	Legislation	Mandatory	N/A	N/A	N/A

Assessment of evidence

Note: Below information taken from both the 1992 regulations and 2022 amendment.

“These Regulations may be cited as the Personal Protective Equipment at Work (Amendment) Regulations 2022 and come into force on 6th April 2022.”

Assessment of evidence

Regulation 4:

“(1) Every employer shall ensure that suitable personal protective equipment is provided to his workers who may be exposed to a risk to their health or safety while at work except where and to the extent that such risk has been adequately controlled by other means which are equally or more effective.”

“(3) […] personal protective equipment shall not be suitable unless—

(a) it is appropriate for the risk or risks involved and the conditions at the place where exposure to the risk may occur;

(b) it takes account of ergonomic requirements and the state of health of the person or persons who may wear it;

(c) it is capable of fitting the wearer correctly, if necessary, after adjustments within the range for which it is designed;

(d) so far as is practicable, it is effective to prevent or adequately control the risk or risks involved without increasing overall risk;

(e) it complies with any enactment (whether in an Act or instrument) which implements in Great Britain any provision on design or manufacture with respect to health or safety in any relevant Community directive listed in Schedule 1 which is applicable to that item of personal protective equipment.,”

Compatibility of PPE:

Regulation 5: “(1) Every employer shall ensure that where the presence of more than one risk to health or safety makes it necessary for his worker to wear or use simultaneously more than one item of personal protective equipment, such equipment is compatible and continues to be effective against the risk or risks in question.”

“(2) Every self-employed person shall ensure that where the presence of more than one risk to health or safety makes it necessary for him to wear or use simultaneously more than one item of personal protective equipment, such equipment is compatible and continues to be effective against the risk or risks in question.”

Assessment of evidence

Assessment of PPE:

Regulation 6:

"(1) Before choosing any personal protective equipment […] an employer or self-employed person shall ensure that an assessment is made to determine whether the personal protective equipment they intend will be provided is suitable.

(2) The assessment required by paragraph (1) shall include—

(a) an assessment of any risk or risks to health or safety which have not been avoided by other means;

(b) the definition of the characteristics which personal protective equipment must have in order to be effective against the risks referred to in sub-paragraph (a) of this paragraph, taking into account any risks which the equipment itself may create;

(c) comparison of the characteristics of the personal protective equipment available with the characteristics referred to in sub-paragraph (b) of this paragraph.

(3) Every employer or self-employed person who is required by paragraph (1) to ensure that any assessment is made shall ensure that any such assessment is reviewed if—

(a) there is reason to suspect that it is no longer valid; or

(b) there has been a significant change in the matters to which it relates,

and where as a result of any such review changes in the assessment are required, the relevant employer or self-employed person shall ensure that they are made."

Maintenance and replacement of PPE:

Regulation 7:

"(1) Every employer shall ensure that any personal protective equipment provided to his workers is maintained (including replaced or cleaned as appropriate) in an efficient state, inefficient working order and in good repair.

Assessment of evidence

(2) Every self-employed person shall ensure that any personal protective equipment provided to him is maintained (including replaced or cleaned as appropriate) in an efficient state, in efficient working order and in good repair."

Accommodation for PPE:

Regulation 8:

"Where an employer or self-employed person is required, by virtue of regulation 4, to ensure personal protective equipment is provided, he shall also ensure that appropriate accommodation is provided for that personal protective equipment when it is not being used."

Information, instruction and training:

Regulation 9:

"(1) Where an employer is required to ensure that personal protective equipment is provided to an worker, the employer shall also ensure that the worker is provided with such information, instruction and training as is adequate and appropriate to enable the worker to know—

(a) the risk or risks which the personal protective equipment will avoid or limit;

(b) the purpose for which and the manner in which personal protective equipment is to be used; and

(c) any action to be taken by the worker to ensure that the personal protective equipment remains in an efficient state, in efficient working order and in good repair as required by regulation 7(1).

(2) Without prejudice to the generality of paragraph (1), the information and instruction provided by virtue of that paragraph shall not be adequate and appropriate unless it is comprehensible to the persons to whom it is provided."

Use of PPE:

Regulation 10:

"(1) Every employer shall take all reasonable steps to ensure that any personal protective equipment provided to his employees by virtue of regulation 4(1) is properly used.

Assessment of evidence

(3) Every worker shall use any personal protective equipment provided to him by virtue of these (4) Regulations in accordance both with any training in the use of the personal protective equipment concerned which has been received by him and the instructions respecting that use which have been provided to him by virtue of regulation 9.

(3) Every self-employed person shall make full and proper use of any personal protective equipment provided to him by virtue of regulation 4(2).

(4) Every worker and self-employed person who has been provided with personal protective equipment by virtue of regulation 4 shall take all reasonable steps to ensure that it is returned to the accommodation provided for it after use."

Reporting loss or defect:

Regulation 11:

"Every worker who has been provided with personal protective equipment by virtue of regulation 4(1) shall forthwith report to his employer any loss of or obvious defect in that personal protective equipment."

2022 Amendment:

The term 'employer' replaced with 'worker'; definition below:

""worker" means an individual who has entered into or works under—

(a) a contract of employment;

(b) any contract, whether express or implied and (if it is express) whether oral or in writing, whereby the individual undertakes to do or perform personally any work or services for another party to the contract whose status is not by virtue of the contract that of a client or customer of any profession or business undertaking carried on by the individual; and any reference to a worker's contract shall be construed accordingly.""

"These Regulations amend the Personal Protective Equipment at Work Regulations 1992 ("PPER 1992") to extend the duties contained in regulations 4 to 11 of the PPER 1992 from employees to workers, and to update cross-references to other legislation."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution (BSI) BS EN 136:1998 Respiratory protective devices - Full face masks. Accessed: 24 March 2023.	British Standard	Level 4	N/A	N/A	N/A
Assessment of evidence					
Overview: “This European Standard specifies minimum requirements for full face masks for respiratory protective devices. Full face masks for diving apparatus are not included in the scope of this European Standard. Laboratory and practical performance tests are included for the assessment of compliance with the requirements.” No access to full text					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution (BSI) BS EN 14387:2004 +A1:2008 Respiratory protective devices. Gas filter(s) and combined filter(s). Requirements, testing, marking. Accessed: 24 March 2023.	British Standard	Level 4	N/A	N/A	N/A

Assessment of evidence

Overview: “BS EN 14387 refers to gas filters and combined filters for use as replaceable components in unassisted respiratory protective devices (RPD) apart from escape devices. Laboratory tests are included for the assessment of compliance with the requirements.

Some filters complying with BS EN 14387 can also be suitable for use with assisted respiratory protective devices and/or escape devices.”

“BS EN 14387 on requirements, testing and marking of gas filters and combined filters in RPDs”

No access to full text

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution (BSI) BS EN 137:2006 Respiratory protective devices. Self-contained open-circuit compressed air breathing apparatus with full face mask. Requirements, testing, marking. Accessed: 24 March 2023.	European Standard	Level 4	N/A	N/A	N/A

Assessment of evidence

Overview: “This European Standard specifies minimum performance requirements for self-contained open-circuit compressed air breathing apparatus with full face mask used as respiratory protective devices, except escape apparatus and diving apparatus. Such equipment is intended for use in work situations where the risk on over pressurisation of the pressure vessels with their valves due to hot environmental conditions is low. Laboratory and practical performance tests are included for the assessment of compliance with the requirements.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution (BSI) BS EN 138:1994 Respiratory protective devices. Specification for fresh air hose breathing apparatus for use with full face mask, half mask or mouthpiece assembly. Accessed: 24 March 2023.	European Standard	Level 4	N/A	N/A	N/A

Assessment of evidence

Overview: “This European Standard specifies minimum requirements for fresh air hose breathing apparatus for use with a full face mask, a half mask or a mouthpiece assembly as a respiratory protective device. Two classes of apparatus are covered, the differentiation resulting from mechanical performance and not respiratory protection. Escape and diving apparatus and that used in abrasive blasting operations are not covered by this standard. Laboratory and practical performance tests are included for the assessment of compliance with the requirements.”

No access to full text

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution (BSI) BS EN 13921:2007 Personal protective equipment. Ergonomic principles Accessed: 24 March 2023.	British Standard	Level 4	N/A	N/A	N/A

Assessment of evidence

Overview: “BS EN 13921 provides guidance on the generic ergonomic characteristics related to personal protective equipment (PPE).

BS EN 13921 specifies for the writers of PPE product standards, principles relating to:

- anthropometric characteristics related to PPE;
- the biomechanical interaction between PPE and the human body;
- the thermal interaction between PPE and the human body;
- the interaction between PPE and the human senses: vision; hearing; smell and taste; and skin contact.

BS EN 13921 does not cover requirements related to the specific hazard for which PPE is designed.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution (BSI) BS EN 134:1998 Respiratory protective devices – Nomenclature of components Accessed: 22 March 2023	European Standard	Level 4	N/A	N/A	N/A
Assessment of evidence					
English language version of EN 134:1998, **Overview:** "This European Standard specifies a harmonized nomenclature for typical components of respiratory protective devices. It does not specify which or how many components are used and where they are located in the apparatus. The illustrations used are given as examples only for the identification of the different parts and the corresponding terms for facilitating the application" No access to full text					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution (BSI) EN 135:1999 Respiratory protective devices - List of equivalent terms Accessed: 22 March 2023.	European Standard	Level 4	N/A	N/A	N/A

Assessment of evidence

“This standard BS EN 135:1999 Respiratory protective devices. List of equivalent terms is classified in these ICS categories:

- 01.040.13 Environment. Health protection. Safety (Vocabularies)
- 13.340.30 Respiratory protective devices

A list of terms used in the field of respiratory protection, in the three official CEN language”

No access to full text

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution (BSI) EN 136:1998 Respiratory protective devices - Full face masks – Requirements, testing, marking. Accessed: 22 March 2023.	European Standards	Level 4	N/A	N/A	N/A

Assessment of evidence

“This European Standard specifies minimum requirements for full face masks for respiratory protective devices. Full face masks for diving apparatus are not included in the scope of this European Standard. Laboratory and practical performance tests are included for the assessment of compliance with the requirements.”

No access to full text

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution (BSI) BS EN 140:1998 Respiratory protective devices – Half masks and quarter masks – Requirements, testing, marking Accessed: 22 March 2023	British Standard	Level 4	N/A	N/A	N/A

Assessment of evidence

Overview: “This European Standard specifies minimum requirements for half masks and quarter masks for use as part of respiratory protective devices, except escape apparatus and diving apparatus. Laboratory and practical performance tests are included for the assessment of compliance with the requirements” (page 3)

Definitions and descriptions are provided for half and quarter masks, see Evidence Table entry for Question 1.

Other information:

- Information for manufacturers requirements are provided, including materials to be used, inhalation and exhalation valves, inward leakage and practical performance
- Testing requirements for manufacturers are also provided, including descriptions of tests to be carried out and accompanying diagrams

Assessment of evidence

- Marking requirements for facepiece and packaging are required
- Information to be supplied by the manufacturer is also described

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution (BSI) BS EN 143:2021 Respiratory protective devices – Particle filters – Requirements, testing, marking Accessed: 22 March 2023	British Standard	Level 4	N/A	N/A	N/A

Assessment of evidence

Overview:

BS EN 143 discusses respiratory protective devices (RPDs). BS EN 143 highlights the minimum requirements for particle filters in specifies particle filters for use as replaceable components in unassisted RPDs except for escape devices and filtering facepieces. Laboratory tests are included for the assessment of compliance with the requirements.

Assessment of evidence
Some filters complying with BS EN 143 can also be suitable for use with other types of respiratory protective devices and/or escape devices. Note: BS EN 143 does not cover requirements concerning respiratory hygiene. Requirements for decrease of the microbiological hazards caused by the growth of bacteria and viruses on the filtration material is not determined." **Classification:** "Particle filters are classified according to their filtering efficiency. There are three classes of particle filters: P1, P2 and P3 in ascending order of the filtering efficiency. The protection provided by a P2 or P3 filter includes that provided by the filter of lower class or classes." (page 6)

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution (BSI) BS EN 148-1:2018 Respiratory protective devices - Threads for facepieces. Standard thread connection. Accessed: 22 March 2023	British Standard	Level 4	N/A	N/A	N/A

Assessment of evidence

Overview: “This document specifies standard threads for respiratory protective devices and the description of test devices necessary for the assessment of some of the requirements. This document does not apply to diving equipment and to positive pressure demand breathing apparatus.”

No access to full text

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution (BSI BS ISO 17420-4:2021 Respiratory protective devices. Performance requirements - Requirements for supplied breathable gas RPD Accessed: 22 March 2023	International Standard	Level 4	N/A	N/A	N/A

Assessment of evidence

Overview:

“ISO 17420-4 is an international standard on requirements for supplied breathable gas respiratory protective devices to ensure protection to wearer from hazardous air.

ISO 17420-4 specifies requirements for the performance and testing of supplied breathable gas respiratory protective devices (RPD) in accordance with their classification and for use in the workplace to protect the wearer from hazardous atmospheres and/or environments.

ISO 17420-4 describes basic requirements for the supplied breathable gas respiratory protective device (RPD) and its elements and components.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution (BSI) BS ISO 17420-2:2021 Respiratory protective devices. Performance requirements - Requirements for filtering RPD Accessed: 22 March 2023	International Standard	Level 4	N/A	N/A	N/A

Assessment of evidence

Overview: “17420-2 is an international standard on performance requirements of filtering RPD.

ISO 17420-2 specifies requirements for the performance and testing of filtering respiratory protective devices (RPD) in accordance with their classification and for use in the workplace to protect the wearer from hazardous atmospheres and/or environments.

Requirements for RPD elements and components are also specified in ISO 17420-2.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution (BSI) PD ISO/TS 17420-9:2021 Respiratory protective devices — Performance requirements — Part 9: Special application chemical, biological, radiological and nuclear (CBRN) supplied breathable RPD	International Standard	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Accessed: 22 March 2023					

Assessment of evidence

Overview: “ISO/TS 17420-9 is the ninth part of multi-series that specifies the requirements for respiratory protective devices. These can be used by workers during the response to incidents involving chemical, biological, radiological, or nuclear (CBRN) materials used with intent to cause harm or in cases of accidental release outside traditional hazardous materials response categories. For the purposes of this specification, all incidents described here are named CBRN incidents.”

The standard is applicable to RPE wearers in emergency medical services and medical personnel treating casualties of CBRN incidents.

No access to full text

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution (BSI) BS EN 13274-1:2001 Respiratory protective devices – Methods of test – Part 1: Determination of	European Standard	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
inward leakage and total inward leakage. Accessed 23 March 2023.					

Assessment of evidence

Overview:

“This European Standard specifies the general procedure for determining:

a) the inward leakage of facepieces; or

b) inward leakage of respiratory protective devices (RPD), which is the total inward leakage excluding any filter penetration; or

c) total inward leakage of respiratory protective devices.

Device preparation, selection of test subjects, test procedure and the method of calculation of leakage are included. Two methods are described, one using an aerosol (sodium chloride aerosol) and one using a gas (sulfur hexafluoride).”

Limitations:

- Use of sodium chloride aerosol to mimic all aerosols. May not be applicable to biological aerosols.
- No access to full text

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution (BSI) EN 13274-2:2019 - Respiratory protective devices – Methods of test – Part 2: Practical performance tests Accessed: 23 March 2023	European Standard	**Level 4**	N/A	N/A	N/A

Assessment of evidence

Overview: “BS EN 13274-2 is the second part of a multi-part series that specifies practical performance tests for respiratory protective devices, except for diving apparatus.

The purpose of the test specified under BS EN 13274-2 is to subjectively assess certain properties, characteristics, and functions of the device when worn by test subjects in simulated practical use, which cannot be assessed by tests described in other standards.”

No access to full text

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution (BSI) EN 13274-3:2001 - Respiratory protective devices – Methods of test – Part 3: Determination of breathing resistance Accessed: 23 March 2023	European Standard	Level 4	N/A	N/A	N/A
Assessment of evidence					
Overview: “This European Standard specifies the general procedure for measurement of breathing resistance of filters for respiratory protective devices and respiratory protective devices incorporating facepieces, except for diving for respiratory protective devices. The requirements and any special conditions for the apparatus, and of filter measurements are described in the relevant device standard.” No access to full text					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution (BSI) BS EN 13274-7:2019 - Respiratory protective devices – Methods of test – Part 7: Determination of particle filter penetration Accessed: 23 March 2023	European Standard	Level 4	N/A	N/A	N/A
Assessment of evidence					
Overview: “BS EN 13274-7 is the seventh part of a multi-part series that specifies the procedure for testing particle filter penetration for respiratory protective devices. BS EN 13274-7 is intended as a supplement to the specific device standards for respiratory protective devices.” No access to full text					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution (BSI) BS ISO 16900-1:2019 Respiratory protective devices — Methods of test and test equipment — Part 1: Determination of inward leakage. Accessed: 31 August 2019	International Standard	Level 4	N/A	N/A	N/A

Assessment of evidence

Overview: “This document specifies the test methods for determining inward leakage of respiratory interfaces (RI) and total inward leakage of complete respiratory protective devices (RPD) using specified test agents and incorporating specified body movements, at specified metabolic work rates.

These tests are conducted in laboratories using specific test agents under specified conditions and therefore do not indicate the performance of the device in actual use.”

No full text access

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution (BSI) BS ISO 16900-2:2017 Respiratory protective devices — Methods of test and test equipment — Part 2: Determination of breathing resistance. Accessed: 23 March 2023	International Standard	**Level 4**	N/A	N/A	N/A
Assessment of evidence					
Overview: “This document specifies the method(s) of test for breathing resistance for — respiratory protective devices (RPDs), — filters for RPDs, and — respiratory interfaces (RI).” No full text access					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution (BSI) BS ISO 16900-3:2012 Respiratory protective devices — Methods of test and test equipment — Part 3: Determination of particle filter penetration Accessed: 23 March 2023	International Standard	Level 4	N/A	N/A	N/A
Assessment of evidence					
Overview: “This part of ISO 16900 specifies the test methods for particle filter penetration of separate or integral filters for respiratory protective devices.”					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution (BSI) BS ISO 16900-7:2020 Respiratory protective devices. Methods of test and test equipment - Practical performance test methods Accessed: 23 March 2023	International Standard	Level 4	N/A	N/A	N/A
Assessment of evidence					
Overview: “ISO 16900 discusses respiratory protective devices (RPD). ISO 16900-7 is the seventh part of the ISO 16900 multi-series, and discusses practical performance test methods for respiratory protective devices.” No full text access					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution (BSI) PD ISO/TS 16975-2: 2016 Respiratory protective devices: selection, use and maintenance condensed guidance to establishing and implementing a respiratory protective device programme. Accessed 23 March 2023	International Standard	Level 4	N/A	N/A	N/A

Assessment of evidence

Overview: “ISO/TS 16975-2 provides brief guidance to assist persons responsible for establishing and implementing a programme for respiratory protective devices (RPD) that meet the performance requirements.”

Shortened version of PD ISO/TS 16975-2:2016, structured under the following headings:

- Basic information, including risk assessment, use of protection factors and ISO protection levels, and types and classes of RPD

Assessment of evidence
• RPD programme elements • Selection procedure • Training of the RPD wearer • Using RPD • Management of the RPD programme • Records • Annex A – RPD selection process and record

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution (BSI) BS EN ISO 16972:2020 Respiratory protective devices – Vocabulary and graphical symbols. Accessed: 23 March 2023	British Standard	Level 4	N/A	N/A	N/A

Assessment of evidence
Overview: “This document defines terms and specifies units of measurement for respiratory protective devices (RPDs), excluding diving apparatus. It indicates graphical symbols that can be required on RPDs, parts of RPD or instruction manuals in order to instruct the person(s) using the RPD as to its operation.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution (BSI) PD ISO/TS 20141:2022 Personal safety – Personal protective equipment – Guidelines on compatibility testing of PPE. Accessed: 23 March 2023	International Standard	Level 4	N/A	N/A	N/A
Assessment of evidence					
UK implementation of ISO/TS 20141:2022 **Overview:** “This document describes compatibility for ensembles of personal protective equipment (PPE) to be used by personnel where operating situations and processes require more than one piece of PPE. Where there is more than one risk to health and safety,					

Assessment of evidence

it is necessary to wear or use more than one item of PPE at the same time. Such equipment should be compatible and continue to be effective to minimise the risks.

This document includes examples of interactions between items of PPE, between PPE and the operating environment and the effects of PPE on the correct functioning of integrated sensors and electronic devices.

This document provides suggestions of test procedures to assess the effects of any interactions and identify unacceptable restrictions to safe operations.

NOTE: The principles of this document are also applicable to assessment of interactions with other items in an ensemble that are necessary to the work and that are not PPE, for example cap lamps, instruments, tools.

This document is also intended to be a general guideline for writers of performance requirements standards and test methods for PPE. This document can also be used by PPE manufacturers, distributors, solutions providers, purchasers, wearers and employers as guidance in PPE design and selection."

Question 3: What design features of disposable respirators are desirable?

Evidence added to 2024 update:

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). Ear loop respirators/masks do not provide protection as tight fitting RPE: Health and Safety Executive - Safety notice. 2022. Accessed: 6 October 2022	Safety Notice	Level 4	N/A	N/A	N/A
Assessment of evidence					
HSE recognise FFP2 respirators with ear loops, and the use of clips and ‘snuggers’ do not provide adequate protection. Instead, respirators with a head harness are to be used. “Target audience: Providers of respiratory protective equipment (RPE) and those required to use tight fitting RPE at work”					

Assessment of evidence

“New HSE research has revealed that respirators/masks which rely on ear loops (including those provided with clips, ‘snuggers’ or other means of tightening the fit of the mask) to hold the respirator/mask in place, do not protect people adequately when used as tight fitting respiratory protective equipment (RPE).”

“HSE has seen an increase in the variety of ear loop respirators/masks, which indicate they offer the protection provided by FFP2 (filtering facepiece respirators or disposable half mask respirators). These products rely on having a good seal with the wearer’s face. For the majority of workers who are required to wear tight fitting RPE in the workplace, this seal cannot be achieved with a respirator/mask relying on ear loops to hold it in place.”

“HSE does not recommend using respirators/masks secured using ear loops as tight fitting RPE”

“Following publication of the previous Safety Alert ‘Use of Face Masks designated KN95’, in June 2020, the NHS took early action to exclude ear loop respirators/masks from their supply chain due to concerns over their protection. As a result, respirators with a head harness will have been supplied and fit test completed with this style of respirator.

Question 4: What design features of powered respirators are desirable?

Evidence added to 2024 update: No evidence identified

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
N/A	N/A	N/A	N/A	N/A	N/A
Assessment of evidence					
N/A					

Evidence from previous update(s):

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
N/A	N/A	N/A	N/A	N/A	N/A
Assessment of evidence					
N/A					

Question 5: What are respirator ‘fit tests’ and ‘fit checks’ and how are they performed?

Evidence added to 2024 update:

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Lam SC, Lee JKL, Lee SY, et al. Sensitivity and specificity of the user-seal-check in determining the fit of N95 respirators. J of Hosp Infect. 2011: 252-256	Cross sectional	Level 3	Investigation of the capability of the user-seal-check in determining the fit of two N95 respirators (3M 1860 S and 3M 1862)	Result for user-seal-check compared with result of QNFT	The sensitivity (true positive) and specificity (true negative) of a user-seal-check Associations of pass rates between sexes

Assessment of evidence

This study was carried out on 204 undergraduate nursing students in Hong Kong. The study identified within this cohort, user-seal-checks on two types of N95 respirators (3M 1860 S and 3M 1862) had sensitivity (true positive) of 15.2% and 23.0%, and a specificity (true negative) of 88.8% and 89.7%, respectively, when comparing against QNFT using a PortaCount. This suggests a user-seal-check should not be used in place of a QNFT.

Findings:

3M 1860S respirator –

- 12.8% of the participants found leakage on the user-seal-check.

Assessment of evidence

- 38.7% failed the QNFT.
- Sensitivity (true positive) of user-seal-check was 15.2%
- Specificity (true negative) of user-seal-check 88.8%

3M 1862 respirator –

- 15.7% of the participants found leakage on the user-seal-check.
- 42.7% failed the QNFT.
- Sensitivity (true positive) of user-seal-check was 23.0%
- Specificity (true negative) of user-seal-check 89.7%
- 37.3% participants passed the QNFT for both respirators, 18.6% failed the QNFT for both respirators
- The user-seal-check was no more accurate among females compared with males with regard to accuracy. No statistical data to support this
- There was no association between sex and QNFT results for the 3M 1860S respirators (X2 = 3.10, P = 0.055)
- The male participants had higher pass rates than the female participants (72.7% vs 58.1%)
- A significant association between sexes for 3M 1862 respirators (X2 = 5.42, P = 0.014).
- The male participants had higher pass rates than the female participants (72.7% vs 53.1%)

Limitations:

- Specific to young adults aged 18-23
- May not generalize to UK health and care settings, study carried out in Hong Kong
- N95 respirators – limited generalisability to other RPE

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Department of Health Infection Prevention and Control (IPC) National Clinical Guideline No. 30 Last updated: May 2023 Accessed: 03 February 2025	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

Target audience: “This National Clinical Guideline applies to all health and social care workers because the control of healthcare associated infection is everyone’s responsibility. It is particularly relevant to Infection Prevention and Control (IPC) Practitioners. IPC Practitioners are those health and social care workers with specific training and expertise in the prevention and control of infection and who provide training, guidance and leadership to others on IPC.”

Recommendations:

Fit testing:

“There are 2 types of facial fit test - qualitative and quantitative. Qualitative fit tests are fast and simple but can be influenced by the wearer. Quantitative fit tests require the use of specialised equipment used by a trained operator.”

Fit checking:

“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. Health care workers must be trained in performance of a fit check.

Assessment of evidence
The procedure for fit checking includes: • placement of the respirator on the face • placement of the headband or ties over the head and at the base of the neck • compressing the respirator to ensure a seal across the face, cheeks and the bridge of the nose • checking the positive pressure seal of the respirator by gently exhaling. The manufacturer's instructions for fit checking of individual brands and types of FFP2 respirator should be referred to at all times."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Caggiari S., Bader D., Packman Z. et al. Retrospective evaluation of factors affecting successful fit testing of respiratory protective equipment during the early phase of COVID-19.	Retrospective cohort study	Level 3	Risk factor: fit test outcome Procedure: qualitative vs quantitative fit test results	Fit test pass or failure	Odds of fit test success (95% CI, p-value)

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
BMJ Open, 2023; 13. Doi: 10.1136/bmjopen-2022-065068.					

Assessment of evidence

Setting: England

Study period: July – August 2020

Methodology:

A quality improvement study performed in NHS England, where five FFP3 models were tested according to HSE Qualitative and Quantitative fit test methods (QLFT and QNFT).

Each trust was provided with a Toolkit to collect relevant information about HCWs (demographic information, etc). Facial measurements were also taken however the findings related to these were descriptive so have been excluded. HCWs were fitted with a respirator and tested. Failed results meant that other respirator models were tried until a pass was achieved.

Inclusion criteria: hospital staff working in areas where FFP3 respirators were required.

Main findings:

N = 5604 participants and 9592 fit test observations included.

Using a QNFT fit test method was associated with lower odds of passing compared to QLFT (OR 0.71, 95% CI 0.61 – 0.82, $p < 0.05$) (mixed-effects logistic regression model).

Limitations:

- Study period only 5 weeks
- Secondary analysis of quality improvement data

Assessment of evidence

- Retrospective study design
- Allocation of FFP3s was not random
- Study limited to 5 FFP3 designs

The findings of this study suggests that a QNFT is more sensitive than a QLFT.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
European Centre for Disease Prevention and Control (ECDC). Personal protective equipment (PPE) needs in healthcare settings for the care of patients with suspected or confirmed novel coronavirus (2019-nCoV), 2020a. Accessed 14 December 2022.	Technical Report	Level 4	N/A	N/A	N/A

Assessment of evidence

Target audience: “Public health authorities and hospital administrators in EU/EEA countries.”

Assessment of evidence
“It is important to perform a fitting test after the respirator has been put on, following the manufacturer’s instructions.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Occupational Safety and Health Administration (OSHA). 2009. Guidance on Preparing Workplaces for an Influenza Pandemic. OSHA 3327-05R.	Guidance	**Level 4**	N/A	N/A	N/A
Assessment of evidence					
Guidance document produced by The Occupational Safety and Health Administration is an agency of the United States Department of Labor. Influenza pandemic guidance. “It should also be noted that there are hooded PAPRs that do not require employees to be fit tested in order to use them.”					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The National Institute for Occupational Safety and Health (NIOSH) Cichowicz J, Coffey C, Fries M. Pittsburgh A guide to Air-Purifying Respirators. 2018a. Accessed: 2 December 2022	Guidance	Level 4	N/A	N/A	N/A
Assessment of evidence					
“The loose-fitting PAPR does not require fit testing. Loose-fitting PAPRs may be an alternative for users who have facial hair or are otherwise not able to pass a fit test with a tight-fitting respirator. However, OSHA does require fit testing for a tight-fitting PAPR.”					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Australian Government National Health and Medical Research Council (NHMRC) Australian Guidelines for the Prevention and Control of Infection in Healthcare 2019 (revised 2024, v11.24) Accessed 11 October 2024	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

Funding: Guidance was co-funded by the NHMRC and Medical Research Council and Australian Commission on Safety and Quality in Health Care.

Aim of guidance (page 20): “By assisting healthcare workers to improve the quality of the care they deliver, these Guidelines aim to promote and facilitate the overall goal of infection prevention and control: the creation of safe healthcare environments through the implementation of evidence-based practices that minimise the risk of transmission of infectious agents.”

Assessment of evidence

Target audience (page 20): “The Guidelines are for use by all those working in acute health care settings —this includes healthcare workers, management and support staff. As some of the principles and recommendations described in this guideline may be applicable to other health care settings, individuals working in other health care settings may also find the guidelines useful.”

Note: P2 respirators meet the relevant Australian standard (AS/NZS 1716:2012 and 1715:2009) and differs to NIOSH, which specifies N95 respirators.

“P2 respirators — fit testing and fit checking –

Fit testing –

“The purpose of fit testing is to identify which size and style of P2 respirator is suitable for an individual, and to ensure that it is worn correctly. It also provides an opportunity to ensure healthcare workers are properly trained in the correct use of the mask. When fit testing is to be undertaken, it should be done so based on relevant state/territory jurisdictional requirements in conjunction with a risk assessment with relevance to the healthcare setting.”

“There are two types of facial fit test—qualitative and quantitative. Qualitative fit tests are fast and simple but can be influenced by the wearer. Quantitative fit tests require the use of specialised equipment used by a trained operator. Standard AS/NZS 1715: 2009 outlines the method by which fit testing is conducted.” Note: Australian standard is not relevant to UK. UK standards would take precedence.

Fit checks –

“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. Healthcare workers must be informed about how to perform a fit check.”

The fit check procedure described is based on guidance by the Australian Government Department of Health (178), as follows:

- “placement of the respirator on the face
- placement of the headband or ties over the head and at the base of the neck
- compressing the respirator to ensure a seal across the face, cheeks and the bridge of the nose

Assessment of evidence

- checking the positive pressure seal of the respirator by gently exhaling. If air escapes, the respirator needs to be adjusted
- checking the negative pressure seal of the respirator by gently inhaling. If the respirator is not drawn in towards the face, or air leaks around the face seal, readjust the respirator and repeat process, or check for defects in the respirator."

"The manufacturer's instructions for fit checking of individual brands and types of P2 respirator should be referred to at all times." (page 123).

Limitations:

- The introduction states that all recommendations are based on systematic reviews, however there is insufficient evidence within the guidance to support this claim.
- Citation 178: Australian Government Department of Health resource that cannot be accessed.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Australian Government Infection Prevention and Control Expert Group. Guidance on the use of personal protective equipment for health workers in the	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
context of COVID-19. 2022. Accessed: 28 November 2022					

Assessment of evidence

Guidance endorsed by the Australian Health Protection Principal Committee.

Recommendations developed with advice from the National COVID-19 Clinical Evidence Taskforce Infection and Prevention and Control Panel (IPC Panel).

Consensus recommendations based on the experience of the IPC panel and ICEG members.

“They reflect emerging evidence concerning all potential modes of viral transmission and the increased transmissibility of SARS-CoV-2”

“The recommendations contained in this document describe the minimum national standard for PPE for health workers in the context of COVID-19.”

“Given the variability across and within health care settings, decisions around the use of PPE may require a nuanced and flexible approach, guided by evidence, contextual factors, and consideration of health worker preferences. This guidance is not meant to be exhaustive but aims to supplement detailed guidance available at a state, territory and institutional level.”

Recommendations:

“Fit testing is a validated method for matching PFRs with an individual’s facial shape.

Fit testing should be performed by an appropriately trained person.

A range of styles and sizes of PFRs may need to be fit tested to find one that achieves a protective seal.”

Assessment of evidence
“Fit checking ensures the PFR fits the user’s face snugly (i.e., creates a seal) to minimise the number of particles that can bypass the filter through gaps between the user’s skin and the respirator seal. A fit check is performed by gently inhaling and exhaling. If the mask is not drawn in towards the face, or air leaks around the face seal, readjust the mask and repeat process or check for defects in the mask.” “Fit testing does not guarantee a respirator will not leak, particularly if a different type or size is used to one previously fit tested.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). Fit testing basics. 2022. Accessed: 7 October 2022	Guidance	Level 4	N/A	N/A	N/A
Assessment of evidence					
“If an employee wears more than one type of tight-fitting facepiece, then each type of facepiece should be fit tested.”					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
National Institute for Occupational Safety and Health (NIOSH) Filtering out Confusion: Frequently Asked Questions about Respiratory Protection, Fit Testing. 2018. Accessed: 5 December 2022.	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

Setting: USA

Fit test:

Respirator fit test required as it “ensures that users are receiving the expected level of protection by minimizing any contaminant leakage into the facepiece.”

“A fit test is conducted to verify that a respirator is both comfortable and correctly fits the user. Fit test methods are classified as either qualitative or quantitative. A qualitative fit test is a pass/fail test that relies on the individual’s sensory detection of a test agent, such as

Assessment of evidence

taste, smell, or involuntary cough (a reaction to irritant smoke*). A quantitative fit test uses an instrument to numerically measure the effectiveness of the respirator."

"The benefits of a fit test include better protection for the employee and verification that the employee is wearing a correctly-fitting model and size of respirator. Higher than expected levels of exposure to a contaminant may occur if the respirator has a poor face seal against the user's skin, which can result in leakage."

"A successful fit test only qualifies an employee to use the specific brand/make/model and size of respirator that he or she wore during that test. Respirator sizing is not standardized across models or brands. For example, a medium in one model may not offer the same fit as a different manufacturer's medium model."

Fit-testing PAPRs:

"Any facepieces that form a tight seal to the wearer's face, e.g., half-masks and full facepieces, must be fit tested. Loose-fitting PAPRs, in which the hood or helmet is designed to form only a partial seal with the wearer's face or hoods which seal loosely around the wearer's neck or shoulders, do not require fit testing."

Limitation: applicability given that NIOSH are in-line with OSHA standards and legislation, which do not apply to Scottish health and care settings.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
National Institute for Occupational Safety and Health (NIOSH) Filtering out Confusion:	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Frequently Asked Questions about Respiratory Protection, User Seal Check 2018. Accessed: 5 December 2022					

Assessment of evidence

Setting: USA

“A user seal check is a procedure conducted by the respirator wearer to determine if the respirator is being properly worn.”

“The user seal check can either be a positive pressure or negative pressure check.

During a positive pressure user seal check, the respirator user exhales gently while blocking the paths for air to exit the facepiece. A successful check is when the facepiece is slightly pressurized before increased pressure causes outward leakage.

During a negative pressure user seal check, the respirator user inhales sharply while blocking the paths for air to enter the facepiece. A successful check is when the facepiece collapses slightly under the negative pressure that is created with this procedure. A user seal check is sometimes referred to as a fit check.”

“It is only applicable when a respirator has already been successfully fit tested on the individual.”

“Not every respirator can be checked using both positive and negative pressure. Refer to the manufacturer’s instructions for conducting user seal checks on any specific respirator.”

Examples of user seal checks –

Assessment of evidence

Positive seal check: “Once the particulate respirator is properly donned, place your hands over the facepiece, covering as much surface area as possible. Exhale gently into the facepiece. The face fit is considered satisfactory if a slight positive pressure is being built up inside the facepiece without any evidence of outward leakage of air at the seal. Examples of such evidence would be the feeling of air movement on your face along the seal of the facepiece, fogging of your glasses, or a lack of pressure being built up inside the facepiece. If the particulate respirator has an exhalation valve, then performing a positive pressure check may be impossible. In such cases, a negative pressure check should be performed.”

Negative seal check: “Negative pressure seal checks are typically conducted on particulate respirators that have exhalation valves. To conduct a negative pressure user seal check, cover the filter surface with your hands as much as possible and then inhale. The facepiece should collapse on your face and you should not feel air passing between your face and the facepiece. In the case of either type of seal check, if air leaks around the nose, use both hands to readjust the nosepiece by placing your fingertips at the top of the metal nose clip. Slide your fingertips down both sides of the metal strip to more efficiently mold the nose area to the shape of your nose. Readjust the straps along the sides of your head until a proper seal is achieved. If you cannot achieve a proper seal due to air leakage, you may need to be fit tested for a different respirator model or size.”

User seal check cannot be used as a substitute to a fit test. “The user seal check does not have the sensitivity and specificity to replace either fit test methods, qualitative or quantitative, that are accepted by OSHA (29 CFR 1910.134). A user should only wear respirator models with which they have achieved a successful fit test within the last year.”

Limitation: applicability given that NIOSH are in-line with OSHA standards and legislation, which do not apply to Scottish health and care settings.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Public Health Agency of Canada (PHAC). Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Healthcare Settings, 2017. Last accessed: 20 December 2022.	Report	Level 4	N/A	N/A	N/A

Assessment of evidence

Setting: Canada

Aim: To present evidence-based recommendations for monitoring, preventing and controlling healthcare associated infections.

Target audience: Infection prevention and control professionals and healthcare providers involved with developing policy and procedure for routine practices in healthcare settings (acute, long-term, ambulatory, home care or prehospital care settings)

Methods: These guidelines were produced by PHAC, advised by PHAC's Steering Committee on Infection Prevention and Control Guidelines Working Group, made up of professionals from different areas of healthcare who provided technical advice (list provided on page 2). They are described as "principles and recommendations" rather than strict standards.

Assessment of evidence

A literature search was conducted for papers from 1999 (details of this search are available to request). Recommendations were graded based on the strength of evidence. This guidance is based on scientific evidence and expert opinion where evidence was lacking, but was graded as expert opinion due to limited methodological detail making it difficult to deduce how systematic methods were.

Appendix V (glossary) –

“Fit-testing − The use of a qualitative or quantitative method to evaluate the fit of a specific make, model and size of respirator on an individual” (page 171). This definition references Canadian Standards Association (233)

Fit check − Refer to Seal check.

“Seal check − A procedure the wearer performs each time a respirator is worn and is performed immediately after putting on the respirator to ensure that there is a good facial seal. Seal check has been called “fit check” in other IPC documents (Refer also to Fit-testing).” (page 176)

In Part A, section B – “Role of organization to reduce exposure to and transmission of infectious agents” under the section on administrative controls (occupational health):

- Fit testing is described as being “used to evaluate how well a given respirator fits a given person by assessing leakage around the face seal. Published literature regarding fit-testing respirators in the healthcare setting is inconclusive however, most Canadian jurisdictions require fit testing for HCWs to determine their ability to obtain a satisfactory seal when using respirators” (page 37)
    - This section references the Canadian Standards Association (233), a CDC study (236) and two experimental study (234 - Lawrence et al., 2006; 235 – Danyluk et al., 2011)
- They also note that fit test results do not carry across models of respirator (page 38)

Part B.IV. includes recommendations for additional precautions, and in subsection iii for patients with known or suspected infections requiring airborne precautions (examples of these include tuberculosis, measles and disseminated zoster):

Assessment of evidence
- Also under personal protective equipment (page 102), the authors state “Healthcare workers should remain clean shaven in the area of the respirator seal to ensure facial seal.” (CII - weak) and the following for “appropriate respirator use (CII - weak): o A seal check should be performed.” Type of respirator is not specified. Although, in the Glossary an N95 respirator is identified as the most commonly used in health care.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Ministry of Health New Zealand. COVID-19: Infection prevention and control recommendations for health and disability care workers. 2022. Last updated: 05 September 2024. Accessed: 04 November 2024	Guideline	Level 4	N/A	N/A	N/A

Assessment of evidence
“Fit testing and fit checking/user seal check: “Fit testing is a procedure through either a qualitative or quantitative test to ‘match’ the right P2/N95 particulate respirator with the wearers face shape to ensure maximum protection.” “Fit checking /user seal check is a ‘quick check’ method used by the wearer to ensure the respirator is properly positioned on their face and there is a tight seal between the respirator and face. A fit check/user seal check must be done every time a P2/N95 is put on.” “In situations where fit testing has not yet been carried out, and a P2/N95 respirator is recommended for use” **Limitations:** - No references are provided. - Specific to health and disability care workers

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Ministry of Health New Zealand. Mask use and visitor guidance for hospitals and other health and disability care settings. 2023.	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Accessed: 28 October 2024					

Assessment of evidence

"This document has been developed to provide guidance on mask use for healthcare workers, patients and visitors for health and disability care settings"

"Fit testing is a procedure through either a qualitative or quantitative test to 'match' the right P2/N95 with the wearers face shape to ensure maximum protection."

"Fit checking /user seal check is a 'quick check' method used by the wearer to ensure the respirator is properly positioned on their face and there is a tight seal between the respirator and face.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Occupational Safety and Health Administration (OSHA). Hospital Respiratory Protection Program Toolkit: Resources for Respirator and	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Program Administrators. May 2015. Accessed: 23 December 2022					

Assessment of evidence

"This toolkit was developed to assist hospitals in developing and implementing effective respiratory protection programs". "This toolkit identifies existing public health guidance where available on the use of respiratory protection."

Taken from their glossary:

"Fit factor—A quantitative estimate of the fit of a particular respirator to a specific individual; typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn."

"Fit test—The use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual."

"Qualitative fit testing (QLFT)—A pass/fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent."

"Quantitative fit testing (QNFT)— An assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator."

"User seal check—An action conducted by the respirator user to determine if the respirator is properly seated to the face. For all tight-fitting respirators, the employer shall ensure that employees perform a user seal check each time they put on the respirator using the procedures in Appendix B-1 of OSHA's Respiratory Protection standard or equally effective procedures recommended by the respirator manufacturer. User seal checks are not substitutes for qualitative or quantitative fit tests."

Assessment of evidence

Seal check –

“Either the positive and negative pressure checks listed in this appendix or the respirator manufacturer's recommended user seal check method shall be used.

I. Facepiece Positive and/or Negative Pressure Checks.

A. Positive pressure check. Close off the exhalation valve and exhale gently into the facepiece. The face fit is considered satisfactory if a slight positive pressure can be built up inside the facepiece without any evidence of outward leakage of air at the seal. For most respirators this method of leak testing requires the wearer to first remove the exhalation valve cover before closing off the exhalation valve and then carefully replacing it after the test.

B. Negative pressure check. Close off the inlet opening of the canister or cartridge(s) by covering with the palm of the hand(s) or by replacing the filter seal(s), inhale gently so that the facepiece collapses slightly, and hold the breath for ten seconds. The design of the inlet opening of some cartridges cannot be effectively covered with the palm of the hand. The test can be performed by covering the inlet opening of the cartridge with a thin latex or nitrile glove. If the facepiece remains in its slightly collapsed condition and no inward leakage of air is detected, the tightness of the respirator is considered satisfactory.

II. Manufacturer's Recommended User Seal Check Procedures. The respirator manufacturer's recommended procedures for performing a user seal check may be used instead of the positive and/or negative pressure check procedures provided that the employer demonstrates that the manufacturer's procedures are equally effective.

“**Fit Testing:**

Fit testing is required for all users of respirators with tight-fitting facepieces, including filtering facepiece respirators. The fit test ensures that, when donned properly, the selected brand and size of respirator fits adequately to protect the wearer from excessive inward leakage of contaminant through the face seal.

Qualitative Tests: There are four qualitative fit test protocols specified in the Respiratory Protection standard. Either the saccharin or Bitrex® fit test protocol may be used for fit testing APRs, including filtering facepiece respirators, for particulate exposure. The APF for qualitative fit tests is limited to 10, even for respirators with a full facepiece. In these tests, the user is exposed to a saccharin (sweet-

Assessment of evidence
tasting) or Bitrex® (bitter tasting) aerosol. It is up to the respirator user to let the tester know if he or she tastes the test aerosol at any time. Because these tests rely on the user's subjective detection of leakage when challenged with a test agent, the protocols require pre-screening to determine each user's ability to detect the specific test agent. **Quantitative Tests:** There are three approved quantitative fit tests and all require an investment in relatively expensive equipment. The most common quantitative protocol used in hospitals is the ambient aerosol condensation nuclei counter (CNC) test. With the correct equipment, this test protocol can be used for all types of respirators and provides an automated calculation of the effectiveness of fit (fit factor) by consecutively measuring and comparing the concentration of airborne particles inside and outside the facepiece." **Limitations:** - No references - May not be applicable to UK health and care settings

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Hon CY, Danyluk Q, Bryce E, et al. Comparison of qualitative and quantitative fit-testing results for three commonly used respirators in	Observational comparative study	Level 3	The study aimed to determine the pass/ fail rates of QLFT and QNFT methods three models of N95s (3M - 1860S, 1860, and 1870).	QNFT and QLFT pass/ fail success rates were compared. The study also compared differences in outcomes based on the respirator model.	No. and percentage of QLFT pass/ fail No. and percentage of QNFT pass/ fail (based on fit factor) Kappa statistic and CIs

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
the healthcare sector. J Occup Environ Hyg. 2017;14(3):175-179. Doi: https://doi.org/10.1080/15459624.2016.1237030.					

Assessment of evidence

This study was carried out on 614 healthcare workers from 24 residential care facilities in Vancouver, Canada. The study investigated if a quantitative fit test (QNFT), using a TSI Portacount Plus Respirator Fit Tester with a TSI N95-Companion, and a qualitative fit test (QLFT), using the Bitrex method, were comparable with three models of N95 FFRs (3M - 1860S, 1860, and 1870).

The study suggests the two test methods are not comparable as they have disparate fit-test outcomes, indicated by the Kappa statistic of 0.63, lower than the ANSI threshold of 0.70 (which would suggest agreement).

More healthcare workers passed the QLFT method than the QNFT method (11.24%, n=69) compared to healthcare workers who passed the QNFT method and failed the QLFT method (0.85%, n=4). This study indicates the QNFT method can identify failures seen as a ‘pass’ when using a QLFT method as there is greater potential to pass a QLFT method that is deemed as a fail when using a QNFT method than passing a QNFT and failing a QLFT method. However, inferences on true positives/ true negatives cannot be made as no method to validate the pass/fail of each test method was carried out. None of the respirator models reached the ANSI threshold of 0.70 and there was no statistically significant difference in the K statistic between the respirator models.

The study also identified that despite a successful fit seal check, it is possible to subsequently fail a fit test (as 13% of individuals failed fit tests despite passing a user seal check). This study is limited by its potential lack of generalizability to a UK health and care setting

Assessment of evidence
and to the wider population. The study should not be used alone, and instead should be used in a wider body of evidence to determine accuracy of fit test models. **Limitations:** • Study specific to 3 models of N95 (3M - 1860S, 1860, and 1870) • May not generalize to UK health and care setting • Predominantly female participants (90%) may not generalize wider population • Aspect of fit test not performed – grimacing • Subjective decision on model suited to face dimensions by one person • Specific to the types of fit tests carried out in this study • Study indicated the TSI Portacount is no longer commercially available

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The British Standard Institution (BSI). BSI ISO 16975-1:2016. Respiratory protective devices – Selection, use and maintenance – Part 1: Establishing and	British Standard	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
implementing a respiratory protective device programme. 2016. Accessed: 12 July 2023.					

Assessment of evidence

Foreword: “The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.”

General fit testing principles:

“Tight-fitting respiratory interfaces, those that have a face or neck seal (classes bT, cT and dT), will not provide optimum performance if they do not fit and therefore need to be fit tested on the individuals who will wear the RPD. All other respiratory interfaces do not require a fit test.

All wearers of tight-fitting RPD shall pass an appropriate qualitative fit test (QLFT) or quantitative fit test (QNFT) as described in ISO 16975-3. The fit test […] shall be conducted by a competent person. The wearer being fit tested shall be free from hair in the area of the sealing surface of the RPD during the fit test and subsequent RPD use.”

“All tight-fitting respiratory interfaces shall be fit tested in the unassisted filtering mode regardless of the mode of operation in which the RPD is used. For breathable gas RPD and assisted RPD, this can be accomplished by temporarily converting the respiratory interface

Assessment of evidence

into a filtering RPD by using appropriate filters, or by using an unassisted filtering RPD with an identical respiratory interface sealing surface."

Qualitative vs quantitative:

"Either qualitative or quantitative fit testing methods may be used where appropriate. Qualitative fit testing may only be used where a required fit factor (RFF) of 100 or less is needed. Quantitative fit testing shall be used when the required fit factor is greater than 100. The quantitative fit factor (QNFF) measured shall be equal to or greater than the RFF." (page 23)

"The RFF determines which fit test methods are acceptable. — For RFF [required fit factor], up to 100 [(Protection class (PC) classes 1, 2 and 3)] QLFT or QNFT may be used. — For RFF from 1 000 to 2 000 [(PC classes 4, 5 and 6)], only QNFT may be used." (page 24)

Table 10 shows PC class 1, 2 and 3 have a required fit factor of 100, PC 4 has 1000, PC 5 and 6 has 2000.

"Methods of fit testing are described in ISO 16975-3."

Limitation: The members of the technical committee(s) who contribute to British Standards is not easily accessible and information regarding how to obtain this information is unclear. For this reason, the extent to which IPC in health and care settings, and subsequent applicability of these standards to these settings may be limited.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The British Standard Institution (BSI). BS ISO 16975-3:2017. Respiratory protective devices – Selection, use and	British Standard	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
maintenance –Part 3: Fit-testing procedures. 2017. Accessed: 12 July 2023.					

Assessment of evidence

"use of a challenge agent and specific protocol to qualitatively or quantitatively determine the effectiveness of the seal between the wearer's face and respiratory interface (3.11) with a specific make, model, and size of an RPD"

Qualitative fit test: "pass/fail test method that relies on the subject's sensory response to detect a challenge agent in order to assess the adequacy of RPD fit"

Qualitative fit factor: "qualitative estimate of the minimum fit of a particular tight-fitting RPD to a specific individual when a qualitative fit test is passed, i.e. the test agent is not detected by the subject's senses"

Quantitative fit test: "test method that uses an instrument to assess (quantify) the amount of face-seal leakage (3.1) into the RPD (3.12) in order to assess the adequacy of its fit"

Quantitative fit factor: "(QNFF) numeric value of the fit of a particular tight-fitting respiratory interface (3.13) to a specific individual Note 1 to entry: It represents only respiratory interface to face leakage. Leakage from other sources (e.g. air-purifying elements, exhalation valve) should be significantly lower than the measured face-seal leakage. The QNFF is measured with specialized instrumentation."

"The purpose of RPD fit testing is to verify that the selected make, model and size of a tight-fitting RPD adequately fits the wearer"

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“Fit testing serves as a validation that the wearer knows how to correctly inspect, don, doff and perform a wearer-seal check on the RPD on a specific make, model and size of RPD. The wearer being fit tested shall be free from hair or jewellery in the RI sealing surface area.”

General fit-test considerations are described (page 5):

Interference concerns:

PPE or other items that can interfere with fit – “When any PPE and/or RPD accessory has the potential to interfere with the seal, it shall be worn during the fit test to ascertain compatibility with the RPD”

RPD used for fit testing – general:

“RPD used for fit testing shall be equipped with filters and/or adapters appropriate for the selected fit-test method. The filter used for fit testing may be different than those used in the workplace. The weight of filters, and/or fit-test adapters used for fit testing can affect fit. Where possible, the RPD assembly used during the fit test should be representative of the RPD used in the workplace. For example, the weight of combination gas/particle filters may be significantly higher than a particle filter alone. RPD modifications made to accommodate fit testing shall not alter the fit of the RPD.”

“All tight-fitting respiratory interfaces shall be fit tested in the negative-pressure mode regardless of the mode of operation in which the RPD is used. For positive-pressure breathable gas RPD and assisted RPD, this can be accomplished by:

- temporarily converting the RI into a negative-pressure RPD by using appropriate adapter and filters; or
- using a negative-pressure RPD with an identical RI sealing surface. […]RPD used for QLFT do not require modifications beyond those discussed above. (In-RI sampling instrumentation is not used for QLFT.)”

“Fit-test sampling adapters used for QNFT shall be completely removed and the RPD restored to its original configuration before that RPD is used for respiratory protection.”

Assessment of evidence

“Either qualitative or quantitative fit-testing methods may be used where appropriate. Qualitative fit testing shall only be used where a required fit factor (RFF) of 100 or less is needed. When performing quantitative fit testing, the overall quantitative fit factor (QNFF) measured shall be equal to or greater than the RFF”

Fit-testing procedures:

“It is essential that the wearer being fit tested is free from hair or jewellery in the RI sealing-surface area.

Fit testing is accomplished by using either a qualitative (QLFT) or quantitative (QNFT) fit test procedure. Proper precautions are necessary to ensure that the RPD being fit tested is configured to remove the test agent ensuring that if the test agent is detected or measured inside the RI, it is because of a leakage via the face/neck seal. Prior to conducting the fit test, the wearer is to be briefed about the test procedure.” (page 10)

Respiratory interface:

“It is preferable to be fit tested using the wearer’s “personal” RI. Where this is not practicable or pooled equipment is used, then a test RI of the same model, size and material should be used. When an individual uses more than one type (i.e. different make and model) of tight-fitting RI, that individual is to be fit tested with each RI. WARNING — Any modifications made to the RI for fit-testing purposes shall be removed, and the RI restored to its original configuration, before it can be used in the workplace.” (page 11)

“Fit testing exercises (for all fit tests apart from the controlled negative pressure method)

a) Normal breathing. In a normal standing position, without talking, the subject shall breathe normally.

b) Deep breathing. In a normal standing position, the subject shall breathe slowly and deeply, taking caution so as not to hyperventilate.

c) Turning head side to side. Standing or sitting, the subject shall slowly turn his/her head from side to side between the extreme positions on each side. The head shall be held at each extreme momentarily so the subject can inhale at each side. Exhalation shall take place through the return movement of the head.

d) Moving head up and down. Standing in place, the subject shall slowly move his/her head up and down. The subject shall be instructed to inhale in the up and down positions. Exhalation shall take place through the return movement of the head.

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e) Talking. The subject shall talk slowly and loud enough so as to be heard clearly by the fit-test operator. The subject can read from a prepared text, count backward from 100 or recite a memorized poem.

f) Bending over. The wearer shall bend at the waist as if to touch their toes and return to an upright position. This shall be repeated. Jogging in place shall be substituted for this exercise when using test equipment, such as shroud type QNFT or QLFT units, that do not permit bending over at the waist.

Normal breathing. Same as exercise a).

Each fit-test exercise shall be performed for at least 60 s. For QNFT, the test exercises should allow for an in-mask sample period of at least 60 s. Instruct the person being fit tested to perform each exercise described above for the entire period. The RPD shall not be adjusted once the fit-test exercises begin. Any adjustment voids the test and the fit test shall be repeated."

Qualitative fit testing:

- "use test agents with distinctive taste or smell for detecting leakage via the respiratory-interface seal
- Three test agents are commonly used: a sweet-tasting aerosol (sodium saccharin CAS# 128-44-9), a bitter-tasting aerosol [(Bitrex® 1) CAS# 3734-33-6)] and a sweet (banana) smelling vapour [isoamyl acetate (IAA) CAS# 123-92-2)].
- fit test is conducted in an atmosphere containing the fit-test agent.
- Specially adapted enclosures are used for creating a localized test atmosphere. If the wearer detects the taste or smell of the fit-test agent during the fit test then the fit is unsatisfactory; the RI should be re-inspected and/or readjusted and the test repeated. During this test, the wearer will carry out a number of specified exercises (see above)
- Qualitative fit-tests do not give a numerical indication of fit; no direct measurements of the test and leak concentrations are made. The reliability of the fit test depends upon the wearer's ability to detect and indicate whether the fit-test agent is sensed. Some wearers may not be sensitive enough to the fit-test agent resulting in face-seal leaks that may not be detected. Therefore, before commencing the fit test, it is necessary to establish whether the wearer is able to detect the fit-test agent at low concentrations. This is called threshold screening. With the use of the threshold-screening step, these qualitative fit-test methods are sensitive

enough to ensure fit factors of 100. Where a fit factor greater than 100 is required, qualitative fit-test methods are not suitable and a quantitative fit-test method should be selected."

- "Because a person's ability to taste the fit-test solution is used to determine whether the RPD fits, he or she should refrain from activities that would affect the sense of taste such as consuming any food or beverage (other than plain water), using tobacco products or chewing gum, for at least 15 min prior to threshold-screening. The fit test shall be done after the threshold-screening, allowing sufficient time for the taste of the threshold fit-test agent to clear. Review the sodium saccharin or Bitrex® safety data sheet (SDS), depending on the chemical being used for the fit-test, for any handling and use precautions."
- Taste-threshold-screening: performed before the fit test to "demonstrates the ability to taste a low concentration of the fit-test agent being used." The selected solution is added to a nebuliser which is placed over the wearer's head (within a fit-test hood). Wearer breaths through mouth and reports if they can detect the test agent taste. Aerosol is then produced using the nebuliser (squeezing up to 10 times) and then wearer reports if they detect taste, this is then repeated 3 times (30 squeezes). If wearer cannot detect taste then the qualitative fit test method cannot be used – other agents can also be used.

Qualitative fit test procedure:

a) "The person being fit tested shall don the RPD and conduct a wearer-seal check. Place the fit-test hood over the person's head positioning the fit-test hood to maximize the space between the front of the fit-test hood and the RPD.

b) Ask the person to breathe through their mouth only. Instruct the person to immediately report if the sweet taste of saccharin or the bitter taste of Bitrex® is detected.

c) Add a small amount of the selected test solution (~ 3 ml) into the nebulizer. If the fit-test solution bottle has crystallized material, do not use it until all of the crystals have been dissolved by gently warming and shaking the solution.

d) Insert the nebulizer nozzle into the opening at the front of the fit-test hood and direct the aerosol into the space between the side of the RPD and the fit-test hood. As an alternative, directing the aerosol to either side of the wearer's RPD is acceptable. Spray fit-test aerosol into the fit-test hood by squeezing the nebulizer bulb 10, 20, or 30 times based on the taste-threshold number assigned during the threshold screening. Be careful not to direct the aerosol spray onto the fit-test hood, RPD or into the eyes. To produce the aerosol, grip the bulb in the palm of the hand (not fingers only) and firmly squeeze the nebulizer bulb so that it

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collapses completely. Then release it and allow it to fully expand. Maintain the nebulizer in an upright (vertical) position when spraying the aerosol. Determine that the nebulizer is working by observing that a visible mist is produced throughout the fit test.

e) Instruct the person to perform the series of fit-test exercises described in 8.4.

f) Replenish the concentration in the fit-test hood every 30 s throughout the remainder of the fit test, by adding half the original number of squeezes (i.e. 5, 10 or 15).

g) The fit is unsatisfactory if the wearer reports tasting the fit-test aerosol at any time while conducting the test exercises. At this point, a decision shall be made, either to retest after re-donning the RPD or select another RPD. In either case, the entire procedure shall be repeated (taste-threshold screening and fit testing). It may take several minutes for the person being fit tested to regain the ability to taste low concentrations of fit-test aerosol. Rinsing the mouth out with plain water and wiping the lips with a wet towel may help. Do not repeat this fit test until the person being fit tested successfully completes the taste threshold screening again.

h) After the completion of all the exercises described in 8.4, if the wearer being fit tested does not report tasting fit-test aerosol during the fit test, instruct them to reach into the fit-test hood and momentarily break the RPD seal while inhaling through their mouth. If the fit-test aerosol taste is not detected after breaking the RPD seal, the fit test is null and void and the reason why the person did not taste the fit-test aerosol shall be identified. If the fit-test aerosol taste is detected after breaking the seal, the fit test is valid and the RI fits the person.

    - If the wearer with the relevant RI has passed, it is assumed to have an equivalent fit factor of at least 100. IMPORTANT — Since the saccharin test solution has a tendency to clog during use, the competent fit-test operator shall make periodic checks to determine that it is not clogged. If clogging occurs during the fit test and it is not immediately cleared or a new nebulizer used, the fit test is invalid."

- Other fit test procedure, e.g., "Vapour qualitative fit test with isoamyl acetate (banana oil)" are described.

Quantitative fit test:

"**General:**

Assessment of evidence

Quantitative fit testing provides a numerical indicator of fit called a fit factor (FF). The tests given in 8.6.2 to 8.6.4 provide a measure of RPD fit. This subclause contains three QNFT methods that have been proven for field use and readily available."

"8.6.2 Generated aerosol quantitative fit-test procedure

8.6.2.1 Operating principles

The RPD used for the fit test shall be equipped with particle filters that do not allow the challenge aerosol to significantly penetrate into the RPD. The aerosol detection instrument cannot differentiate between body-generated particles, face-seal particle penetration, exhalation valve leakage and filter leakage. Leakage from all sources other than face-seal leakage can result in erroneously low fit factors. To minimize leakage from the sources other than face-seal leakage:

- the RPD shall be inspected for proper function prior to fit testing;
- the RPD shall be equipped with particle filters that do not allow the challenge aerosol to penetrate significantly (particle filter class F3, F4 or F5);
- care shall be taken to minimize body-generated particles inside the RPD. (For example, particles may be released from the lungs for a period of time after smoking cigarettes or e-cigarettes. Therefore, fit testing should not be conducted within 30 min of smoking.)"

An aerosol challenge agent is introduced into a fit-test chamber that surrounds the head and shoulders, or the entire body, of the RPD wearer. An instrument is used to measure concentrations of the challenge aerosol outside, C out, and inside, C in, the RPD, while the person being fit tested performs a series of fit-test exercises designed to stress the face/neck seal in ways that approximate anticipated workplace movements.

The RPD used for the fit test shall be equipped with particle filters that do not allow the challenge aerosol to significantly penetrate into the RPD. Thus, it is assumed that the aerosol inside the RPD has entered through a face/neck-seal leak.

The quantitative fit factor (QNFF) is calculated as the ratio of the two aerosol concentrations"

Assessment of evidence

Further information regarding equipment, equipment setup, conducting the fit test, and interpretation of results are provided for this QNFT method.

“8.6.3 Ambient aerosol condensation nuclei-counting (CNC) instrument quantitative fit-test procedure

CNC-counting instruments are capable of measuring the number concentration of particles in a given aerosol sample by counting single particles. When used for QNFT, the particle concentration of the fit-test challenge aerosol around the head and shoulders (C out) and the particle concentration inside the RPD (C in) are both measured while the person being fit tested performs a series of exercises designed to stress the face/neck seal in ways that approximate anticipated workplace movements.

CNC-counting instruments for fit testing typically use the particles in the ambient air as the challenge aerosol. This eliminates the need for aerosol generators and fit-test chambers, however they can be used to augment aerosol concentration when needed (i.e. clean environments like hospitals).”

Above operating principles (8.6.2.1) apply also for this method.

Further information regarding equipment, diagnostic checks, prepare to fit test, fit testing, and interpretation of results are provided for this QNFT method.

“8.6.4 Controlled negative-pressure (CNP) REDON quantitative fit-test procedure NOTE REDON is used to distinguish this protocol from earlier CNP protocols. This protocol is called REDON because the respirator is removed and then re-donned two times during the test

8.6.4.1 Operating principle

During CNP fit testing, in-RI negative challenge pressures are selected that simulate a range of work rates. The primary factors affecting in-RI negative pressure during inhalation are work rate and air flow resistance through the filters. The CNP fit-test method is based on exhausting air from a temporarily sealed RPD. Measurement of the air exhaust rate required to hold the in-RI pressure constant while the air inlets are sealed with leak-tight test adapters yield a direct measure of leakage air flow into the RPD. The rate of air leakage is directly related to the amount of negative pressure created inside the RPD during inhalation.

Assessment of evidence

Air is the fit-test challenge agent for a CNP fit-test. The amount of air that leaks into the RPD is assumed to represent face/neck-seal leakage. The rate of air leakage is directly related to the pressure differential created inside the RPD during inhalation.

The CNP fit-testing system is activated to establish and maintain a negative challenge pressure in the temporarily sealed RPD. The exhaust flow rate required to maintain a constant challenge pressure is averaged over the duration of the measurement, and represents a direct measure of RPD leakage flow rate.

A CNP fit factor is calculated from the ratio of the modelled inspiratory flow rate and measured leakage flow rate. Fit factors cannot be measured during exercises in controlled negative-pressure fit-testing. Therefore, measurements of RI leakage are made at the end of each fit-test exercise while the wearer neither moves nor breathes.

Two criteria shall be met to use this fit-test method: a) this fit-test method can only be used on RPD with replaceable filters (this method cannot be used on filtering-facepiece style RPD); b) this fit-test method can only be used when the fit-test equipment manufacturer has the special leak-tight test adapters available for the model of RPD being used."

Further information regarding equipment, system calibration and operational checks, prepare to fit test, fit testing, and interpretation of results are provided for this QNFT method.

Quantitative fit test procedure:

"The following steps outline the general procedure for conducting the generated aerosol QNFT.

a) Instruct the person being fit tested to don the RPD as trained.

b) Have the person being fit tested enter the test chamber and connect the RPD used for the fit test to the sample line.

c) Perform fit test according to the instrument manufacturer instructions using the exercises described in 8.4." (see above for exercises)

Limitation: The members of the technical committee(s) who contribute to British Standards is not easily accessible and information regarding how to obtain this information is unclear. For this reason, the extent to which IPC in health and care settings, and subsequent applicability of these standards to these settings may be limited.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The British Standard Institution (BSI). BS EN ISO 16972:2020, Respiratory protective devices – Vocabulary and graphical symbols. 2020. Accessed: 12 July 2023.	British Standard	Level 4	N/A	N/A	N/A

Assessment of evidence

Fit test – “use of a challenge agent and specific protocol to qualitatively or quantitatively determine the effectiveness of the seal between the wearer's (3.257) face and respiratory interface (3.202) with a specific make, model and size of a respiratory protective device (3.203)” (page 9)

Required fit factor (RFF) – “numeric value established as a pass/fail point or acceptance criterion for quantitative fit testing” (page 19)

Qualitative fit factor (QLFF) – “qualitative estimate of the minimum fit of a particular tight-fitting respiratory interface (3.241) to a specific individual when a qualitative fit test (3.189) is passed, i.e. the test agent is not detected by the subject’s senses” (page 18)

Qualitative fit test (QLFT) – “pass/fail test method that relies on the subject’s sensory response to detect a challenge agent in order to assess the adequacy of a respiratory protective device (3.203) fit 3.190” (page 18)

Assessment of evidence
Quantitative fit factor (QNFF) – “numeric value of the fit of a particular tight-fitting respiratory interface (3.241) to a specific individual Note 1 to entry: It represents only the respiratory interface (3.202) to face leakage. Leakage from other sources [e.g. air-purifying elements, exhalation valve (3.79)] should be significantly lower than the measured face-seal leakage (3.84). The QNFF is measured with specialized instrumentation. 3.191” (page 18) **Quantitative fit test (QNFT)** – “test method that uses an instrument to assess (quantify) the amount of face-seal leakage (3.84) into the respiratory protective device (3.203) in order to assess the adequacy of its fit” (page 18) **Wearer-seal check** – “action conducted by the wearer (3.257) to determine if the tight-fitting respiratory protective device (3.203) is properly donned (3.71) and sealed on the face” (page 24) **Limitation:** The members of the technical committee(s) who contribute to British Standards is not easily accessible and information regarding how to obtain this information is unclear. For this reason, the extent to which IPC in health and care settings, and subsequent applicability of these standards to these settings may be limited.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Health Security Agency (UKHSA). Putting on (donning) personal protective equipment (PPE) for aerosol generating procedures (AGPs). Airborne	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Precautions – Gown version. 2020. Accessed: 13 December 2022					
Assessment of evidence					
COVID-19 guidance “Note: this must be the respirator that you have been fit tested to use. Where goggles or safety spectacles are to be worn with the respirator, these must be worn during the fit test to ensure compatibility. Perform a fit check [as part of donning process] The technique for this will differ between different makes of respirator. Instructions for the correct technique are provided by manufacturers and should be followed for fit checking.”					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centers for Disease Control and Prevention (CDC). How to Use Your N95 Respirator.	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
2022. Updated 16 May 2023. Accessed: 29th October 2024					
Assessment of evidence					
Detailed in donning process for N95 respirator: To check for gaps, gently place your hands on the N95, covering as much of it as possible, then breathe out. If you feel air leaking out from the edges of the N95, or if you are wearing glasses and they fog up, it is not snug. Adjust the N95 and try again." **Limitation:** not HCW specific.					

Evidence from previous update(s):

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). The Control of Substances Hazardous to Health Regulations 2002. Approved Code of Practice and	Regulation	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
guidance. 6th Edition. 2013. ISBN: 9780717665822					

Assessment of evidence

This document contains the “Approved Code of Practice (ACOP) to the Control of Substances Hazardous to Health Regulations 2002 (as amended) (COSHH) and covers all substances to which the Regulations apply.” “The ACOP describes the preferred or recommended methods that can be used (or the standards to be met) to comply with the Regulations and the duties imposed by the Health and Safety at Work etc Act 1974 (HSW Act). The accompanying guidance also provides advice on achieving compliance, or it may give information of a general nature, including explanation of the requirements of the law, more specific technical information or references to further sources of information.”

Regulation 7 (9):

“Regulation 7 Prevention or control of exposure to substances hazardous to health

(9) Personal protective equipment provided by an employer in accordance with this regulation shall be suitable for the purpose and shall –

- comply with any provision in the Personal Protective Equipment Regulations 2002 which is applicable to that item of personal protective equipment; or
- in the case of respiratory protective equipment, where no provision referred to in sub-paragraph (a) applies, be of a type approved or shall conform to a standard approved, in either case, by the Executive.”

[Mandatory]

Assessment of evidence

ACOP:

“To be suitable, RPE must be capable of adequately controlling the inhalation exposure using as a guide the equipment’s assigned protection factor as listed in HSE’s Respiratory protective equipment at work.”

“In selecting and providing suitable RPE, consider:

- the fit for the wearer. Tight-fitting RPE (i.e., full and half masks) should be face-fit tested, using a suitable method, by a competent person (see regulation 7 of the MHSW Regulations and regulation 12(4) of COSHH). Loose-fitting devices, such as powered respirators with a visor or hood, need not be face-fit tested but still need to fit observably close to the face;
- the presence of a ‘CE’ mark showing that it is manufactured to meet minimum legal requirements, or (if the Personal Protective Equipment Regulations 2002 do not apply to the RPE in question) is of a type approved by, or conforms to a standard approved by HSE;
- the proper training and supervision of employees in its use. This will include wearers being clean-shaven in the area of the face seal when using tight-fitting RPE;
- regular cleaning, checking and maintenance to ensure that it remains effective.”

[Expert Opinion]

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). Respiratory protective equipment at work:	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
A practical guide. HSG53 (4th Ed.) 2013. ISBN: 978 0 7176 6454 2.					

Assessment of evidence

About this guidance:

- This guide prepared by the HSE “in consultation with industry: employers, trade unions and trade associations”, is stated to support “the Approved Code of Practice (ACOP) to the Regulations that apply (see paragraphs 36–39)”.
- “The guide contains practical guidelines to help you select the correct RPE and manage its use in your workplace to ensure effective protection.”
- “As an employer, you have a legal responsibility under all the Regulations listed in paragraphs 36–39”

“Facepiece fit testing is a method of checking that a tight-fitting facepiece matches the wearer’s facial features and seals adequately to their face. It will also help to identify unsuitable facepieces that should not be used. Remember that tight-fitting RPE will only provide effective protection if the wearer is clean shaven, so they should also be clean shaven when fit tested.”

“For RPE with tight-fitting facepieces, the user should carry out a ‘fit check’ of the seal when the device is first put on. For reusable masks this can be done by placing a hand over the filter or inlet valve(s) and breathing in. If there is a good seal, the user will experience the mask sucking in toward their face. The wearer should hold their breath for ten seconds and the facepiece should not loosen. If it does, the facepiece should be readjusted and the seal checked again. Do not use RPE if a good seal cannot be achieved. The RPE manufacturer’s instructions will provide details of how to perform a fit check.”

“Appendix 4 Fit testing –

Assessment of evidence

“There are two basic types of RPE fit testing: qualitative and quantitative.”

Qualitative fit testing:

“Qualitative fit testing is a pass/fail test based on the wearer’s subjective assessment of any leakage from the face seal region, by sensing the introduction of a test agent. These tests are suitable for half masks. They are not suitable for full face masks. Examples of qualitative fit testing methods are:

- method based on bitter- or sweet-tasting aerosol;
- method based on odour compounds”

Quantitative fit testing:

“Quantitative fit testing provides a numerical measure of the fit, called a fit factor. These tests give an objective measure of face fit. They require specialised equipment and are more complicated to carry out than qualitative methods. Quantitative methods are suitable for full face masks (but can also be used for half masks). Examples of quantitative fit testing methods are:

- laboratory test chamber;
- portable fit test devices, such as a particle counting device”

“RPE fit testing should be conducted by a competent person. Competence can be demonstrated through achieving accreditation under the Fit2Fit RPE Fit Test Providers’ Accreditation scheme. This scheme has been developed by the British Safety Industry Federation (BSIF) together with industry stakeholders and is supported by HSE. The scheme is not compulsory, and you are free to take other action to comply with the law.”

Powered respirators with hoods/helmets: “Fit testing required – No”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). Guidance on respiratory protective equipment (RPE) fit testing (INDG479). 2019. ISBN: 9780717667062.	Guidance	**Level 4**	N/A	N/A	N/A

Assessment of evidence

This guidance is stated as “not compulsory and you are free to take other actions to comply with the requirements of the law”.

“HSE does not approve nor recommend any particular fit testing equipment. Any equipment included in this guidance provides representative information.”

“Fit testing is therefore a method for checking that a specific model and size of tight-fitting facepiece matches the wearer’s facial features and seals adequately to the wearer’s face. It will also help to identify unsuitable facepieces which should not be used.”

“A pre-use wearer-seal check should be carried out each time a fit-tested facepiece is worn and before entering the hazardous environment. This check is to determine whether the wearer has correctly donned a facepiece before entering a contaminated work area. The RPE manufacturer will provide instructions on how to carry it out. Note, however, that a pre-use wearer-seal check is not a substitute for fit testing.”

“There are two basic types of RPE fit testing – qualitative and quantitative.

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Qualitative fit testing (QLFT) –

Qualitative fit testing (QLFT) is a pass/fail test based on the wearer's subjective assessment of any leakage through the face seal region by detecting the introduction of bitter- or sweet-tasting aerosol as a test agent. QLFT methods are suitable for disposable and reusable half masks; they are not suitable for full-face masks. Although this type of test is based on subjective detection and response by the wearer of the RPE, it is important that it is administered by a fit tester competent in using this method.

Quantitative fit testing (QNFT) –

Quantitative fit testing (QNFT) provides a numerical measure of how well a facepiece seals against a wearer's face; this is called a fit factor. These tests give an objective measure of face fit. QNFT methods are suitable for disposable and reusable half masks and full-face masks. Examples of QNFT methods are:

- ambient particle counting;
- controlled negative pressure (CNP)."

"The type of fit test method used depends on the type of RPE to be fit tested. Table 1 shows which fit test methods are applicable."

Table 1 describes Quantitative fit test method using ambient particle counting can be used for disposable respirators (half mask), reusable respirators (half and full mask) and powered respirators (half and full mask). Quantitative fit test method using controlled negative pressure can be used for reusable respirators (half and full mask) and powered respirators (half and full mask). Qualitative fit tests can be used for disposable respirators (half mask), reusable respirators (half mask only) and powered respirators (half mask only).

"Facepieces used for fit testing can be one of the following:

- the wearer's individually assigned facepiece;
- a test facepiece of the same type, class and size; or
- a surrogate facepiece with the same sealing surfaces, materials, head straps and breathing resistance as the facepiece assigned to the wearer. You should confirm this with the RPE manufacturer/supplier"

Assessment of evidence

“The practice of multiple repeat fit tests with the aim of achieving a pass with a given facepiece, i.e., force fitting, should not be carried out. If after two fit tests the result is still a fail, an alternative facepiece should be tried.”

Preparing the wearer -

> “When you are conducting a qualitative fit test, you should advise wearers not to eat, drink (except still, unflavoured water), smoke or chew gum for at least 30 minutes before the test. When you are conducting an ambient particle counting fit test the wearer should refrain from smoking (including e-cigarettes) for at least 60 minutes before the fit test.”
>
> “Do not conduct fit tests if there is any hair growth between the wearer’s skin and the facepiece sealing surface, such as stubble beard growth, beard, moustache, sideburns or low hairline, which cross the respirator sealing surface. You should ensure that any type of non-PPE apparel or adornment (eg piercing) does not interfere with the fit of the facepiece.”
>
> “If the wearer needs to use in-facepiece spectacles they should wear them during the fit test. Wearers should wear any other PPE that could potentially interfere with the fit of the facepiece during the fit test. If they cannot wear the PPE properly without affecting the function of the RPE or vice versa, choose alternative PPE.”

Preparing for a quantitative fit test (all methods)

In table 2, the minimum required fit factors are provided. This shows FFP-1, 2, 3s, and half-face masks all have a QNFF of 100, and full-face masks have a QNFF of 2000.”

Detailed information provided in this document on:

- preparing for a quantitative fit test using the ambient particle counting method
- preparing for a quantitative fit test using the controlled negative pressure method
- preparing for a qualitative fit test based on taste
- Fit test exercises and their descriptions provided in annex 2, table 3.

“The criteria for evaluating fit test methods given in BS ISO 16975-3 Annex C7 are recommended.”

Assessment of evidence

"The following standards are recommended as suitable references:

BS ISO 16975-3:2017, Respiratory protective devices – Selection, use and maintenance. Part 3: Fit-testing procedures

European Standards covering inward leakage testing: BS EN 136,8 BS EN 1409 and BS EN 149.10"

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Coia JE, Ritchie L, and Adisesh A, et al. Guidance on the use of respiratory and facial protection equipment. J. Hosp. Infect. 2013; 85:170-182. Doi: 10.1016/j.jhin.2013.06.020.	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

Setting: UK

Best practice guidance based on a non-systematic literature review published separately (Bunyan D, Ritchie L, Jenkins D, Coia JE. Respiratory and facial protection: a critical review of recent literature. J Hosp Infect 2013;85:165e169).

"The Scientific Development Committee of the Healthcare Infection Society established a short-life working group in May 2011 to develop appropriate guidance. The working group included representation from the Healthcare Infection Society, Public Health England,

Assessment of evidence

Health and Safety Executive (HSE), Association of National Health Occupational Physicians, Health Protection Scotland, Infection Prevention Society, Intensive Care Society, Clinical Virology Network and British Infection Association."

Fit Testing:

"Before using FFP respirators, it must be verified that each user has a respirator suitable for their face shape, and that they can put it on such that it leaves no gaps between the mask and their face for air to pass though unfiltered. This process is known as 'fit testing'. This is commonly done by a user putting a respirator on and then being challenged with a particulate spray of something they can taste, should it pass through the respirator. It is a legal requirement that those required to use respirators are fit tested by a competent person, the results are satisfactory, and those results are recorded and available for inspection.

Ensure the FFP respirator is 'fit tested' as it will be worn in practice (i.e. with eye protection if required) (see Appendix 1).

Information from Appendix 1 below,

Fit check:

- "Cover the front of the respirator with both hands, being careful not to disturb the position of the respirator on the face.
- For an unvalved product - exhale sharply.
- For a valved product - inhale sharply.
- If air flows around the nose, re-adjust the nosepiece; if air flows around the edges of the respirator, re-adjust the headbands.
- A successful fit check is when there is no air leaking from the edges of the respirator.
- If a successful fit check cannot be achieved, remove and refit the respirator.
- If you still cannot obtain a successful fit check, do not enter the work area."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The British Standard Institution (BSI). BS EN 529 2005. Respiratory protective devices – Recommendations for selection, use, care and maintenance – Guidance document. 2005.	British Standard	Level 4	N/A	N/A	N/A

Assessment of evidence

Use (page 16):

“Respiratory protective devices should be used in accordance with the manufacturers or suppliers instructions for use and they should not be modified. The device wearer should carry out pre-use checks which should include:
…d) fit-checking to ensure that the facepiece has been donned correctly each time the respiratory protective device is worn. Details on facepiece fit assessment are given in Annex E.”

Annex E provides more information on assessing the fit of tight fitting facepieces (fit checking, fit test methods) (page 46):

“A facepiece (quarter, half and full face mask and filtering half mask) will not provide optimum performance if they leak. Leakage can result from either a bad fit on the face or from faults in the facepiece such as dirty exhalation valve or a damaged face seal on the facepiece. The facepiece provided with a respiratory protective device should fit the wearer properly and the wearer should know how to check the fit. One size of facepiece is unlikely to fit all users within a workforce. Assessment of correct fitting is an essential part of initial

Assessment of evidence

selection process and every day use. This annex describes some of the commonly used methods for assessing the fit of facepiece. These fall in to two broad categories – fit checking methods and fit test methods."

Fit checking "provides a simple assessment of the correct fitting of a facepiece, based on the opinion of the wearer. Fit checking methods are quick and simple, but can be relatively insensitive to small leaks."

Negative pressure fit check: "This method is generally used for tight fitting facepieces. Fit the facepiece in accordance with the manufacturers instructions. Block off the air inlet (filtering element of the filtering device) and inhale gently until the facepiece collapses slightly onto the face. Hold the breath for about 10 s. If there are no significant leaks the facepiece will remain collapsed for several seconds. If leakage is detected, re-adjust the facepiece/straps and re-test. If a satisfactory fit check cannot be achieved the wearer should not use the device."

Positive pressure fit check: "This method may be used for unvalved filtering facepiece device (FF) and valveless half masks (FM) type. Fit the facepiece in accordance with the manufacturer's instructions. Cover the filtering element of the filtering device with the hands and exhale sharply. If leakage is detected by air escaping around the edges of the facepiece, re-adjust the facepiece/straps and re-test. If a satisfactory fit check cannot be achieved the wearer should not use the device."

Fit test methods:

Qualitative fit testing is described, suitable for half masks, filtering face pieces and full face masks –

"In this method test agents (e.g. saccharin, bitrex or amyl acetate) with distinctive taste or smell are used for detecting leaks. This method is suitable for half masks, filtering facepieces and full face masks. If for reasons of high protection factors full face masks are required, this method is unlikely to be suitable. A quantitative fit testing is recommended. The wearer will be exposed to an atmosphere containing the suitable test agent. Specially adapted chambers/hoods may be used for creating a localised atmosphere. Commercial kits are available for this purpose. If the wearer detects the substance the facepiece should be readjusted and the test repeated. Some people may not be sensitive enough to the agent at very low concentrations and as a consequence of this leaks may not be detected. Therefore, it is first necessary to establish whether the person under test will be able to detect the agent at low concentrations."

Assessment of evidence

Quantitative fit testing is described, including test chamber method, non chamber methods, particle counting method and pressure method –

Test chamber method: “This test is a measure of the fit and provides a numerical value. It can be sensitive to any leaks. Fit testing using an aerosol of sodium chloride particles or sulphur hexafluoride tracer gas, can be carried out in a test chamber. Measurements are made of the chamber concentration and inside the facepiece. During the measurements the wearer will carry out a series of exercises. The value obtained is personal to the wearer and the facepiece involved. Fit factor can be derived from this value. This factor is different from the protection factor (see Annex C) and should not be confused.”

“**Non chamber methods:** There are alternative methods which employ commercially available portable equipment measuring fit. These methods are relatively easy to do and can be inexpensive compared to a test chamber method.”

“**Particle counting method:** A particle counting device counts the number of ambient particles leaking into the facepiece and compares this with the particle number challenging the facepiece while the wearer carries out a number of specified exercises. This method can either use particles in the ambient or generated aerosols as the test challenge.”

“**Pressure method:** A device generates and then maintains a constant pressure inside the facepiece whilst the wearer remains motionless. The rate of air exhausted is controlled so that a constant negative pressure is maintained in the facepiece during the fit test. The amount of exhaust air that is required to hold the pressure in the temporarily sealed facepiece constant, yields a direct measure of leakage airflow into the facepiece. The leak is converted into an equivalent fit factor. This method requires a facepiece that can be sealed and therefore is not applicable to filtering facepieces.”

Limitation: The members of the technical committee(s) who contribute to British Standards is not easily accessible and information regarding how to obtain this information is unclear. For this reason, the extent to which IPC in health and care settings, and subsequent applicability of these standards to these settings may be limited.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
World Health Organization (WHO). Infection prevention and control of epidemic-and pandemic prone acute respiratory infections in health care. 2014. Accessed: 24 January 2023	Guidance	AGREE: Recommend (with provisos)	N/A	N/A	N/A

Assessment of evidence

"The development of the guidelines followed the process established in the WHO handbook for guideline development, which involved active participation of the Global Infection Prevention and Control Network (GIPCN). The resulting recommendations were peer reviewed by internal and external experts." This guidance is deemed expert opinion as it is unclear the edition of the "WHO handbook for guideline development" that was used. Further to this, the elements of the systematic review process, such as the search strategies, are not provided.

Funding: "Financially supported by the United States Centers for Disease Control and Prevention (CDC), the United States Agency for International Development (USAID), the German Agency for International Cooperation (GIZ), and the French Ministry of Social Affairs and Health"

Assessment of evidence

Aim of guidance: “The guidance is intended to help policy-makers, administrators and health-care workers to prioritize effective IPC measures”

Target audience: “Recommendations, best practices, and principles for non-pharmacological aspects of infection prevention and control (IPC) for acute respiratory infections (ARI) in health care” intended for policy-makers, administrators and health-care workers, including doctors, nurses, allied health professionals, auxiliary and community health workers, and others involved in provision of health care.

“**Considerations for health-care facilities:**

• The fit and seal of disposable particulate respirators are important for effective function. If the fit and seal are poor, airborne particles may be inhaled from leaks, and the particulate respirator may not be effective. Consider undertaking respirator fit-testing with users, to determine which model or models will achieve an acceptable fit, before procuring large stocks of respirators.”

“Sequence of steps in a particulate respirator seal check

“5A Positive seal check

- Exhale sharply. A positive pressure inside the respirator = no leakage. If leakage, adjust position and/or tension straps. Retest the seal.
- Repeat the steps until respirator is sealed properly.”

“5B Negative seal check

- Inhale deeply. If no leakage, negative pressure will make respirator cling to your face.
- Leakage will result in loss of negative pressure in the respirator due to air entering through gaps in the seal.”

Question 6: When should a ‘fit test’ and a ‘fit check’ be performed?

Evidence added to 2024 update:

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Department of Health Infection Prevention and Control (IPC) National Clinical Guideline No. 30 Last updated: May 2023 Accessed: 03 February 2025	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

“In order for an FFP2 respirator to offer the maximum desired action the wearer should be properly fitted and trained in its safe use.”

“The Health and Safety Authority indicate that where a risk assessment indicates that HCW’s need to use a close-fitting respirator mask for their protection that every effort should be made to comply with the requirement for fit testing of the worker, as far as is reasonably practicable. When fit testing of all staff is not immediately possible, then fit testing should be prioritised for those at greatest risk. Priority groups for fit testing include the following:

• HCW’s most likely to be involved in performing AGPs, in particular endotracheal intubation

Assessment of evidence
• HCW's most likely to have the most frequent or prolonged exposure to airborne infection. The following represent opportunities when fit testing may be considered: • at the commencement of employment for employees who will be working in clinical areas where there is a significant risk of exposure to infectious microorganisms transmitted via the airborne route - assessment of the significance of risk will involve consideration of the location, for example risk is higher in an intensive care unit, and activities to be undertaken, for example a physiotherapist performing a procedure to induce sputum production in potentially infectious patients is considered at risk of exposure to infectious aerosols" "When fit testing is undertaken, it should be done based on relevant requirements in conjunction with the risk assessment with relevance to the healthcare setting." "Health care facilities should ensure that they have a respiratory protection programme that regularly evaluates the risk to which health care workers are exposed and determines which employees are required to undertake fit testing." "Check the fit of the respirator mask every time you wear it"

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Association for Professionals in Infection Control and Epidemiology (APIC) Guide to Infection Prevention in	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Emergency Medical Services. Last updated: January 2013. Accessed: 07 January 2025					
Assessment of evidence					
Target audience: Emergency medical professional staff, USA "Departments required to use masks should provide personnel with well-fitting surgical/ medical or N95 respirators. If employers choose the NIOSH-approved N95 respirator they are required by OSHA to conduct an initial medical clearance, provide fit testing (respirator fit testing performed to determine if an employee can maintain an acceptable respiratory fit and seal), education on proper use, and conduct periodic (annual at a minimum) re-evaluation."					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
European Centre for Disease Prevention and Control (ECDC) Considerations for infection prevention and control practices	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
in relation to respiratory viral infections in healthcare settings Last updated: 6 February 2023 Accessed: 6 January 2025					

Assessment of evidence

"**Scope:** This document aims to support the development of guidance for healthcare facilities and healthcare providers in the European Union/European Economic Area (EU/EEA) on infection prevention and control (IPC) measures for the management of patients with respiratory tract viral infection in healthcare settings.

Target audience: National public health agencies, healthcare facility administrators, IPC and other professionals developing relevant IPC guidance and healthcare workers in EU/EEA countries."

Recommendation:

"Respirators are mainly used by healthcare workers to protect themselves, especially during aerosol-generating procedures, and require a fitting test to ensure proper protection."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Martin, T. C. S., Curtin, G., Martin, N. K. et al. Annual N95 respirator fit-testing: an unnecessary burden on healthcare. Infection Control & Hospital Epidemiology, 2024; 45, pp 250- 252. Doi: 10.1017/ice.2023.187.	Retrospective Cohort	Level 3	Failing a qualitative fit test	Pass and fail results	Probability of survival free from fit-test failure (%, 95% CI) p-value

Assessment of evidence

Setting: USA

Methodology:

Fit tests were qualitative using saccharin and/or denatomium benzoate solutions (using OSHA-approved method). N95 respirator models included: 3M1870, 3M1870þ Aura, 3M1860, 3M1860þ, Gerson2130)

Kaplem-Meier survival analysis was used, where probability of survival free from a fit-test failure at 3 and 5 years after passing a fit test using the same respirator model was estimated.

Main findings:

Assessment of evidence

Median follow-up was 1.9 years (IQR 1.0 – 2.7). 55 fit-test failures that occurred within 3 months of a pass were identified and incorporated into the survival analysis.

15, 757 HCWs with at least one fit test result were identified; 49, 290 fit test results were identified. 98.6% (n = 48, 615) were passes, 0.7% (n = 323) were fails and 0.7% (n = 352) were incomplete.

Reasons for incomplete fit tests were: presence of a beard (338), allergy history (5), claustrophobia (2), and other reasons unrelated to RPE fit (7)

The survival analysis included 12,065 HCWs, which represented 31, 270 person mask-years for follow-up.

At 3 years (54 events reported), probability of survival free from fit-test failure was 99.45% (95% CI 99.2 – 99.6%). At 5 years, probability was estimated to be 99.4% (95% CI 99.2 – 99.6%)

This study provides evidence to suggest that the likelihood of failing a qualitative fit test 3 years and 5 years following passing a qualitative fit test using the same respirator model is low.

Limitations:

- Study performed in the USA with 5 respirator types
- The fit test was qualitative, which is less accurate than a quantitative fit test
- The study was a short communication therefore the findings and methodology are relatively brief
- Single study site
- Retrospective study relying on accuracy of electronic records – authors highlight this issue is likely the case due to missing information regarding fit test failures, and participants fit test result changing within 3 months
- Authors stated that reliability of findings past 5 years is limited due to changes in respirator types used in their setting

The findings limit the generalisability of these findings to a quantitative fit test, or other respirator types.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Ministry of Health New Zealand. Mask use and visitor guidance for hospitals and other health and disability care settings. 2023. Accessed: 28 October 2024	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence
“Fit testing is strongly recommended for all Healthcare workers who wear a P2/N95 at least once, and then repeated if any major changes to face shape occur or if available products change.” “A fit check/user seal check must be done every time a P2/N95 particulate respirator is put on.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Australian Government National Health and Medical Research Council (NHMRC) Australian Guidelines for the Prevention and Control of Infection in Healthcare 2019 (revised 2024, v11.24) Accessed 11 October 2024	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

Funding: Guidance was co-funded by the NHMRC and Medical Research Council and Australian Commission on Safety and Quality in Health Care.

Aim of guidance (page 20): “By assisting healthcare workers to improve the quality of the care they deliver, these Guidelines aim to promote and facilitate the overall goal of infection prevention and control: the creation of safe healthcare environments through the implementation of evidence-based practices that minimise the risk of transmission of infectious agents.”

Assessment of evidence

Target audience (page 20): “The Guidelines are for use by all those working in acute health care settings —this includes healthcare workers, management and support staff. As some of the principles and recommendations described in this guideline may be applicable to other health care settings, individuals working in other health care settings may also find the guidelines useful.”

The introduction states that all recommendations are based on systematic reviews, however there is insufficient evidence within the guidance to support this claim.

Note: P2 respirators meet the relevant Australian standard (AS/NZS 1716:2012 and 1715:2009) and differs to NIOSH, which specifies N95 respirators.

Recommendations:

Fit testing:

“While fit testing may be complex and resource intensive, it is a valuable practice which provides an opportunity to educate healthcare professionals. Fit testing programs may be considered:

- at the commencement of employment for employees who will be working in clinical areas where there is a significant risk of exposure to infectious agents transmitted via the airborne route— assessment of the significance of risk will involve consideration of the location (e.g. risk is higher in an intensive care unit) and activities to be undertaken (e.g. a physiotherapist performing induced sputum is at risk of exposure to infectious aerosols);
- when there is a significant change in the wearer’s facial characteristics that could alter the facial seal of the respirator (e.g. significant change in body weight, facial surgery); and
- at regular intervals — Standard AS/NZS 1715: 2009 recommends annual fit testing. Healthcare facilities should ensure that they have a respiratory protection program that regularly evaluates the risk to which healthcare workers are exposed and determines which employees are required to undertake fit testing.” (page 123)

Assessment of evidence
Fit checking: "Healthcare workers must perform fit checks every time they put on a P2 respirator to ensure it is properly applied. No clinical activity should be undertaken until a satisfactory fit has been achieved." (page 123)

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Association for Professionals in Infection Control and Epidemiology (APIC) Do's & Don'ts for wearing N95 respirators in non-surgical healthcare settings. 2015. Accessed :16 November 2020	Poster	Level 4	N/A	N/A	N/A

Assessment of evidence
Format: Poster that is endorsed by The American Nurses Association (ANA), Association of Occupational Health Professionals in Healthcare and the Association of PeriOperative Nurses (AORN).

Assessment of evidence

Target audience: staff working in non-surgical settings

Setting: USA

Recommendations:

- “Complete face seal check after donning the respirator.”
- “DON’T wear an N95 respirator that hasn’t been properly fit tested. Proper fit is essential.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Association of perioperative Registered Nurses (AORN) Guideline Quick View: Transmission-Based Precautions. 2019. AORN Journal; 109(4); 529-536. Doi: 10.1002/aorn.12675	Expert opinion guidance	Level 4	N/A	N/A	N/A

Assessment of evidence
References not provided. Guidance developed for nursing staff working in the USA. **Recommendations:** “Perform a user seal check (ie, fit check) for each use” Recommendations on administrative controls for TB suggest that a staff member requires a fit test and certification prior to using an N95 respirator.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
World Health Organization (WHO). Infection prevention and control guidance for long-term care facilities in the context of COVID-19 – Interim Guidance. 2021. Accessed on: 24 November 2022	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

Context: “This document provides interim guidance Long Term Care Facilities (LTCF) managers and IPC focal points to prevent SARS CoV-2 from entering a facility and from spreading within and beyond the facility, and to support safe conditions for visiting through the rigorous application of IPC procedures, for the residents’ well-being.”

Document states that this guidance is “based on published WHO guidance for IPC in the context of COVID-19 (WHO guidance on IPC for health care settings; on mask use; and on prevention, identification, and management of HW infections (1,2,3) and ongoing reviews of the available scientific evidence on COVID-19 in LTCF settings and on the effectiveness of IPC precautions in these settings.” Although this has been mentioned, none of these systematic reviews have been listed/detailed or referenced in the document.

Recommendations:

“Proper use of N95 respirators requires a programme to regularly fit-test employees for their use.” (Citation 1)

Citation 1: Infection prevention and control during health care when coronavirus disease (COVID-19) is suspected or confirmed: interim guidance, 29 June 2020. Geneva: World Health Organization; 2020: Now been updated and incorporated in the living guidance

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
World Health Organization (WHO). Infection prevention and control in the context of coronavirus disease	Guidance	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
(COVID-19): a living guideline. 2023. Accessed: 29 October 2024					

Assessment of evidence

Funding: “The development of the document was provided by the United States Center for Disease Control and Prevention (US CDC), in addition to WHO core funds”

Aim of guidance: “Provides users with the latest evidence-informed recommendations for IPC in health care and community settings.” It “guides decision makers and IPC professionals to develop and implement policies on mask use in health care and settings”.

Target audience: “Policy and decision-makers, public health professionals, IPC professionals at the national and facility levels, health care facility administrators, managers and other health workers.”

Health workers in this document are defined as “people primarily engaged in actions with the primary intent of enhancing health. This includes health service providers, such as doctors, nursing and midwifery professionals, public health professionals, technicians (laboratory, health, medical, and non-medical), personal care workers, healers, and practitioners of traditional medicine. It also includes health management and support workers, such as cleaners, drivers, hospital administrators, district health managers, social workers and other occupational groups in health-related activities. This group includes those who work in acute care facilities and long-term care, public health, community-based care and other occupations in the health and social care sectors.”

Recommendations:

“Appropriate mask fitting should always be ensured for respirators, through fit testing and a user seal check when a filtering facepiece respirator is donned”

Assessment of evidence
“Qualitative or quantitative fit testing should be performed annually and for new staff at the employer's expense to ensure that the respirator model fits each health worker's unique facial features and provides a consistent seal” (Citation 51) Citation 51: Fit testing procedures (mandatory) Part I. OSHA-accepted fit test protocols. “A seal check should be performed on FFRs whenever donned by a health worker to determine if the adequate fit is achieved by the specific FFR they have donned.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Australian Government National COVID-19 Clinical Evidence Taskforce. Australian guidelines for SARS-CoV-2 infection prevention and control of COVID-19 in healthcare workers. 2021. Accessed: 25 November 2022	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

Authors describe the document as 'living guidance', developed using the same methodology as the general IPC living guidance produced by the Australian Government. Evidence captured for the guidance is assessed using GRADE.

Purpose of guidance document: to provide evidence-based recommendations to prevent SARS-CoV-2 infection amongst Australian HCWs. HCWs may work in primary, secondary or tertiary care setting; including residential care facilities, transport and quarantine facilities.

The document links to both a technical report and generic methods document for all living guidance. Though a search strategy is provided, it is unclear if the process used to retrieve and grade evidence is rigorous (e.g. specific research questions, use of two independent authors to screen and appraise evidence, specific inclusion/exclusion criteria).

Recommendations:

- "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."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Australian Government. Infection Prevention and Control Expert Group Guidance on the use of personal protective equipment for health workers in the context of COVID-19, 2022. Accessed: 28 November 2022	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

Guidance endorsed by the Australian Health Protection Principal Committee.

- Consensus recommendations based on the experience of the IPC panel and ICEG members.
- "The recommendations contained in this document describe the minimum national standard for PPE for health workers in the context of COVID-19."

Recommendations:

- "Health workers who wear PFRs should complete fit testing before first use and perform a fit check each time they are used."

Assessment of evidence
• “A repeat fit test is required for each different PFR utilised.” • “Fit testing does not guarantee a respirator will not leak, particularly if a different type or size is used to one previously fit tested.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The National Institute for Occupational Safety and Health (NIOSH) Cichowicz J, Coffey C, Fries M. Pittsburgh A guide to Air-Purifying Respirators. 2018a. Accessed: 2 December 2022	Guidance	Level 4	N/A	N/A	N/A
Assessment of evidence					
Filtering Facepiece respirators:					

Assessment of evidence
“Because the effectiveness of this type of respirator relies upon the breathing air travelling through the filter, a tight seal to the user’s face is very important. Therefore, the Occupational Safety and Health Administration (OSHA) (29 CFR 1910.134) requires an annual respirator fit test to ensure that users receive the expected level of protection by minimizing any leakage of unfiltered contaminant through gaps between the face and facepiece. When used with a respiratory protection program, including annual fit-testing, an FFR will reduce exposures by 1/10th.” **Elastomeric Half Facepiece Respirator:** “The facepiece of the elastomeric respirator must form a tight seal against the user’s face, covering the nose and mouth just like the disposable FFRs; therefore, fit testing is required.” **Elastomeric Full Facepiece Respirator:** Annual fit testing required. **Powered Air-Purifying Respirator:** Not required if loose-fitting PAPRs. Fit testing required for tight-fitting PAPRs.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The National Institute for Occupational Safety and Health (NIOSH) Filtering out Confusion: Frequently Asked Questions about Respiratory Protection, fit testing. 2018b. Accessed: 5 December 2022	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence
“In addition to fit testing upon initially selecting a model of respirator, OSHA requires that fit testing be conducted annually, and repeated “whenever an employee reports, or the employer or the physician or other licensed health care professional makes visual observations of changes in the employee’s physical condition that could affect respirator fit (e.g., facial scarring, dental changes, cosmetic surgery, or an obvious change in body weight).” The appropriate length of time between respirator fit tests has been a point of debate and discussion for many years due to its use of workplace time and resources, especially in reference to the commonly-used filtering facepiece respirator (FFR).3 In response to these concerns, NIOSH completed a study that confirmed the necessity of the current OSHA respirator fit testing requirement, both annually and when physical changes have occurred.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centers for Disease Control and Prevention (CDC) Sequence for putting on personal protective equipment, 2019a. Accessed: 22 November 2024	Poster	Level 4	N/A	N/A	N/A
Assessment of evidence					
Fit checks should be performed when donning a respirator					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centers for Disease Control and Prevention (CDC) Understanding the difference, 2019. Accessed 5 December 2022	Infographic	Level 4	N/A	N/A	N/A
Assessment of evidence					
N95 and Elastomeric half facepiece respirators: User seal check required each time they are donned. A fit test is also required (unclear on timing of fit test).					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The National Institute for Occupational Safety and Health (NIOSH) Filtering out Confusion: Frequently Asked Questions about	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Respiratory Protection, User Seal Check. 2018. Accessed: 5th December 2022					

Assessment of evidence

"A user seal check is sometimes referred to as a fit check. A user seal check should be completed each time the respirator is donned (put on). It is only applicable when a respirator has already been successfully fit tested on the individual."

"Once a fit test has been done to determine the best respirator model and size for a particular user, a user seal check should be done every time the respirator is to be worn to ensure an adequate seal is achieved."

"Can a user seal check be considered a substitute for a fit testing?

No. The user seal check does not have the sensitivity and specificity to replace either fit test methods, qualitative or quantitative, that are accepted by OSHA (29 CFR 1910.134). A user should only wear respirator models with which they have achieved a successful fit test within the last year."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Health Security Agency (UKHSA) Putting on (donning) personal protective	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
equipment (PPE) for aerosol generating procedures (AGPs). Airborne Precautions – Gown version, 2020. Accessed: 13 December 2022					

Assessment of evidence

This COVID-19 guidance advises that, when donning a respirator following a coverall, a fit check should be performed when donning the respirator, following adjusting the nose piece and pressing the respirator down to facilitate a good fit around the face.

This guidance also provides pictures to aid user understanding.

Prior to donning, it is advised that healthcare workers should be hydrated, have their hair tied back, remove jewellery and check the correct size of PPE is available.

Following donning the fluid repellent disposable gown, the respirator should be donned as such:

“Note: this must be the respirator that you have been fit tested to use. Where goggles or safety spectacles are to be worn with the respirator, these must be worn during the fit test to ensure compatibility.

Position the upper straps on the crown of your head, above the ears and the lower strap at the nape of the neck. Ensure that the respirator is flat against your cheeks. With both hands mould the nose piece from the bridge of the nose firmly pressing down both sides of the nose with your fingers until you have a good facial fit. If a good fit cannot be achieved DO NOT PROCEED.

Assessment of evidence
Perform a fit check. The technique for this will differ between different makes of respirator. Instructions for the correct technique are provided by manufacturers and should be followed for fit checking." (please note that this guidance is the same as the UKHSA guidance for donning a respirator with coveralls)

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Government Department of Health and Social Care Infection prevention and control (IPC) in adult social care: acute respiratory infection (ARI). 2024 Accessed: 17 October 2024	Guidance	Level 4	N/A	N/A	N/A
Assessment of evidence					
"The use of FFP3s is governed by health and safety regulations and they should be fit tested to the user to ensure the required protection is provided. FFP3 respirators must be fit checked each time they are used. HSE provides information and tools to help select and manage the use of respiratory protective equipment (RPE)."					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
European Centre for Disease Prevention and Control (ECDC) Personal protective equipment (PPE) needs in healthcare settings for the care of patients with suspected or confirmed novel coronavirus (2019-nCoV), 2020a. Accessed: 14 December 2022	Technical Report	**Level 4**	N/A	N/A	N/A
Assessment of evidence					
Target audience: "Public health authorities and hospital administrators in EU/EEA countries." "Given that the fitting of different types of respirator will vary for each user, the respirator will require a fitting test in order to find the best match of PPE to user." "It is important to perform a fitting test after the respirator has been put on […]"					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
NHS England Supporting fit testing: steps and actions to be taken where staff may require the use of FFP3 masks Year unknown. Accessed: 20 December 2022	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

The algorithm below has been produced to help NHS organisations to identify the steps they should take where staff are to be deployed to clinical areas which require FFP3 respirator masks to be worn. It will assist organisations to determine actions required when an individual passes or fails a fit test.

(see image in URL for more details on fit testing)

Note: The British Safety Industry Federation provide an accredited fit-testing service and face fit training. Their website states that BSIF has developed this service with HSE. Their resources link to HSE guidance however this guidance does not specify two years (See HSE, 2019)

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Public Health Agency of Canada (PHAC). Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Healthcare Settings. 2017. Accessed: 20 December 2022	Recommendations Report	Level 4	N/A	N/A	N/A

Assessment of evidence

Aim: To present evidence-based recommendations for monitoring, preventing and controlling healthcare associated infections.

Target audience:

Infection prevention and control professionals and healthcare providers involved with developing policy and procedure for routine practices in healthcare settings (acute, long-term, ambulatory, home care or prehospital care settings)

Methods: These guidelines were produced by PHAC, advised by PHAC's Steering Committee on Infection Prevention and Control Guidelines Working Group, made up of professionals from different areas of healthcare who provided technical advice (list provided on page 2). They are described as "principles and recommendations" rather than strict standards.

Assessment of evidence

A literature search was conducted for papers from 1999 (details of this search are available to request).

Recommendations were graded based on the strength of evidence

This guidance is based on scientific evidence and expert opinion where evidence was lacking, but was graded as expert opinion due to limited methodological detail making it difficult to deduce how systematic methods were.

Recommendations:

- The authors suggest that organisations with respirators should have a program which encompasses fit-testing/retesting for all healthcare workers (page 37)
- They also note that fit test results do not carry across models of respirator (page 38)
- “Each time HCWs put on a respirator, they are to perform a seal check (sometimes referred to as fit check) to enable proper functioning of the respirator” (page 38)
    - This section references the Canadian Standards Association (233)
- “Visitors should be instructed to perform a seal check if wearing a respirator” (page 104)
- “Healthcare workers should only use respirators to which they were fit-tested.” (page 38)

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Ontario Agency for Health Protection and Promotion. Provincial Infectious Diseases Advisory Committee (PIDAC). Best Practices for Infection Prevention and control Programs in Ontario. In All Health Care Settings, 3rd edition. 2012. Accessed: 21 December 2022	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

Aim: To outline the elements of and provide recommendations for the Infection prevention and control program and allocating resources.

Target audience: Senior administration, administrators in local health integration networks, medical officers of health and others in management.

Although these guidelines are evidence-based, they do not provide much detail on methodology to deduce if they are systematic so are graded expert opinion. “The recommendations in this document are based on Level AII evidence unless stated otherwise. Level AII evidence is good evidence to support a recommendation for use with evidence from at least one well-designed clinical trial without

Assessment of evidence
randomization, from cohort or case-controlled analytic studies, preferably from more than one centre, from multiple time series, or from dramatic results in uncontrolled experiments (source: Public Health Agency of Canada)." "Staff who are required to wear an N95 respirator to provide care to clients/patients/residents must participate in a respiratory protection program with respirator fit-testing, at least every two years." (best practice) (page 28)

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Occupational Safety and Health Administration (OSHA). Hospital Respiratory Protection Program Toolkit: Resources for Respirator and Program Administrators. 2015. Accessed: 23 December 2022	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence
“This toolkit was developed to assist hospitals in developing and implementing effective respiratory protection programs”. “This toolkit identifies existing public health guidance where available on the use of respiratory protection.” “The fit test must be repeated annually and whenever the employee reports—or the employer, PLHCP, supervisor, or program administrator makes visual observations of—any changes in the employee’s physical condition, such as weight gain or loss, facial scarring, or dental changes, that could alter fit of the facepiece.” “User seal check—[…] For all tight-fitting respirators, the employer shall ensure that employees perform a user seal check each time they put on the respirator […] User seal checks are not substitutes for qualitative or quantitative fit tests.” **Limitations:** - No references - May not be applicable to UK health and care settings

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution (BSI). PD ISO/TS 16975-1:2016 Respiratory protective devices: selection, use and maintenance establishing and	British Standard	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
implementing a respiratory protective device programme.					

Assessment of evidence

Fit testing:

“The fit test shall be performed prior to the RPD being first issued to the wearer during the selection process and shall be conducted by a competent person.”

“National or local regulations can require periodic repeat fit testing. It is recommended that it be done at least annually.” (page 23)

Annex D provides detail on methods for suitability assessment (page 49):

Supplemental information to ensure that the wearer uses RPD in line with instructions and training, reports damage/defects and physical/medical limitations or changes impacting ability to wear the RPD correctly (page 5)

General fit testing principles:

“Tight-fitting respiratory interfaces, those that have a face or neck seal (classes bT, cT and dT), will not provide optimum performance if they do not fit and therefore need to be fit tested on the individuals who will wear the RPD. All other respiratory interfaces do not require a fit test.

Where this type of RPD is selected for use, a fit test should be conducted to ensure that the RPD will fit the wearer correctly

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
European Centre of Disease Prevention and Control (ECDC). Guidance for wearing and removing personal protective equipment in healthcare settings for the care of patients with suspected or confirmed COVID-19. 2020. Accessed: 14 December 2022	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence
"**Scope of this document** This document provides support to healthcare workers managing suspected or confirmed cases of novel coronavirus 2019 (COVID-19). The general objectives of the document are: • to present the minimal set of personal protective equipment (PPE) required for managing suspected or

Assessment of evidence
• confirmed COVID-19 cases; • to make healthcare workers aware of the critical aspects of the donning and doffing of PPE; and • to strengthen occupational safety in healthcare workers for patients suspected of, or confirmed with, COVID19. This document is based on current COVID-19 knowledge and PPE best practices. ECDC will update this document based on the evolving situation and if new relevant information arises. Target audience Healthcare workers and infection prevention and control personnel in EU/EEA countries and in the United Kingdom." FFP respirator: "require a fitting test to ensure proper protection" which indicates that a fit test should be performed before use.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). COSHH essentials: Respiratory protective equipment. UK Standard Assigned Protection Factor 4 (APF 4)	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Supplementary advice. 2006. Accessed: 15 February 2022					
Assessment of evidence					
This supplementary advice provided by HSE states “This information will help employers comply with the Control of Substances Hazardous to Health Regulations 2002 (COSHH), as amended, to control exposure to chemicals and protect workers’ health.” “Using RPE Users should check the fit every time they put on RPE.”					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). COSHH essentials: Respiratory protective equipment. UK Standard Assigned Protection Factor 10	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
(APF 10). Supplementary advice. 2006. Accessed: 15 February 2022					
Assessment of evidence					
This supplementary advice provided by HSE states “This information will help employers comply with the Control of Substances Hazardous to Health Regulations 2002 (COSHH), as amended, to control exposure to chemicals and protect workers’ health.” “Using RPE Users should check the fit every time they put on RPE.”					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). COSHH essentials: Respiratory protective equipment. UK Standard Assigned	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Protection Factor 20 (APF 20) Supplementary advice, 2006. Accessed: 15 February 2022					
Assessment of evidence					
This supplementary advice provided by HSE states “This information will help employers comply with the Control of Substances Hazardous to Health Regulations 2002 (COSHH), as amended, to control exposure to chemicals and protect workers’ health.” “Using RPE Users should check the fit every time they put on RPE.”					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive. COSHH essentials: Respiratory protective equipment. UK Standard Assigned	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Protection Factor 40 (APF 40). Supplementary advice. 2006. Accessed: 15 February 2022					
Assessment of evidence					
This supplementary advice provided by HSE states “This information will help employers comply with the Control of Substances Hazardous to Health Regulations 2002 (COSHH), as amended, to control exposure to chemicals and protect workers’ health.” “Using RPE Users should check the fit every time they put on RPE.”					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centers of Disease Control and Prevention (CDC). How to Use Your N95 Respirator	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
2022.Updated 16 May 2023. Accessed: 29th October 2024					
Assessment of evidence					
“check for gaps every time you put on your N95” Detailed in donning process for N95 respirator: Your N95 must form a seal to your face to work properly. Your breath must pass through the N95 and not around its edges. Jewelry, glasses, and facial hair can cause gaps between your face and the edge of the mask. The N95 works better if you are clean shaven. Gaps can also occur if your N95 is too big, too small, or it was not put on correctly.					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Government of Canada. Infection prevention and control for COVID-19: Interim guidance for long-term care homes. 2022.	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
(Accessed: 17th April 2023)					
Assessment of evidence					
This Canadian interim guidance aimed to provide interim COVID-19 guidance related to IPC, to be considered in conjunction with the Canadian Government's Omicron variant guidance. It is specific to long term care homes. The guidance is broadly in line with acute care, ambulatory and outpatient settings guidance. "All staff using PPE should … Participate in N95 or equivalent respirator fit-testing"					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Government of Canada. Infection prevention and control for COVID-19: Interim guidance for outpatient and ambulatory care settings. 2022.	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Accessed 17 April 2023					

Assessment of evidence

This Canadian interim guidance aimed to provide interim COVID-19 guidance related to IPC, to be considered in conjunction with the Canadian Government's Omicron variant guidance. It is specific to outpatient and ambulatory care. The guidance is broadly in line with acute care and long term care home guidance.

PPE:

"All staff using PPE should:

participate in N95 or equivalent respirator fit-testing"

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Government of Canada. Infection prevention and control for COVID-19: Interim guidance for acute healthcare settings. 2022.	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Accessed 17 April 2023					

Assessment of evidence

This Canadian interim guidance aimed to provide interim COVID-19 guidance related to IPC, to be considered in conjunction with the Canadian Government's Omicron variant guidance. It is specific to acute care settings. The guidance is broadly in line with long term care homes, ambulatory and outpatient settings guidance.

Personal protective equipment:

All HCWs who use PPE should:

"Participate in the facility's RPP [respiratory protective program], including N95 or equivalent respirator fit-testing"

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Diaz KT and Smaldone GC. Quantifying exposure risk: surgical masks and respirators. American journal of infection control. 2010; 38(7):501-8.	Simulation (manikin)	**Level 3**	Experimental set-ups assessed exposure, dilution, deflection and filtrated of aerosols. The nebuliser contained 3 ml 0.9% saline labelled with	• No PPE • NIOSH-approved N95 respirator (No. 1860S size small; 3M) • Ear loop surgical mask	Maximum exposure (Max Ex): % of nebulised particles (i.e. inhaled particles) captured by the receiver – direct result of dilution, i.e. exhaled particles from the

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Doi: 10.1016/j.ajic.2010.06.002.			technetium-99m and run to dryness (approx. 10 minutes).	(SM) (model No. GCFCXS; Crosstex International Inc). SMs were tested both loosely or tightly fitted on the source or receiver depending on experiment conditions. • N95s fitted with no obvious leaks. Additional experiments were performed with N95 sealed to face with Vaseline	source mixing with ambient air. Ratio of Max Ex to actual exposure defined as the simulated workplace protection factor (sWPF) Results presented as means and 95% confidence intervals with “separation of confidence intervals defined statistical significance”. Particle distribution and mass median aerodynamic diameters (MMAD) (uM) also presented.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
				to prevent leaks.	

Assessment of evidence

Methodology:

- Chamber (5ft x 4.5ft x 6ft, 135 ft3) with a fixed flow providing 0 or 6 air changes/hr within the chamber.
- Nebuliser (AeroTech II) connected to an air tank with flow of 10L/min was used to create aerosols (3 devices used in rotation). Environmental flow within the chamber was regulated using an opening between the chamber and a hood. The nebuliser contained 3 ml 0.9% saline labelled with technetium-99m and run to dryness (approx. 10 minutes).
- Source aerosols were exhaled via a manikin head (Brad CPR adult manikin head, no 2512, Simulaids) directed towards a receiver; a ventilated manikin head was also placed in the chamber to simulate the receiver. Manikin heads were both connected to Harvard pumps (Harvard Apparatus SN A52587) with a tidal volume of 500 mL, respiratory rate of 15 breaths/min and duty cycle of 0.5 to simulate a tidal breathing pattern.
- Manikin heads were placed 3 feet from each other (distance chosen in line with CDC recommendation to represent 2 individuals sitting in a room). The ventilators of the manikin heads were not synchronised and triggered randomly.
- Aerodynamic distribution of particles expelled by source near the receiver measured in triplicate using an 8-stage cascade impactor. Aerosols near the receiver were also measured with and without masks placed on the source – a filter (model No. 041B0522; Pari, Starnberg, German) was placed on the receiver head to capture inhaled particles (capturing radioactivity using a calibrated well counter (≤10 µCi; Kemble Instruments, Hamden, Ct) or a calibrated Ratemeter (≥10 µCi; Ludlum Measurements Inc, Sweetwater, TX).)

Assessment of evidence

- Smoke trace experiments were performed to define ambient air currents. Chamber flow (CFM) towards the hood that the chamber was connected to using a balometer (ft3/min). Flow was measured at 14 CFM or 0 CFM (where 14 CFM is equivalent to 6 air changes/hour). Local linear velocity was 0.670 ft/sec. Temperature 20-22ºC and relative humidity 21-26%.

Main findings:

Note: Results from experiments with no airflow have been excluded due to lack of generalisability to real-life clinical settings.

Authors state that “particles leaving the source were similar to exhaled droplets in vivo because approximately 95% of the particles were less than 2 mm, with an average MMA9D of 1.046 mm (95% CI: 0.984-1.11)”

No masks worn by source or receiver (control): the authors described the particles near the receiver as significantly smaller (75% sub-micron and 0.633µm, [95% CI 0.506-0.757]) where air flow was 14CFM 6 air change per hour compared to when no airflow was used (MMAD was 0.905 [(95% CI: 0.909-0.991]). No value provided to the second set of figures. It is assumed these are ‘µm’ but this is not confirmed.

- Experiments with environmental flow, i.e. 6 air changes/hour:
- Exposure (source manipulation vs receiver manipulation), illustrated as percentage of nebulised particles:

Applying a surgical mask or N95 respirator to the source resulted in reduction of the sWPFs of 172 to 317 (95% CI not provided). Applying a SM or respirator to the receiver did not reduce exposure when compared to the use of no masks (sWPF 1.37 – 2.21)

- Mask filtration: % of nebulised particles:

Filtration at the receiver did not significantly alter protection according to the receiver wearing a loose fitting surgical mask (0.0855%, 95% - 0.00564 – 0.177), tight surgical mask (0.107%, 95% CI 0.591 – 0.156) or N95 (0.252%, 95% CI 0.027-0.377 – sWPF 2.21 vs no mask sWPF 1.37).

When the N95 was tightly applied to the source using Vaseline to represent filtration plus deflection, sWPF was highest (4082); filtration captured 81.0% (95% CI 59.5 – 103) of particles. When the N95 was tightly applied to the receiver using Vaseline, sWPF was 118, capturing 0.453% (95% CI – 0.0200 – 0.926) particles on average.

Assessment of evidence

- Deflection at source (receiver not wearing PPE):

sWPF decreased from 172 to 5.92 for loose fitting SMs, 288 to 129 for tight fitting surgical masks and 317 to 15.1 for N95s.

Limitations:

- Air flow towards receiver may not reflect real air flow (multiple persons in health settings, both inhalation and exhalation in progress during interactions). Flow towards receiver may overinflate source control results.
- Experimental study with simulation may not generalize to health and care settings.
- No human participants and constant flow rate
- Radiolabelled wet particles may not reflect infectious particles and may be affected by humidity (though controlled 22-26%)
- Fit – may not generalize.
- Represents exposure at 3 feet only.
- Unclear number of replications nor statistical power.
- Comparators limited (both source and control wearing surgical mask not assessed).
- 10 minutes of sampling and unclear replications – power calculations not provided – possible validity and reliability issues.

Within this specific experimental setting, an N95 respirator worn at the source (sealed using Vaseline) resulted in greater average filtration efficiency (35.7%, 95% CI 27.7 – 43.7) when compared to a surgical mask tightly fitted to the source (14.8%, 95% CI 10.1 – 19.6) and a surgical mask loosely fit on the source (6.07%, 95% CI 5.43 – 6.72). **Filtration at the receiver did not significantly alter protection according to the receiver wearing a loose fitting surgical mask (0.0855%, 95% - 0.00564 – 0.177), tight surgical mask (0.107%, 95% CI 0.591 – 0.156) or N95 (0.252%, 95% CI 0.027-0.377 – sWPF 2.21 vs no mask sWPF 1.37).**

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Mansour MM and Smaldone GC. Respiratory Source Control Versus Receiver Protection: Impact of Facemask Fit. J Aerosol Med Plum. 2020;26(3);pp:131.137. Doi:10.1089/jamp.2012.0998	Simulation (manikin)	Level 3	The use of two mannequins (a source and a receiver) with simulated tidal breathing at 3ft apart to determine the degree of protection for source N95 and surgical mask combinations as well as receiver N95 and surgical mask combinations.	Several surgical mask/N95 iterations worn by the source or receiver: No mask on source/receiver; surgical mask tightly fitted on source; surgical mask looped around ears of source; N95 worn by the source; surgical mask tightly fitted on receiver; surgical mask looped on ears of receiver; N95 on receiver; N95 sealed using Vaseline on source or receiver.	Particle distributions and mass median aerodynamic diameters (MMAD) Exposure data - expressed as % of nebulised activity*. * Nebulized activity represented the difference between initial nebulizer charge and that remaining after nebulization Exposure data also expressed as simulated workplace protection factor (sWPF) defined as ratio of max exposure to actual exposure. “The protective effect of each intervention in

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
					reducing exposure is best illustrated by the magnitude of the sWPF." Mask filtration – radioactivity captured by each mask, reported as a % of activity exhaled at source. Separation of 95% CIs indicated statistical significance.

Assessment of evidence

Main findings:

Particle distributions and MMAD (mass median aerodynamic diameters) (diameter vs probability):

- At the source, approx. 90% of particles were <2µm
- Average MMAD = 0.95µm (95% CI: + 0.119)
- The MMAD of particles reaching the vicinity of the receiver was 0.69µm (95% CI: + 0.0663).

Assessment of evidence

Control: Maximum Exposure (Max Ex) (i.e. aerosol inhaled by receiver) average = 1.363% (95% CI: 0.912–1.81%). As this was the 'no protection' control, sWPF = 1.

SFM/N95 worn by source, i.e. patient:

- N95 (no Vaseline): 0.00019% (95% CI: 0.00012– 0.00027%), sWPF = 7,174
- Compared to the control, these were deemed statistically significant reduction in aerosol exposure.
- N95 sealed with Vaseline to mimic tight fit:
    - Source wearing N95 with Vaseline vs source wearing N95 without Vaseline: sWPF was 17,038 (exposure 0.00008%, 95% CI -0.00007, 0.00023) versus 7,174 (exposure 0.00019, 95% CI 0.00012, 0.00027), respectively.
    - The difference in reduction of exposure when using a non-tightly fitted N95 vs a sealed N95s was not statistically significant due to overlapping 95% CIs (see bullet point above)

SFM/N95 worn by receiver, i.e. staff, visitor:

- SFM naturally fitted: 1.38% (95% CI: 0.992–1.77%), sWPF =0.99
- SFM tightly fitted: 0.669% (CI: 0.0641–1.27%), sWPF = 2.04
- N95 (no Vaseline): 0.181% (95% CI: 0.106–0.256), sWPF of 7.53
- Compared to the control, these results were not statistically significantly lower than the control.
- N95 sealed with Vaseline to mimic tight fit:
    - 0.0216% (95% CI -0.006, 0.0492), sWPF 63.1. This is significantly different when compared to the control, therefore the only PPE item to confer protection of the receiver. This is also significantly different compared to the receiver wearing a non-tightly fitted N95, indicating the importance of achieving a tight fit, i.e. performing a fit check.

Assessment of evidence

Conclusion:

When the N95 respirator was sealed to the receiver, there was significant increase in sWPF when compared to the N95 being placed on the receiver head without the use of Vaseline. This indicates the importance of adequate N95 fit without face seal leakage, contributing to the evidence-base that a user seal check or fit test should be performed every time a respirator is donned by a staff member. Although the sealed N95 respirator conferred maximum protection when worn at the source, this was not statistically significant when compared to the use of a non-sealed N95 and SFMs, indicated by the overlapping 95% CIs.

Limitations:

- in-vitro nature
- set parameters of air flow, air changes and 3ft distancing between source and receiver
- “wet radioactive particles” unlikely to generalize behaviour of infectious particles
- No fit testing of respirators, only visual checking
- Use of Vaseline to seal respirator not applicable to real life scenario, may not fully represent a fit tested N95.
- One model of mask and one model of respirators used
- Unknown no. of replicate of experiments to obtain an average

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Lee SA, Hwang DC, Li HY, et al. Particle size-selective assessment of	Simulation (human participants)	Level 3	The relationship between protection factors and fit factors.	FFP1, FFP2, FFP3	Fit test pass rate (%)– PortaCount Plus (TSI Inc, St Paul, USA). With

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
protection of European standard FFP respirators and surgical masks against particles-tested with human subjects. J Healthc Eng. 2016; 8572493. Doi: 10.1155/2016/8572493.					equation for fit factor provided on page 5. Protection factor (PF) – ratio based on a comparison of sampling from inside and outside a face mask. % of PF below Assigned Protection Factor (APF) values 4, 10 and 20. Statistical analysis – ANOVA, t-test, pearsons correlation.
Assessment of evidence					
This observational experimental study carried out in Taiwan investigated the filtering efficiency of FFP respirators (supplied by two manufacturers) and SMs (from three manufacturers) against nebulized NaCl in controlled conditions.					

Assessment of evidence

The protection factors (PF) of the respirators were 1.1-1.4 times greater when a prior fit test was carried out and passed, however this finding was not statistically significant ($p > 0.05$). There was a weak, statistically significant positive correlation between fit factor scores and protection factor scores ($r = 0.378$, $p < 0.05$).

A significant decrease in protection factors (PFs) score was seen when a fit test had been carried out ($p < 0.05$); this association was no longer significant when only considering those who passed a fit test ($p > 0.05$).

Limitations:

- Small number of participants
- Patients were 18-24 – may not generalize.
- Taiwan based – may not generalize.
- NaCl particles may not reflect infectious viral/bacterial/fungal particles.
- Type of surgical face mask – not clear.
- Test chamber may not generalize to health and care facilities. Air changes per hour not clear (though noted as capable 0-60).
- The filtration efficacy displaced as ratio but how this impacts practice is not clear.
- Small sample and unclear power – may be underpowered and lack validity/reliability.
- ratio based on a comparison of sampling from inside and outside a face mask was used as a measure of ‘protection’ however the actual filtration values or aerosol sampling concentrations are not provided. One value provided (not per exercise)
- Rest periods between exercises/experiments not clear. Cleaning equipment noted but unclear if this was used – for example between each person/experiment.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Patel RB. Skaria SD, Mansour MM, et al. Respiratory source control using a surgical mask: An in vitro study. J Occup Environ Hyg. 2016; 13(7); 569-576. Doi: 10.1080/15459624.2015.1043050.	Simulation (manikin)	**Level 3**	The use of two manikins (a source and a receiver) with simulated breathing or coughing at 3ft apart to determine the degree of protection provided by a respirator (N95) and SM	Protection provided in three room conditions (zero ACH, six ACH, 12 ACH)	Aerosol particle distribution - MMAD (mass median aerodynamic diameter, µm) and GSD (Geometric standard deviation). Receiver protection factor (RPF) – defined as ratio of Max exposure (Max Ex) to actual exposure Mask capture efficiency

Assessment of evidence

Findings:

Aerosol particle distribution:

- "In all three rooms, during coughing, at the Source, distributions contained larger particles than during tidal breathing."
- Tidal breathing
    - Source (MMAD, GSD):
        - No flow room – 0.96µm,1.80
        - Hospital room – 1.09 µm 1.84

Assessment of evidence

        - Negative pressure room – 1.07 μm, 1.63
    - Receiver:
        - No flow room – 1.04 μm, 1.58
        - Hospital room – 0.72 μm, 1.81
        - Negative pressure room – 0.98 μm, 1.99
- Coughing
    - Source:
        - No flow room – 1.45 μm, 1.85
        - Hospital room – 1.52 μm, 1.92
        - Negative pressure room – 1.30 μm, 2.29
    - Receiver:
        - No flow room – 1.04 μm, 1.60
        - Hospital room – 0.53 μm, 2.02
        - Negative pressure room – 0.61 μm, 2.74

Exposure and mask protection: **Tidal breathing**

- "In the No flow, Hospital and Negative pressure rooms, Max Ex averaged 1.146% (95% CI: 1.037–1.255%), 0.617% (95% CI: 0.577–0.657%), and 0.0167% (95% CI: 0.0152–0.0182%),a respectively."
- Significant ($p<0.05$) decrease in exposure (when compared with max exposure) for:
    - No air flow room
        - Source Secure fit surgical mask
        - Source N95
        - Source N95 Vaseline
        - Receiver N95 Vaseline
    - Hospital room
        - Source N95
        - Source N95 Vaseline
        - Receiver N95
        - Receiver N95 Vaseline

Assessment of evidence

- Negative pressure room
  - Source natural fit surgical mask
  - Source secure fit surgical mask
  - Source N95
  - Source N95 Vaseline
  - Receiver N95
  - Receiver N95 Vaseline

Exposure and mask protection: **cough**

- **“**In general, for all rooms, mask on Source was superior to mask on Receiver.”
- Significant ($p<0.05$) decrease in exposure (when compared with max exposure) for:
  - No air flow room
    - Source secure fit surgical mask
    - Source N95
    - Source N95 Vaseline
    - Receiver N95 Vaseline
  - Hospital room
    - Source secure fit surgical mask
    - Source N95
    - Source N95 Vaseline
    - Receiver N95 Vaseline
  - Negative pressure room
    - Source natural fit surgical mask
    - Source secure fit surgical mask
    - Source N95
    - Source N95 Vaseline

Filtration at source

During tidal breathing: the natural fit surgical mask captured particles ~5–20%, the N95 ~ 80–90%, and a sealed N95 Limitations:

Assessment of evidence

- Funding not stated
- in-vitro nature
- set parameters of air flow and 3ft distancing between source and receiver
- “wet radioactive particles” unlikely to generalize behaviour of infectious particles
- Limited generalizability out with these conditions (use of manikins)
- No fit testing of respirators, only soap testing – confounding factor
- Use of Vaseline to seal respirator not applicable to real life scenario, may not fully represent a fit tested N95.
- Use of N95 limits generalisability to other RPE. Additionally online one model of mask and one model of respirators used.
- Unknown no. of repetitions of experiments to obtain an average

This in-vitro experimental study involved two manikin heads which represented 3-foot distancing between a source and receiver. The study suggests significant reduction to exposure of particles is seen, when comparing to max exposure (no mask worn on source or receiver) when the source is wearing a respirator in all three airflow conditions (no airflow, hospital room (6ACH) and negative pressure room (12 ACH)). A significant reduction in exposure is also seen when the receiver is wearing an N95 sealed with Vaseline in a no air flow room and an N95 both sealed and unsealed in a hospital room. However, this study is severely limited by its in-vitro nature, and potential lack of generalizability to real-life scenarios due to set parameters of air flow, and distancing between source and receiver.

Evidence from previous update(s):

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
World Health Organization (WHO) Infection prevention and control of epidemic-and pandemic prone acute respiratory infections in health care, 2014. Accessed: 24 January 2023	Guidance	AGREE: Recommend (with provisos)	N/A	N/A	N/A

Assessment of evidence

Funding: “Financially supported by the United States Centers for Disease Control and Prevention (CDC), the United States Agency for International Development (USAID), the German Agency for International Cooperation (GIZ), and the French Ministry of Social Affairs and Health”

Aim of guidance: “The guidance is intended to help policy-makers, administrators and health-care workers to prioritize effective IPC measures”

Target audience: “Recommendations, best practices, and principles for non-pharmacological aspects of infection prevention and control (IPC) for acute respiratory infections (ARI) in health care” intended for policy-makers, administrators and health-care workers, including doctors, nurses, allied health professionals, auxiliary and community health workers, and others involved in provision of health care.

Assessment of evidence
Methods: “The development of the guidelines followed the process established in the WHO handbook for guideline development, which involved active participation of the Global Infection Prevention and Control Network (GIPCN). The resulting recommendations were peer reviewed by internal and external experts.” This guidance is deemed expert opinion as it is unclear the edition of the “WHO handbook for guideline development” that was used. Further to this, the elements of the systematic review process, such as the search strategies, are not provided. **Recommendations:** “When putting on a disposable particulate respirator, always check the seal” “that they [users] understand the need to perform the seal check every time the respirator is worn” (Ref 158) Citation 158 (Hannum et al. 1996). The effect of respirator training on the ability of healthcare workers to pass a qualitative fit test. This a dated reference particularly in regard to the scope of the current review.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). Respiratory protective equipment at work: A practical guide. HSG53 (4th Ed.) 2013. ISBN: 978 0 7176 6454 2.	Expert opinion	Level 4	N/A	N/A	N/A

Assessment of evidence

About this guidance:

This guide prepared by the HSE “in consultation with industry: employers, trade unions and trade associations”, is stated to support “the Approved Code of Practice (ACOP) to the Regulations that apply (see paragraphs 36–39)”.

“The guide contains practical guidelines to help you select the correct RPE and manage its use in your workplace to ensure effective protection.”

“71 If you are considering RPE with a tight-fitting facepiece, you should make sure that each wearer undergoes a fit test.”

“If RPE is used frequently it is good practice to ensure repeat fit testing is carried out on a regular basis.”

“Users of tight-fitting facepieces should have passed a fit test for the particular RPE device they are using”

“86 It is also good practice to have a system to ensure repeat fit testing is carried out on a regular basis. This is especially important when RPE is used frequently as a primary means of exposure control, eg annual testing for workers involved in licensed asbestos removal. If there are any changes to a person’s face through, for example, weight loss/gain, scars etc, a repeat fit test will be necessary.”

Fit testing and the options per respirator type:

- Disposable half mask respirators: “fit testing required – Yes”, “Fit testing options – Qualitative and Quantitative”
- Reusable half mask respirators – particle filter: “Fit testing required – Yes”, “Fit testing options - Qualitative and Quantitative”
- Full face mask respirators – particle filter: “Fit testing required – Yes”, “Fit testing options – Qualitative and Quantitative”
- Powered respirators with masks: “Fit testing required – Yes”, “Fit testing options – Half mask fit test option: Qualitative and Quantitative, Full face mask fit test option: Only Quantitative”
- Powered respirators with hoods/helmets: “Fit testing required – No”

Assessment of evidence
“You should carry out a fit test as part of the initial selection of the RPE.” “A fit test should be carried out: • as part of the initial selection of the RPE; • where an untested facepiece is already in use.” “You should always conduct a repeat fit test if the wearer: • loses or gains weight; • undergoes any substantial dental work; • develops any facial changes (scars, moles etc) around the face seal area.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). Guidance on respiratory protective equipment (RPE) fit testing (INDG479). 2019.	Guidance	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
ISBN: 9780717667062.					

Assessment of evidence

"A fit test should be repeated whenever there is a change to the RPE type, size, model or material or whenever there is a change to the circumstances of the wearer that could alter the fit of the RPE; for example:

- weight loss or gain;
- substantial dental work;
- any facial changes (scars, moles, effects of ageing etc) around the face seal area;
- facial piercings;
- introduction or change in other head-worn personal protective equipment (PPE)."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Loveday HP, Wilson JA, Pratt RJ, et al. epic3: National Evidence-Based Guidelines for Preventing Healthcare-	Guidance	AGREE: Recommend (with provisos)	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Associated Infections in NHS Hospitals in England J Hosp Infect. 2014;pp:1-70.					
Assessment of evidence					
These guidelines were commissioned by The Department of Health (England) for preventing HCAI in hospital or other acute heal and care settings. It is unclear how the evidence/expert opinion formulated the following recommendations, this document is also outdated as an update was due to be published in 2017. The guideline development team was comprised of individuals with varied specialties within IPC including, nursing, microbiology, infectious diseases. The guideline advisory team was formed of consultants, trust and lay members amongst others. “Where RPE is required, it must fit the user properly and the user must be fully trained in how to wear and adjust it.177” – not explicit recommendation					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Siegel JD, Rhinehart E, Jackson M, Chiarello L. 2007 guideline for isolation	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
precautions: preventing transmission of infectious agents in health care settings. American Journal of Infection Control. 2007 Dec 1;35(10): S65-164. Last updated: September 2024 Accessed: 28 October 2024					

Assessment of evidence

Aim: To provide recommendations for healthcare settings embedded with infection prevention principles that can be sensibly modified depending on the setting.

Target audience: Infection control staff, health care epidemiologists, healthcare administrators, nurses, other health care providers and persons involved in infection control programs (developing, implementing and evaluating) for healthcare settings.

Methodology: Expert opinion by CDC and HIPAC (members listed). This guidance presents narrative synthesis summary of literature and how it contributes to IPC guidance. New emerging pathogens, rising concern for known pathogens, new therapy development and rising concern for bioterrorism prompt updates. Little detail is provided on the methodology for literature search and review process.

Assessment of evidence

The reference list was screened for papers/guidance which may be relevant for RPE review. Unless otherwise stated, CDC guidance is cited to support these deadlines.

Relevant recommendations regarding fit checks include:

“Wear a fit-tested NIOSH-approved N95 or higher-level respirator for respiratory protection when entering the room or home of a patient when the following diseases are suspected or confirmed: Infectious pulmonary or laryngeal tuberculosis, or when infectious tuberculosis skin lesions are present and procedures that would aerosolize viable organisms (e.g, irrigation, incision and drainage, whirlpool treatments) are performed.” Citations include CDC guidance (12) and two studies from before 2000 (1023 - Hutton et al., 1990; 1024 - Frampton, 1992)

“No recommendation for fit testing of patients who are using respirators.”

Part two contains a narrative synthesis of scientific evidence on the components required to prevent transmission of infectious agents in healthcare settings.

Under the heading “Personal Protective Equipment for Health Care Workers”:

“The subject of respiratory protection as it applies to preventing transmission of airborne infectious agents, including the need for and frequency of fit testing is under scientific review and was the subject of a 2004 CDC workshop. Respiratory protection currently requires the use of a respirator with N95 or higher-level filtration to prevent inhalation of infectious particles. Information about respirators and respiratory protection programs is summarized in the Guideline for Preventing Transmission of Mycobacterium tuberculosis in Health Care Settings.” (page 56). This guidance cites CDC guidance (12) and a link that does not work (762).

“OSHA program components include medical clearance to wear a respirator; provision and use of appropriate respirators, including fit-tested NIOSH-certified N95 and higher-level particulate filtering respirators; education on respirator use, and periodic reevaluation of the respiratory protection program. When selecting particulate respirators, models with inherently good fit characteristics (i.e, those expected to provide protection factors of 10 or more to 95% of wearers) are preferred and theoretically could preclude the need for fit testing.” (page 56)

Assessment of evidence

This guidance references a mathematical modelling study (764 - Campbell et al., 2001) and a TB-specific study which was excluded after second screen for the 2019 review (765 - Lee et al., 2004) – excluded from discussion.

“A user-seal check (formerly called a ‘‘fit check’’) should be performed by the wearer of a respirator each time that the respirator is donned, to minimize air leakage around the face piece. The optimal frequency of fit testing has not been determined; retesting may be indicated if there is a change in wearer’s facial features, onset of a medical condition that would affect respiratory function in the wearer, or a change in the model or size of the respirator that was initially assigned.” (page 57)

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
BS ISO 16975-3:2017 Respiratory protective devices - Selection, use and maintenance Part 3: Fit-testing procedures. Accessed: 12 July 2023.	British Standard	Level 4	N/A	N/A	N/A

Assessment of evidence

"A fit test shall be performed prior to first use of the RPD and shall be conducted by a competent fit-test operator."

General fit-test considerations are described (page 5):

- Frequency of testing:
  - "After completing health surveillance, persons wearing a tight-fitting RPD shall be fit tested prior to initial use of the RPD and whenever a different RI (size, style, model, material or make) is used. National or local regulations can require periodic repeat fit testing. It is recommended that it be done at least annually"
  - "A fit test shall also be repeated when a person has experienced a change that may affect the RI seal, such as:

a) a significant change in body weight;

b) a change to the face in the sealing area (e.g. scarring, facial surgery);

c) dental changes;

d) wearer discomfort."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution (BSI) BS EN 529:2005 Respiratory protective devices — Recommendations	British Standard	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
for selection, use, care and maintenance — Guidance document. Accessed: 11 July 2023.					
Assessment of evidence					
“fit-checking to ensure that the facepiece has been donned correctly each time the respiratory protective device is worn.” (page 18) “They are used as a daily pre-use check for a facepiece already matched to the wearer by use of a fit testing method.”					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Munoz-Price LS, Banach DB, Bearman G, et al. The Society for Healthcare Epidemiology of America (SHEA) Expert Guidance:	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Isolation Precautions for Visitors. Infect. Control Hosp. Epidemiol. 2015; 36(7). Doi: 10.1017/ice.2015.67.					

Assessment of evidence

This guidance is developed by The Society for Healthcare Epidemiology of America (SHEA) “based on a synthesis of limited evidence, theoretical rationale, practical considerations, a survey of SHEA membership and the SHEA Research Network, author opinion, and the consideration of potential harm, where applicable.” Recommendations are intended for endemic pathogens in non-outbreak situations and “primarily for acute facilities, similar considerations may apply to other healthcare settings (e.g, post-acute care).” Due to a “lack of evidence required for a more formal guideline using a GRADE system” ... “no grading of the evidence level is provided”.

“For visitors to patients on airborne precautions, we recommend the use of surgical masks. An alternative is an N95 respirator; however, this equipment is best used with training and fit testing”

“With regard to airborne isolation, the use of N95 respirators among unfitted visitors is not warranted. If a visitor is considered at risk of an airborne pathogen and lacks previous exposure, then consideration should be given to limiting entrance” -

Discussion section:

“Fit testing of visitors for N95 respirators is beyond the capability of most infection control departments and would be logistically difficult for most hospitals to incorporate routinely; however, it could potentially be done on a case-by-case basis”

Limitations:

- No systematic process to literature review

Assessment of evidence
• Use of a survey to obtain expert opinion, with no clear methods as to how guidelines were developed (i.e., no consensus process explained) • No mention of planned updates, may be dated • No description of “airborne precautions” or “airborne isolation

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Occupational Safety and Health Administration (OSHA). 2009. Guidance on Preparing Workplaces for an Influenza Pandemic. OSHA 3327-05R.	Guidance	**Level 4**	N/A	N/A	N/A

Assessment of evidence
Guidance document produced by The Occupational Safety and Health Administration is an agency of the United States Department of Labor. Influenza pandemic guidance. The following suggests that fit tests should typically performed whenever a respirator is donned:

Assessment of evidence
“A “fit test” is necessary for most models of respirators because it is the only way to know for certain whether a proper seal has been established between the respirator and the user’s face”. This point is made in Table 1, page 50 – where it is stated that a fit check is required for respirators that require seal to be effective. “It should also be noted that there are hooded PAPRs that do not require employees to be fit tested in order to use them.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Coia J. E., Ritchie L., and Adisesh, A. et al. Guidance on the use of respiratory and facial protection equipment. Journal of Hospital Infection, 2013; 85;170-182; doi: 10.1016/j.jhin.2013.06.020.	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence
Best practice guidance based on a non-systematic literature review published separately (Bunyan D, Ritchie L, Jenkins D, Coia JE. Respiratory and facial protection: a critical review of recent literature. J Hosp Infect 2013;85:165e169).

Assessment of evidence

“The Scientific Development Committee of the Healthcare Infection Society established a short-life working group in May 2011 to develop appropriate guidance. The working group included representation from the Healthcare Infection Society, Public Health England, Health and Safety Executive (HSE), Association of National Health Occupational Physicians, Health Protection Scotland, Infection Prevention Society, Intensive Care Society, Clinical Virology Network and British Infection Association.”

There is no stipulated frequency for repeat fit tests as it is the responsibility of the employer to consider what is appropriate and reasonable for the staff within their organization. It is good practice to have a policy of repeat fit testing in a local RPE ‘fit testing’ programme to ensure that the face piece is still providing adequate protection to the wearer as faces change shape over time. A period of every two years is a good starting position. Further information on fit testing is provided on the HSE website.16 In addition, a ‘fit check’ should be performed each time a respirator is worn (see below).

The Control of Substances Hazardous to Health (COSHH) regulations recommend that fit testing should be repeated in the following circumstances: if it is necessary to change to another type of face piece (e.g. if new types of respirator are procured by the organization); if the wearer has lost or gained weight; if the wearer has undergone substantial dental work; or if the wearer has developed facial imperfections such as scars, moles around the face seal area etc.

Ensure the FFP respirator is ‘fit checked’. This should be undertaken every time a respirator is worn (see Appendix 1)

Information from Appendix 1 below.

Fit check:

“Always perform a fit check before entering the work area.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). The Control of Substances Hazardous to Health (COSHH) - Approved Code of Practice and guidance. 6th ed. 2013. ISBN: 9780717665822.	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

This document contains the “Approved Code of Practice (ACOP) to the Control of Substances Hazardous to Health Regulations 2002 (as amended) (COSHH) and covers all substances to which the Regulations apply.” “The ACOP describes the preferred or recommended methods that can be used (or the standards to be met) to comply with the Regulations and the duties imposed by the Health and Safety at Work etc Act 1974 (HSW Act). The accompanying guidance also provides advice on achieving compliance, or it may give information of a general nature, including explanation of the requirements of the law, more specific technical information or references to further sources of information.”

ACOP:

“In selecting and providing suitable RPE, consider:

Assessment of evidence
• … Fit testing will need to be repeated when there is any change in equipment or the facial characteristics of the wearer that could affect the fit. “

Question 7: What if a fit test or fit check is unsuccessful?

Evidence added to 2024 update:

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Department of Health Infection Prevention and Control (IPC) National Clinical Guideline No. 30 Last updated: May 2023 Accessed: 03 February 2025	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

Target audience: "This National Clinical Guideline applies to all health and social care workers because the control of healthcare associated infection is everyone's responsibility. It is particularly relevant to Infection Prevention and Control (IPC) Practitioners. IPC Practitioners are those health and social care workers with specific training and expertise in the prevention and control of infection and who provide training, guidance and leadership to others on IPC."

Recommendations:

"If the respirator is not drawn in towards the face, or air leaks around the face seal, readjust the respirator and repeat process or check for defects in the respirator."

Assessment of evidence
“Healthcare workers who have facial hair, including a one to two-day beard growth, must be aware that an adequate seal cannot be guaranteed between the FFP2 respirator and the wearer’s face.” “if a good facial seal cannot be achieved, for example the intended wearer has a beard or long moustache, an alternative respirator such as a powered air purifying respirator should be used”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Caggiari S., Bader D., Packman Z. et al. Retrospective evaluation of factors affecting successful fit testing of respiratory protective equipment during the early phase of COVID-19. BMJ Open, 2023; 13. Doi: 10.1136/bmjopen-2022-065068.	Retrospective cohort study	Level 3	Risk factor: fit test outcome Procedure: qualitative vs quantitative fit test results	Fit test pass or failure	Odds of fit test success (95% CI, p-value)

Assessment of evidence

Setting: England

Study period: July – August 2020

Methodology:

A quality improvement study performed in NHS England, where five FFP3 models were tested according to HSE Qualitative and Quantitative fit test methods (QLFT and QNFT).

Each trust was provided with a Toolkit to collect relevant information about HCWs (demographic information, etc). Facial measurements were also taken however the findings related to these were descriptive so have been excluded. HCWs were fitted with a respirator and tested. Failed results meant that other respirator models were tried until a pass was achieved.

Inclusion criteria: hospital staff working in areas where FFP3 respirators were required.

Main findings:

Odds of successful FFP3 respirator fit was higher for males compared to females (OR 1.51, 95% CI 1.27 – 1.81, $p < 0.05$). White ethnicity had higher odds of successful respirator fit compared to black (OR 0.65, 95% CI 0.51 – 0.83), Asian (OR 0.62, 95% CI 0.52 – 0.74), and mixed (OR 0.60, 95% CI 0.45 – 0.79) ethnicities, $p < 0.05$ for all associations. BMI < 18.5 was associated with lower odds of achieving a successful fit compared to all other BMI categories (OR 0.516, 95% CI 0.362 – 0.735; $p = 0.000$).

Limitations:

- Study period only 5 weeks
- Secondary analysis of quality improvement data
- Retrospective study design
- Allocation of FFP3s was not random
- Study limited to 5 FFP3 designs

Assessment of evidence
The findings of this study suggests that a QNFT is more sensitive than a QLFT.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
World Health Organization (WHO). Infection prevention and control in the context of coronavirus disease (COVID-19): a living guideline. https://www.who.int/publications/i/item/WHO-2019-nCoV-ipc-guideline-2023.1 2023. Accessed: 29 October 2024	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

Funding: “The development of the document was provided by the United States Center for Disease Control and Prevention (US CDC), in addition to WHO core funds”

Aim of guidance: “Provides users with the latest evidence-informed recommendations for IPC in health care and community settings.” It “guides decision makers and IPC professionals to develop and implement policies on mask use in health care and settings”.

Target audience: “Policy and decision-makers, public health professionals, IPC professionals at the national and facility levels, health care facility administrators, managers and other health workers.”

Health workers in this document are defined as “people primarily engaged in actions with the primary intent of enhancing health. This includes health service providers, such as doctors, nursing and midwifery professionals, public health professionals, technicians (laboratory, health, medical, and non-medical), personal care workers, healers, and practitioners of traditional medicine. It also includes health management and support workers, such as cleaners, drivers, hospital administrators, district health managers, social workers and other occupational groups in health-related activities. This group includes those who work in acute care facilities and long-term care, public health, community-based care and other occupations in the health and social care sectors.”

Recommendations:

“Ensure a range of FFR sizes are available to accommodate different face shapes and sizes, especially for those with small faces.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Australian Government National Health and Medical Research Council (NHMRC)	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Australian Guidelines for the Prevention and Control of Infection in Healthcare 2019 (revised 2024, v11.24) Accessed 11 October 2024					

Assessment of evidence

Funding: Guidance was co-funded by the NHMRC and Medical Research Council and Australian Commission on Safety and Quality in Health Care.

Aim of guidance (page 20): “By assisting healthcare workers to improve the quality of the care they deliver, these Guidelines aim to promote and facilitate the overall goal of infection prevention and control: the creation of safe healthcare environments through the implementation of evidence-based practices that minimise the risk of transmission of infectious agents.”

Target audience (page 20): “The Guidelines are for use by all those working in acute health care settings —this includes healthcare workers, management and support staff. As some of the principles and recommendations described in this guideline may be applicable to other health care settings, individuals working in other health care settings may also find the guidelines useful.”

The introduction states that all recommendations are based on systematic reviews, however there is insufficient evidence within the guidance to support this claim.

Assessment of evidence

Note: P2 respirators meet the relevant Australian standard (AS/NZS 1716:2012 and 1715:2009) and differs to NIOSH, which specifies N95 respirators.

Recommendations:

“If a good facial seal cannot be achieved (e.g. the intended wearer has a beard or long moustache), an alternative respirator such as a powered air-purifying respirator (PAPR) should be used” This consideration is based on one citation [Citation 176]:

Coia JE, Ritchie L, Adisesh A, Booth CM, Bradley C, Bunyan D, et al. : Guidance on the use of respiratory and facial protection equipment. Journal of Hospital Infection 2013;85 170-182 Journal Website

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
American Society of Anaesthesiologists (ASA), Anaesthesia Patient Safety Foundation (APSF), American Academy of Anaesthesiologist Assistants (AAAA) and American Association of Nurse Anaesthetists (AANA)	Position Statement	4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Revised: The Use of Personal Protective Equipment by Anaesthesia Professionals during the COVID-19 Pandemic. 2020. Accessed: 17th November 2022					
Assessment of evidence					
Position statement for the safety of anaesthesia professionals in the context of the COVID-19 pandemic in the USA. "PAPRs should be used by individuals who are not N95 fit-tested, have facial hair, or fail N95 fit-testing."					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Australian Government Infection Prevention and Control Expert Group.	Expert opinion	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Guidance on the use of personal protective equipment for health workers in the context of COVID-19. 2022. Accessed: 28 November 2022					

Assessment of evidence

Guidance endorsed by the Australian Health Protection Principal Committee.

Recommendations developed with advice from the National COVID-19 Clinical Evidence Taskforce Infection and Prevention and Control Panel (IPC Panel).

Consensus recommendations based on the experience of the IPC panel and ICEG members.

“They reflect emerging evidence concerning all potential modes of viral transmission and the increased transmissibility of SARS-CoV-2”

“The recommendations contained in this document describe the minimum national standard for PPE for health workers in the context of COVID-19.”

“Given the variability across and within health care settings, decisions around the use of PPE may require a nuanced and flexible approach, guided by evidence, contextual factors, and consideration of health worker preferences. This guidance is not meant to be exhaustive but aims to supplement detailed guidance available at a state, territory and institutional level.”

Assessment of evidence

Recommendations:

“If a suitable PFR cannot be found, an alternative (e.g., elastomeric or powered air purifying respirators (PAPRs) should be considered.”

“When a PFR is worn with facial hair, an airtight protective seal is difficult to achieve, which may allow infectious airborne particles to leak in and out of the PFR.

- the face must be smooth and/or clean-shaven to achieve a good airtight seal.
- facial hair should be removed or an alternative type of PFR be considered.
- the NSW Clinical Excellence Commission provides resources on beard wrapping techniques.”

“A PAPR may be considered as an alternative to a PFR in some circumstances (e.g., when the fit of a PFR is compromised […])”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE) Fit testing basics. 2022. Accessed on: 7 October 2022.	Expert opinion	Level 4	N/A	N/A	N/A

Assessment of evidence

“If there are good reasons for having a beard (e.g for religious reasons), alternative forms of RPE, that do not rely on a tight fit to the face, are available.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centers for Disease Control and Prevention (CDC). Types of Respiratory Protection. 2019. Accessed: 22 November 2024	Poster	Level 4	N/A	N/A	N/A
Assessment of evidence					
“Loose-fitting PAPRs do not require fit testing and can be used with facial hair.“					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
National Institute for Occupational Safety and Health (NIOSH) Filtering out Confusion: Frequently Asked Questions about Respiratory	Expert opinion	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Protection, Fit Testing. 2018. Accessed: 5 December 2022					

Assessment of evidence

“If you cannot achieve a proper seal due to air leakage, you may need to be fit tested for a different respirator model or size.”

“Research tells us that the presence of facial hair under the sealing surface causes 20 to 1000 times more leakage compared to clean-shaven individuals.4 Gases, vapors, and particles in the air will take the path of least resistance and bypass the part of the respirator that captures or filters hazards out. A common misconception is that human hair can act as a crude filter to capture any particles that are in the airstream between the sealing surface and the user’s skin. However, while human hair appears to be very thin to the naked eye, hair is much larger in size than the particles inhaled. Facial hair is not dense enough and the individual hairs are too large to capture particles like an air filter does; nor will a beard trap gases and vapors like the carbon bed in a respirator cartridge. Therefore, the vast majority of particles, gases, and vapors follow the air stream right through the facial hair and into respiratory tract of the wearer. In fact, some studies have shown that even a day or two of stubble can begin to reduce protection.”

Note: citation 4 in the above text was published in 1988.

“Facial hair that lies along the sealing area of a respirator, such as beards, sideburns, or some mustaches, will interfere with respirators that rely on a tight facepiece seal to achieve maximum protection.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
NHS England Supporting fit testing: steps and actions to be taken where staff may require the use of FFP3 masks Year unknown. Accessed: 20 December 2022	Poster	Level 4	N/A	N/A	N/A

Assessment of evidence
The algorithm below has been produced to help NHS organisations to identify the steps they should take where staff are to be deployed to clinical areas which require FFP3 respirator masks to be worn. It will assist organisations to determine actions required when an individual passes or fails a fit test. See fit testing algorithm via link for more information.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution (BSI) PD ISO/TS 16975-1:2016 Respiratory protective devices: selection, use and maintenance establishing and implementing a respiratory protective device programme. Accessed: 11 July 2023.	Standard	Level 4	N/A	N/A	N/A

Assessment of evidence

Page 24, part of suitability assessment:

“Facial characteristics. The RPD selected shall accommodate the facial characteristics of the wearer, such as deep scars or grooves. Where these facial characteristics prevent a good fit, consider the use of a loose-fitting respiratory interface, which does not rely on a tight seal in this region. Body jewellery which affects the fit shall be removed while wearing the RPD, or a different type of RI may be considered.”

Assessment of evidence

“Hair. No hair comes between the sealing surfaces of a tight-fitting respiratory interface and the wearer’s skin, or interferes with the function of the RPD, e.g. interference with the operation of valves shall not be permitted. Where any hair comes between the sealing surface, the use of loose fitting respiratory interface, which do not rely on a tight seal in this region may be considered.”

Annex D provides detail on methods for suitability assessment (page 49):

Supplemental information to ensure that the wearer uses RPD in line with instructions and training, reports damage/defects and physical/medical limitations or changes impacting ability to wear the RPD correctly (page 5)

Facial characteristics of the wearer: “Facial characteristics have to be considered within the suitability assessment because fit will impact the overall protection provided by the RPD. Facial characteristics which are surface-related, such as scarring, wrinkles, jewellery or unshaven hair can significantly affect the protection offered by some tight-fitting RPD. In these cases, loose-fitting respiratory interfaces may be more suitable. In this context, unshaven means hair which has not been shaved within the previous 8-hour period prior to the work shift, since studies have shown that even less than one day’s growth can dramatically increase face seal leakage. Tight-fitting respiratory interfaces will not provide the expected protection unless they fit the contours of the wearer’s face properly and securely….. If a successful fit test cannot be achieved, alternative tight-fitting respiratory interfaces should be assessed or a loose-fitting respiratory interface should be selected.”

Corrective lenses

Spectacles: “The use of corrective spectacles can interfere with the protection offered by many types of RPD. Where corrective spectacles are required, they should be of a design which is compatible with the RPD. Spectacles may be available (as an accessory from the RPD manufacturer) which fit completely inside the respiratory interface without breaking the face seal. Alternatively, an RPD which allows use of the corrective spectacles can be selected, e.g. loose-fitting RPD. Advice on this aspect should be sought from the RPD manufacturer.”

Contact lenses: “Contact lenses may be used where the wearer has successfully worn contact lenses before and practiced wearing them with the RPD. An assessment should be made as to whether the wearer can use contact lenses with his RPD.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). COSHH essentials: Respiratory protective equipment. UK Standard Assigned Protection Factor 4 (APF 4) Supplementary advice, 2006a. Accessed: 15 February 2022	Expert opinion	Level 4	N/A	N/A	N/A

Assessment of evidence
This supplementary advice provided by HSE states “This information will help employers comply with the Control of Substances Hazardous to Health Regulations 2002 (COSHH), as amended, to control exposure to chemicals and protect workers’ health.” “Using RPE The RPE needs to fit the person. If the RPE depends on a face seal, it won’t work if the worker has face hair or stubble.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). COSHH essentials:2 Respiratory protective equipment. UK Standard Assigned Protection Factor 10 (APF 10) Supplementary advice, 2006b. Accessed: 15 February 2022	Expert opinion	Level 4	N/A	N/A	N/A
Assessment of evidence					
This supplementary advice provided by HSE states “This information will help employers comply with the Control of Substances Hazardous to Health Regulations 2002 (COSHH), as amended, to control exposure to chemicals and protect workers’ health.” “Using RPE The RPE needs to fit the person. If the RPE depends on a face seal, it won’t work if the worker has face hair or stubble.”					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). COSHH essentials: Respiratory protective equipment. UK Standard Assigned Protection Factor 20 (APF 20) Supplementary advice, 2006c. Accessed: 15 February 2022	Expert opinion	Level 4	N/A	N/A	N/A

Assessment of evidence
This supplementary advice provided by HSE states “This information will help employers comply with the Control of Substances Hazardous to Health Regulations 2002 (COSHH), as amended, to control exposure to chemicals and protect workers’ health.” “Using RPE The RPE needs to fit the person. If the RPE depends on a face seal, it won’t work if the worker has face hair or stubble.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive. COSHH essentials: Respiratory protective equipment. UK Standard Assigned Protection Factor 40 (APF 40) Supplementary advice. 2006d. Accessed: 15 February 2022	Expert opinion	Level 4	N/A	N/A	N/A

Assessment of evidence
This supplementary advice provided by HSE states “This information will help employers comply with the Control of Substances Hazardous to Health Regulations 2002 (COSHH), as amended, to control exposure to chemicals and protect workers’ health.” “Using RPE The RPE needs to fit the person. If the RPE depends on a face seal, it won’t work if the worker has face hair or stubble.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centers for Disease Control and Prevention (CDC) How to Use Your N95 Respirator. 2022. Updated 16May 2023. Accessed: 29th October 2024	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

Detailed in donning process for N95 respirator – fit check:

“Your N95 must form a seal to your face to work properly. Your breath must pass through the N95 and not around its edges. Jewellery, glasses, and facial hair can cause gaps between your face and the edge of the mask. The N95 works better if you are clean shaven. Gaps can also occur if your N95 is too big, too small, or it was not put on correctly.”

“If you cannot get a tight seal, try a different size or style. Even if you cannot get the N95 sealed against your face, it will provide protection that is likely better than a cloth mask.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
European Centre for Disease Prevention and Control (ECDC) Guidance for wearing and removing personal protective equipment in healthcare settings for the care of patients with suspected or confirmed COVID-19. 2020. Accessed: 14 December 2022	Guidance	**Level 4**	N/A	N/A	N/A

Assessment of evidence
"**Scope of this document** This document provides support to healthcare workers managing suspected or confirmed cases of novel coronavirus 2019 (COVID-19). The general objectives of the document are:

Assessment of evidence
• to present the minimal set of personal protective equipment (PPE) required for managing suspected or confirmed COVID-19 cases; • to make healthcare workers aware of the critical aspects of the donning and doffing of PPE; and • to strengthen occupational safety in healthcare workers for patients suspected of, or confirmed with, COVID-19. • This document is based on current COVID-19 knowledge and PPE best practices. ECDC will update this document based on the evolving situation and if new relevant information arises. **Target audience:** Healthcare workers and infection prevention and control personnel in EU/EEA countries and in the United Kingdom." "If you cannot achieve a proper fit, position the straps crosswise. However, this minor modification could imply a deviation from the recommendations in the manufacturer's product manual"

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Milosevic, M., Biswas RK. and Innes, L. et al. P2/N95 filtering facepiece respirators: Results of a large-scale quantitative mask fit testing program in	Single cohort study (Australia) (n = 6441 participants)	Level 3	Risk factor: The ability of particulate fluid filtering facepiece respirators (FFRs) to fit HCWs	Age, sex and FFR model	Fit pass/failure rate (%) Note: "A trial was considered a pass provided there was at least 1 successful fit test within a trial,

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Australian health care workers. American Journal of Infection Control; 2021; 50; 509-515.					even when other fit tests failed.”

Assessment of evidence

Methodology:

HCWs initially performed fit testing according to the quantitative OSHA 29CFR1910.134 standard protocol (See Ref XX. OSHA 1910.134), which requires a pass level fit factor (FF) of ≥ 100. From March 2021, authors state an ‘equivalent modified’ protocol was adopted for efficiency: fit testing was performed using a Portacount Pro+ Respirator Fit Tester 8038 by operators who had formal training. Several brands were tested (including duckbill and cup style).

Main findings:

N = 6441/11,550 (55.8%) fit tests passed. 93.3% (n = 5868) HCWs had successful fit tests for at least one of the FFRs available.

55% CWs passed the first model, 21% required 2, 14% required 3 and 9% required 4 or more models to achieve a fit test pass.

Fit testing pass rates were significantly associated with age, sex and FFR model (p <0.001 for all associations)

Logistic regression results:

Age:

HCWs aged 18 – 29 had highest odds of passing a fit test (58.9%, OR = 1). Compared to this age group, odds of passing a fit test trial was 0.79 (95% CI 0.79 – 0.88, p < 0.001) for ages 30 – 39, 0.77 (95% CI 0.68 – 0.88, p < 0.001) for ages 40 – 49, 0.78 (95% CI 0.69 –

Assessment of evidence

0.91, p 0.001) for ages 50-55. Odds for passing fit tests for ages 60+ were not significant when compared to the 18 – 29 age group (0.88 (95% CI 0.77 – 1.01, p = 0.073)).

Sex:

Compared to females, males had significantly lower odds of passing fit tests (OR 0.85, 95% CI 078-0.93), p < 0.001l; 59.9% pass rate for females vs 48.1 pass rate for males).

Logistic regression results according to FFR brand are outside the scope of the RPE systematic review.

Assessment of evidence:

This study demonstrates that fit test pass/failure rates are significantly associated by HCW age and sex, as well as brand/model. For this reason, multiple respirator brands should be available for HCWs within a health or care setting.

Limitations:

- Results would have benefited to stratifying FFRs according to duckbill vs cup-style, rather than by model/brand.
- Unclear how participants were recruited
- Study performed in Australia, where the brands/styles use may not be available in NHS Scotland. Authors also state that manufactures alter names of FFR models according to country, again limited generalisability and applicability of findings.
- Factors that may affect fit test pass and failure rates, e.g. training, assistance when donning, facial anthropometrics, HCW race, HCW weight were not considered.
- OSHA fit test regulations and modified guidance used. These differ to ISO regulations relevant in NHS Scotland.

This provides evidence to support that multiple respirator models should be available for fit tests in case of initial fit test failure. It also demonstrates that fit test results may be affected by age and sex.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Sandaradura I, Goeman E, Pontivivo G, et al. A close shave? Performance of P2/N95 respirators in health care workers with facial hair: results of the BEARDS (Adequate Respiratory Defences) study. Journal of Hospital Infection. 2021; 104(4); 529-533. Doi: 10.1016/j.jhin.2020.01.006.	Single cohort study (105 male HCWs)	Level 3	The fit of standard FFR among a cohort of hospital-based male HCW was examined.	Fit according to various demographic and other covariates. Facial hair was categorised as follows: 0 – clean shaven 1 – light stubble 2 – medium to heavy stubble 3 – full beard 4 – other (e.g. moustache without beard, goatee, sideburns)	Adequate fit (n, %) defined as an overall fit factor of 100, as required for an N95 according to OSHA.

Assessment of evidence

Methodology:

Facial photographs of fit-testing participants were made and examined. Disposable 3M® Flatfold 1870 Health Care Particulate N95 FFR Respirators (3M, St Paul, MN, USA) were chosen. Quantitative fit testing was performed using a Portacount Pro+ Respirator Fit Tester 8038, according to US standards (29CFR1910.134) and manufacturer instructions.

Assessment of evidence

Respirators were fitted with a sampling port (for the Portacount) prior to donning. Each participant was provided instruction on respirator usage. Once donned, the investigators visually assessed fit and the participants performed a respirator seal check (by gently exhaling and inhaling) and rated their perception of fit as satisfactory or unsatisfactory.

The testing protocol was 8-minutes including 7 cycles: normal breathing, deep breathing, talking, and movements such as head turning side-to-side, head nodding up and down, and bending over.

Main findings:

Beard category (n, %) (p = 0.001)

0. (clean-shaven) fit testing: [fail] 20 (28%), [pass] 18 (53%)
1. (light stubble) fit testing [fail] 12 (17%) [pass] 8 (24%)
2. (heavy stubble) fit testing [fail] 15 (21%) [pass] 6 (18%)
3. (full beard) fit testing [fail] 20 (28%) [pass] 0
4. (miscellaneous) 4 (6%) [pass] 2 (6%)

Relative to those who were clean shaven, the odds for a respirator fit pass was 0.74 (95% CI 0.21-2.52, p = 0.08) for those with light stubble, 0.45 (95% CI, 0.12 to 1.57, p=0.26) for participants with moderate to heavy stubble and 0.04 ([95% CI, 0 to 0.28, p<0.001) for participants with full beards. Odds were non significant for those with facial hair in the miscellaneous category (OR 0.56, 95% CI, 0.05 to 4.48, p=0.85).

After excluding those in the misc. category, there was a significant trend towards less frequent fit with increasing beard length (p for trend = 0.0003)

All other covariates were non-significant.

Assessment of evidence

Assessment of evidence:

In this cohort, fit factor using one N95 respirator model was significantly lower for those with varying degrees of facial hair. There was a significant trend towards less frequent fit pass rates with increasing beard length.

Limitations:

- Only one N95 respirator model used
- They did not test-retest reproducibility
- No control group
- No measurements over time
- Single study site in Australia
- Survey used to gather data on factors such as facial shape, which is subjective. Survey data is also subject to recall bias

This study suggests that individuals who cannot adequate fit due to facial hair may consider being clean shaven. However, this study should be considered as part of a wider evidence base given its limitations.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Green, S., Gani, A., Bailey, M., et al. Fit-testing of respiratory protective equipment in the UK during the	Retrospective cohort study	Level 3	Risk factor: Outcome of mask fit testing across NHS hospitals	FFP3 brand/model	Primary outcome: RPE fit-test failure rates among mask types

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
initial response to the COVID-19 pandemic. The Journal of hospital infection. 2021; 113; 180–186. https://doi.org/10.1016/j.jhin.2021.04.024					Secondary outcomes (%): • Gender failure rates • Mask specific gender failure rates • Ethnicity failure rates • Mask types frequently used • Overall failure rates if data was provided by hospital

Assessment of evidence

Main findings:

Fit-failure rate according to gender was provided by 7 hospitals. 19.98% of 4863 males failed fit tests vs 19.89% of 17,920 females (p = 0.398).

Fit-failure rate according to gender, stratified according to FFP3 model/brand was provided by 1 hospital. Overall fit failure rate at this site 24.70% (61/247) versus 35.05% (225/642) failure rate for men and women, respectively (p = 0.002).

Fit failure rate according to ethnicity was provided by 4 hospitals. Fit-failure rate was higher for BAME staff (25.69%, n = 644/2507) versus non-BAME staff (16.83%, 2265/13,456), p < 0.001.

Assessment of evidence

Assessment of evidence:

In this retrospective cohort study assess FFP3 fit-test failure data across UK hospitals, fit failure rates were compared according to gender and ethnicity.

Overall fit-failure rates were not significantly different according to gender using data collected from 7 hospitals. One hospital provided fit-failure rates according to gender and found failure rates were significantly higher for females when compared to males ($p = 0.002$).

Data on fit-failure rates according to ethnicity was provided by 4 hospitals. Fit failure rate was significantly higher for BAME staff when compared to non-BAME staff ($P<0.001$).

Limitations:

- Details on BAME healthcare staff not given for example race, country of origin therefore findings should be generalized with caution
- Authors mention that analysed data only included binary genders but not non-disclosed/non-binary genders
- Ethnicity specific data on fit failure was collected from only 4 hospitals, therefore may not be representative of the general healthcare staff of UK hospitals. Furthermore, data regarding ethnicity was stratified according to BAME versus non-BAME staff, further limiting generalisability of the findings.
- Gender failure data according to mask type was provided by one hospital therefore may not be representative of the general healthcare staff population among UK hospitals
- Hospitals from which data was collected from were not listed or given, therefore difficult to know if hospitals were distributed across the country
- Authors highlight that there were unable to determine if bank staff worked in more than one hospital and therefore accounted for more than one data point
- Fit pass rates limited to FFP3 respirators, limiting generalisability to other respirator types.

Assessment of evidence

- Proportions of males and females were substantially different, which may have affected fit test scores according to gender. Authors state information on male:female pass rates were provided by eight hospitals, then state in the same paragraph that this information was provided by seven hospitals.
- Distribution of fit test methods for sub-group analysis according to gender/ethnicity not provided.

This study relates to the research question, 'What if a fit test or fit check is unsuccessful?' highlighting that BAME staff members may experience higher fit-failure rates when compared to non-BAME staff. However, the findings should be generalized with caution given the limitations of the study and lack of information on the reasons for fit failure.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Wilkinson, I. J., Pisaniello, D., Ahmad, J., et al. Evaluation of a large-scale quantitative respirator-fit testing program for healthcare workers: survey results. Infection control and hospital epidemiology. 2010;	Cross-sectional observational study (n = 6160)	Level 3	Fit of P2 respirators	N/A	Fit factor score > 100

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
31(9), 918–925. https://doi.org/10.1086/655460.					

Assessment of evidence

This cross-sectional observational study evaluated the fit of five P2 respirator models across HCW staff in ambulatory care, home nursing care and acute hospitals across South Australia over a 7-month period. No statistically significant difference was noted in the pass and failure rates between men and women. However, statistically significant differences in failure rates were observed between occupational categories (P=0.007) and between racial groups (P = 0.011).

Limitations:

- Authors mention that racial groups were not evenly distributed among occupational categories therefore results should be generalized to other groups with caution
- The convenience/opportunistic nature of the study means that there is a likelihood of bias
- No anthropometric measurements were taken therefore results are not based on accurate facial configurations therefore inferences about the relative pass-fail rate of the various models of respirator should not be made from these data
- No prescribed method of respirator selection, subjects were not tested with each of the available respirator models
- Authors also mention that they are unsure of how many people who required additional testing attended
- Source of bias: use of the risk matrix to select subjects for fit testing
- Unclear if missing data meant that both the tester and subject did not complete questionnaire, or 1 of 2 did not complete questionnaire

Assessment of evidence
This study demonstrates that fit test pass rates of the P2 respirators may be significantly associated with race and facial characteristics. This suggests that there should be mitigation measures in case of fit test failure.

Evidence from previous update(s):

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). Respiratory protective equipment at work: A practical guide. HSG53 (4th Ed.) 2013. ISBN: 978 0 7176 6454 2.	Expert opinion	Level 4	N/A	N/A	N/A

Assessment of evidence
About this guidance: This guide prepared by the HSE “in consultation with industry: employers, trade unions and trade associations”, is stated to support “the Approved Code of Practice (ACOP) to the Regulations that apply (see paragraphs 36–39)”. “The guide contains practical guidelines to help you select the correct RPE and manage its use in your workplace to ensure effective protection.”

Assessment of evidence

“As an employer, you have a legal responsibility under all the Regulations listed in paragraphs 36–39”

Taken from table 3, suitability factors to consider:

“Higher breathing rates can cause contaminants to leak in, and sweating can cause facepieces to slip and leak.”

“Facial hair and markings

Affects where a face mask seals to the face and will cause leakage.

1 Beard, stubble or any hair in the region where a face mask seals; 2 Deep cuts or scars, wrinkles, moles, warts present in the face seal area

Consider the use of loose-fitting facepieces, which do not rely on a tight seal in this region”

“Spectacles

Spectacles with side arms are incompatible with full face masks as they break the face seal and they may also interfere with the fit of half masks.

RPE manufacturers can supply special frames, which fit inside their masks. It is the responsibility of the employer to find and provide an appropriate solution.”

“Contact lenses

Wearers may suffer discomfort or, if the lenses are dislodged, the wearer may remove the RPE to replace them while still in the hazardous area.*

Use spectacles (in mask if necessary) instead”

“The performance of tight-fitting facepieces depends on achieving a good contact between the wearer’s skin and the face seal of the facepiece. People’s faces vary significantly in shape and size so it is unlikely that one type or size of RPE facepiece will fit everyone. Inadequate fit will significantly reduce the protection provided to the wearer. Any reduction in protection can put the RPE wearer’s life in danger or may lead to immediate or long-term ill health.”

Assessment of evidence
“The wearer needs to be clean-shaven around the face seal to achieve an effective fit when using tight-fitting facepieces […] If workers have beards, or are unable to be clean-shaven, a tight-fitting device will not be suitable so an appropriate loose-fitting device should be chosen.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). Guidance on respiratory protective equipment (RPE) fit testing (INDG479). 2019. ISBN: 9780717667062.	Expert opinion	Level 4	N/A	N/A	N/A

Assessment of evidence
This guidance is stated as “not compulsory and you are free to take other actions to comply with the requirements of the law”. “If it is not possible for the wearer to obtain an adequate fit with the first choice of facepiece you should attempt fit testing using an alternative make, model or size of tight-fitting facepiece. Where you cannot achieve an adequate fit you should select another type of RPE that does not rely on a tight-fitting face seal, such as a loose fitting respirator hood or helmet.”

Assessment of evidence
“If after two fit tests the result is still a fail, an alternative facepiece should be tried.” “If they cannot wear the PPE properly without affecting the function of the RPE or vice versa, choose alternative PPE.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
World Health Organization (WHO). Infection prevention and control of epidemic-and pandemic prone acute respiratory infections in health care. 2014. Accessed: 24 January 2023	Guidance	AGREE: Recommend (with provisos)	N/A	N/A	N/A

Assessment of evidence
Funding: “Financially supported by the United States Centers for Disease Control and Prevention (CDC), the United States Agency for International Development (USAID), the German Agency for International Cooperation (GIZ), and the French Ministry of Social Affairs and Health”

Assessment of evidence

Aim of guidance: “The guidance is intended to help policy-makers, administrators and health-care workers to prioritize effective IPC measures”

Target audience: “Recommendations, best practices, and principles for non-pharmacological aspects of infection prevention and control (IPC) for acute respiratory infections (ARI) in health care” intended for policy-makers, administrators and health-care workers, including doctors, nurses, allied health professionals, auxiliary and community health workers, and others involved in provision of health care.

“The development of the guidelines followed the process established in the WHO handbook for guideline development, which involved active participation of the Global Infection Prevention and Control Network (GIPCN). The resulting recommendations were peer reviewed by internal and external experts.” This guidance is deemed expert opinion as it is unclear the edition of the “WHO handbook for guideline development” that was used. Further to this, the elements of the systematic review process, such as the search strategies, are not provided.

“Facial hair impedes good fit, and a seal may not be achieved, decreasing the efficiency of the particulate respirator. Health-care workers with facial structure abnormalities also may be unable to obtain a good seal and need alternative approaches for respiratory protection.” (No reference given in the document)

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution (BSI) BS ISO 16975-3:2017	British Standard	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Respiratory protective devices - Selection, use and maintenance Part 3: Fit-testing procedures. Accessed: 12 July 2023.					

Assessment of evidence

General fit-test considerations are described (page 5):

Selecting RPD

“No one size or model of RPD can be expected to fit all faces. Different sizes and models will accommodate more individuals. If fit is unsatisfactory, a different model or size of RI should be selected and the test repeated. Therefore, an appropriate number of sizes and models to accommodate the wearers shall be made available. Factors that should be considered in determining the number of RPD to be made available include the number of wearers and wearer acceptance.

If there is no make or model of tight-fitting RI to be found that fits satisfactorily, other RPD alternatives should be considered. Changing the model or size of potentially-interfering PPE may also be considered. Fit-test operators shall not force-fit the RPD being fit tested but should inspect to make sure that there were no donning issues that might compromise the seal. Offering a reasonable assortment of RPD types and/or sizes should eliminate the inclination to force-fit.

“Repeat fit testing can be accomplished on the same make, model, style and size RPD without repeating the selection process if the wearer still finds that RPD acceptable. If fit testing shows that a person can obtain an acceptable fit with two or more models of the

selected class of RPD, then the person should be permitted to use their preferred RPD model, provided that it is adequate and suitable for the intended use"

Interference concerns:

Facial hair – "Skin contacting respiratory-interface sealing surfaces shall be shaved within 24 h of testing, preferably within 12 h. A person shall not be fit tested if:

a) hair comes between the sealing surface of the RI and the face or neck;

and b) hair interferes with valves and/or RPD function."

Foreign material – "A fit test shall not be conducted if there is any foreign material or substance between the sealing surface of the respiratory interface and the face or neck. Examples include temple bars or straps for eyewear, gels and creams."

Other conditions – "The fit test should be conducted with the RPD worn in the manner in which it is used. Not every individual may be able to obtain a satisfactory fit.", guidance for those with dentures are provided

Facial characteristics of the wearer: "Facial characteristics which are surface-related, such as scarring, wrinkles, jewellery or unshaven hair can significantly affect the protection offered by some tight-fitting RPD. In these cases, loose-fitting respiratory interfaces may be more suitable. In this context, unshaven means hair which has not been shaved within the previous 8-hour period prior to the work shift, since studies have shown that even less than one day's growth can dramatically increase face seal leakage. Tight-fitting respiratory interfaces will not provide the expected protection unless they fit the contours of the wearer's face properly and securely. Where this type of RPD is selected for use, a fit test should be conducted to ensure that the RPD will fit the wearer correctly."

Fit-testing procedures:

"A fit test shall not be conducted if there is any hair growth such as beard stubble, beard, moustache or long sideburns, any jewellery or other article of clothing that cross between the face or neck and the sealing surface of the tight-fitting RPD."

Selecting RPD:

"If fit is unsatisfactory, a different model or size of RI should be selected and the test repeated."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution (BSI) BS EN 529:2005 Respiratory protective devices — Recommendations for selection, use, care and maintenance. Guidance document. Accessed: 11 July 2023.	British Standard	Level 4	N/A	N/A	N/A
Assessment of evidence					
“Facial characteristics such as scarring or unshaven facial hair can significantly affect the protection offered by some devices. This will particularly be true for devices such as half and full face masks which rely on a tight face seal to achieve protection. These devices should not be selected where there is unshaven hair or an irregular facial feature in the area of the face seal. In this context unshaven means hair which has not been shaved within the previous 8 h period prior to the work shift, since studies have shown that even less than 1 day’s growth can dramatically increase face seal leakage. Devices which rely on a tight face seal will not provide the expected protection unless they fit the contours of the face properly and securely. Where this type of device is intended an assessment should therefore be made to check that the intended device will fit the individual					

Assessment of evidence

correctly. Possible methods of fit checking and fit testing are described in Annex E. If the fit cannot be determined as adequate, devices not relying on a tight face seal such as hoods, helmets and suits may need to be considered." (pages 43-44).

Spectacles:

"The use of standard prescription spectacles will interfere with the protection offered by many types of devices, particularly full face masks. Where prescription spectacles are required, they should be of a design which is compatible with the full face mask. Designs are available which fit completely inside the mask without breaking the face seal. Alternatively, a respiratory protective device which allows use of the standard spectacles can be selected, e.g. certain compressed air line or powered filtering devices incorporating hood or helmet. Advice on this aspect should be sought from the respiratory protective device manufacturer."

Non-PPE:

"Certain accessories worn for religious or personal reasons may interact with respiratory protective devices reducing protection or causing additional risks. Examples could include wrist or fob watches, necklaces, scarves, bracelets or bangles, turbans or other headgear, earrings or other body piercing jewellery. Cellular telephones, pagers or bunches of keys carried on the person could also cause problems. If these items cannot for any reason be removed for the duration of the device use, selection of a suitable device will need to include an assessment of any possible interaction with the personal items. Most critically, the device selected should not catch on any personal items when being donned, worn or removed. There should be no interference with any face, neck, wrist or waist seal and the normal air flow of the device should not be impeded in use. Any discomfort caused by interaction may tempt the wearer to remove or interfere with their respiratory protective device reducing protection."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Occupational Safety and Health Administration (OSHA). 2009. Guidance on Preparing Workplaces for an Influenza Pandemic. OSHA 3327-05R. Accessed: 15 December 2022.	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence
Guidance document produced by The Occupational Safety and Health Administration is an agency of the United States Department of Labor. Influenza pandemic guidance. “It should also be noted that there are hooded PAPRs that do not require employees to be fit tested in order to use them.” i.e. for those with facial hair

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Coia J. E., Ritchie L., and Adisesh, A. et al. Guidance on the use of respiratory and facial protection equipment. Journal of Hospital Infection. 2013; 85;170-182; doi: 10.1016/j.jhin.2013.06.020.	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

Best practice guidance based on a non-systematic literature review published separately (Bunyan D, Ritchie L, Jenkins D, Coia JE. Respiratory and facial protection: a critical review of recent literature. J Hosp Infect 2013;85:165e169).

“The Scientific Development Committee of the Healthcare Infection Society established a short-life working group in May 2011 to develop appropriate guidance. The working group included representation from the Healthcare Infection Society, Public Health England, Health and Safety Executive (HSE), Association of National Health Occupational Physicians, Health Protection Scotland, Infection Prevention Society, Intensive Care Society, Clinical Virology Network and British Infection Association.”

A good fit can only be achieved if the area where the respirator seals against the skin is clean shaven. Beards, long moustaches and stubble may cause leaks around the respirator. Other types of RPE (e.g. powered hoods and helmets) are available and should be considered if a good fit cannot be achieved with disposable respirators. A powered respirator might be the only type suitable for some HCWs.”

“If a good fit cannot be achieved, try another size or design of FFP3.”

Question 8: When should RPE be worn by health and care staff?

Evidence added to 2024 update:

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The Scottish Government DL (2022) 10 Last updated: 19 April 2022 Accessed: 20 November 2025	Directorate Letter (guidance)	Level 4	N/A	N/A	N/A
Assessment of evidence					
"With this in mind, Infection and Prevention Control (IPC) managers do not have a role in the process to allow staff access to an FFP3 mask, if it is being done on the basis of their own personal choice. Rather, an individual risk assessment should be carried out by the line manager, in line with current guidance and with consideration of the staff member's overall health, safety, physical and psychological wellbeing, as well as personal views/concerns about risks. This guidance also clarifies the process and risk assessments for FFP3 masks for health and social care staff in the following circumstances: DL (2022) 10 19 April 2022 Addresses For action Chief Executives NHS Boards and Local Authorities, NHS Chairs, Human Resource Directors, NHS Nurse Directors, NHS Medical Directors, Registered care home providers (adults and older people), Registered care at home providers, Supported housing providers. For information Infection Control Managers, Public Health Directors, Employee Directors, Workforce Senior Leadership Group, Chief Officers Health and Social Care Partnerships, Chief Social Work Officers, ARHAI Scotland, Public Health Scotland, Care Inspectorate,					

Assessment of evidence
Scottish Care, CCPS, COSLA. Enquiries to: Scottish Government Directorate for Health Workforce St. Andrew's House Regent Road Edinburgh EH1 3DG E-mail • When performing an Aerosol Generating Procedure (AGP). • When working in the respiratory pathway in a clinical area deemed as having an unacceptable risk of transmission following rigorous application of the Hierarchy of Controls and there is no other suitable area for placement of these patients. In summary there are now three processes for staff accessing FFP3 masks. These differ depending on the circumstance and staff and line managers should make themselves familiar with the processes. The three are: • When undertaking an AGP in a respiratory pathway (as before). • When undertaking an AGP in a non-respiratory pathway and the staff member has concerns about potential COVID-19 exposure to themselves (as before). • Based on a staff member's personal preference (new)"

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centres for Disease Control and Prevention (CDC) The National Personal Protective	British Standard	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Technology Library (NPPTL) The Respiratory Protection Information Trusted Source. Healthcare Setting Specific FAQs. Last updated: 5 July 2022 Accessed: 6 January 2025					

Assessment of evidence

“Can I use an N95 respirator between different Operating Room (OR) cases or from patient to patient?

Respirators can become contaminated after each use. Ideally, you should discard used respirators after each patient encounter. When worn during aerosol-generating procedures, discard disposable N95 respirators after the procedure.

Healthcare facilities can extend the use of disposable N95 respirators by training personnel on extended use of respirators. This includes training on wearing them during consecutive patient encounters without removing or re-donning between encounters.

[…]

Is cross contamination a concern if I wear the same N95 from patient room to patient room?

Assessment of evidence
Yes, especially if you wear a respirator in a room with any type of aerosol-generating procedure. Or if your patient has a suspected or confirmed case of an infectious disease.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Department of Health Infection Prevention and Control (IPC) National Clinical Guideline No. 30 Last updated: May 2023 Accessed: 03 February 2025	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence
Target audience: “This National Clinical Guideline applies to all health and social care workers because the control of healthcare associated infection is everyone’s responsibility. It is particularly relevant to Infection Prevention and Control (IPC) Practitioners. IPC Practitioners are those health and social care workers with specific training and expertise in the prevention and control of infection and who provide training, guidance and leadership to others on IPC.”

Assessment of evidence

Recommendations:

“When there is a high probability of airborne transmission due to the infectious microorganism or procedures performed on infectious people (for example bronchoscopy on a patient with suspected or confirmed infection) sound scientific principles support the use of fit-tested and fit-checked FFP2 respirators to prevent airborne transmission.” References not provided.

“Wear correctly fitted and fit checked respiratory protection (FFP2 respirator) when entering the patient-care area when an airborne-transmissible infectious microorganism is known or suspected to be present and when entering the patient care area where AGPs associated with an increased risk of infection are performed on people with known or suspected infectious microorganisms normally transmitted by the droplet route.” “Strong recommendation, weak evidence” Routine care: FFP2 respirator required for airborne precautions

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Association for Professionals in Infection Control and Epidemiology (APIC) Guide to Preventing Clostridium difficile infection. Last updated: 2013	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Accessed: 07 January 2025.					
Assessment of evidence					
“During aerosol-generating procedures on patients with suspected or proven infections transmitted by respiratory aerosols (e.g., severe acute respiratory syndrome [SARS]), wear a fit-tested N95 or higher respirator in addition to gloves, gown, and face/eye protection.”					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Health Security Agency (UKHSA) Investigation and initial clinical management of possible human cases of avian influenza with potential to cause severe human disease. Last updated: 28 February 2024	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Accessed: 07 January 2025.					
Assessment of evidence					
Guidance providing information for health professionals regarding avian influenza. A “correctly fitted FFP3 respirator” should be worn by staff when initially assessing a patient and if the patient meets the case definition.					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
European Centre for Disease Prevention and Control (ECDC) Monkeypox infection prevention and control guidance for primary and acute care settings Last updated: 16 August 2022 Accessed: 07 January 2025.	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence
“Scope: This document provides guidance on infection prevention and control (IPC) measures for primary and acute healthcare settings in the European Union/European Economic Area (EU/EEA) to prevent healthcare-associated transmission of monkeypox (MPX). Target audience: Healthcare workers (HCWs) in general practitioner (GP) offices and primary care clinics as well as HCWs in acute care hospitals and hospital administrators in the EU/EEA.” Patient transportation: transportation should be performed via ambulance where ambulance staff can wear an FFP2 respirator or equivalent. Patient management: An FFP2 or equivalent respirator should be worn by staff caring for suspected or confirmed mpox patients. FFP2 respirator or equivalent should be worn for “environmental cleaning and disinfection of environments exposed to mpx”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
European Centre for Disease Prevention and Control (ECDC) Investigation protocol for human exposures and cases of avian influenza in the EU/EEA. Last updated: 16 December 2023	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Accessed: 07 January 2025.					

Assessment of evidence

Scope: “The objective of this document is to provide guidance for the investigation and control of a potential avian influenza outbreak in humans. Investigation findings can be used to inform risk assessments.”

Target audience: “This protocol provides guidance on how public health authorities in EU/EEA countries can investigate and respond to potential, probable and confirmed human cases of avian influenza. It is intended as a reference for public health authorities in human sectors dealing with surveillance of respiratory viruses. It aims to provide guidance for case investigation, contact tracing and management of individuals – including healthcare workers – who have had contact with human cases of avian influenza and preventive measures.”

Recommendations:

“Recommended PPE include a well-fitted FFP2 respirator (or higher, e.g. FFP3 or PAPR), gown, gloves and goggles, which should be used for prolonged contact in close proximity to the patient, including the performance of aerosol-generating procedures.”

“Healthcare workers treating patients with confirmed AIV infection should monitor every day for signs of illness for 10−14 days following exposure and patients should be managed as a probable case if they develop compatible symptoms during this period. Healthcare workers should wear an FFP2 respirator (or, if unavailable, a surgical face mask) when in contact with other patients or other people for 10−14 days after last exposure. In the event of frequent contact with cases, regular screening of healthcare workers using RADTs and/or RT-PCR can be considered.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Association for Professionals in Infection Control and Epidemiology (APIC) Guide to Infection Prevention in Emergency Medical Services. Last updated: January 2013. Accessed: 07 January 2025	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence
Target audience: Emergency medical professional staff, USA “During aerosol-generating procedures on patients with suspected or proven infections transmitted by respiratory aerosols (e.g., SARS), wear a fit-tested N95 or higher respirator in addition to gloves, gown, and face/eye protection. As part of respiratory etiquette, EMS system responders are advised to wear an approved mask or respirator and eye protection when examining and caring for patients with signs and symptoms of a respiratory infection.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
European Centre for Disease Prevention and Control (ECDC) Considerations for infection prevention and control practices in relation to respiratory viral infections in healthcare settings. Last updated: 6 February 2023 Accessed: 6 January 2025	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

"**Scope:** This document aims to support the development of guidance for healthcare facilities and healthcare providers in the European Union/European Economic Area (EU/EEA) on infection prevention and control (IPC) measures for the management of patients with respiratory tract viral infection in healthcare settings.

Target audience: National public health agencies, healthcare facility administrators, IPC and other professionals developing relevant IPC guidance and healthcare workers in EU/EEA countries."

Assessment of evidence

Recommendations:

“High-risk medical procedures (‘Aerosol-generating procedures’): Several medical procedures have been linked to increased risk of transmission of microorganisms, including respiratory viruses, transmitted through respiratory droplets and aerosols, presumably due to the increased aerosolisation of infectious respiratory secretions. Therefore these procedures require respiratory protection measures [41]. Such procedures are known as aerosol-generating procedures. […] High-risk medical procedures in patients with respiratory viral infections should ideally be performed in a single room and, if possible, in a negative pressure airborne-isolation room. The number of people in the room should be limited to a minimum during such procedures. All those present should wear a well-fitted respirator”

SARS-CoV-2: “Negative RADT or RT-PCR test results for SARS-CoV-2 can also be used to support the decision for discontinuation of transmission-based precautions in patients with COVID-19 [57]. In the event of prolonged RT-PCR positivity for SARSCoV-2 (RNA shedding), high Ct values (≥30) could be used as a proxy of low likelihood of transmissibility, while low Ct values (<24) indicate a higher likelihood of transmissibility, with the caveat that these are not standardised thresholds and differ across laboratories. Wearing a respirator (see 'Definitions') or medical face mask until 10 days after the onset of symptoms or until a negative RADT test is obtained, can be considered as an additional measure.”

“Staff members with confirmed COVID-19 or influenza may return to work in accordance with relevant national advice or five days after the onset of symptoms, resolution of fever or clinical improvement of other symptoms. If feasible for COVID-19 cases, staff should obtain a negative RADT or RT-PCR SARS-CoV-2 test result before returning to work. If no testing is available or recommended, wearing a respirator (see ‘Definitions’) for five more days after onset of COVID-19 symptoms is recommended for health professionals”

“Healthcare workers caring for patients with a respiratory viral infection should apply standard precautions, including appropriate hand hygiene. Wearing a medical face mask is recommended, as a minimum, for contact with patients where there is no close proximity to the patient. For prolonged contact in close proximity to the patient, including the performance of high-risk procedures, a well-fitted respirator (see ‘Definitions’) and eye protection (e.g. goggles) are recommended.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Public Health Wales Infection Prevention and Control Measures for Acute Respiratory Infections (ARI) for Health and social Care Settings - WALES 2024 Version 3.0. Last updated: 2024 Accessed: 06 January 2025	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

"Before undertaking any procedure, staff should assess any likely blood and body fluid exposure risk and ensure PPE is worn that provides adequate protection against the risks associated with the procedure or task being undertaken."

"Airborne PPE (When undertaking or if AGPs are likely) (3) Or if an unacceptable risk of transmission remains following application of the hierarchy of controls (4)": "Single use FFP3 (2) or reusable respirator/powered respirator hood (RPE)"

"(3) Consideration may need to be given to the application of airborne precautions where the number of cases of respiratory infections requiring AGPs increases and patients cannot be managed in single or isolation rooms.

(4) Where a risk assessment indicates it, RPE should be available to all relevant staff. The risk assessment should include e valuation of the ventilation in the area, operational capacity, and prevalence of infection/new SARS-CoV-2 variants of concern in the local area. The

Assessment of evidence
hierarchy of controls can be used to inform the risk assessment. Staff should be provided with training on correct use) links directly to NHSScotland NIPCM.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The National Institute for Occupational Safety and Health (NIOSH) Donning and Doffing PPE: Proper Wearing, Removal, and Disposal. Last updated: October 2022 Accessed: 6 January 2025	Guidance	Level 4	N/A	N/A	N/A
Assessment of evidence					
“What respirator is appropriate when treating active tuberculosis (TB) patients? A NIOSH-approved N95 respirator has the minimum filtration performance required when treating patients with suspected or confirmed TB. When the potential for TB exposure is high (i.e., aerosol-generating procedures), healthcare personnel may need a more protective respirator. For more information, see the CDC’s guidelines for preventing the transmission of TB in healthcare settings.					

Assessment of evidence
[…] Can I use a N95 respirator that is not a surgical N95 respirator in patient settings? It depends on the setting. You can use NIOSH-approved N95 respirators to reduce your exposures to hazardous particulates in a patient setting. However, you should wear NIOSH-approved surgical N95 respirators when working in a sterile field. If you're exposed to high-velocity splashes, sprays, or splatters of blood or body fluids, wear a surgical N95 respirator."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Lai J, Coleman KK, Tai SH, German J, Hong F, Albert B, Esparza Y, Rastogi D, Srikakulapu A, Kalliomäki P, Schanz M. Relative efficacy of masks and respirators as source control for viral aerosol shedding from people infected with SARS-CoV-2: a controlled human	Observational	Level 3	No mask, N95, KN95, surgical mask, cloth mask use for source control	Exhaled breath aerosol	Viral load, defined as fraction of unmasked aerosol detected in masked samples. Source-control factor (similar to established definition for fit factor), defined as the percentage reduction in viral load realised in the environment (%)

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
exhaled breath aerosol experimental study. 2024; 104, 105157.					Relative efficacy of mask/respirator (%), calculated using ration of outward leakage. Exhaled breath aerosols were considered in total (combined) and for coarse (>5 uM) and fine (≤5 uM) aerosol particles.

Assessment of evidence

Setting: University in USA

Methodology:

This controlled human experimental study assessed paired samples (exhalations with and without a mask) from 44/106 participants who had one or more samples positive for SARS-CoV-2. The aim of this study was to analyse the efficacy of various face masks (surgical, cloth, KN95, N95) as source control (through a measure of reduction in total exhaled particles (both fine and coarse), fine particles and coarse particles) for SARS-CoV-2 positive persons.

Assessment of evidence

The study took place un a US university between 2020 and 2022. There were some variations in the methods used depending on the type of mask, activities (speaking the alphabet, shouting and speaking the 'happy birthday' song loudly or breathing) based on symptoms, time the person took part. Generally, participants were asked to undertake speaking or shouting activities with and without a mask for up to 30 minutes. A particle counter (Gesundheit-II (G-II) human exhaled bioaerosol collector) was utilised to measure 'exhaled' particles. Outcomes were measured for total exhaled particles as well as fine (≤5 µm) or coarse (>5 µm) particles. Mask use compared to no mask use and efficacy between types of masks were considered within the analyses. The statistical analysis was based on a sample of 44 and it is not indicated by the authors if this met any conducted power calculation.

Main findings:

44 participants provided 60 same-day paired exhaled breath aerosol (EBA) samples (SARS-CoV-2 detected in at least one sample). Of 44 participants, 16 provided two sample pairs on different days; the rest provided one pair on one day.

Paired samples: "The analysed paired samples included 8 with cloth masks, 26 with surgical masks (25 Kimtech™ M3 and 1 unknown brand), 13 with KN95 respirators (10 Powecom and 3 unknown brands), and 13 with N95 respirators"

Comparison: "Cloth and surgical mask pairs were mainly collected before the emergence of Delta and Omicron and from unvaccinated volunteers. Conversely, most KN95 and N95 pairs were collected during the Delta and Omicron waves from volunteers who had completed the initial vaccination series (fully vaccinated) and/or had received at least one booster dose"

Viral load in exhaled breath aerosols: Note that "Volunteers who provided paired samples for KN95 respirators shed a higher amount of viral RNA when they were not wearing a mask compared to the other three masked groups". When compared to wearing no mask or respirator, wearing cloth masks, surgical masks, KN95 and N95 respirators reduced geometric mean of viral load in total exhaled breath aerosol ($p < 0.05$) in crude analysis.

Source control factors and improvement in source control for viral RNA in total exhaled breath: In paired modelling analysis, all mask/respirator types reduced viral RNA copies in fine, course and total exhaled breath aerosols when compared to wearing no mask (Fig. 3 – comparisons were not made between mask types. 95% CIs provided for comparisons, p-values not reported).

Assessment of evidence

Controlling for number of coughs, age, sex, BMI and SARS-CoV-2 variant, viral load decreased by 98% (95% CI 97 – 99%) with use of N95 respirators. This percentage decrease in viral load was then followed by cloth masks (87% (95% CI 77 – 92)), surgical masks (74% (95% CI 65 – 81), KN95 respirators (71% (95% CI 59 – 79%; increased to 76% (95% CI 64 – 84%) after excluding unknown KN95 respirator brands). The non-overlapping 95% CIs confidence intervals suggest this is statistically significant, although p-values were not reported.

Cloth masks performed better than surgical masks (p = 0.027) and KN95 respirators (when including unknown brands) (p = 0.014) for source control factors for total RNA aerosol. When limiting analysis to fine and course aerosol fractions, the comparisons were not statistically significant.

Limitations:

- Recruitment was from community testing facilities, it is unclear if there were other people (not within the 106) who were also tested but who chose not to participate. Differences between those eligible/ineligible, are not provided.
- Lack of replicability – unclear how far away the particle collector was from the participant and if this was standardized for all experiments. It was stated that participants had no prior training of wearing RPE. It is not clear if fit checking/testing was conducted.
- Participants were asked to wear their own or a supplied mask the brand/type of supplied mask is provided. It is not clear how many masks were brought by patients, it is stated “mostly cloth” indicating some SFM or RPE may have been supplied by the participants and it is not clear if these met minimum standards. The indication for use was reported as the researchers decided they were “well-fitted”.
- It is not clear how far away the particle counter was from the participant and it difficult to state with any certainty how this would impact a clinical interaction. It is also not clear how a mask (of any type) worn by the ‘receiver’ (in addition to the ‘source’) may impact the risk of transmission.
- Small sample (44 in total but under 27 per group of masks), unclear power.

Assessment of evidence
• Variations in sampling time, activities undertaken (happy birthday, shouting), differences in level of illness (as demonstrated by some people being reported as too unwell to undertake the speaking activities). Impact (if any) of these differences are unclear. • Variations in the type of mask (provided SFM are described but unclear how many if any were brought by the participant). • Lack of replicability and applicability - room humidity, temperature, distance of counter from participant, ventilation in place and other persons in the room are unclear. • It is unclear how this experimental setup may compare to real clinical interactions within health and care settings. • The true risk of transmission is unclear. This study highlights that the tested N95 respirators may provide statistically significant reductions in emitted particles compared to the tested surgical face masks but that this superiority may not be consistently reported with other respirator types (KN95). The clinical significance of these differences are unclear and the transmission risk is also not clear.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Onishi, K and Nojima, M. Comparison of the inward leakage rate between N95 filtering facepiece respirators and modified surgical masks during the	Observational	Level 3	The study assessed the inward leakage of an unadjusted surgical mask, a surgical mask adjusted to improve fit and N95 respirators. NaCl particles (particle size: 0.075 ± 0.02	Inward leakage rate according to mask/respirator type	Inward leakage rate

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
COVID-19 pandemic. Environmental Health and Preventative Medicine. 2024; 29(8), doi: 10.1265/ehpm.23-00303.			uM) at 85 L/min flow rate were used to assess filtration-collection efficiency.		

Assessment of evidence

Setting: University hospital, Tokyo, Japan

Methodology:

Volunteers from the general population as well as healthcare workers ((HCWs)) including nursing students). N = 54 participants in total (20 men, 34 women; 31 from general population; 23 HCWs).

Leakage rates of included masks were assessed using various measurements:

- Measurement 1 - Mask B (surgical mask) worn with pleats spread out and the nose wire pressed down onto the nose
- Measurement 2 – Mask B (surgical mask) worn with nose wire adjusted to a 'W' shape prior to donning, according to the shape of the participants' noses. To standardise this approach, the researcher's bent the wire to the appropriate shape according to the participant's nose.
- Measure 5 – Mask D (N95) were put on by participants after the researchers taught them how to achieve a tight fit. A fit test was performed on some participants (n = 39) to validate fit.

Assessment of evidence

The fit check was performed using an optical particle counter (MT-05U; SIBATA, Tokyo, Japan). Ambient particles (>0.3 uM in diameter) inside and outside of masks were counted. To validate these results, a CNC counter was used to count particles 0.15 – 1 uM in size (AccuFIT 9000 PRO 3000-J1. Kanomax Japan Ink, Osaka, Japan). Exercises were taken from the OSHA CNC QNFT protocol were used (29 CFR 1910.134, OSHA), namely: 1) normal breathing, 2) bending over, 3) moving head up and down, 4) turning head side to side, 5) talking (counting down from 100), 6) normal breathing.

NaCl particles (particle size: 0.075 ± 0.02 uM) at 85 L/min flow rate were used to assess filtration-collection efficiency and inhalation resistance.

Fit factor (FF; number of particles outside mask / number of particles inside of mask) was calculated using mean of FF for each exercise, then converted to inward leakage rate (ILR) based on the fine particular matter number in order to compare results.

Statistical analysis: Wilcoxon signed-rank test with Bonferroni correction used for paired comparisons of masks B and D.

Main findings:

Median ILR (IQR) of N95 0.78 (0.29 – 2.55) versus surgical mask with nose-wire adjusted to W shape: 50.82 (35.36 – 76.82), p-value < 0.001, p-value with Bonferonni's correction < 0.001; and N95 versus a surgical mask with the filter wire pressed down onto nose: 96.44 (72-100), p-value <0.0001, p-value with Bonferonni's correction. <0.001.

In this observational study, inward leakage rate was significantly lower for participants wearing an N95 respirator when compared to a surgical mask with the nosewire pressed down, and with the nose-wire shaped into a 'W' according to the participant's nose shape and size.

Limitations:

- Small sample size
- Large proportion of participants were from the general population, thus lack relevant experience of wearing SFM and RPE in clinical settings.
- Single study site

Assessment of evidence

- Only one respirator type included, where it is unclear if multiple brands of this type have been used. This limitation also applies to surgical masks.
- N95 duckbill type not typically used in NHSScotland, limiting generalisability of findings.
- Fit test only performed on 39 participants.
- Unclear if surgical mask if fluid resistant
- Optical particle counter measured ambient particles >0.3 uM in diameter. Particles smaller than this were not counted, which may impact the findings. It is unclear in which direction this would bias the findings.

This study contributes to the evidence base that in a controlled, experimental setting, N95 respirators have higher filtration efficiency when compared to surgical masks. However, the methods used are not designed to assess the function of a surgical mask, and the findings do not translate to infection risk in a real-life clinical setting.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Pennington, E. R., Griffin, J. S., McInroe E. M. et al. Variation in the fitted filtration efficiency of disposable face masks by sex. Journal of Exposure Science & Environmental	Cohort	Level 3	Filtration efficiency	N95 versus surgical mask	Mean fitted filtration efficiency (FFE) (%, s.d.)

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Epidemiology, 2024; doi: 10.1038/s41370-024-00697-4.					

Assessment of evidence

Setting: North Carolina, USA

Methodology:

N = 100 healthy individuals recruited to participate (50% female, 50% male, predominantly Caucasian (n = 60). Participants were excluded if: BMI < 19.0, BMI > 33.4, history of cardiovascular disease, cancer, uncontrolled hypertension or diabetes All participants were clean shaven.

A modified version of the OSHA QNFT was performed using NaCl. A particle counter was used to count particles in the breathing space and ambient air chamber.

Surgical mask: 3-ply (surgical mask (Hannah Linen, Portland, OR, USA) – unclear if fluid resistant. N95: tri-fold (3M N95 Aura 9205+).

The masks/RPE were fitted with an aluminium port for testing, and a study team member assisted with donning.

Main findings:

FFE according to use of ear loop clips have been excluded from this appraisal due to lack of applicability in NHSScotland.

N95s had highest FFE (97.8% ± 3.2) when compared to KN95s (69.4 ± 12.2), surgical masks (57.5 ± 9.9) and KF94 (55.2 ± 15.6); P < 0.001 for all comparisons. The difference between FFE between males (98.2 ± 2.9) and females (97.4 ±3.4) was not significantly different for N95s.

Assessment of evidence

FFE was higher for males compared to females for KN95s and KF94s but this is not applicable to NHSScotland.

Assessment of evidence:

In this cohort study of healthy individuals based in the USA, FFE was significantly higher for N95s (97.8% ± 3.2) when compared to SFMs (57.5% ± 9.9).

Limitations:

- Cohort of health individuals
- Relatively small sample size
- No power calculation
- Unclear on recruitment methods
- Unclear of the standards that SFM and N95 used in study met
- No indication that a formal fit check was performed after donning RPE (perhaps because FFE was being assessed via QNFT)

The above limitations limit generalisability of the findings but add to the evidence base regarding that RPE are potentially more effective at filtering particles when compared to surgical masks, KF94s and KFN95s, but does not give clear indication of how this translates infection risk amongst staff, patients or visitors.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Ministry of Health New Zealand. Mask use and visitor guidance for hospitals and other health and disability care settings. 2023. Accessed: 28 October 2024	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

“Respiratory (airborne or droplet) Precautions PPE use, under Transmission Based Precautions.

Clinical staff (nursing, medical, allied health, midwifery and other health and support staff) who are providing care to patients with symptoms of acute respiratory viral infections (including suspected or confirmed COVID-19, influenza or RSV) must wear personal protective equipment (PPE) required by transmission-based precautions (typically a P2/N95 particulate respirator +/- eye protection).”

Table 1 suggests PPE worn by healthcare workers in secondary care settings that is required, recommended and optional –

The table states “Healthcare workers are required to wear mask as part of Transmission based precautions when providing care to patient with suspected or confirmed respiratory virus infection (note follow local policies; may require N95/P2 respirator use).” This is the case for:

- hospitals, hospices and other secondary care facilities:
- community-based acute health care (e.g., GP, Iwi, Pacific health, oral care, urgent care, ambulance staff)

Assessment of evidence
• other non-acute community based care e.g., diagnostic services, allied health, and outpatient services, psychotherapy or counselling services, mental health and addictions services • aged and residential care (aged and disability related)

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Australian Government National Health and Medical Research Council (NHMRC) Australian Guidelines for the Prevention and Control of Infection in Healthcare 2019 (revised 2024, v11.24) Accessed 11 October 2024	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

Funding: Guidance was co-funded by the NHMRC and Medical Research Council and Australian Commission on Safety and Quality in Health Care.

Aim of guidance (page 20): “By assisting healthcare workers to improve the quality of the care they deliver, these Guidelines aim to promote and facilitate the overall goal of infection prevention and control: the creation of safe healthcare environments through the implementation of evidence-based practices that minimise the risk of transmission of infectious agents.”

Target audience (page 20): “The Guidelines are for use by all those working in acute health care settings —this includes healthcare workers, management and support staff. As some of the principles and recommendations described in this guideline may be applicable to other health care settings, individuals working in other health care settings may also find the guidelines useful.”

The introduction states that all recommendations are based on systematic reviews, however there is insufficient evidence within the guidance to support this claim.

Note: P2 respirators meet the relevant Australian standard (AS/NZS 1716:2012 and 1715:2009).

Use of P2 respirators by staff for airborne precautions:

“It is suggested that a correctly fitted P2 respirator is worn when entering the patient-care area when an airborne-transmissible infectious agent is known or suspected to be present. [Conditional recommendation]” (page 12)

Note - Definition of airborne transmission:

“Airborne transmission may occur via particles containing infectious agents that remain infective over time and distance. Small-particle aerosols (often smaller than 5 microns) are created during breathing, talking, coughing or sneezing and secondarily by evaporation of larger droplets in conditions of low humidity. Aerosols containing infectious agents can be dispersed over long distances by air currents (e.g. ventilation or air conditioning systems) and inhaled by susceptible individuals who have not had any contact with the infectious person. These small particles can transmit infection into small airways of the respiratory tract. An example of infectious agents primarily transmitted via the airborne route are M. tuberculosis and rubeola virus (measles).” (page 28)

Assessment of evidence

Airborne precautions:

"Airborne precautions are used for patients known or suspected to be infected with agents transmitted person-to-person by the airborne route" (page 30)

"Airborne precautions are based on evidence that shows that:

- the use of P2 respirators prevents the inhalation by healthcare workers of small particles that may contain infectious agents transmitted via the airborne route
- the use of negative pressure rooms reduces the transmission of infection
- wearing of correctly-fitted surgical masks by coughing patients prevents dispersal of respiratory secretions into the air (close monitoring is required to minimise respiratory risk) [87]."

Although the above suggests that airborne precautions are based on evidence, only one citated is provided (Citation 87: Siegel JD, Rhinehart E, Jackson M, Chiarello L, Health Care Infection Control Practices Advisory Committee : Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings (2007). Centers for Disease Control and Prevention 2007. Expert opinion that will be included in this ARHAI Scotland review).

Evidence to decision for airborne precautions takes into considerations benefits and harms, certainty of evidence, values and preferences and resources and other considerations, as follows:

- As highlighted above, the guidance considers the evidence behind airborne precautions as a whole, i.e. not only the evidence for the use of respirators for airborne precautions
- Certainty of evidence (Decision: Moderate): "The Centers for Disease Control and Prevention [164] strongly recommends (Category 1A) applying airborne precautions." and "The Public Health Agency of Canada [237] strongly recommends the implementation of airborne precautions for patients known or suspected to be infected with infectious agents transmitted person-to-person by airborne route, such as infectious pulmonary tuberculosis." "The overall quality of evidence regarding the use of face masks is low due to poorly controlled studies. The epic3 Guidelines [79] present Class D evidence (general practice statements) stating that it is best practice to use correctly fitted respirators in situations where a risk-assessment deems it

necessary. The Public Health Agency of Canada [237] present CII evidence (general practice statements) stating that it is best practice for healthcare workers to wear respirators when caring for patients with airborne infections." Epic3 guidance [Citation 79] is included in this ARHAI Scotland Review. Citation 237 will also be considered, however this citation is considered expert opinion guidance and may be outdated as was it was last updated in 2012.

- **Rationale:** "This advice is based on limited empirical evidence, but on sound theoretical principles and supported by expert advice. Wearing a correctly fitted P2 respirator when entering the patient-care area of a patient under airborne precautions is justified to reduce healthcare associated infection."
    - Citation 164: Siegel JD, Rhinehart E, Jackson M, Chiarello L, Health Care Infection Control Practices Advisory Committee : Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings (2007). Centers for Disease Control and Prevention 2007 is considered expert opinion guidance and will be included in the ARHAI Scotland RPE literature review.
    - Citation 237: Provincial Infectious Diseases Advisory Committee - Ontario Agency for Health Protection and Promotion: Best Practices for Infection Prevention and Control Programs in Ontario: All Health Care Settings, 3rd Edition. Public Health Ontario 2012 is expert opinion guidance that will be considered for this review. However, it is important to note it may be outdated as it was last updated in 2012.

"It is suggested that a correctly fitted P2 respirator is worn when entering the patient-care area when an airborne-transmissible infectious agent is known or suspected to be present." [Conditional recommendation]

Note: a conditional recommendation is considered a weak recommendation. Definition for weak recommendation is found in the glossary (page 264), as follows: "Concludes that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects. Overall the recommendation is based on supportive evidence and a strong theoretical rationale and is recommended for implementation."

"When there is a high probability of airborne transmission due to the infectious agent or procedure (e.g. bronchoscopy), sound scientific principles support the use of P2 respirators to prevent transmission. P2 respirators are designed to help reduce the wearer's respiratory exposure to airborne contaminants such as particles, gases or vapours.

Assessment of evidence
For example, influenza does not usually require the routine use of a P2 respirator except when there is a pandemic strain of influenza." Note: Although the quoted information states that this information is based on 'sound scientific principles' citations and scientific evidence is not provided. Table 13 (page 103) compares P2 and N95 respirators. It states the intended use for both are as follows: • "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" Note: Citations are not provided for the above information. It is also unclear which procedures involve the aerosolisation of particles. "There is insufficient evidence to support the use of P2 respirators for reducing the risk of infections transmitted by the droplet route" (page 98)

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
American Society of Anaesthesiologists (ASA), Anaesthesia Patient Safety Foundation (APSF), American Academy of Anaesthesiologist Assistants (AAAA) and American	Joint Position Statement	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Association of Nurse Anaesthetists (AANA) Revised: The Use of Personal Protective Equipment by Anaesthesia Professionals during the COVID-19 Pandemic. 2020. Accessed: 17 November 2022					

Assessment of evidence

Position statement for the safety of anaesthesia professionals in the context of the COVID-19 pandemic in the USA.

Recommendation:

Appropriate PPE should be used for all patients during aerosol generating procedures (AGPs). This has been recommended given the incubation time of SARS-CoV-2, potential asymptomatic patients, and lack of sensitivity of the test used to detect infection. List of AGPs are not provided.

Note that appropriate PPE includes: fitted N95 respirator, PAPRs, or other CDC or NIOSH-approved respirator.

Limitations:

- Specific to COVID-19 pandemic setting

Assessment of evidence

- Potentially outdated, early in pandemic (June 2020)

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Association of perioperative Registered Nurses (AORN) Guideline Quick View: Transmission-Based Precautions. AORN Journal. 2019; 109(4):529-536. Doi: 10.1002/aorn.12675.	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

Setting and context: Guidance developed for nursing staff working in the USA.

Note: References not provided.

Recommendations:

Assessment of evidence
• “Don a NIOSH-approved, fit-tested, surgical N95 respirator or higher-level respirator before performing aerosol-generating procedures on patients with suspected or proven infections transmitted by respiratory aerosols (eg, severe acute respiratory syndrome, avian influenza, pandemic influenza, viral hemorrhagic fevers).” • “Don a NIOSH-approved, fit-tested, surgical N95 respirator or higher-level respirator before entering the room of a patient with suspected or proven infections transmitted by the airborne route (eg, Mycobacterium tuberculosis [TB], rubeola virus [measles], varicella-zoster virus [chickenpox], disseminated herpes zoster).”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
World Health Organization (WHO) Infection prevention and control in the context of coronavirus disease (COVID-19): a living guideline. 2023. Accessed: 29 October 2024	Guidance	Level 4	N/A	N/A	N/A
Assessment of evidence					
Target audience: “Policy and decision-makers, public health professionals, IPC professionals at the national and facility levels, health care facility administrators, managers and other health workers.” – health workers work across all health and care settings.					

Assessment of evidence

Relevant recommendations:

- “A respirator should always be worn along with other PPE (gown, gloves, eye protection) by health workers performing aerosol-generating procedures (AGP) and by health workers on duty in settings where AGP are regularly performed on patients with suspected or confirmed COVID-19, such as intensive care units, semi-intensive care units or emergency departments.” (Citation 32, 33, 52) (Strong recommendation but based on very low certainty evidence)
- “At a minimum, Filtering Face Respirators (FFRs) that meet FFP2 and N95 performance levels are recommended to be worn by health workers in areas where AGPs are performed (Citation 21).”
- “Respirators should be worn in the following situations:
    - In care settings where ventilation is known to be poor or cannot be assessed, or the ventilation system is not properly maintained
    - Based on health workers' values and preferences and on their perception of what offers the highest protection possible to prevent SARS-CoV-2 infection.” (Respirator type not clear)
- “A respirator or a medical mask should be worn by health workers along with other PPE– a gown, gloves and eye protection – before entering a room where there is a patient with suspected or confirmed COVID-19. This applies to any setting where regular care is provided to patients with suspected or confirmed COVID-19, including home care, long-term care facilities and community care settings.” (54, 55, 56, 57, 58, 59, 60, 61, 62, 63)
- “In the context of universal masking, some health workers may prefer to wear respirators instead of a medical mask, based on their perception of what offers the better protection to prevent SARS-CoV-2 infection and emergent evidence that the use of respirators might be more effective in the control of transmission of some variants of concern such as Omicron. There are no substantial variabilities in values and preferences.”

Relevant references cited to support the above recommendations:

- Citation 21: WHO. 2020. Technical specifications of personal protective equipment for COVID-19. Outside scope.

Assessment of evidence

- Citation 32: Chou et al. 2020. A narrative living rapid review
- Citation 33: Update to the living rapid review. Update; epidemiology of and risk factors for coronavirus infection in health care workers.
- Citation 52: Tran et al. 2012. Aerosol generating procedures and risk of transmission of acute respiratory infections to healthcare workers: a systematic review. Outside scope of current review.
- Citation 54 (Fletcher et al 2019): Excluded at first screen in the current review as study looked at outbreak investigation
- Citation 55 (Sims et al): Excluded at first screen in the current review as it looked at seropositive and asymptomatic rates
- Citation 56 (Piapan et al. 2020): Excluded at first screen as it is out of scope for current review. Outbreak investigation
- Citation 57 (Venugopal et al 2021): Excluded at first screen as it was outside scope of the current review. Outbreak investigation
- Citation 58 (Haller et al 2022): Excluded in current review due to: results from questionnaire subject to recall bias. Adherenece to IPC measures estimated by investigators. Preferential use of FFPs reported, introducing bias. Seroconversion included in the analysis as indicator of infection.
- Citation 59 (Jefferson et al. 2021). Systematic review included in current review – Excluded from this update
- Citation 60 (Loeb et al 2009): Included in previous review – Excluded from this update
- Citation 61 (Long et al. 2020): Meta analysis included in current review – Excluded from this update
- Citation 62 (MacIntyre 2011): Included in previous review – Excluded from this update
- Citation 63 (MacIntyre 2013): Included in previous review – Excluded from this update

Overall the strength of this evidence was rated as insufficient in the document.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
World Health Organization (WHO) Infection prevention and control guidance for long-term care facilities in the context of COVID-19 – Interim Guidance. 2021. Accessed: 24 January 2023	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

Context and development: “This document provides interim guidance Long Term Care Facilities (LTCF) managers and IPC focal points to prevent SARS CoV-2 from entering a facility and from spreading within and beyond the facility, and to support safe conditions for visiting through the rigorous application of IPC procedures, for the residents’ well-being.”

Document states that this guidance is “based on published WHO guidance for IPC in the context of COVID-19 (WHO guidance on IPC for health care settings; on mask use; and on prevention, identification, and management of HW infections (1,2,3) and ongoing reviews of the available scientific evidence on COVID-19 in LTCF settings and on the effectiveness of IPC precautions in these settings.” Although this has been mentioned, none of these systematic reviews have been listed/detailed or referenced in the document.

Assessment of evidence

Recommendation:

- "When caring for any resident with suspected or confirmed SARS-CoV-2 infection who is undergoing any aerosol generating procedures, contact and airborne precautions should be used: the medical mask should be replaced with an N95, FFP2 or FFP3 respirator or equivalent level of mask." (Citation 1)

Relevant references cited to support the above recommendations:

Citation 1: Infection prevention and control during health care when coronavirus disease (COVID-19) is suspected or confirmed: interim guidance, 29 June 2020. Geneva: World Health Organization; 2020: Now been updated and incorporated in the living guidance

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Australian Government National COVID-19 Clinical Evidence Taskforce. Australian guidelines for SARS-CoV-2 infection prevention and control of COVID-19 in healthcare workers. 2021a.	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Accessed: 25 November 2022					

Assessment of evidence

Setting: Australia

Methods: Authors describe the document as 'living guidance', developed using the same methodology as the general IPC living guidance produced by the Australian Government. Evidence captured for the guidance is assessed using GRADE. Recommendations were developed in collaboration with the Infection Control Expert Group (ICEG) and a range of other Australian organisations focussed on health and care, forming the Steering Committee (see pages 6 and 7). The document links to both a technical report and generic methods document for all living guidance. Though a search strategy is provided, it is unclear if the process used to retrieve and grade evidence is rigorous (e.g. specific research questions, use of two independent authors to screen and appraise evidence, specific inclusion/exclusion criteria).

Purpose of guidance document: to provide evidence-based recommendations to prevent SARS-CoV-2 infection amongst Australian HCWs. HCWs may work in primary, secondary or tertiary care setting; including residential care facilities, transport and quarantine facilities.

Recommendations:

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

Assessment of evidence

  - 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"

- "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

Assessment of evidence
○ 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” The guidance document also assessed evidence regarding P2/N95 respirators versus surgical masks to reduce the risk of SARS-CoV-2 infection in HCWs. Given that single ORs are reported after discussing multiple observational studies, this suggests that meta-analysis was performed. However, given that no methodology was provided, the findings have been excluded and the reference list of the document has been screened so that the primary studies included in their analysis are considered for inclusion within the ARHAI Scotland RPE literature review.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centers for Disease Control and Prevention (CDC) Infection Control Guidance: SARS-CoV-2. 2023	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Accessed: 30 October 2024					

Assessment of evidence

Context: “This interim guidance has been updated based on currently available information about COVID-19 and the current situation in the United States. Updates were made to reflect the high levels of vaccine-and infection-induced immunity and the availability of effective treatments and prevention tools. This guidance provides a framework for facilities to implement select infection prevention and control practices (e.g., universal source control) based on their individual circumstances (e.g., levels of community transmission). This guidance is applicable to all U.S. settings where healthcare is delivered (including nursing homes and home health).”

Recommendations:

- Options for HCW source control include:
  - “A NIOSH-approved particulate respirator with N95 filters or higher;”
  - “A respirator approved under standards used in other countries that are similar to NIOSH-approved N95 filtering facepiece respirators (Note: These should not be used instead of a NIOSH-approved respirator when respiratory protection is indicated);”
  - Source control: “Source control refers to use of respirators or well-fitting facemasks or cloth masks to cover a person’s mouth and nose to prevent spread of respiratory secretions when they are breathing, talking, sneezing, or coughing.”

“Source control is recommended for individuals in healthcare settings who:

- Have suspected or confirmed SARS-CoV-2 infection or other respiratory infection (e.g., those with runny nose, cough, sneeze); or

Assessment of evidence

- Had close contact (patients and visitors) or a higher-risk exposure (HCP) with someone with SARS-CoV-2 infection, for 10 days after their exposure; or

  Source control is recommended more broadly as described in CDC's Core IPC Practices in the following circumstances:

- By those residing or working on a unit or area of the facility experiencing a SARS-CoV-2 or other outbreak of respiratory infection; universal use of source control could be discontinued as a mitigation measure once the outbreak is over (e.g., no new cases of SARS-CoV-2 infection have been identified for 14 days)"
- Facility-wide or, based on a facility risk assessment, targeted toward higher risk areas (e.g., emergency departments, urgent care) or patient populations (e.g., when caring for patients with moderate to severe immunocompromise) during periods of higher levels of community SARS-CoV-2 or other respiratory virus transmission"

"NIOSH-approved particulate respirators with N95 filters or higher used for:

- All aerosol-generating procedures (refer to Which procedures are considered aerosol generating procedures in healthcare settings?).
- All surgical procedures that might pose higher risk for transmission if the patient has SARS-CoV-2 infection (e.g., that generate potentially infectious aerosols or involving anatomic regions where viral loads might be higher, such as the nose and throat, oropharynx, respiratory tract).
- NIOSH-approved particulate respirators with N95 filters or higher can also be used by HCP working in other situations where additional risk factors for transmission are present, such as the patient is unable to use source control and the area is poorly ventilated. They may also be considered if healthcare-associated SARS-CoV-2transmission is identified and universal respirator use by HCP working in affected areas is not already in place.

Assessment of evidence

- To simplify implementation, facilities in counties with high transmission may consider implementing universal use of NIOSH-approved particulate respirators with N95 filters or higher for HCP during all patient care encounters or in specific units or areas of the facility at higher risk for SARS-CoV-2 transmission."

- "HCP who enter the room of a patient with suspected or confirmed SARS-CoV-2 infection should adhere to Standard Precautions and use a NIOSH-approved particulate respirator with N95 filters or higher, gown, gloves, and eye protection"
- Dental Facilities: "When performing aerosol-generating procedures on patients who are not suspected or confirmed to have SARS-CoV-2infection, ensure that DHCP correctly wear the recommended PPE (including consideration of a NIOSH-approved particulate respirator with N95 filters or higher in counties with high levels of transmission)."
- Ambulance without an isolated driver compartment: "Before entering the driver's compartment, the driver (if they were involved in direct patient care) should remove their gown, gloves and eye protection and perform hand hygiene to avoid soiling the compartment. They should continue to wear their NIOSH-approved particulate respirator with N95 filters or higher."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Government Department of Health and Social Care Infection prevention and control (IPC) in adult social care: acute respiratory infection (ARI). 2024	Guidance	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Accessed: 17 October 2024					
Assessment of evidence					
“Filtering face piece class 3 (FFP3) respirators for use during AGPs FFP3 respirators are required when undertaking an aerosol generating procedure (AGP – see Definitions section) on a person with symptoms of ARI or another infection spread by the airborne or droplet route.”					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Government Department of Health and Social Care Infection prevention and control: resource for adult social care. 2022b. Accessed: 13 December 2022	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

“This resource contains general infection prevention and control (IPC) principles to be used in combination with advice and guidance on managing specific infections. It is for those responsible for setting and maintaining standards of IPC within adult social care in England.”

“RPE may be considered if there is a significant risk of exposure to infectious airborne particles that cannot be mitigated by the application of other control measures. All other control measures to reduce risk must be applied before considering RPE.

RPE may be recommended for use in social care settings when undertaking AGPs where there is a risk of infection or more broadly in response to a novel infection spread through the airborne route. A risk assessment in response to a novel airborne infection would need to consider:

- if workers will need to be in close contact with people who are infectious (for example, to carry out personal care)
- if the environment cannot be well ventilated
- whether use of FFP3s would be likely to reduce the risk of transmission

On its own, RPE will not provide total protection and should only be used when a risk assessment indicates this is an appropriate action for the care task, the client, the care worker and the environment.”

References are not provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
European Centre for Disease Prevention and Control (ECDC) Personal protective equipment (PPE)	Technical Report	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
needs in healthcare settings for the care of patients with suspected or confirmed novel coronavirus (2019-nCoV), 2020a. Accessed 14 December 2022.					

Assessment of evidence

Target audience: “Public health authorities and hospital administrators in EU/EEA countries.”

Setting: EU/EEA

Recommendation:

“In the event of the need to assess a suspected case or in the management of a confirmed case, ECDC suggests the use of filtering face piece (FFP) respirators class 2 or 3 (FFP2 or FFP3). An FFP3 respirator should always be used when performing aerosol-generating procedures.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
European Centre for Disease Prevention and Control (ECDC) Guidance for wearing and removing personal protective equipment in healthcare settings for the care of patients with suspected or confirmed COVID-19; 2020b. Accessed: 14 December 2022	Guidance	**Level 4**	N/A	N/A	N/A

Assessment of evidence

"**Scope of this document**

This document provides support to healthcare workers managing suspected or confirmed cases of novel coronavirus 2019 (COVID-19). The general objectives of the document are:

- to present the minimal set of personal protective equipment (PPE) required for managing suspected or confirmed COVID-19 cases;

Assessment of evidence

- to make healthcare workers aware of the critical aspects of the donning and doffing of PPE; and
- to strengthen occupational safety in healthcare workers for patients suspected of, or confirmed with, COVID-19.
- This document is based on current COVID-19 knowledge and PPE best practices.

ECDC will update this document based on the evolving situation and if new relevant information arises.

Target audience: Healthcare workers and infection prevention and control personnel in EU/EEA countries and in the United Kingdom."

Recommendations:

- "ECDC suggests the use of class 2 or 3 filtering face-piece (FFP) respirators (FFP2 or FFP3, Figure 1) when assessing a suspected case or managing a confirmed case. A FFP3 respirator should be always used when performing aerosol-generating procedures." – FFPs may be valved or non-valved.
- "Healthcare workers and LTCF staff coming into contact with residents who have symptoms compatible with COVID-19 should wear a medical face mask or an FFP2 respirator if available" – context of document indicates that FFP respirators are the preferred option.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
European Centre for Disease Prevention and Control (ECDC) COVID-19 infection prevention and control measures for	Technical Report	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
primary care, including general practitioner practices, dental clinics and pharmacy settings: first update, 2020c. Accessed: 14 December 2022					

Assessment of evidence

"**Scope of this document:** This document provides guidance on infection prevention and control (IPC) measures to healthcare providers in the European Union/European Economic Area (EU/EEA) and the United Kingdom (UK) in order to prevent COVID-19 infection.

Target audience: Healthcare workers in general practitioner (GP) offices, primary care clinics, dental offices/clinics, and pharmacies in the EU/EEA and the UK."

Recommendations:

"Healthcare professionals should wear PPE in the following situations:

- when performing triage, examining or providing care to patients with symptoms compatible with COVID-19

- when performing high-risk procedures (e.g. physical examination of the oropharynx or nasopharyngeal swabbing) in patients with or without symptoms compatible with COVID-19.

- The suggested set of PPE includes:

Assessment of evidence

− FFP2/3 respirator[1] (or medical face mask if there is a shortage of FFP2/3 respirators) […]

[1] Due to the risk posed by asymptomatic and pre-symptomatic patients, the use of a facial filtering piece (FFP) respirator class 2 or 3 should also be considered when caring for patients without COVID-19-compatible symptoms during the COVID-19 pandemic."

Dental care:

"The suggested set of PPE for staff when caring for all patients includes:

− an FFP2/3 respirator[2]

- FFP2/3 respirators should be prioritised for:

  − aerosol-generating procedures (AGPs)[3]

  − when caring for patients showing COVID-19-compatible symptoms for whom treatment cannot be deferred […]

- The choice between a FFP2/3 respirator rather than a medical face mask should be aided by an on-site risk assessment that takes into account the local prevalence of COVID-19 and the likelihood that the consultation will include an AGP

[2]. Due to the risk posed by asymptomatic and pre-symptomatic patients, the use of a facial filtering piece (FFP) respirator class 2 or 3 should also be considered when caring for patients without COVID-19-compatible symptoms during the COVID-19 pandemic."

"The choice between a FFP2/3 respirator rather than a medical face mask should be aided by an on-site risk assessment that takes into account the local prevalence of COVID-19 and the likelihood that the consultation will include an AGP."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Lynch JB, Davitkov P, Anderson DJ, et al. Infectious Diseases Society of America Guidelines on Infection Prevention in Patients with Suspected or Known COVID-19. Infectious Diseases Society of America 2021; Version 2.0.0. Accessed: 22 November 2022	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

Aim of guidance: To rapidly develop COVID-19 guidance to support HCW in making IPC decisions when caring for COVID-19 patients (suspected/confirmed) based on evidence.

Target Audience: health care workers who care for suspected or confirmed COVID-19 patients.

Panellists: Guideline panel assembled March 2020 with 11 members including frontline clinicians, infectious disease specialists, experts in infection prevention and guideline methodologists. The panel also included experts in preventive care, public health, medical

Assessment of evidence

microbiology, pediatrics, critical care medicine and gastroenterology. Organizational representatives were included on the panel from the Society for Healthcare Epidemiology of America (SHEA) and the Pediatric Infectious Diseases Society (PIDS).

Relevant recommendations:

- "Recommendation 1: The IDSA guideline panel recommends that healthcare personnel caring for patients with suspected or known COVID-19 use either a medical/surgical mask or N95 (or N99 or PAPR) respirator compared with no mask as part of appropriate PPE. (Strong recommendation, moderate certainty of evidence)"
    - No direct comparative data from RCTs was identified, it is stated that the best available evidence was from a large cross-sectional, comparative study. References contributing to the evidence base behind this recommendation included studies not relevant to the review.
    - The majority were excluded at first screen, with two not identified in the search but deemed irrelevant (serology testing and associations with wearing RPE)
- "Recommendation 5: The IDSA guideline panel recommends that healthcare personnel involved with aerosol-generating procedures on suspected or known COVID-19 patients use an N95 (or N99 or PAPR) respirator instead of a medical/surgical mask, as part of appropriate PPE*. (Strong recommendation, very low certainty of evidence)
    - Remark: Despite the very low quality and indirect evidence supporting this recommendation, the IDSA guideline panel placed a high value on avoiding serious harms to exposed healthcare personnel."
    - "The overall certainty of evidence was very low due to limitations in the retrospective observational data and recall bias. However, the IDSA guideline panel made a strong recommendation for N95 or higher-level respirators, placing a high value on preventing infection among HCP."

Three references contributing to evidence base not relevant to this review.

Limitations:

Assessment of evidence
• Selection process unclear for studies details provided about study type. Unclear involvement of studies labelled as high risk of bias. • “an overall judgment of certainty of evidence is made based on critical outcomes.” Unclear on how this was carried out. • Vague description on how expert panellists reached consensus. • Included studies are considered as out-with the scope and/or subject to bias and therefore excluded from current or previous (2019) surgical face mask review updates. • Unclear involvement of patients/public • No pilot and applicability limited. • No clear planning for updates to this document. No description of how “new data” is sought.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Ministry of Health New Zealand. Infection prevention and control. 2022a. Last updated: 01 November 2024. Accessed: 04 November 2024	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence
“Infection Prevention and Control (IPC) refers to practical, evidence-based practices and procedures to protect patients, visitors, residents, clients and health workers from being harmed by avoidable infections in the healthcare setting. “ “Airborne Precautions Airborne Precautions are required when interacting with people known or suspected to have diseases spread by very small particles that can suspend in the air and can be inhaled into the lungs. The following Airborne Precautions apply for all interactions: • Wear a P2/N95 particulate respirator […].” No references are provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Public Health Agency of Canada (PHAC). Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Healthcare Settings. 2016.	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Accessed: 4 May 2023					

Assessment of evidence

Aim: To present evidence-based recommendations for monitoring, preventing and controlling healthcare associated infections.

Target audience: Infection prevention and control professionals and healthcare providers involved with developing policy and procedure for routine practices in healthcare settings (acute, long-term, ambulatory, home care or prehospital care settings)

Methods:

- These guidelines were produced by PHAC, advised by PHAC's Steering Committee on Infection Prevention and Control Guidelines Working Group, made up of professionals from different areas of healthcare who provided technical advice (list provided on page 2). They are described as "principles and recommendations" rather than strict standards.
- A literature search was conducted for papers from 1999 (details of this search are available to request).
- Recommendations were graded based on the strength of evidence
- This guidance is based on scientific evidence and expert opinion where evidence was lacking, but was graded as expert opinion due to limited methodological detail making it difficult to deduce how systematic methods were.

Recommendations:

In Part A, section B – "Role of organization to reduce exposure to and transmission of infectious agents" under the section on administrative controls (occupational health):

- "Respirators should be used for the care of patients with suspected or confirmed airborne respiratory pathogens (e.g., TB, measles), and in some situations when AGMPs are performed" and then refers to the below recommendations page 37)

Assessment of evidence

In Part A, section C – “Role of the healthcare worker” under the section on measures healthcare workers can take to reduce exposure and transmission:

- The authors state that respirators offer respiratory protection from airborne infection, i.e. in cases with airborne transmission risk and for aerosol generating medical procedures on some patients (page 57)
- “The use of a respirator or the need for airborne precautions is determined by a PCRA. (point of care risk assessment) Factors to be considered are the specific infectious agent, known or suspected infection status of the patient involved, the patient care activity to be performed, the immune status of the HCW and the patient’s ability to perform respiratory hygiene.” (page 57)

Part B.IV. includes recommendations for additional precautions, and in subsection iii for patients with known or suspected infections requiring airborne precautions (examples of these include tuberculosis, measles and disseminated zoster):

- The authors recommend that, during aerosol generating medical procedures, “Respirators should be worn by all personnel in the room during the procedure” (page 99)
- For patient transfer – “If transport is in a confined space (e.g., ambulance), the transport personnel should wear a respirator during transport.” (CI - weak) and “For other conditions (i.e., measles, varicella), immune transport personnel will not need a respirator” (CII - weak) (page 100)
- For management of patients with airborne infections, the authors recommend respirators when entering the room of a patient with varicella or measles (page 101)

Under personal protective equipment (page 102), the authors recommend respirators for when:

- “caring for a patient with suspected or confirmed respiratory tuberculosis” and “when infectious tuberculosis skin lesions are present and procedures that would aerosolize viable tubercle bacilli organisms (e.g. irrigation) are performed” (CII - weak)
    - This recommendation references outbreak reports on tuberculosis (162 – Hutton et al., 1990; 163 – Frampton,1992; and 164 – Keijman et al., 2001)

Assessment of evidence

- “caring for a patient with vaccine preventable airborne infections (i.e. varcilla, measles) to which they are not immune” (CII - weak)
- “performing or assisting with aerosol-generating medical procedures (as per Part B, Section IV, subsection iii, 1b) (the recommendations) on patients with signs and symptoms of severe acute respiratory syndrome or with a respiratory pathogen for which transmission characteristics are not yet known.” (BII - moderate)
    - This recommendation references outbreak reports (150 - Fowler, 2004; 151 – Scales et al., 2003; 152 – Christian et al., 2004; 155 – Yu et al., 2005) and Catanzaro,1995 (153) and Larson et al., 2001 (154)
- “caring for a patient with suspect or confirmed monkeypox or smallpox” (CII - weak)

Part C table 4 contains a table containing different conditions and the relevant precautions, suggesting respirators for:

- non-immune people entering an infected measles patient or susceptible contact’s room (pages 138-139)
- all those entering the room of a patient with smallpox (page 150)
- non-immune persons entering the room of those with varicella zoster virus and varicella (chickenpox) (page 157)
- non-immune persons entering the room of those with herpes zoster (shingles), disseminated (page 158)

Type of respirator is not specified. Although, in the Glossary an N95 respirator is identified as the most commonly used in health care.

“In cohort settings, respirators may be used for successive patients”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Ministry of Health New Zealand. Caring for a suspected or known COVID-19 case. 2023. Accessed: 22 November 2024	Infographic	Level 4	N/A	N/A	N/A

Assessment of evidence

Context: “This is intended as a high-level reference document when caring for a probable or confirmed COVID-19 case, or someone who meets the Clinical and Higher Index of Suspicion (HIS) Criteria

Setting: NZ, health and disability care, including domiciliary care.

The infographic states a P2/N956 is to be worn by:

- Health and disability workers, “Caring for or contact with probable or confirmed COVID-19 cases, or someone who meets the Clinical and Higher Index of Suspicion (HIS) Criteria.1”
    - When providing “Care in community based healthcare settings, including a person's place of residence”, “Care in hospital (including emergency departments and wards)5”, and “Aerosol generating procedures2”

“1. Case definition: www.health.govt.nz/covid19-case-definition

2. Frequently Asked Questions about PPE, Available from: www.health.govt.nz/ppe-health

4. Includes all health care team. For example: nurses, medical team, cleaners, orderlies, healthcare assistants.

Assessment of evidence
5. Minimise number of people in the room at one time, or in a transfer team.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Ministry of Health New Zealand. COVID-19: Infection prevention and control recommendations for health and disability care workers. 2022. Last updated 05 September 2024. Accessed: 04 November 2024	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence
Context: Sessional (or continuous) use of PPE is the ability to wear specific PPE items without needing to remove and replace each and every time you have undertaken and completed a task or activity.

Assessment of evidence

A ‘session’ refers to a period of time where a health care worker is undertaking duties in a specific care setting or exposure environment for example on a ward round or providing on-going care for in-patients. The duration of a session will vary depending on the task or activity being undertaken.

Recommendations:

A medical mask or particulate respirator must be changed every 4 hours or earlier if,

- it is soiled/ contaminated or becomes damp
- it is uncomfortable
- it is damaged

PPE items that can be worn sessionally:

- P2/N95 particulate respirators

PPE should be removed and disposed of safely after each session or earlier if damaged, soiled, or uncomfortable.”

Limitations:

No references are provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Health Security Agency (UKHSA) Principles for control of non-HCID mpox	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
in the UK: 4 nations consensus statement 2023. Updated September 2024 Accessed: 31 October 2024					

Assessment of evidence

Aim: On 8 December 2022, UKHSA published the UK strategy for mpox control, 2022 to 2023. This is an overarching public health strategy for controlling mpox across the UK, agreed between the UK's 4 public health agencies.

Target audience: Professionals involved in developing UKHSA, NHS and other organisations' operational guidance

Recommendations:

- Risk assessment is advised to determine which PPE to use, considering the hierarchy of controls.
- Minimum PPE for suspected cases includes "fluid repellent surgical facemask (FRSM) (an FRSM should be replaced with an FFP3 respirator and eye protection if the case presents with a lower respiratory tract infection with a cough and/or changes on their chest x-ray indicating lower respiratory tract infection)"
- Minimum recommended PPE for confirmed or highly probable cases who need "ongoing clinical management (for example inpatient care or repeated assessment of an individual who is clinically unwell or deteriorating)" includes "fit-tested FFP3 respirator"

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Government of Canada. Updated guidance for infection prevention and control in health care settings when COVID-19 is suspected or confirmed – April 2024. Accessed: 1 November 2024	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

"This document, which updates previous national Infection Prevention and Control (IPC) guidance developed for health care settings for IPC interventions to prevent and control COVID-19, was informed using expert advice from the National Advisory Committee on Infection Prevention and Control (NAC-IPC)"

"The Public Health Agency of Canada (PHAC) develops national evidence-informed IPC guidance to complement provincial and territorial public health efforts in monitoring, preventing, and controlling healthcare-associated infections. […] This guidance is for all healthcare settings (acute care, long-term care, home care and ambulatory/outpatient care)."

Recommendations:

- "Recommended PPE for direct care of patients with suspected or confirmed COVID-19:

Assessment of evidence

- Fit-tested, seal-checked N95 respirator"

"Recommended PPE for all patient encounters should be based on a point of care risk assessment (PCRA), which should include consideration of:

- patient not yet clinically evaluated (e.g., Emergency Areas)
- likelihood of exposure to SARS-CoV-2 and other pathogens based on:
  - specific interaction (e.g., requirement of extensive or prolonged close proximity)
  - specific task (e.g., performance of higher risk examinations, such as those of the mouth, nose, and throat)
  - specific patient factors
  - specific environment, (e.g., patient's ability to tolerate a mask), patient signs, symptoms, and behaviours (such as shouting, coughing, or heavy breathing)"
- A PCAR may include:
  - community epidemiology of COVID-19
  - ventilation
- "Consider implementing universal use of respirators for all HCWs during all patient care encounters in specific units or areas of facility at higher risk of SARS-CoV-2 transmission, e.g., COVID-19 designated units, emergency departments, open space critical care areas, areas with high frequency of aerosol-generating medical procedures (AGMPs), etc."

AGPs:

"[…] it is prudent to continue to use fit tested, seal-checked N95 respirators […] for all AGMPs."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Government of Canada. Infection prevention and control for COVID-19: Interim guidance for long-term care homes. 2022a. Accessed: 17th April 2023	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

This Canadian interim guidance aimed to provide COVID-19 guidance related to IPC, to be considered in conjunction with the Canadian Government's Omicron variant guidance.

It is specific to long term care homes.

The guidance is broadly in line with acute care, ambulatory and outpatient settings guidance.

Recommendations:

- Sessional use of N95 respirator is not recommended. They recommend substituting a surgical mask for an N95 or equivalent respirator based on a point-of-care risk (PCRA) assessment, prior to interacting with a resident and/or the environment.
- "All staff who enter the room, or come within 2 metres, of a resident who is considered exposed to, or suspected or confirmed to have COVID-19 wear gloves, a gown, a medical mask or N95 or equivalent respirator, and eye protection, in addition to following Routine Practices"

Assessment of evidence

- “Staff wear a fit-tested N95 or equivalent respirator, along with gloves, gown, and eye protection for AGMPs on residents who are considered potentially infectious with SARS-CoV-2”
- “The selection and use of PPE during resident interactions should always be determined by the PCRA [point of care risk assessment].”, conducted by all long term care home staff before resident interaction. PCRA is “based on staff professional judgment (i.e., knowledge, skills, reasoning and education) about the clinical situation or encounter, the environment, policies and procedures in place, and the use and availability of PPE”
- “For interactions with residents who are considered exposed to, or suspected or confirmed to have COVID-19, PPE consistent with a minimum of Droplet and Contact Precautions (e.g., gloves, a gown, a medical mask and eye protection) should be worn. An N95 or equivalent respirator should be worn in place of a mask when performing or exposed to an AGMP. Use of an N95 or equivalent respirator may be considered in other circumstances under which risk of exposure to aerosolized virus may occur.”
- Minimum of droplet and contact precautions are advised for residents with potential COVID-19 (i.e. contacts, confirmed diagnosis or symptomatic):
    - “An N95 or equivalent respirator should be worn in place of a mask when an AGMP is being performed on a resident who is considered potentially infectious with COVID-19
    - Use of an N95 or equivalent respirator may be considered in other circumstances under which the risk of exposure to aerosolized virus may occur”
- “AGMPs on a resident who is considered potentially infectious with SARS-CoV-2 should only be performed when all staff in the room are wearing a fit-tested, seal-checked N95 or equivalent respirator, gloves, a gown and eye protection.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Government of Canada Infection prevention and control for COVID-19: Interim guidance for acute healthcare settings 2022b. Accessed: 17th April 2023	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

This Canadian interim guidance aimed to provide interim COVID-19 guidance related to IPC, to be considered in conjunction with the Canadian Government's Omicron variant guidance. It is specific to acute care settings. The guidance is broadly in line with long term care home, ambulatory and outpatient settings guidance.

Recommendations:

- "All HCWs who enter the patient room or bedspace, or come within 2 metres of a patient who is considered exposed to, or suspected or confirmed to have COVID-19, wear gloves, a gown, a medical mask or N95 or equivalent respirator, and eye protection, in addition to following Routine Practices
- An N95 or equivalent respirator, along with gloves, a gown and eye protection are worn for AGMPs on patients who are considered potentially infectious with SARS-CoV-2"

Assessment of evidence

- “The selection and use of PPE during patient interactions should always be determined by the PCRA.”, conducted by all healthcare workers before patient interaction. PCRA (point of care risk assessment) is “based on the HCW professional judgment (i.e., knowledge, skills, reasoning and education) about the clinical situation, up-to-date information on how the specific acute healthcare facility has designed and implemented engineering and administrative controls, and the use and availability of PPE”
- “An N95 or equivalent respirator should be worn in place of a mask when performing an AGMP or when frequent or unexpected exposure to AGMPs is anticipated (e.g., on dedicated COVID-19 units). Use of an N95 or equivalent respirator may be considered in other circumstances under which risk of exposure to aerosolized virus may occur.”
- “A minimum of Droplet and Contact Precautions should be implemented for all patients who are considered exposed to, diagnosed with, or who are presenting with signs or symptoms of COVID-19”:
    - “An N95 or equivalent respirator should be worn in place of a mask when an AGMP is being performed on a patient who is considered potentially infectious with SARS-CoV-2 or when frequent or unexpected exposure to AGMPs is anticipated (e.g., on dedicated COVID-19 units)”
    - “Use of an N95 or equivalent respirator may be considered in other circumstances under which the risk of exposure to aerosolized virus may occur”
- “AGMPs on a patient who is considered potentially infectious with SARS-CoV-2 should only be performed when all HCWs in the room are wearing a fit-tested, seal-checked N95 or equivalent respirator, gloves, a gown and eye protection.”
- “An N95 or equivalent respirator should be worn in place of a mask when an AGMP is being performed on a patient who is considered potentially infectious with SARS-CoV-2 or when frequent or unexpected exposure to AGMPs is anticipated (e.g., on dedicated COVID-19 units)”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Government of Canada. Infection prevention and control for COVID-19: Interim guidance for outpatient and ambulatory care settings. 2022c. Accessed: 17th April 2023	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

This Canadian interim guidance aimed to provide interim COVID-19 guidance related to IPC, to be considered in conjunction with the Canadian Government's Omicron variant guidance. It is specific to outpatient and ambulatory settings. The guidance is broadly in line with long term care home and acute care settings guidance.

Recommendations:

- Sessional use of N95 respirator is not recommended. They recommend substituting a surgical mask for an N95 or equivalent respirator based on a point-of-care risk (PCRA) assessment, prior to interacting with a resident and/or the environment.

Assessment of evidence

- “All staff who enter the room, or come within 2 metres, of a patient who is considered exposed to, or suspected or confirmed to have, COVID-19 wear gloves, a gown, a medical mask or N95 or equivalent respirator, and eye protection, in addition to following Routine Practices”
- “Staff wear a fit-tested N95 or equivalent respirator, along with gloves, gown, and eye protection for AGMPs on patients who are considered potentially infectious with SARS-CoV-2”
- “The selection and use of PPE during patient interactions should always be determined by the PCRA.”, conducted by all healthcare workers before patient interaction. PCRA (point of care risk assessment) is “based on staff professional judgment (i.e., knowledge, skills, reasoning and education) about the clinical situation or encounter, the environment, policies and procedures in place, and the use and availability of PPE”
- “An N95 or equivalent respirator should be worn in place of a mask when performing or exposed to an AGMP. Use of an N95 or equivalent respirator may be considered in other circumstances under which risk of exposure to aerosolized virus may occur.”
- “Masks or N95 or equivalent respirators worn as source control, and eye protection worn for the full duration of shifts (i.e., not when used for encounters with patients on Additional Precautions), may be worn for extended periods. Any extended use policies should be developed with IPC expert consultation or guidance.”
    - Context for source control: “Given ongoing community spread of COVID-19 within Canada and evidence that transmission occurs from those who have few or no symptoms, masking for the full duration of shifts or visits for all outpatient and ambulatory care setting staff and visitors (e.g., essential companions or external service providers) is recommended. The rationale for full-shift or visit masking of all staff and visitors is to reduce the risk of transmitting COVID-19 infection from staff or visitors to others, at a time when no signs or symptoms of illness are recognized, but the virus can be transmitted. Staff should support visitors to ensure appropriate use of medical masks.”
- “AGMPs on a patient who is considered potentially infectious with SARS-CoV-2 should only be performed when all staff in the room are wearing a fit-tested, seal-checked N95 or equivalent respirator, gloves, a gown and eye protection.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Lindsley WG, Blachere, FM and Law, BF. et al. Efficacy of face masks, neck gaiters and face shields for reducing the expulsion of simulated cough-generated aerosols. Aerosol Science and Technology. 2021;55(4), pp. 449-457.	Simulation (manikin)	3	Efficacy of respirators and surgical masks (termed 'procedure mask') as source control to reduce cough particles emitted into the environment.	Comparators: N95 respirator (3M 1860), ASTM level 3 Procedure mask (ASTM Level 3 = FDA's highest grading for medical and surgical masks) (Kimberly Clark, 47107). Procedure mask is fluid resistant. N95 and procedure mask did not have exhalation valves.	Collection efficiency: percentage of aerosol particles blocked by the PPE under investigation (%) when compared to experiments without the use of PPE. Air particle mass in collection chamber (ug) as a proxy measure for how effectively the PPE under study reduced the mass of air particles emitted into the environment.

Assessment of evidence

Setting: USA

Methodology:

- 14% KCl and 0.4% sodium fluorescein solution was nebulised using a single jet Collison nebuliser. Mask/respirator placed on the manikin head, where each item was used for 2 consecutive tests.

Assessment of evidence

- Portacount used to perform a respirator fit test (for both procedure mask and N95) and determine the fit factor (ratio aerosol concentration outside respiratory device: aerosol concentration inside the device)
- Simulated cough was expelled via the mouth of the manikin head into an enclosed collection chamber
- After sample collection from an Anderson impactor, plates were prepared and fluorescence was measured using a fluorometer.

Main findings:

Collection efficiency - Mean % (standard deviation)

- No device: N/A – control comparator
- Procedure mask: 58.5 (6.9)
- N95: 98.6 (0.3)

Comparison of air particle mass (uG) into the collection chamber (mean difference, 95% CI, p-value)

- N95 vs no device: -504 (-567, -422) $p<0.0001$
- N95 vs procedure mask: -205 (-277, -133), $p<0.0001$

Assessment of evidence:

In this study, the N95 was more effective than both the procedure mask and the use of no PPE, at reducing mean air particle mass (uG) in the enclosed chamber when placed over the mouth of the manikin in an enclosed chamber where one cough was simulated, producing particles <0.6 uM – 7 uM in size.

Limitations:

- N95 findings cannot be applied to other RPE

Assessment of evidence

- Unclear on the flow rate chosen for the simulated cough. The flow rate chosen was based on one study on influenza patients. It is also unclear if the investigators used the peak flow rate from this investigation, or mean flow rate. Only peak flow rate is mentioned in their results section
- Only one brand of N95 and procedure mask tested, respectively
- Simulation experiment using a manikin head has limited generalisability to real-life clinical settings
- Results are based on two repeats for each PPE item under investigation
- Inhalation following expelled cough not taken into consideration in the experimental model
- As stated by authors, the simulation only involved one cough, one air flow profile and one aerosol size distribution, limiting generalisability
- Breathing/speaking not assessed – again limiting generalisability as air velocity and air particle distribution would differ for these activities
- Authors state collection efficiencies may have been underestimated due to particles settling on surfaces of the collection chamber. Authors state that impaction, where particles in the air travel along their original path (sticking to a surface) instead of turning with air, may also have led to underestimation of collection efficiency
- Only one manikin head used, limiting generalisability to individuals with facial compositions that differ to the manikin (unclear of the dimensions of the manikin used)

This provides weak evidence to potentially suggest that an N95 respirator may be more effective than a fluid resistant procedure mask as a form or source control. However, given its limitations, particularly those relating to generalisability, this study must be considered as part of a wider evidence base.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Asadi, S., Cappa, CD, Barreda, S. et al. Efficacy of masks and face coverings in controlling outward aerosol particle emission from expiratory activities. 2020. Nature Scientific Reports, 2020; 10(15665). doi: 10.1038/s41598-020-72798-7.	Simulation (human participants)	Level 3	Efficacy of RPE/PPE in reducing aerosol particle emission rates when participants were breathing, speaking and coughing.	Surgical mask (ValuMax 5130E-SB), tested by 10 participants Non-vented KN95 respirator (GB2626-2006, Nine Five Production Technology), tested by 10 participants A vented N95 respirator (NIOSH N95, Safety Plus, TC-84A-7449), tested by 2 participants	Particle emission rate (particle/second) Observed particle size distribution (particle fraction (%))

Assessment of evidence

Setting: USA

Methodology:

Participants were instructed to sit with their mouth at the entrance of a funnel attached to an aerodynamic particle sizer (APS) (to count particles between 0.3 and 20μm), within a HEPA-filtered laminar flow hood.

Assessment of evidence

The participants undertook a number of tasks (breathing, talking, coughing, and jaw movement) while wearing no mask or one of the assessed masks.

Air was pulled in by the APS at 5L/min, with 1L/min (20%) focused into the detector to count and size the cumulative number of particles at 1 second intervals.

Main findings:

NOTE: Statistics were not presented within the text, only as part of figures. All reported as $p<0.05$.

Breathing (through the mouth):

When wearing no mask, the median particle emission rate was 0.31 particles/s. This was significantly reduced (approx. 6-fold) by the wearing a surgical mask or KN95 respirator (0.06 and 0.07 particles/s respectively).

Talking:

Talking resulted in a higher rate of outward emission across the mask types, without a mask the median rate was 2.77 particles/s.

Both surgical masks and KN95 respirators significantly decreased the outward emission rate to 0.18 and 0.36 particles/s, respectively.

Coughing:

It was noted that there was variation in participants coughing output in terms of number of coughs, duration of coughing, and output of aerosol particles, however, a similar trend in reduction/increase of outward emission rate was observed across the mask types.

Without a mask a median of 10.1 particles/s were produced, wearing surgical masks significantly reduced the median outward emission rate to 2.44 particles/s, and wearing a KN95 reduced the median outward emission rate to 6.15 particles/s, however this was not statistically significant.

Results related to vented KN95s were based on two participants therefore statistical testing was not performed (results therefore excluded)

Assessment of evidence:

Assessment of evidence

In this study, compared to the use of no masks/RPE, using both surgical masks and KN95 masks (unvented) significantly reduced outward emission of particles when breathing and talking. When coughing, only the use of surgical masks resulted in significantly reduced outward emission of particles.

Limitations:

- Small sample size
- It was noted that, due to mask wearing, some expired airflow may move in a non-outward direction, and so the measurements reported in this study are not expected to represent the absolute number of emitted particles
- Authors note that the particle counter likely underestimates the true number of particles between 0.3 – 0.5 uM
- Unclear if participants had experience of providing clinical care and/or donning RPE/PPE
- Limited presentation of statistical significance
- Vented KN95 tested by only 2 participants therefore significance testing was not performed
- Simulation experiment where simulated coughing, breathing and talking may not mimic clinical scenarios
- Particle sizes under investigation limited to 0.3 – 20 uM. where authors note that the particle counter likely underestimates the true number of particles between 0.3 – 0.5 uM.
- Only KN95s assessed, therefore limited generalisability to other RPE types

The findings suggest that use of a KN95 or surgical mask may be beneficial to reduce emission of particles when a person is breathing or talking, however, it is unclear whether a KN95 is more beneficial than the use of a surgical mask. Furthermore, compared to the use of no mask/RPE, unlike the use of surgical masks, KN95s do not significantly reduce outward particle emission when worn by a person who is coughing.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Diaz KT and Smaldone GC. Quantifying exposure risk: surgical masks and respirators. American journal of infection control. 2010; 38(7):501-8. Doi: 10.1016/j.ajic.2010.06.002.	Simulation (manikin)	3	Experimental set-ups assessed exposure, dilution, deflection and filtrated of aerosols. The nebuliser contained 3 ml 0.9% saline labelled with technetium-99m and run to dryness (approx. 10 minutes).	• No PPE • NIOSH-approved N95 respirator (No. 1860S size small; 3M) • Ear loop surgical mask (SM) (model No. GCFCXS; Crosstex International Inc). SMs were tested both loosely or tightly fitted on the source or receiver depending on experiment conditions. • N95s fitted with no	Maximum exposure (Max Ex): % of nebulised particles (i.e. inhaled particles) captured by the receiver – direct result of dilution, i.e. exhaled particles from the source mixing with ambient air. Ratio of Max Ex to actual exposure defined as the simulated workplace protection factor (sWPF) Results presented as means and 95% confidence intervals with “separation of confidence intervals defined statistical significance”.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
				obvious leaks. Additional experiments were performed with N95 sealed to face with Vaseline to prevent leaks.	Particle distribution and mass median aerodynamic diameters (MMAD) (uM) also presented.

Assessment of evidence

Methodology:

Chamber (5ft x 4.5ft x 6ft, 135 ft^3) with a fixed flow providing 0 or 6 air changes/hr within the chamber.

Nebuliser (AeroTech II) connected to an air tank with flow of 10L/min was used to create aerosols (3 devices used in rotation). Environmental flow within the chamber was regulated using an opening between the chamber and a hood. The nebuliser contained 3 ml 0.9% saline labelled with technetium-99m and run to dryness (approx. 10 minutes).

Source aerosols were exhaled via a manikin head (Brad CPR adult manikin head, no 2512, Simulaids) directed towards a receiver; a ventilated manikin head was also placed in the chamber to simulate the receiver. Manikin heads were both connected to Harvard pumps (Harvard Apparatus SN A52587) with a tidal volume of 500 mL, respiratory rate of 15 breaths/min and duty cycle of 0.5 to simulate a tidal breathing pattern.

Assessment of evidence

Manikin heads were placed 3 feet from each other (distance chosen in line with CDC recommendation to represent 2 individuals sitting in a room). The ventilators of the manikin heads were not synchronised and triggered randomly.

Aerodynamic distribution of particles expelled by source near the receiver measured in triplicate using an 8-stage cascade impactor. Aerosols near the receiver were also measured with and without masks placed on the source – a filter (model No. 041B0522; Pari, Starnberg, German) was placed on the receiver head to capture inhaled particles (capturing radioactivity using a calibrated well counter (≤10 µCi; Kemble Instruments, Hamden, Ct) or a calibrated Ratemeter (≥10 µCi; Ludlum Measurements Inc, Sweetwater, TX).)

Manikin heads were cleaned and the chamber was opened and flushed with a fan between experiments.

Smoke trace experiments were performed to define ambient air currents. Chamber flow (CFM) towards the hood that the chamber was connected to using a balometer (ft^3/min). Flow was measured at 14 CFM or 0 CFM (where 14 CFM is equivalent to 6 air changes/hour). Local linear velocity was 0.670 ft/sec. Temperature 20-22ºC and relative humidity 21-26%.

Main findings:

Note: Results from experiments with no airflow have been excluded due to lack of generalisability to real-life clinical settings.

Authors state that "particles leaving the source were similar to exhaled droplets in vivo because approximately 95% of the particles were less than 2 mm, with an average MMA9D of 1.046 mm (95% CI: 0.984-1.11)"

No masks worn by source or receiver (control): the authors described the particles near the receiver as significantly smaller (75% sub-micron and 0.633µm, [95% CI 0.506-0.757]) where air flow was 14CFM 6 air change per hour compared to when no airflow was used (MMAD was 0.905 [(95% CI: 0.909-0.991]). No value provided to the second set of figures. It is assumed these are 'µm' but this is not confirmed.

- Experiments with environmental flow, i.e. 6 air changes/hour:
    - Exposure (source manipulation vs receiver manipulation), illustrated as percentage of nebulised particles:

Applying a surgical mask or N95 respirator to the source resulted in reduction of the sWPFs of 172 to 317 (95% CI not provided). Applying a SM or respirator to the receiver did not reduce exposure when compared to the use of no masks (sWPF 1.37 – 2.21)

Assessment of evidence

- Mask filtration: % of nebulised particles:

Source control: An N95 respirator worn at the source resulted in greater average filtration efficiency (35.7%, 95% CI 27.7 – 43.7) when compared to a surgical mask tightly fitted to the source (14.8%, 95% CI 10.1 – 19.6) and a surgical mask loosely fit on the source (6.07%, 95% CI 5.43 – 6.72). However, this did not correlate with reduction in exposure by the receiver when compared with the use of a tightly fitting or loosely fitting surgical mask fit on the source. The authors suggest this means that deflection (particles not captured by mask and deflected away from receiver) was a dominant factor.

Protection to wearer: Filtration at the receiver did not significantly alter protection according to the receiver wearing a loose fitting surgical mask (0.0855%, 95% - 0.00564 – 0.177), tight surgical mask (0.107%, 95% CI 0.591 – 0.156) or N95 (0.252%, 95% CI 0.027-0.377 – sWPF 2.21 vs no mask sWPF 1.37).

When the N95 was tightly applied to the source using Vaseline to represent filtration plus deflection, sWPF was highest (4082); filtration captured 81.0% (95% CI 59.5 – 103) of particles. When the N95 was tightly applied to the receiver using Vaseline, sWPF was 118, capturing 0.453% (95% CI – 0.0200 – 0.926) particles on average.

  - Deflection at source (receiver not wearing PPE):

sWPF decreased from 172 to 5.92 for loose fitting SMs, 288 to 129 for tight fitting surgical masks and 317 to 15.1 for N95s.

Limitations:

- Air flow towards receiver may not reflect real air flow (multiple persons in health settings, both inhalation and exhalation in progress during interactions). Flow towards receiver may overinflate source control results.
- Experimental study with simulation may not generalize to health and care settings.
  - No human participants and constant flow rate
  - Radiolabeled wet particles may not reflect infectious particles and may be affected by humidity (though controlled 22-26%)
  - Fit – may not generalize.

Assessment of evidence

- Represents exposure at 3 feet only.
- Unclear number of replications nor statistical power.
- Comparators limited (both source and control wearing surgical mask not assessed).
- 10 minutes of sampling and unclear replications – power calculations not provided – possible validity and reliability issues.

Source control: Within this specific experimental setting, an N95 respirator worn at the source (sealed using Vaseline) resulted in greater average filtration efficiency (35.7%, 95% CI 27.7 – 43.7) when compared to a surgical mask tightly fitted to the source (14.8%, 95% CI 10.1 – 19.6) and a surgical mask loosely fit on the source (6.07%, 95% CI 5.43 – 6.72).

Protection to wearer: Filtration at the receiver did not significantly alter protection according to the receiver wearing a loose-fitting surgical mask (0.0855%, 95% - 0.00564 – 0.177), tight surgical mask (0.107%, 95% CI 0.591 – 0.156) or N95 (0.252%, 95% CI 0.027-0.377 – sWPF 2.21 vs no mask sWPF 1.37). This result may have been impacted by the fact that the N95 respirator was not tightly sealed to the manikin head in this experimental condition. These findings suggest that at a distance of 3 feet, N95s and SFMs may be comparable when worn by a receiver. However, given that fit testing/checking of respirator to the manikin head was not performed, these findings should be treated with caution.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
He, X., Reponen, T., Mckay, RT and Grinshpun, SA. Effect of Particle Size on the Performance of an	Simulation (manikin)	Level 3	Filtration efficiency and total inward leakage of N95 versus FRSM according to particle	N95 respirator versus fluid-resistant surgical mask. Manufacturers are unclear. Authors reference previous study, but this study	Filter penetration (%) (“determined as the ratio of the corresponding size-specific number concentrations inside and outside of

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
N95 Filtering Facepiece Respirator and a Surgical Mask at Various Breathing Conditions. Aerosol Science and Technology. 2013a;47;1180-1187. Doi: 10.1080/15459620903120086.			size, flow rate and breathing frequency.	and the studies they cited are unclear. "SM model chosen for this study is expected to provide at least 95% filter efficiency for particles of 100 nm (according to its manufacturer, no flowrate is specified)"	the [N95/FRSM] sealed to the headform") Total inward leakage (%) (particle size specific) Most penetrating particle size (MPPS) (i.e. size of particle most able to pass through filter) (nm)

Assessment of evidence

Methodology:

- Filtration efficiency of N95s and FRSMs assessed by placing them on a mannequin head. N95/FRSMs replaced after 20 consecutive tests to minimise aerosol loading. The choice of this cut-off was not supported by literature.
- Experiments conducted in a 24.3 m^3 respirator test chamber maintained at 17 - 22°C and 30 – 60% relative humidity
- NaCl particles (count median diameter (CMD): 125 nm; geometric standard deviation (GSD): 1.6) were generated using a particle generator (3054, TSI Inc.). The particle generator was operated for 1 hour prior to the start of experiments to ensure there was consistent NaCl concentration within the chamber. The particles were released into the test chamber, where the mannequin was connected to a breathing recorder and simulation system (BRSS)

Assessment of evidence

- A HEPA filter was placed between the mannequin head and the BRSS to prevent particles from re-entering the respirator cavity during exhalation.
- N95 and FRSMs were both exposed to charge-equilibrated challenge particles (authors state that FRSMs are typically challenged against non-neutralised particles which is more conservative as “electrically charged particles have greater capture efficiency”).
- Mean inspiratory flow (MIF) rates assessed: 15, 30, 55 and 85 L/min. 10, 15, 20, 25 and 30 breaths/min also assessed. 20 total combinations of these variables.
- Nanoparticle spectrometer (“measures particles based on their electrical mobility so that the particle number concentration determined for each channel represent the mean electromobility particle diameter corresponding to this channel”) utilised to determine particle sizes inside/outside of N95/FRSM (sampling flow rate: 0.2 L/min). 6-minute sampling period used to determine particle-size specific concentration.
- The above process where the N95/FRSM were also placed on manikin head without sealing to the headform to assess TIL

Note: Charged-particle equilibrium: where the number of charged particles entering/leaving a volume are equal for each energy and type of particle.

Main findings:

N95 filter penetration increased as MIF increased ($p < 0.05$). Particle size did not significantly affect total inward leakage of N95 ($p > 0.05$) for particles > 50 nm at any MIF or breathing frequency. Increased MIF was associated with decreased TIL of N95 ($p < 0.05$)

“Compared to the N95 FFR, the SM had a much higher filter penetration ($p < 0.05$), which is expected given its primary function to protect others from the aerosol exhaled by the wearer.”

Assessment of evidence:

In this study, the N95 had higher filtration efficiency when compare to SFMs ($p < 0.05$). Particle size did not affect total inward leakage of N95 when particles > 50 nm. Filter penetration of N95s significantly increased as MIF increased ($p < 0.05$).

Assessment of evidence

Limitations:

- HEPA filtration rate not provided
- No independent experiment repeats
- Simulation study which has limited generalisability to real-life clinical settings
- Unclear if breathing rates and mean inspiratory flow chosen for the experiment are based on
- Authors suggest that experimental set-up and instruments used impacted the findings, in particular, most penetrating particle size for the N95/FRSM
- Only one N95 respirator and one FRSM brand assessed.
- Limited generalisability to NHS Scotland given use of N95s and no investigation of respirators with other filtration efficiencies e.g. FFP3s.
- Funding source and conflicts of interest not disclosed
- Use of mannequin head lacks generalisability to real-life clinical settings
- Unclear how N95/FRSM were sealed to the mannequin head to assess filtration efficiency accurately
- Data presented in graphs, thus only possible to discuss p-values
- N95/FRSMs were used for 20 consecutive tests. This may have impacted filtration efficiency. Direction of bias is unclear.

This study suggests that N95s have greater filtration efficiency when compared to FRSMs, thus N95s are preferred when being used to protect the wearer from particles emitted by others. These findings should be considered as part of a wider evidence base given its limitations.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
He X, Reponen T, McKay R, et al. How Does Breathing Frequency Affect the Performance of an N95 Filtering Facepiece Respirator and a Surgical Mask Against Surrogates of Viral Particles? J Occup Environ Hyg. 2013b;11;178-185. Doi: 10.1080/15459624.2013.848037.	Simulation (manikin)	3	The study aims to address the effects of breathing frequency and flow rate on filter efficiency and faceseal leakage of a N995 FFR and a SM challenged with NaCl particles (sized between 0.02 and 0.5µm)	Filter penetration and total inward leakage with varying levels of breathing frequency and flow rate	Effect of mean inspiratory flows (MIF) and breathing frequency on Filter penetration (PFilter) Effect of MIF and breathing frequency on TILs N95 Faceseal Leakage-to-Filter Ratio

Assessment of evidence

Methodology:

- Carried out in a room-size (24.3m3)
- Temp. 17°C – 22°C and relative humidity 30-60%
- Manikin connected to breathing recording and simulation system

Assessment of evidence

- "Particle size independent (overall) concentrations inside and outside the FFR/SM were obtained using a condensation particle counter (Model 3007, TSI Inc.)"
    - Total sampling time of 3 min with a time resolution of 1 sec
- Experiments conducted at four cyclic breathing flows (MIF= 15, 30, 55, 95 L/min) and five different breathing frequencies (10, 15, 20, 25, and 30 breaths/min).

Main findings:

Filter Penetration (PFilter)

N95s

Pfilter consistently increased with /increasing MIF.

Both MIF and breathing frequency had a significant effect on filter penetration ($p<0.0001$).

- MIFs: "Pairwise multiple comparison results (see Table I) show that the four MIFs produced four different Pfilter groups with the highest mean Pfilter (0.72%, Tukey grouping A) occurring at the highest MIF of 85 L/min, and the lowest mean Pfilter (0.05%, Tukey grouping D) occurring at the lowest MIF of 15 L/min."
- Breathing frequency: "The breathing frequency comparisons show that 10 and 15 breaths/min produced higher values of Pfilter (0.39% and 0.38%, Tukey grouping I) than those observed at 20, 25, and 30 breaths/min (0.25%, 0.23%, and 0.26%, respectively, Tukey grouping II)."

SMs

"Compared to the N95 FFR, the SM had a much higher filter penetration." "Increasing MIF frequently resulted in an increase in filter penetration, especially at the lowest breathing frequency."

Both MIF and breathing frequency had a significant effect on filter penetration ($p<0.0143$)

Assessment of evidence

- MIFs: “The pairwise multiple comparisons (see Table III) show the highest MIF (85 L/min) produced the highest mean Pfilter (9.65%, Tukey grouping A), whereas the lowest Pfilter (5.41%, Tukey grouping C) occurred at the lowest MIF (15 L/min).”
- Breathing frequency: “the mean Pfilter = 7.81% (Tukey grouping I) obtained at 30 breaths/min was significantly higher ($p < 0.05$) than Pfilter = 6.67% (Tukey grouping II) obtained at 20 breaths/min. However, no consistent trend was identified throughout the frequency scale”

TIL

N95s

“MIF of 15 L/min produced the highest TILs”. “the TIL increased with increasing the breathing frequency”.

Both MIF (=0.0019) and breathing frequency (p=0.0025) had a significant effect on TIL.

- MIF: “The pairwise multiple comparison results presented in Table II show that the lowest MIF (15 L/min) was associated with the highest mean TIL (1.93%, Tukey grouping A).”
- Breathing frequency: “. The highest breathing frequency (30 breaths/min) produced the highest mean TIL (1.73%, Tukey grouping I) compared to the lowest mean TIL (1.22%, Tukey grouping II) with the lowest breathing frequency (10 breaths/min). The highest and lowest breathing frequencies were significantly different (Tukey groups I and II).”

SM

Increasing MIF caused the mean TIL to decrease

“While ANOVA revealed that both MIF and breathing frequency had a significant effect on the TIL ($p<0.05$), no consistent trend of increase or decrease of TIL with breathing frequency was observed.”

Limitations:

- Model of N95 FFR and SM not provided
- Unknown why 20 tests was cut off for minimizing loading effect, no tests to establish this as sufficient

Assessment of evidence

- Unknown how N95 and SM is sealed to manikin
- HEPA filtration rate not provided
- Simulation study which has limited generalisability to real-life clinical settings
- Unclear if breathing rates and mean inspiratory flow chosen for the experiment are based on
- Only one N95 respirator and one FRSM brand assessed.
- Limited generalisability to NHS Scotland given use of N95s and no investigation of respirators with other filtration efficiencies e.g. FFP3s.
- Funding source and conflicts of interest not disclosed
- Data presented in graphs, thus only possible to discuss p-values
- Method to seal N95 not provided

This simulation study involving manikins suggests that with increasing breathing frequency and increasing MIF, filter penetration of a sealed N95 significantly increased ($p<0.0001$). Filter penetration was higher for a sealed SM. TIL from a non sealed N95 significantly increased with increasing breathing frequency ($p=0.0025$), and significantly decreased with increasing MIF ($=0.0019$).

This study is greatly limited by its experimental nature with use of manikins affecting its generalizability in real life scenarios.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Lee SA, Hwang DC, Li HY, et al. Particle size-selective assessment of protection of European standard FFP respirators and surgical masks against particles-tested with human subjects. J Healthc Eng. 2016; 8572493. Doi: 10.1155/2016/8572493.	Simulation (human participants)	Level 3	The filtering efficiency of FFP respirators (FFP1, FFP2, and FFP3 from two manufacturers) against different sizes of particles (nebulized NaCl). The relationship between protection factors and fit factors. Comparison of FFP3 and surgical face mask filtering efficacy.	N/A	Fit test pass rate (%) – PortaCount Plus (TSI Inc, St Paul, USA). With equation for fit factor provided on page 5. Geometric mean (GM) of protection factors (PF) – ratio based on a comparison of sampling from inside and outside a face mask. Comparison of GM of PF with SM vs respirators Statistical analysis – ANOVA, t-test, pearsons correlation.

Assessment of evidence

This observational experimental study carried out in Taiwan investigated the filtering efficiency of FFP respirators (supplied by two manufacturers) and SMs (from three manufacturers) against nebulized NaCl in controlled conditions.

Methodology:

- Participants underwent a fit test before undergoing the total inward leakage test.
- When the particle concentrations were stable in the test chamber, the subjects equipped with the personal system donned the test respirators and performed the OSHA fit testing exercises. Participant was trained to wear respirator.
- User-seal-check performed when respirator put on subjects face. OSHA fit test exercises (normal breathing, deep breathing, turn head side to side, moving head up and down, talking, grimace, bending over and returning to normal breathing). Fit factor for each exercise recorded.
- Fit factor was recorded using a PortaCount Plus. Note the Portacount plus measures ambient particles
- Overall fit factor calculated (Grimace exercise excluded) – according to the OSHA standard – "calculation of overall fit factor using individual exercise fit factors involves converting the exercise fit factors to penetration values, determining the average, and then converting that result back to a fit factor"
- Repeated OSHA fit test exercises. Each exercise was performed for two minutes and the particle concentrations inside the respirator were averaged over the second minute. The concentration inside the respirator (Cin) for the entire test was averaged over all the exercises, excluding the grimace manoeuvre.

Main findings:

This study identified no significant difference in protection factor (PF) between the class of FFP used (p>0.05). The lowest PF was seen for particles sized 0.263 to 0.384μm. However, PFs were not significantly different among different particle sizes in the size range of 0.093– 1.61 μm (p > 0.05). With respect to the geometric mean of PFs, the overall PF provided by SMs was 11.5 times less than that for FFP1 respirators, 15.9 times less than that for FFP2 respirators, and 15.7 times less than that for FFP3 respirators (p < 0.05).

Assessment of evidence

Comparison of PF of SM and FFPs:

"With respect to the geometric mean of PFs, the overall PF provided by SMs was 11.5 times less than that for FFP1 respirators, 15.9 times less than that for FFP2 respirators, and 15.7 times less than that for FFP3 respirators ($p < 0.05$)."

Limitations:

- Small sample size
- Patients were 18-24 – may not generalize
- Taiwan based – may not generalize
- NaCl particles may not reflect infectious viral/bacterial/fungal particles
- Type of surgical face mask – not clear
- Correlations not causation
- Test chamber may not generalize to health and care facilities. Air changes per hour not clear (though noted as capable 0-60)
- The filtration efficacy displaced as ratio but how this impacts practice is not clear
- Small sample and unclear power – may be underpowered and lack validity/reliability
- ratio based on a comparison of sampling from inside and outside a face mask was used as a measure of 'protection' however the actual filtration values or aerosol sampling concentrations are not provided. One value provided (not per exercise)
- Rest periods between exercises/experiments not clear. Cleaning equipment noted but unclear if this was used – for example between each person/experiment

In this cohort, this study identified FFPs of all classes provide a significantly greater protection factor (PF) than SMs ($p<0.05$). The class of FFPs did not appear to have a significant impact on PF, and PFs are not significantly different among different particle sizes

Assessment of evidence
ranging 0.093– 1.61 μm (p > 0.05). This study must be considered as part of a wider evidence base as it is severely limited by its generalisability to real-life scenarios due to its experimental nature.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Mansour MM and Smaldone GC. Respiratory Source Control Versus Receiver Protection: Impact of Facemask Fit. J Aerosol Med Plum. 2013;26(3);pp:131.137. Doi:10.1089/jamp.2012.0998	Simulation (manikin)	Level 3	The use of two manikins (a source and a receiver) with simulated tidal breathing at 3ft apart to determine the degree of protection for source N95 and surgical mask combinations as well as receiver N95 and surgical mask combinations.	Several surgical mask/N95 iterations worn by the source or receiver: No mask on source/receiver; surgical mask tightly fitted on source; surgical mask looped around ears of source; N95 worn by the source; surgical mask tightly fitted on receiver; surgical mask looped on ears of receiver; N95 on receiver;	Particle distributions and mass median aerodynamic diameters (MMAD) Exposure data - expressed as % of nebulised activity*. * Nebulised activity represented the difference between initial nebulizer charge and that remaining after nebulization Exposure data also expressed as simulated workplace

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
				N95 sealed using Vaseline on source or receiver.	protection factor (sWPF) defined as ratio of max exposure to actual exposure. “The protective effect of each intervention in reducing exposure is best illustrated by the magnitude of the sWPF.” Mask filtration – radioactivity captured by each mask, reported as a % of activity exhaled at source Separation of 95% CIs indicated statistical significance.

Assessment of evidence

Experimental set-up:

- Two Resusci Anne CPR mannequin heads (no. 310200; Laerdal Medical, Wappingers Falls, NY) were placed in the enclosure, 3 ft apart.
- Both heads fitted with respiratory tubing and ventilated by a Harvard pump (Harvard Apparatus SN no. A52587; Millis, MA) simulating a tidal breathing pattern (volume of 500 mL, respiratory rate of 15 breaths/min, and duty cycle of 0.5 sec).
- Source head was connected to an AeroTech II nebulizer (three devices used in rotation; Biodex, Shirley, NY) powered by an air tank with a flow of 10 L/min
- nebulizer was filled with 3 mL of 0.9% normal saline labeled with technetium-99m and run to dryness over 10 min, producing radioactive wet aerosols
- Receiver head had no modifications and was ventilated through nose and mouth
- Exposure quantification by a filter (model no. 041B0522; PARI, Starnberg, Germany) was connected to receiver head to capture inhaled particles
- Aerosol exposure data – quantified by measuring radioactivity captured by receiver filter

Main findings:

Particle distributions and MMAD (mass median aerodynamic diameters) (diameter vs probability):

At the source, approx. 90% of particles were <2µm

Average MMAD = 0.95µm (95% CI: + 0.119)

The MMAD of particles reaching the vicinity of the receiver was 0.69µm (95% CI: + 0.0663).

Control: Maximum Exposure (Max Ex) (i.e. aerosol inhaled by receiver) average = 1.363% (95% CI: 0.912–1.81%). As this was the ‘no protection’ control, sWPF = 1.

Assessment of evidence

SFM/N95 worn by source, i.e. patient:

- SFM naturally fitted: Exposure decreased to 0.000637% (95% 95% CI: 0.00163–0.01110%), SWPF = 214
- SFM tightly fitted: Exposure decreased to 0.00019% (0.00023% (95% CI: 0.00009–0.00038%), sWPF = 5,850
- N95 (no Vaseline): 0.00019% (95% CI: 0.00012– 0.00027%), sWPF = 7,174
- Compared to the control, these were deemed statistically significant reduction in aerosol exposure.

N95 sealed with Vaseline to mimic tight fit:

- Source wearing N95 with Vaseline vs source wearing N95 without Vaseline: sWPF was 17,038 (exposure 0.00008%, 95% CI -0.00007, 0.00023) versus 7,174 (exposure 0.00019, 95% CI 0.00012, 0.00027), respectively.
- The difference in reduction of exposure when using a non-tightly fitted N95 vs a sealed N95s was not statistically significant due to overlapping 95% CIs (see bullet point above)

SFM/N95 worn by receiver, i.e. staff, visitor:

- SFM naturally fitted: 1.38% (95% CI: 0.992–1.77%), sWPF =0.99
- SFM tightly fitted: 0.669% (CI: 0.0641–1.27%), sWPF = 2.04
- N95 (no Vaseline): 0.181% (95% CI: 0.106–0.256), sWPF of 7.53
- Compared to the control, these results were not statistically significantly lower than the control.

N95 sealed with Vaseline to mimic tight fit:

- 0.0216% (95% CI -0.006, 0.0492), sWPF 63.1. This is significantly different when compared to the control, therefore the only PPE item to confer protection of the receiver. This is also significantly different compared to the receiver wearing a non-tightly fitted N95, indicating the importance of achieving a tight fit, i.e. performing a fit check.

Assessment of evidence

Limitations:

- in-vitro
- set parameters of air flow, air changes and 3ft distancing between source and receiver
- “wet radioactive particles” unlikely to generalize behaviour of infectious particles
- Limited generalizability out with these conditions (use of manikins)
- No fit testing of respirators, only visual checking – confounding factor
- Use of Vaseline to seal respirator not applicable to real life scenario, may not fully represent a fit tested N95.
- Use of N95, not recommended in UK
- One model of mask and one model of respirators used, specific to this
- Unknown no. of replicate of experiments to obtain an average
- Unclear if the source manikin wore a mask/respirator when the experiments involving source masking occurred. Therefore, any comparisons between receiver and source control are omitted from the conclusion.

Conclusion:

Source control: This in-vitro experimental study involved two mannequin heads which represented 3-foot distancing between a source and receiver. The study suggests a sealed N95 with Vaseline (attempting to mimic a fit tested N95) used as source control provides greatest reduction to exposure when compared with maximum exposure, where no masks were worn by either source or receiver mannequins. Significant reductions in exposure were seen when the source manikin wore a SM naturally fitted (looped around ears), SM tightly fitted (stretched across mannequin head), and an unsealed N95. However, the difference in reduction between the N95s and SFMs when worn at the source (excluding the N95 tightly fitted using Vaseline) was non-significant. This indicates that in this experimental scenario, SFMs worn by the source, i.e. patient, provided sufficient protection to the receiver, i.e. staff, visitor.

Assessment of evidence
Protection to wearer: The N95 respirator was assessed using two configurations: with and without Vaseline used to seal the respirator to the manikin head. When the N95 respirator was sealed to the receiver, there was significant increase in sWPF when compared to the N95 being placed on the receiver head without the use of Vaseline. This indicates the importance of adequate N95 fit without face seal leakage, contributing to the evidence-base that a user seal check or fit test should be performed every time a respirator is donned by a staff member. Although the sealed N95 respirator conferred maximum protection when worn at the source, this was not statistically significant when compared to the use of a non-sealed N95 and SFMs, indicated by the overlapping 95 CIs.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Patel RB. Skaria SD, Mansour MM, et al. Respiratory source control using a surgical mask: An in vitro study. J Occup Environ Hyg. 2016; 13(7); 569-576. Doi: 10.1080/15459624.2015.1043050.	Simulation (manikin)	Level 3	The use of two manikins (a source and a receiver) with simulated breathing or coughing at 3ft apart to determine the degree of protection provided by a respirator (N95) and SM	Protection provided in three room conditions (zero ACH, six ACH, 12 ACH)	Aerosol particle distribution - MMAD (mass median aerodynamic diameter, µm) and GSD (Geometric standard deviation). Receiver protection factor (RPF) – defined as ratio of Max exposure (Max Ex) to actual exposure Mask capture efficiency

Assessment of evidence

Findings:

Aerosol particle distribution:

- “In all three rooms, during coughing, at the Source, distributions contained larger particles than during tidal breathing.”
- Tidal breathing
    - Source (MMAD, GSD):
        - No flow room – 0.96μm,1.80
        - Hospital room – 1.09 μm 1.84
        - Negative pressure room – 1.07 μm, 1.63
    - Receiver:
        - No flow room – 1.04 μm, 1.58
        - Hospital room – 0.72 μm, 1.81
        - Negative pressure room – 0.98 μm, 1.99
- Coughing
    - Source:
        - No flow room – 1.45 μm, 1.85
        - Hospital room – 1.52 μm, 1.92
        - Negative pressure room – 1.30 μm, 2.29
    - Receiver:
        - No flow room – 1.04 μm, 1.60

Assessment of evidence

- Hospital room – 0.53 μm, 2.02
- Negative pressure room – 0.61 μm, 2.74

Exposure and mask protection: **Tidal breathing**

- "In the No flow, Hospital and Negative pressure rooms, Max Ex averaged 1.146% (95% CI: 1.037–1.255%), 0.617% (95% CI: 0.577–0.657%), and 0.0167% (95% CI: 0.0152–0.0182%),a respectively."
- Significant ($p<0.05$) decrease in exposure (when compared with max exposure) for:
  - No air flow room
    - Source Secure fit surgical mask
    - Source N95
    - Source N95 Vaseline
    - Receiver N95 Vaseline
  - Hospital room
    - Source N95
    - Source N95 Vaseline
    - Receiver N95
    - Receiver N95 Vaseline
  - Negative pressure room
    - Source natural fit surgical mask
    - Source secure fit surgical mask

Assessment of evidence

- Source N95
- Source N95 Vaseline
- Receiver N95
- Receiver N95 Vaseline

Exposure and mask protection: **cough**

- “In general, for all rooms, mask on Source was superior to mask on Receiver.”
- Significant ($p<0.05$) decrease in exposure (when compared with max exposure) for:
  - No air flow room
    - Source secure fit surgical mask
    - Source N95
    - Source N95 Vaseline
    - Receiver N95 Vaseline
  - Hospital room
    - Source secure fit surgical mask
    - Source N95
    - Source N95 Vaseline
    - Receiver N95 Vaseline
  - Negative pressure room
    - Source natural fit surgical mask

Assessment of evidence
▪ Source secure fit surgical mask ▪ Source N95 ▪ Source N95 Vaseline Filtration at source - During tidal breathing: the natural fit surgical mask captured particles ~5–20%, the N95 ~ 80–90%, and a sealed N95 ~100%. - During coughing: both the secure fit surgical mask and the N95 capture ~ 100% of the exhaled aerosol.

Evidence from previous update(s):

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Association of PeriOperative Nurses (AORN) Recommended Practices for Prevention of Transmissible Infections in the Perioperative Practice Setting. AORN J. 2007; 85(2); 383-396. Doi:	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
10.1016/S0001-2092(07)60049-0.					

Assessment of evidence

USA guidance for register perioperative nurses. Recommendations proposed are considered optimal level of practice. The guidance acknowledges that “Policies and procedures will reflect variations in practice settings and/or clinical situations that determine the degree to which the recommended practices can be implemented.”

N95 respirator recommendations:

- “Health care personnel entering the OR suite immediately following a patient on airborne precautions should use an N95 mask and use proper PPE.”
- “When surgical procedures are performed on patients who may have infectious TB, respiratory protection worn by personnel protects the sterile field from the respiratory secretions of the health care worker and protects the health care worker from the infectious droplets generated by patients” This recommendation was based on one citation (32).

Citation 1: CDC isolation precaution guidance from 1996.

Citation 32: CDC guidance on transmission of mycobacterium tuberculosis from 2005.

Airborne precautions: “Airborne precautions should be used when caring for patients who are known or suspected to be infected with microorganisms that can be transmitted by the airborne route (eg, rubeola, varicella, tuberculosis [TB], and smallpox).”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
World Health Organization (WHO) Infection prevention and control of epidemic-and pandemic prone acute respiratory infections in health care, 2014. Accessed: 24th January 2023	Guidance	AGREE: Recommend (with provisos)	N/A	N/A	N/A

Assessment of evidence

Funding: “Financially supported by the United States Centers for Disease Control and Prevention (CDC), the United States Agency for International Development (USAID), the German Agency for International Cooperation (GIZ), and the French Ministry of Social Affairs and Health”

Aim of guidance: “The guidance is intended to help policy-makers, administrators and health-care workers to prioritize effective IPC measures”

Target audience: “Recommendations, best practices, and principles for non-pharmacological aspects of infection prevention and control (IPC) for acute respiratory infections (ARI) in health care” intended for policy-makers, administrators and health-care workers, including doctors, nurses, allied health professionals, auxiliary and community health workers, and others involved in provision of health care.

Assessment of evidence

Development: The development of the guidelines followed the process established in the WHO handbook for guideline development, which involved active participation of the Global Infection Prevention and Control Network (GIPCN). The resulting recommendations were peer reviewed by internal and external experts." This guidance is deemed expert opinion as it is unclear the edition of the "WHO handbook for guideline development" that was used. Further to this, the elements of the systematic review process, such as the search strategies, are not provided.

Recommendations:

- "Use appropriate PPE as determined by risk assessment (according to the procedure and suspected pathogen). Appropriate PPE when providing care to patients presenting with ARI syndromes may include a combination of: medical mask (surgical or procedure mask); gloves; long-sleeved gowns; and eye protection (goggles or face shields)." (Citation 51)
- "Use PPE, including […] facial mask (surgical or procedure mask, or particulate respirators) during aerosol-generating procedures that have been consistently associated with an increased risk of transmission of ARI pathogens." (Citation 51 and 149)
- If caring for patients with an airborne infection (e.g. pulmonary TB), or undertaking aerosol-generating procedures associated with an increased risk of transmission of ARI pathogens, select the highest level of respiratory protection equipment available, preferably a particulate respirator. (Citation 27 and 149)
- "When entering the isolation room or area, or when providing care to a patient with an obligate or preferential airborne infectious disease in other settings, use a particulate respirator that is at least as protective as a NIOSH-certified N95 or equivalent (Annex A).
- "When performing aerosol-generating procedures associated with pathogen transmission, use a particulate respirator that is at least as protective as a NIOSH-certified N95, EU FFP2 or equivalent, and wear gloves, gowns and eye protection (e.g. goggles) (86, 120, 250)."
- "Newly emerging ARIs: Implement additional IPC precautions at the time of admission, and continue for the duration of symptomatic illness, modifying according to the pathogen and patient information. Base the precautions used and their duration

Assessment of evidence

on information about transmission risk as it becomes available, and on local health authority recommendations. It may be prudent to implement the highest level of IPC precautions possible, including the use of particulate respirators, until the mode of transmission is clarified."

Note: "Airborne pathogens are transmitted through inhalation of droplet nuclei that remain infectious over a long distance (e.g. > 1 m), and require special air handling (4, 5). Their transmission is further classified as obligate or preferential (9):

- obligate airborne transmission applies to agents naturally transmitted exclusively through droplet nuclei deposited in the distal part of the lung (e.g. Mycobacterium tuberculosis causing pulmonary TB); and
- preferential airborne transmission applies to pathogens (e.g. measles) that are transmitted by droplet nuclei deposited in the airways but can also be transmitted by other routes."

References:

- Citation 4: Mayhall CG. Hospital epidemiology and infection control. Philadelphia, Lippincott Williams & Wilkins, 2004. (This is a book)
- Citation 5: Wenzel RP. Prevention and control of nosocomial infections. Philadelphia, Lippincott Williams & Wilkins, 2003 (This is a book)
- Citation 86: Chen et al 2006. Outbreak study investigating a SARs outbreak (out of scope/not relavent for current review)
- Citation 120: Chaovavanich et al 2004. Study implementing a bundle of IPC measures (including PPE) to contain a SARs outbreak within a hospital
- Citation 250: Cheung et al. 2004. Study investigating the effectiveness of non-invasive positive pressure ventilation
- Citation 27 (WHO 2009): WHO policy on TB infection control in health-care facilities, congregate settings and household 2009.
- Citation 158 (Hannum et al. 1996). The effect of respirator training on the ability of healthcare workers to pass a qualitative fit test. This a dated reference particularly in regard to the scope of the current review.

Assessment of evidence

- Citation 51 (Jefferson et al. 2011 51): A Cochrane review published in 2011 to identify the physical interventions to interrupt the spread of respiratory viruses. Total number of participants not included because of a heterogeneity. Only case control data included in the meta-analysis
- Citation 149 (Tran et al. 2011): A systematic review from 2011 which assessed the clinical evidence on the risk of transmission of ARIs to HCWs exposed to AGPs. However, the included studies were of very low quality as also identified by the authors.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). Respiratory protective equipment at work: A practical guide. HSG53 (4th Ed.) 2013. ISBN: 978 0 7176 6454 2.	Expert opinion	Level 4	N/A	N/A	N/A

Assessment of evidence

About this guidance:

- This guide prepared by the HSE “in consultation with industry: employers, trade unions and trade associations”, is stated to support “the Approved Code of Practice (ACOP) to the Regulations that apply (see paragraphs 36–39)”.

Assessment of evidence

- “The guide contains practical guidelines to help you select the correct RPE and manage its use in your workplace to ensure effective protection.”
- “As an employer, you have a legal responsibility under all the Regulations listed in paragraphs 36–39”

Recommendations:

RPE selection:

- “43 To select RPE that will protect the wearer you will need a basic understanding of: the hazardous substance and the amount in the air (exposure); the form of the substance in the air (eg gas, particle, vapour); the type of work being carried out; any specific wearer requirements, such as other PPE or a need for spectacles.”
- 53 You need to ensure that the RPE you select can protect the worker from the hazardous substance in the air around them. Your decision will depend on the amount in the air and its form (eg particles, vapour). There are various types of respirator and BA available. The protection they offer will be determined by a number of things, including the protection factor. In simple terms, this is the ratio of hazardous substance outside the RPE to the amount inside the RPE.
- 54 To help you, each RPE type and class is categorised by an assigned protection factor (APF). […] When calculating the protection factor, always choose an APF above the calculated value”

Continuous wear time – Less than 1 hour” for following due to comfort “Unpowered tight fitting masks become uncomfortable to wear for long periods and wearers may be tempted to loosen or remove the RPE”:

- Disposable half mask respirators- particle filter (sometimes referred to as a filtering facepiece or orinasal respirator
- Reusable half mask respirators – particle filter
- Full face mask respirators

“Dispose of masks marked NR (not reusable) after a single shift (8 hours).” – Figure 8 Disposable half mask respirator

“8 Filters are additionally marked:

Assessment of evidence
• NR = Not reusable – Designed for a single work shift (eight hours) and must be disposed of safely at the end. R = Reusable.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Coia JE., Ritchie L., and Adisesh, A. et al. Guidance on the use of respiratory and facial protection equipment. Journal of Hospital Infection, 2013; 85;170-182. Doi: 10.1016/j.jhin.2013.06.020.	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence
Best practice guidance based on a non-systematic literature review published separately (Bunyan D, Ritchie L, Jenkins D, Coia JE. Respiratory and facial protection: a critical review of recent literature. J Hosp Infect 2013;85:165e169). “The Scientific Development Committee of the Healthcare Infection Society established a short-life working group in May 2011 to develop appropriate guidance. The working group included representation from the Healthcare Infection Society, Public Health England,

Assessment of evidence

Health and Safety Executive (HSE), Association of National Health Occupational Physicians, Health Protection Scotland, Infection Prevention Society, Intensive Care Society, Clinical Virology Network and British Infection Association."

Particles grouped into:

- Splashes: large particles >100 uM in diameter
- Droplets: Larger than aerosols (approx. 5 – 100 uM in diameter)
- Aerosols: Lightweight particles (<5 uM)

Relevant recommendations:

- "The requirement for and selection of appropriate respiratory and facial protection is determined by a number of factors that involve a risk-assessment-based approach considering:
    - the task or procedure to be undertaken;
    - the suspected or known infectious status of the patient; and
    - the presenting symptoms of the patient."
- An algorithm is included within the document to specify when an FFP3 respirator should be worn. This algorithm is included in the current version of the RPE literature review (being removed in this update).
    - An FFP3 respirator is advised when a patient is known or suspected to be infected with an organism spread wholly or partially by airborne or droplet route when performing AGPs.
    - FFP3 respirators should also be worn when is patient is known or suspected to be infected with an organism spread wholly or partially by the airborne route, irrespective of if whether there is likely splashing or spraying of blood/body fluids from patient contact or procedure.

Assessment of evidence

- “For a very small number of pathogens truly transmissible via the airborne route, or where AGPs involving infectious body fluids are being undertaken, a respirator will be required” – airborne transmission given as the main route of transmission for Mycobacterium tuberculosis (SARS coronavirus and Varicella zoster virus given ‘droplet/airborne’)
- FFP3 respirator recommended for the following patient (until a patient is no longer considered infectious):
    - Measles (main route of transmission: droplet/aerosol transmission)
    - Mycobacterium tuberculosis (main route of transmission: aerosol)
    - SARS coronavirus (main route of transmission: droplet/aerosol)
    - Varicella zoster virus (main route of transmission: droplet/aerosol)
    - Note that transmission routes are outside the scope of the RPE literature review and the evidence presented in this guidance document was based on non-systematic review of evidence.
- “The extended use of some forms of PPE may be considered where a local risk assessment has occurred in conjunction with staff training. This is a suitable option in cohort wards. This strategy can be applied to masks, protective eyewear and face shields and gowns.”
- “If patients with known or suspected airborne infections (e.g., pulmonary TB) are cohorted in a common area or in several rooms on a nursing unit, and if multiple patients will be visited sequentially, it may be practical for a health-care worker to wear a single particulate respirator for the duration of the activity. This type of use requires that the respirator not be removed at any time during the activity, and that the user does not touch the respirator. If the respirator gets wet or dirty with secretions, it must be changed immediately.” (158)

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Loveday HP, Wilson JA, Pratt RJ, et al. epic3: National Evidence-Based Guidelines for Preventing Healthcare-Associated Infections in NHS Hospitals in England J Hosp Infect 2014;pp:1-70.	Guidance	AGREE: Recommend (with provisos)	N/A	N/A	N/A

Assessment of evidence

These guidelines were commissioned by The Department of Health (England) for preventing HCAI in hospital or other acute heal and care settings. It is unclear how the evidence/ expert opinion formulated the following recommendations, this document is also outdated as an update was due to be published in 2017. The guideline development team was comprised of individuals with varied specialties within IPC including, nursing, microbiology, infectious diseases. The guideline advisory team was formed of consultants, trust and lay members amongst others.

Recommendations:

- “The selection of the most appropriate respiratory protective equipment (RPE) should be based on a suitable risk assessment that includes the task being undertaken, the characteristics of the biological agent to which there is a risk of exposure, as well as the duration of the task and the local environment.”

Assessment of evidence
• "Appropriate respiratory protective equipment should be selected according to a risk assessment that takes account of the infective microorganism, the anticipated activity and the duration of exposure. Class D/GPP/H&S" • "Where the activity involves procedures likely to generate aerosols of biological agents transmitted by an airborne route (e.g. intubation), RPE with an assigned protection factor (APF) of 20 (equivalent to FFP3) should be used. In other circumstances, such as where the agent is transmitted via droplet rather than aerosol or where the level of aerosol exposure is low, the risk assessment may conclude that other forms of RPE (e.g. APF10/ FFP2) or a physical barrier (e.g. surgical face mask) may be appropriate, such as when caring for patients with influenza." – not an explicit recommendation

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Siegel JD, Rhinehart E, Jackson M, Chiarello L. 2007 guideline for isolation precautions: preventing transmission of infectious agents in health care settings. American journal of infection control.	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
2007 Dec 1;35(10):S65-164. Last updated: September 2024 Accessed: 28 October 2024					

Assessment of evidence

Target audience: Infection control staff, health care epidemiologists, healthcare administrators, nurses, other health care providers and persons involved in infection control programs (developing, implementing and evaluating) for healthcare settings.

Methodology:

- Expert opinion by CDC and HIPAC (members listed). This guidance presents narrative synthesis summary of literature and how it contributes to IPC guidance. New emerging pathogens, rising concern for known pathogens, new therapy development and rising concern for bioterrorism prompt updates. Little detail is provided on the methodology for literature search and review process.
- Consistent with the TBP review, this was AGREE Not Recommend based on lack of detail on review methods.
- The reference list was screened for papers/guidance which may be relevant for RPE review. Unless otherwise stated, CDC guidance is cited to support these recommendations.

Recommendations:

- “Wear a fit-tested NIOSH-approved N95 or higher-level respirator for respiratory protection when entering the room or home of a patient when the following diseases are suspected or confirmed:

Assessment of evidence

- Infectious pulmonary or laryngeal tuberculosis, or when infectious tuberculosis skin lesions are present and procedures that would aerosolize viable organisms (eg, irrigation, incision and drainage, whirlpool treatments) are performed."
  - Category IB, meaning that it's strongly recommended and supported by experimental, clinical and/or epidemiology studies as well as theory. Citations include CDC guidance (12) and two studies from before 2000 (1023 - Hutton et al., 1990; 1024 - Frampton, 1992).
- "Smallpox (vaccinated and unvaccinated). Respiratory protection is recommended for all HCWs, including those with a documented ''take'' after smallpox vaccination due to the risk of a genetically engineered virus against which the vaccine may not provide protection, or of exposure to a very large viral load (from, e.g, high risk aerosol-generating procedures, immunocompromised patients, hemorrhagic or flat smallpox)"
  - Category II, meaning it's being put forward based on clinical, epidemiological or theoretical studies. Citations include two studies from before 2000 (108 - Fenner et al., 1988; 129 – Gelfand and Posch, 1971).
- "No recommendation is made regarding the type of PPE (ie, surgical mask or respiratory protection with a N95 or higher-level respirator) to be worn by susceptible HCWs who must have contact with patients with known or suspected measles, chickenpox, or disseminated herpes zoster."

- "The use of a particulate respirator is recommended during aerosol-generating procedures when the aerosol is likely to contain M tuberculosis, SARS-CoV, or avian or pandemic influenza viruses" (page 59)

Under the heading "Transmission-Based Precautions":

- For airborne precautions, "HCWs caring for patients on Airborne Precautions wear a mask or respirator, depending on the disease-specific recommendations (see Section II.E.4, Table 2, and Appendix A), that is donned before room entry" (page 74)
  - This section cites the section on personal protective equipment, table 2 outlining transmission based precautions whilst waiting on confirmatory diagnosis and appendix A, an up to date list of infectious agents, their precautions and duration (relevant entries described below)

Assessment of evidence

Appendix A (page 97) for disease-specific recommendations:

- “Severe acute respiratory syndrome (SARS)” “Airborne Precautions preferred; D [droplet precautions] if AIIR unavailable. N95 or higher-level respiratory protection; surgical mask if N95 is unavailable; aerosol-generating procedures and ‘‘supershedders’’ are at highest risk for transmission through small droplet nuclei and large droplets. (see http://www.cdc.gov/ncidod/sars).” (page 115)
    - This entry cites CDC guidance and a study included in the 2019 review (93 – Loeb et al., 2004), two studies not specific to respirators (94 – Fowler et al., 2004 and 96 - Scales et al., 2003)
- “Smallpox (variola; see vaccinia for management of vaccinated persons)” “Until all scabs have crusted and separated (3 to 4 weeks). N95 or higher-level respiratory protection for susceptible and successfully vaccinated individuals.”
    - This entry cites CDC guidance (1036), studies from before 2000 (108 – Fenner et al., 1988; 129 - Gelfand and Posch, 1971; 1035 – Salzman et al., 1998) and a study not specific to respirators (1034 – Watson et al., 2000)
- “In some health care settings, particulate respirators used to provide care for patients with M tuberculosis are reused by the same HCW. This is an acceptable practice providing that the respirator is not damaged or soiled, the fit is not compromised by a change in shape, and the respirator has not been contaminated with blood or body fluids. No data are available on which to base a recommendation regarding the length of time that a respirator may be safely reused.” (Page 57)

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The National Institute for Health and Care Excellence (NICE) Healthcare-associated infections: prevention and control in primary and community care. Clinical guideline CG139. 2012. Updated 2017. Accessed: 20th December 2022	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence
Context: “This clinical guideline is a partial update of 'Infection control: prevention of healthcare associated infection in primary and community care' (NICE clinical guideline 2; 2003)”. The relevant information within this document is from the 2003 version of this document (was not updated). Population covered in guideline: “all adults and children receiving healthcare for which standard infection-control precautions apply in primary care and community care” **Target audience**: “all healthcare workers employed in primary and community care settings, including ambulance services”

Assessment of evidence

Guideline: “1.1.3 Use of personal protective equipment

- Selection of protective equipment must [7] be based on an assessment of the risk of transmission of microorganisms to the patient, and the risk of contamination of the healthcare worker's clothing and skin by patients' blood, body fluids, secretions or excretions. [2003].
- Respiratory protective equipment, for example a particulate filter mask, must [7] be used when clinically indicated. [2003]”

*The authors state as follows: “The methodology of writing NICE guidelines has changed substantially since the previous guideline, therefore the updated sections are in a very different style and clearly present evidence tables, evidence statements and linking evidence to recommendation sections, detailed in the methodology chapter, which are not present in the sections that have not been reviewed in this update. The presentation of evidence remains the same as in the original 2003 guideline for recommendations not updated.” As the RPE and surgical face mask recommendations have not been updated since 2003 and are based on limited research and expert opinion they are graded as level 4.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The National Institute for Health and Care Excellence (NICE) Tuberculosis. NICE Guideline NG33. 2016.	Guidance	AGREE: Recommend	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Accessed: 20th December 2022.					

Assessment of evidence

Guideline scope:

“This guideline covers preventing, identifying and managing latent and active tuberculosis (TB) in children, young people and adults.”

Update info:

“January 2016: This guideline was published. It is an update of NICE guideline CG117 (published March 2011) and replaces it. It also incorporates and adapts NICE guideline PH37 (published March 2012).

Through the scoping process we work with stakeholders to identify, prioritise and agree areas of the guideline to update. This means that areas outside the scope were not reviewed during this update and the recommendations may not reflect current practice. Areas that have not been reviewed in this update may be addressed 2 years after publication, when NICE next considers updating this guideline. NICE may undertake an update of discrete areas of the guideline if new and relevant evidence is published.”

Recommendations:

“Multidrug-resistant TB Staff […] and visitors should wear filtering face piece (FFP3) masks during contact with a person with suspected or known multidrug resistant TB while the person is thought to be infectious. [2016]”* *”[2016] if the evidence has been reviewed but no change has been made to the recommended action”

Limitations:

- Update is due, checked in January 2022 and stated it will be updated with a focus on adherence
- Screening process of evidence by NICE involved two persons independently, however this can be done on a % (as little as 10%) of articles retrieved. They do however set out a method to ensure agreement is >90% of the % of articles independently reviewed

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution (BSI) BSI Standards Publication 529:2005 Respiratory protective devices — Recommendations for selection, use, care and maintenance — Guidance document.	British Standard	Level 4	N/A	N/A	N/A

Assessment of evidence

Criteria for using respiratory protective devices (page 12):

“Respiratory protective devices should only be used when one or more of the following conditions are met:

- other protective measures are in place, yet an unacceptable inhalation exposure risk still exists;
- exposures exceed the relevant occupational exposure limit value and protective measures are in the process of being installed;
- emergency work which cannot wait until other protective measures at source are put in place;
- exposures are infrequent and of short duration and permanent installation of other protective measures are not practicable;

Assessment of evidence

- respiratory protective device is needed for escape in the event of an emergency;
- emergency rescue work by trained personnel. However, there are situations where adequate control measures may be in place and the employer may decide to provide suitable respiratory protective devices as an extra precaution."

Risk assessment for respiratory protective device use (page 12):

"Where a respiratory protective device is needed for minimising the exposure it should only be used when a suitable respiratory protective device programme is in place. The elements of a respiratory protective device programme will include the following:

- hazard appreciation and identification;
- risk assessment to comply with legal requirements;
- selection of adequate and suitable devices;
- training for users and others involved in the programme;
- maintenance of the devices in accordance with manufacturer's instructions;
- record keeping which will include programme policy, management systems implementing the programme, risk assessments, adequacy and suitability assessment, training details and maintenance records;
- auditing of the programme;
- management systems for implementing the programme."

"The exposure to hazardous substances at work should be eliminated. If this is not reasonably practicable then the exposure should be minimised by other means at source before using respiratory protective devices." (page 11)

"The process of selecting a correct device should only be undertaken after an appropriate risk assessment has been carried out. The next step in a selection process should be the determination of adequacy. Once the adequacy has been established suitability should be determined for the correct selection of the device." (page 15)

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Occupational Safety and Health Administration (OSHA). Guidance on Preparing Workplaces for an Influenza Pandemic. OSHA 3327-05R. 2009.	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

Guidance document produced by The Occupational Safety and Health Administration is an agency of the United States Department of Labor. Influenza pandemic guidance.

Explanation provided on the spread of influenza:

“Influenza is thought to be primarily spread through large droplets (droplet transmission) that directly contact the nose, mouth or eyes. These droplets are produced when infected people cough, sneeze or talk, sending the relatively large infectious droplets and very small sprays (aerosols) into the nearby air and into contact with other people. Large droplets can only travel a limited range; therefore, people should limit close contact (within 6 feet) with others when possible. To a lesser degree, human influenza is spread by touching objects contaminated with influenza viruses and then transferring the infected material from the hands to the nose, mouth or eyes. Influenza may also be spread by very small infectious particles (aerosols) traveling in the air. The contribution of each route of exposure to influenza transmission is uncertain at this time and may vary based upon the characteristics of the influenza strain.”

Assessment of evidence

Recommendations:

“The decision on whether or not to require employees to use either surgical/procedure masks or respirators must be based upon a hazard analysis of the employees’ specific work environment and the differing protective properties of each type of personal protective equipment”

PPE recommendations according to exposure level to pandemic influenza – recommendations are not healthcare specific – applied to non-health settings also:

- Low exposure risk (infrequent contact with general contact) – respirators not mentioned in recommendations
- Medium exposure risk (frequent close contact between employees/general public/symptomatic ill) – administrative + engineering controls implemented firstly – “Use of a respirator may be considered if there is an expectation of close contact with persons who have symptomatic influenza infection or if employers choose to provide protection against a risk of airborne transmission.”
- Very high/high exposure risk (contact with known/suspected infected persons; contact within 6 feet) – “Respiratory protection for protection against small droplets from talking, coughing or sneezing and also from small airborne particles of infectious material.
    - N95 or higher rated filter for most situations.

Then goes on to state “The appropriate form of respirator will depend on the type of exposure and on the transmission pattern of the particular strain of influenza” and links to NIOSH respirator selection logic (CDC/NIOSH (2004) selection logic)

Question 9: When should valved versus unvalved respirators be worn?

Evidence added to 2024 update:

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centre for Disease Control and Prevention (CDC) The National Institute for Occupational Safety and Health (NIOSH) Community Respirators and Masks – Types of Masks and Respirators Last updated: 16 May 2023 Accessed: 07 January 2025	Guidance	Level 4	N/A	N/A	N/A
Assessment of evidence					
Target audience: Community, USA					

Assessment of evidence
How Well It Protects Others Around You: Some EHMRs and EQMRs, such as those without exhalation valves, filter the air you breathe out and you can use them to protect others around you. If the EHMR or EQMR do not filter the air you breathe out, you should not use them if your goal is to protect others around you.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
European Centre for Disease Prevention and Control (ECDC) Considerations for infection prevention and control practices in relation to respiratory viral infections in healthcare settings Last updated: 6 February 2023 Accessed: 6 January 2025	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence
“Scope: This document aims to support the development of guidance for healthcare facilities and healthcare providers in the European Union/European Economic Area (EU/EEA) on infection prevention and control (IPC) measures for the management of patients with respiratory tract viral infection in healthcare settings. Target audience: National public health agencies, healthcare facility administrators, IPC and other professionals developing relevant IPC guidance and healthcare workers in EU/EEA countries.” “Some valved respirators do not prevent the release of exhaled respiratory particles from the wearer into the environment and therefore may not be appropriate for use as a means of source control in the case of respiratory infections.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The National Institute for Occupational Safety and Health (NIOSH) Donning and Doffing PPE: Proper Wearing, Removal, and Disposal. Last updated: October 2022 Accessed: 6 January 2025	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

“Are respirators with an exhalation valve acceptable in healthcare settings?

It depends on the type of respirator and the setting. Healthcare personnel (HCP) can use an FFR with an exhalation valve for source control. However, when it is important to maintain a sterile field, HCP cannot use an FFR with an exhalation valve. Source control refers to the ability to prevent disease transmission to others via the spread of respiratory secretions. A NIOSH technical report summarizes research on filtering facepiece respirators with an exhalation valve. Findings suggest FFRs with exhalation valves provide the same or better source control than surgical masks or procedure masks. This finding is the same even without covering the valve.

However, FFRs with exhalation valves are not fluid resistant. HCP should not use these types of respirators in situations requiring a sterile field. For example, during an invasive procedure in an operating or procedure room. The exhalation valve may allow unfiltered exhaled air to escape into the sterile field. In situations requiring a fluid resistant respirator (e.g., in surgical settings), HCP should wear a Surgical N95.

HCP should not use elastomeric respirators with unfiltered exhalation valves as source control in surgical and other healthcare settings. This is due to concerns that air coming out of the exhalation valve may contaminate the sterile field. The NIOSH Certified Equipment List identifies the elastomeric respirators without exhalation valves or with filtered exhalation valves. HCP can use both types in surgical settings.

Healthcare facilities may have their own policies regarding the use of respirators with exhalation valves. Check with your Occupational Health Clinic or Infection Control Staff to understand your facility’s policies.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Myers, W. et al. Laboratory assessment of bacterial contamination of a sterile environment when using respirators not traditionally used in a sterile field environment, Infection Control and Hospital Epidemiology/ 2022; 43(12); 1867-1872. Doi: 10.1017/ice.2022.122.	Simulation study (with participants)	Level 3	Risk factor 1: Contamination levels from the air exhaled from wearers of PAPRs, elastomeric half-mask respirators (EHMRs), and N95 filtering facepiece respirators. Risk factor 2: The difference in contamination between N95s with and without a valve Risk factor 3: The difference in contamination between loose-fitting PAPRs with (Assigned protection factor (APF) = 1000)	Five different RPE tested, using surgical masks as baseline: 1) 3M 9205+ (N95 disposable particulate respirator without exhalation valve) 2) 3M 8511 (N95 disposable particulate respirator with exhalation valve) 3) MSA (elastomeric half-mask respirator (EHMR) with exhalation valve) 4) B-PAPR (Bullard EVA PAPR system – without shroud and hood)	Difference in mean CFU/m^3 (SE, 95% CI)) and particle size distribution (geometric mean aerodynamic diameter) of the exhaled air for each respirator type. CFU/m^3 was aligned with each of the distances that impactors were placed from the head of the bed as a categorical variable; the 30.48cm difference with the surgical mask was used as the reference.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
			and without (APF = 25) a hood and shroud	5) V-PAPR (Versaflo PAPR – with shroud and hood).	Pairwise comparison between the RPE and use of surgical masks was also performed.

Assessment of evidence

Setting: USA

Significant difference in CFU/m^3 observed between the 3M 9205+ (without exhalation valve) and 3M 8511 respirator (with exhalation valve). Mean difference -2.7 between 3M 9205+ and 3M 8511, Bonferonni significance = 0.03.

Mean increase of CFU/m3 was significantly higher for respirators with exhalation valves (3M 8511 and MSA EHMR) when compared to surgical masks (OR 1.48 (95% CI 1.24 – 1.76), p = <.05 and OR 1.44 (95% CI 1.21 – 1.72), p = <.05, respectively). Mean CFU/m3 was also significantly higher for the respirator with an exhalation valve (3M 8511) when compared to the respirator with an exhalation valve (3M 8511) (Mean difference -2.7 between 3M 9205+ and 3M 8511, Bonferonni significance = 0.03); this difference was not observed between other respirator types. Finally, mean difference in CFU/m3 was significantly higher for the MSA EHMR (11.4) when compared to the B-PAPR, Bonferonni significance = <0.1 (reported as 0.00). Mean CFU/m3 was not significantly different between surgical masks and a disposable N95 respirator without an exhalation valve, and PAPRs with or without a shroud or hood.

Limitations:

- Only two styles of disposable N95 respirators (same brand) and one style/brand of other RPE types assessed, limiting generalisability of findings both to other RPE types and brands
- No information on methods of microbiological analysis, other than brief mention of use of agar plates

Assessment of evidence

- Simulation study has limited generalisability to real-life clinical settings
- Study findings cannot be generalised outside of the simulation conditions, i.e. CPR or talking
- No information on respirator fit check method
- Unclear why p-value reported as 0 for significant findings, changed to p <.05 as this is the significance threshold

The findings suggest that disposable N95 respirators and EHMRs with an exhalation valve should not be used as source control. The findings also suggest that PAPRs (with/without a shroud or hood) and N95s without an exhalation valve may offer an alternative to surgical masks for source control but are not superior to using surgical masks as source control (in terms of mean cfu/m3 of air contamination). These findings have limited generalisability outside of this simulation experiments and should be considered as part of a wider evidence base if being used to inform NHS Scotland IPC recommendations.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The National Personal Protective Technology Laboratory (NPPTL), Centers for Disease Control and Prevention (CDC) 2020b.	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Respirator Exhalation Valve Research. Accessed: 4th January 2023					

Assessment of evidence

Information page with no references. The target audience is also unclear.

Recommendations:

Respirators with exhalation valves are thought to provide more comfort and may be better suited for longer periods of use. […]

Because an exhalation valve can introduce unfiltered exhaled air into the surroundings, the CDC does not recommend the use of a respirator with an exhalation valve in certain healthcare situations, including but not limited to operating rooms, because the valve may allow contaminants to escape and reach others."

"During the COVID-19 pandemic, medical professionals have expressed concern that healthcare personnel infected withSARS-CoV-2, the virus that causes COVID-19, may spread the disease from unfiltered exhaled air passing through their respirator's exhalation valve. While preliminary data suggests that the exhaust of particles through respirators with valves is less than or comparable to that of masks without valves (e.g., cloth masks, procedure masks), research gaps remain.

Importantly, the potential for infection from breath exhausted through the respirator's exhalation valve has not been fully studied. Therefore, NIOSH research is evaluating several areas associated with respiratory disease transmission." No citations provided

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
European Centre for Disease Prevention and Control (ECDC). Infection prevention and control and preparedness for COVID-19 in healthcare settings. Sixth update, 2021. Accessed 14th December 2022.	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

Scope of this document:

This document provides support to healthcare workers managing suspected or confirmed cases of novel coronavirus 2019 (COVID-19). The general objectives of the document are:

- to present the minimal set of personal protective equipment (PPE) required for managing suspected or
- confirmed COVID-19 cases
- to make healthcare workers aware of the critical aspects of the donning and doffing of PPE; and
- to strengthen occupational safety in healthcare workers for patients suspected of, or confirmed with, COVID19

This document is based on current COVID-19 knowledge and PPE best practices.

Assessment of evidence
ECDC will update this document based on the evolving situation and if new relevant information arises. **Target audience**: Healthcare workers and infection prevention and control personnel in EU/EEA countries and in the United Kingdom." **Recommendation**: Some valved respirators do not prevent the release of exhaled respiratory particles from the wearer into the environment and therefore may not be appropriate for use as a means of source control in the case of respiratory infections [155]."

Evidence from previous update(s):

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Occupational Safety and Health Administration (OSHA). Guidance on Preparing Workplaces for an Influenza Pandemic. OSHA 3327-05R. 2009.	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

Guidance document produced by The Occupational Safety and Health Administration is an agency of the United States Department of Labor. Influenza pandemic guidance.

“respirators with exhalation valves should not be used when there is a need to protect others from possible contamination by the respirator wearer (e.g., a healthcare provider performing surgical or other sterile medical procedures or a person with known or suspected pandemic influenza who could transmit infection to others).”

Question 10: When should a patient wear RPE?

Evidence added to 2024 update:

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Lai J, Coleman KK, Tai SH, et al Relative efficacy of masks and respirators as source control for viral aerosol shedding from people infected with SARS-CoV-2: a controlled human exhaled breath aerosol experimental study. EBioMedicine. 2024 May 28.	Observational	Level 3	No mask, N95, KN95, surgical mask, cloth mask use for source control	Exhaled breath aerosol	Viral load, defined as fraction of unmasked aerosol detected in masked samples. Source-control factor (similar to established definition for fit factor), defined as the percentage reduction in viral load realised in the environment (%) Relative efficacy of mask/respirator (%), calculated using ration of outward leakage.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
					Exhaled breath aerosols were considered in total (combined) and for coarse (>5 uM) and fine (≤5 uM) aerosol particles.

Assessment of evidence

Setting: University in USA

Methodology:

This controlled human experimental study involved paired samples (exhalations with and without a mask) from 44/106 participants who had one or more samples positive for SARS-CoV-2. The aim of this study was to analyze the efficacy of various face masks (surgical, cloth, KN95, N95) as source control (through a measure of reduction in total exhaled particles (both fine and coarse), fine particles and coarse particles) for SARS-CoV-2 positive persons.

The study took place un a US university between 2020 and 2022. There were some variations in the methods used depending on the type of mask, activities (saying the alphabet, shouting and saying happy birthday song loudly or breathing) based on symptoms, time the person took part. Generally, participants were asked to undertake speaking or shouting activities with and without a mask for up to 30 minutes. A particle counter (Gesundheit-II (G-II) human exhaled bioaerosol collector) was utilized to measure ‘exhaled’ particles. Outcomes were measured for total exhaled particles as well as fine (≤5 µm) or coarse (>5 µm) particles. Mask use compared to no mask use and efficacy between types of masks were considered within the analyses. The statistical analysis was based on a sample of 44 and it is not indicated by the authors if this met any conducted power calculation.

Assessment of evidence

Main findings:

44 participants provided 60 same-day paired exhaled breath aerosol (EBA) samples (SARS-CoV-2 detected in at least one sample). Of 44 participants, 16 provided two sample pairs on different days; the rest provided one pair on one day.

Paired samples: “The analysed paired samples included 8 with cloth masks, 26 with surgical masks (25 Kimtech™ M3 and 1 unknown brand), 13 with KN95 respirators (10 Powecom and 3 unknown brands), and 13 with N95 respirators”

Comparison: “Cloth and surgical mask pairs were mainly collected before the emergence of Delta and Omicron and from unvaccinated volunteers. Conversely, most KN95 and N95 pairs were collected during the Delta and Omicron waves from volunteers who had completed the initial vaccination series (fully vaccinated) and/or had received at least one booster dose”

Viral load in exhaled breath aerosols: Note that “Volunteers who provided paired samples for KN95 respirators shed a higher amount of viral RNA when they were not wearing a mask compared to the other three masked groups”. When compared to wearing no mask or respirator, wearing cloth masks, surgical masks, KN95 and N95 respirators reduced geometric mean of viral load in total exhaled breath aerosol ($p < 0.05$) in crude analysis.

Source control factors and improvement in source control for viral RNA in total exhaled breath: In paired modelling analysis, all mask/respirator types reduced viral RNA copies in fine, course and total exhaled breath aerosols when compared to wearing no mask (Fig. 3 – comparisons were not made between mask types. 95% CIs provided for comparisons, p-values not reported).

Controlling for number of coughs, age, sex, BMI and SARS-CoV-2 variant, viral load decreased by 98% (95% CI 97 – 99%) with use of N95 respirators. This percentage decrease in viral load was then followed by cloth masks (87% (95% CI 77 – 92)), surgical masks (74% (95% CI 65 – 81), KN95 respirators (71% (95% CI 59 – 79%) (increased to 76% (95% CI 64 – 84%) after excluding unknown KN95 respirator brands. The non-overlapping 95% CIs confidence intervals suggest this is statistically significant, although p-values not reported.

Cloth masks performed better than surgical masks ($p = 0.027$) and KN95 respirators (when including unknown brands) ($p = 0.014$) for source control factors for total RNA aerosol. When limiting analysis to fine and course aerosol fractions, the comparisons were not statistically significant.

Assessment of evidence

Limitations:

- Recruitment was from community testing facilities, it is unclear if there were other people (not within the 106) who were also tested but who chose not to participate. Differences between those eligible/ineligible, are not provided.
- Lack of replicability – unclear how far away the particle collector was from the participant and if this was standardized for all experiments. It was stated that participants had no prior training of wearing RPE. It is not clear if fit checking/testing was conducted.
- Participants were asked to wear their own or a supplied mask the brand/type of supplied mask is provided. It is not clear how many masks were brought by patients, it is stated “mostly cloth” indicating some SFM or RPE may have been supplied by the participants and it is not clear if these met minimum standards. The indication for use was reported as the researchers decided they were “well-fitted”.
- It is not clear how far away the particle counter was from the participant and it difficult to state with any certainty how this would impact a clinical interaction. It is also not clear how a mask (of any type) worn by the ‘receiver’ (in addition to the ‘source’) may impact the risk of transmission.
- Small sample (44 in total but under 27 per group of masks), unclear power.
- Variations in sampling time, activities undertaken (happy birthday, shouting), differences in level of illness (as demonstrated by some people being reported as too unwell to undertake the speaking activities). Impact (if any) of these differences are unclear.
- Variations in the type of mask (provided SFM are described but unclear how many if any were brought by the participant).
- Lack of replicability and applicability - room humidity, temperature, distance of counter from participant, ventilation in place and other persons in the room are unclear.
- It is unclear how this experimental setup may compare to real clinical interactions within health and care settings. • The true risk of transmission is unclear.

Assessment of evidence
This study highlights that the tested N95 respirators may provide statistically significant reductions in emitted particles compared to the tested surgical face masks but that this superiority may not be consistently reported with other respirator types (KN95). The clinical significance of these differences are unclear and the transmission risk is also not clear.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Onishi, K. and Nojima, M. Comparison of the inward leakage rate between N95 filtering facepiece respirators and modified surgical masks during the COVID-19 pandemic. Environmental Health and Preventative Medicine. 2024; 29(8), doi: 10.1265/ehpm.23-00303.	Observational	Level 3	The study assessed the inward leakage of an unadjusted surgical mask, and a surgical mask adjusted to improve fit. NaCl particles (particle size: 0.075 ± 0.02 uM) at 85 L/min flow rate were used to assess filtration-collection efficiency.	Inward leakage rate according to mask/respirator type	Inward leakage rate

Assessment of evidence

Setting: University hospital, Tokyo, Japan

Methodology:

Volunteers from the general population as well as healthcare workers ((HCWs)) including nursing students). N = 54 participants in total (20 men, 34 women; 31 from general population; 23 HCWs).

Leakage rates of included masks were assessed using various measurements:

- Measurement 1 - Mask B (surgical mask) worn with pleats spread out and the nose wire pressed down onto the nose
- Measurement 2 – Mask B (surgical mask) worn with nose wire adjusted to a 'W' shape prior to donning, according to the shape of the participants' noses. To standardise this approach, the researcher's bent the wire to the appropriate shape according to the participant's nose.
- Measure 5 – Mask D (N95) were put on by participants after the researchers taught them how to achieve a tight fit. A fit test was performed on some participants (n = 39) to validate fit.

The fit check was performed using an optical particle counter (MT-05U; SIBATA, Tokyo, Japan). Ambient particles (>0.3 uM in diameter) inside and outside of masks were counted. To validate these results, a CNC counter was used to count particles 0.15 – 1 uM in size (AccuFIT 9000 PRO 3000-J1. Kanomax Japan Ink, Osaka, Japan). Exercises were taken from the OSHA CNC QNFT protocol were used (29 CFR 1910.134, OSHA), namely: 1) normal breathing, 2) bending over, 3) moving head up and down, 4) turning head side to side, 5) talking (counting down from 100), 6) normal breathing.

NaCl particles (particle size: 0.075 ± 0.02 uM) at 85 L/min flow rate were used to assess filtration-collection efficiency and inhalation resistance.

Fit factor (FF; number of particles outside mask / number of particles inside of mask) was calculated using mean of FF for each exercise, then converted to inward leakage rate (ILR) based on the fine particular matter number in order to compare results.

Statistical analysis: Wilcoxon signed-rank test with Bonferroni correction used for paired comparisons of masks B and D.

Assessment of evidence

Main findings:

Median ILR (IQR) of N95 0.78 (0.29 – 2.55) versus surgical mask with nose-wire adjusted to W shape: 50.82 (35.36 – 76.82), p-value < 0.001, p-value with Bonferonni's correction < 0.001; and N95 versus a surgical mask with the filter wire pressed down onto nose: 96.44 (72-100), p-value <0.0001, p-value with Bonferonni's correction. <0.001.

In this observational study, inward leakage rate was significantly lower for participants wearing an N95 respirator when compared to a surgical mask with the noses wire pressed down, and with the nose-wire shaped into a 'W' according to the participant's nose shape and size.

Limitations:

- Small sample size
- Large proportion of participants were from the general population, thus lack relevant experience of wearing SFM and RPE in clinical settings.
- Single study site
- Only one respirator type included, where it is unclear if multiple brands of this type have been used. This limitation also applies to surgical masks.
- N95 duckbill type not typically used in NHSScotland, limiting generalisability of findings.
- Fit test only performed on 39 participants.
- Unclear if surgical mask if fluid resistant
- Optical particle counter measured ambient particles >0.3 uM in diameter. Particles smaller than this were not counted, which may impact the findings. It is unclear in which direction this would bias the findings.

Assessment of evidence
This study contributes to the evidence base that in a controlled, experimental setting, N95 respirators have higher filtration efficiency when compared to surgical masks. However, the methods used are not designed to assess the function of a surgical mask, and the findings do not translate to infection risk in a real-life clinical setting.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Pennington, E. R., Griffin, J. S., McInroe E. M. et al. Variation in the fitted filtration efficiency of disposable face masks by sex. Journal of Exposure Science & Environmental Epidemiology, 2024; doi: 10.1038/s41370-024-00697-4.	Cohort	Level 3	Filtration efficiency	N95 versus surgical mask	Mean fitted filtration efficiency (FFE) (%, s.d.)
Assessment of evidence					
Setting: North Carolina, USA					

Assessment of evidence

Methodology:

N = 100 healthy individuals recruited to participate (50% female, 50% male, predominantly Caucasian (n = 60). Participants were excluded if: BMI < 19.0, BMI > 33.4, history of cardiovascular disease, cancer, uncontrolled hypertension or diabetes All participants were clean shaven.

A modified version of the OSHA QNFT was performed using NaCl. A particle counter was used to count particles in the breathing space and ambient air chamber.

Surgical mask: 3-ply (surgical mask (Hannah Linen, Portland, OR, USA) – unclear if fluid resistant. N95: tri-fold (3M N95 Aura 9205+).

The masks/RPE were fitted with an aluminium port for testing, and a study team member assisted with donning.

Main findings:

FFE according to use of ear loop clips have been excluded from this appraisal due to lack of applicability in NHSScotland.

N95s had highest FFE (97.8% ± 3.2) when compared to KN95s (69.4 ± 12.2), surgical masks (57.5 ± 9.9) and KF94 (55.2 ± 15.6); P < 0.001 for all comparisons. The difference between FFE between males (98.2 ± 2.9) and females (97.4 ±3.4) was not significantly different for N95s.

FFE was higher for males compared to females for KN95s and KF94s but this is not applicable to NHSScotland.

Assessment of evidence:

In this cohort study of healthy individuals based in the USA, FFE was significantly higher for N95s (97.8% ± 3.2) when compared to SFMs (57.5% ± 9.9).

Limitations:

- Cohort of health individuals
- Relatively small sample size

Assessment of evidence

- No power calculation
- Unclear on recruitment methods
- Unclear of the standards that SFM and N95 used in study met
- No indication that a formal fit check was performed after donning RPE (perhaps because FFE was being assessed via QNFT)

The above limitations limit generalisability of the findings but add to the evidence base regarding that RPE are potentially more effective at filtering particles when compared to surgical masks, KF94s and KFN95s, but does not give clear indication of how this translates infection risk amongst staff, patients or visitors.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Australian Government National Health and Medical Research Council (NHMRC) Australian Guidelines for the Prevention and Control of Infection in Healthcare 2019 (revised 2024, v11.24)	Expert opinion guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Accessed 11 October 2024					

Assessment of evidence

Funding: Guidance was co-funded by the NHMRC and Medical Research Council and Australian Commission on Safety and Quality in Health Care.

Aim of guidance (page 20): “By assisting healthcare workers to improve the quality of the care they deliver, these Guidelines aim to promote and facilitate the overall goal of infection prevention and control: the creation of safe healthcare environments through the implementation of evidence-based practices that minimise the risk of transmission of infectious agents.”

Target audience (page 20): “The Guidelines are for use by all those working in acute health care settings —this includes healthcare workers, management and support staff. As some of the principles and recommendations described in this guideline may be applicable to other health care settings, individuals working in other health care settings may also find the guidelines useful.”

The introduction states that all recommendations are based on systematic reviews, however there is insufficient evidence within the guidance to support this claim.

Recommendation:

Information taken from Table 13, page 122:

“Care must be taken if placing respirators on patients and must suit clinical need (i.e. if the patient has chronic obstructive airways disease [COAD] or is in respiratory distress, the respirator will exacerbate symptoms).” Further information/recommendations regarding the use of RPE by patients is not provided. Furthermore, citations were not provided to support this statement.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Association for Professionals in Infection Control and Epidemiology (APIC) Do's & Don't's for wearing N95 respirators in non-surgical healthcare settings, 2015. Accessed: 16th November 2022	Poster	Level 4	N/A	N/A	N/A

Assessment of evidence
Format: Poster that is endorsed by The American Nurses Association (ANA), Association of Occupational Health Professionals in Healthcare and the Association of PeriOperative Nurses (AORN). **Target audience**: staff working in non-surgical settings **Setting**: USA **Recommendation**: "DON'T let patients or visitors wear N95 respirators unless they've been fit tested to wear them."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centers for Disease Control and Prevention (CDC) Infection Control Guidance: SARS-CoV-2. 2023 Accessed: 30 October 2024	Expert opinion guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

Note: “This interim guidance has been updated based on currently available information about COVID-19 and the current situation in the United States. Updates were made to reflect the high levels of vaccine-and infection-induced immunity and the availability of effective treatments and prevention tools. This guidance provides a framework for facilities to implement select infection prevention and control practices (e.g., universal source control) based on their individual circumstances (e.g., levels of respiratory virus transmission in the community). This guidance is applicable to all U.S. settings where healthcare is delivered (including nursing homes and home health).”

Recommendation:

- “People, particularly those at high risk for severe illness, should wear the most protective form of source control they can that fits well and that they will wear consistently.”
- “Even when a facility does not require masking for source control, it should allow individuals to use a mask or respirator based on personal preference, informed by their perceived level of risk for infection based on their recent activities (e.g., attending crowded indoor gatherings with poor ventilation) and their potential for developing severe disease if they are exposed.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Public Health Agency of Canada (PHAC). Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Healthcare Settings, 2017. Accessed: 20th December 2022	Expert opinion guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

Aim: To present evidence-based recommendations for monitoring, preventing and controlling healthcare associated infections.

Target audience: Infection prevention and control professionals and healthcare providers involved with developing policy and procedure for routine practices in healthcare settings (acute, long-term, ambulatory, home care or prehospital care settings)

Methods:

- These guidelines were produced by PHAC, advised by PHAC's Steering Committee on Infection Prevention and Control Guidelines Working Group, made up of professionals from different areas of healthcare who provided technical advice (list provided on page 2). They are described as "principles and recommendations" rather than strict standards.

Assessment of evidence

- A literature search was conducted for papers from 1999 (details of this search are available to request).
- Recommendations were graded based on the strength of evidence
- This guidance is based on scientific evidence and expert opinion where evidence was lacking, but was graded as expert opinion due to limited methodological detail making it difficult to deduce how systematic methods were.

Recommendations:

- Part B.IV. includes recommendations for additional precautions, and in subsection iii for patients with known or suspected infections requiring airborne precautions (examples of these include tuberculosis, measles and disseminated zoster):
- The authors recommend that patients should not be asked to wear a respirator when out-with their isolation room (page 98)
- This recommendation references an outbreak report (209 – Coronado et al., 1993), an in vivo study of surgical masks and respirators (368 – Johnson et al., 2009) and an observational study investigating the association between tuberculin conversion and ventilation (486 - Menzies et al., 2000)
- Type of respirator is not specified. Although, in the Glossary an N95 respirator is identified as the most commonly used in health care.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Lindsley, WG., Blachere, FM. and Law, BF. et al. Efficacy of face masks, neck gaiters	Simulation (manikin)	Level 4	Efficacy of respirators and surgical masks (termed 'procedure mask') as source control to reduce	Comparators: N95 respirator (3M 1860), ASTM level 3 Procedure mask (ASTM Level 3 = FDA's highest	Collection efficiency: percentage of aerosol particles blocked by the PPE under investigation (%) when compared

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
and face shields for reducing the expulsion of simulated cough-generated aerosols. Aerosol Science and Technology. 2021; 55(4), pp. 449-457. Doi: 10.1080/02786826.2020.1862409.			cough particles emitted into the environment.	grading for medical and surgical masks) (Kimberly Clark, 47107). Procedure mask is fluid resistant. N95 and procedure mask did not have exhalation valves.	to experiments without the use of PPE. Air particle mass in collection chamber (ug) as a proxy measure for how effectively the PPE under study reduced the mass of air particles emitted into the environment.

Assessment of evidence

Setting: USA

Methodology:

- 14% KCl and 0.4% sodium fluorescein solution was nebulised using a single jet Collison nebuliser. Mask/respirator placed on the manikin head, where each item was used for 2 consecutive tests.
- Portacount used to perform a respirator fit test (for both procedure mask and N95) and determine the fit factor (ratio aerosol concentration outside respiratory device: aerosol concentration inside the device)
- Simulated cough was expelled via the mouth of the manikin head into an enclosed collection chamber
- After sample collection from an Anderson impactor, plates were prepared and fluorescence was measured using a fluorometer.

Assessment of evidence

Main findings:

Collection efficiency - Mean % (standard deviation)

- No device: N/A – control comparator
- Procedure mask: 58.5 (6.9)
- N95: 98.6 (0.3)

Comparison of air particle mass (uG) into the collection chamber (mean difference, 95% CI, p-value)

- N95 vs no device: -504 (-567, -422) p<0.0001
- N95 vs procedure mask: -205 (-277, -133), p<0.0001

Assessment of evidence:

In this study, the N95 was more effective than both the procedure mask and the use of no PPE, at reducing mean air particle mass (uG) in the enclosed chamber when placed over the mouth of the manikin in an enclosed chamber where one cough was simulated, producing particles <0.6 uM – 7 uM in size.

Limitations:

- N95 findings cannot be applied to other RPE
- Unclear on the flow rate chosen for the simulated cough. The flow rate chosen was based on one study on influenza patients. It is also unclear if the investigators used the peak flow rate from this investigation, or mean flow rate. Only peak flow rate is mentioned in their results section.
- Only one brand of N95 and procedure mask tested, respectively
- Simulation experiment using a manikin head has limited generalisability to real-life clinical settings
- Results are based on two repeats for each PPE item under investigation

Assessment of evidence

- Inhalation following expelled cough not taken into consideration in the experimental model
- As stated by authors, the simulation only involved one cough, one air flow profile and one aerosol size distribution, limiting generalisability
- Breathing/speaking not assessed – again limiting generalisability as air velocity and air particle distribution would differ for these activities
- Authors state collection efficiencies may have been underestimated due to particles settling on surfaces of the collection chamber. Authors state that impaction, where particles in the air travel along their original path (sticking to a surface) instead of turning with air, may also have led to underestimation of collection efficiency.
- Only one manikin head used, limiting generalisability to individuals with facial compositions that differ to the manikin (unclear of the dimensions of the manikin used)

This provides weak evidence to potentially suggest that an N95 respirator may be more effective than a fluid resistant procedure mask as a form or source control. However, given its limitations, particularly those relating to generalisability, this study must be considered as part of a wider evidence base.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Asadi, S., Cappa, CD, Barreda, S. et al. Efficacy of masks and face coverings in controlling	Simulation (human participants)	Level 3	Efficacy of RPE/PPE in reducing aerosol particle emission rates when participants were	Surgical mask (ValuMax 5130E-SB), tested by 10 participants Non-vented KN95 respirator (GB2626-	Particle emission rate (particle/second) Observed particle size distribution (particle fraction (%))

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
outward aerosol particle emission from expiratory activities. 2020. Nature Scientific Reports, 2020; 10(15665). doi: 10.1038/s41598-020-72798-7.			breathing, speaking and coughing.	2006, Nine Five Production Technology), tested by 10 participants A vented N95 respirator (NIOSH N95, Safety Plus, TC-84A-7449), tested by 2 participants	

Assessment of evidence

Setting: USA

Methodology:

Participants were instructed to sit with their mouth at the entrance of a funnel attached to an aerodynamic particle sizer (APS) (to count particles between 0.3 and 20μm), within a HEPA-filtered laminar flow hood. Authors note that the particle counter likely underestimates the true number of particles between 0.3 – 0.5 uM.

The participants undertook a number of tasks (breathing, talking, coughing, and jaw movement) while wearing no mask or one of the assessed masks.

Air was pulled in by the APS at 5L/min, with 1L/min (20%) focused into the detector to count and size the cumulative number of particles at 1 second intervals. It was noted that, due to mask wearing, some expired airflow may move in a non-outward direction, and so the measurements reported in this study are not expected to represent the absolute number of emitted particles.

Assessment of evidence

Main findings:

NOTE: Statistics were not presented within the text, only as part of figures. All reported as $p<0.05$.

Breathing (through the mouth):

- When wearing no mask, the median particle emission rate was 0.31 particles/s. This was significantly reduced (approx. 6-fold) by the wearing a surgical mask or KN95 respirator (0.06 and 0.07 particles/s respectively).

Talking:

- Talking resulted in a higher rate of outward emission across the mask types, without a mask the median rate was 2.77 particles/s
- Both surgical masks and KN95 respirators significantly decreased the outward emission rate to 0.18 and 0.36 particles/s, respectively. The homemade paper mask reduced the rate to 1.21 particles/s, which was not significant. The double-layer t-shirt mask also did not have a significant effect, while the single-layer t-shirt mask significantly increased outward emission rate to 16.37particles/s

Coughing:

- It was noted that there was variation in participants coughing output in terms of number of coughs, duration of coughing, and output of aerosol particles, however, a similar trend in reduction/increase of outward emission rate was observed across the mask types.
- Without a mask a median of 10.1 particles/s were produced, wearing surgical masks significantly reduced the median outward emission rate to 2.44 particles/s, and wearing a KN95 reduced the median outward emission rate to 6.15 particles/s, however this was not statistically significant.

Assessment of evidence:

In this study, compared to the use of no masks/RPE, using both surgical masks and KN95 masks (unvented) significantly reduced outward emission of particles when breathing and talking. When coughing, only the use of surgical masks resulted in significantly reduced outward emission of particles.

Assessment of evidence

Limitations:

- Small sample size
- Unclear if participants had experience of providing clinical care and/or donning RPE/PPE
- Limited presentation of statistical significance
- Vented KN95 tested by only 2 participants therefore significance testing was not performed
- Simulation experiment where simulated coughing, breathing and talking may not mimic clinical scenarios
- Particle sizes under investigation limited to 0.3 – 20 uM. where authors note that the particle counter likely underestimates the true number of particles between 0.3 – 0.5 uM.
- Only KN95s assessed, therefore limited generalisability to other RPE types

The findings suggest that use of a KN95 or surgical mask may be beneficial to reduce emission of particles when a person is breathing or talking, however, it is unclear whether a KN95 is more beneficial than the use of a surgical mask. Furthermore, compared to the use of no mask/RPE, unlike the use of surgical masks, KN95s do not significantly reduce outward particle emission when worn by a person who is coughing. This study should not be used in isolation to inform NHS Scotland recommendations due to limitations relating to lack of generalisability.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Lee SA, Hwang DC, Li HY, et al. Particle size-selective	Simulation (human participants)	Level 3	The filtering efficiency of FFP respirators (FFP1, FFP2, and FFP3	N/A	Fit test pass rate (%)– PortaCount Plus (TSI Inc, St Paul, USA). With

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
assessment of protection of European standard FFP respirators and surgical masks against particles-tested with human subjects. J Healthc Eng. 2016; 8572493. Doi: 10.1155/2016/8572493.			from two manufacturers) against different sizes of particles (nebulized NaCl). The relationship between protection factors and fit factors. Comparison of FFP3 and surgical face mask filtering efficacy.		equation for fit factor provided on page 5. Geometric mean (GM) of protection factors (PF) – ratio based on a comparison of sampling from inside and outside a face mask. Percentage of PF below Assigned Protection Factor (APF) values 4, 10 and 20. Comparison of GM of PF with SM vs respirators Statistical analysis – ANOVA, t-test, pearsons correlation.

Assessment of evidence

This observational experimental study carried out in Taiwan investigated the filtering efficiency of FFP respirators (supplied by two manufacturers) and SMs (from three manufacturers) against nebulized NaCl in controlled conditions.

Methodology:

- Participants underwent a fit test before undergoing the total inward leakage test.
- When the particle concentrations were stable in the test chamber, the subjects equipped with the personal system donned the test respirators and performed the OSHA fit testing exercises. Participant was trained to wear respirator.
- User-seal-check performed when respirator put on subjects face. OSHA fit test exercises (normal breathing, deep breathing, turn head side to side, moving head up and down, talking, grimace, bending over and returning to normal breathing). Fit factor for each exercise recorded.
- Fit factor was recorded using a PortaCount Plus. Note the Portacount plus measures ambient particles
- Overall fit factor calculated (Grimace exercise excluded) – according to the OSHA standard – "calculation of overall fit factor using individual exercise fit factors involves converting the exercise fit factors to penetration values, determining the average, and then converting that result back to a fit factor"
- Repeated OSHA fit test exercises. Each exercise was performed for two minutes and the particle concentrations inside the respirator were averaged over the second minute. The concentration inside the respirator (Cin) for the entire test was averaged over all the exercises, excluding the grimace manoeuvre.

Main findings:

This study identified no significant difference in protection factor (PF) between the class of FFP used (p>0.05). The lowest PF was seen for particles sized 0.263 to 0.384μm. However, PFs were not significantly different among different particle sizes in the size range of 0.093– 1.61 μm (p > 0.05). With respect to the geometric mean of PFs, the overall PF provided by SMs was 11.5 times less than that for FFP1 respirators, 15.9 times less than that for FFP2 respirators, and 15.7 times less than that for FFP3 respirators (p < 0.05).

Comparison of PF of SM and FFPs:

Assessment of evidence

"With respect to the geometric mean of PFs, the overall PF provided by SMs was 11.5 times less than that for FFP1 respirators, 15.9 times less than that for FFP2 respirators, and 15.7 times less than that for FFP3 respirators (p < 0.05)."

Limitations:

- Small sample size
- Participants were 18-24 – may not generalize.
- Taiwan based – may not generalize.
- NaCl particles may not reflect infectious viral/bacterial/fungal particles.
- Type of surgical face mask – not clear.
- Correlations not causation.
- Test chamber may not generalize to health and care facilities. Air changes per hour not clear (though noted as capable 0-60).
- The filtration efficacy displaced as ratio but how this impacts practice is not clear.
- Small sample and unclear power – may be underpowered and lack validity/reliability.
- ratio based on a comparison of sampling from inside and outside a face mask was used as a measure of 'protection' however the actual filtration values or aerosol sampling concentrations are not provided. One value provided (not per exercise)
- Rest periods between exercises/experiments not clear. Cleaning equipment noted but unclear if this was used – for example between each person/experiment.

In this cohort, this study identified FFPs of all classes provide a significantly greater protection factor (PF) than SMs (p<0.05). The class of FFPs did not appear to have a significant impact on PF, and PFs are not significantly different among different particle sizes ranging 0.093– 1.61 μm (p > 0.05). This study must be considered as part of a wider evidence base as it is severely limited by its generalisability to real-life scenarios due to its experimental nature.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Mansour MM and Smaldone GC. Respiratory Source Control Versus Receiver Protection: Impact of Facemask Fit. J Aerosol Med Plum. 2020;26(3);pp:131.137. Doi: 10.1089/jamp.2012.0998	Simulation (manikin)	Level 3	The use of two manikins (a source and a receiver) with simulated tidal breathing at 3ft apart to determine the degree of protection for source N95 and surgical mask combinations as well as receiver N95 and surgical mask combinations.	Several surgical mask/N95 iterations worn by the source or receiver: No mask on source/receiver; surgical mask tightly fitted on source; surgical mask looped around ears of source; N95 worn by the source; surgical mask tightly fitted on receiver; surgical mask looped on ears of receiver; N95 on receiver; N95 sealed using Vaseline on source or receiver.	Particle distributions and mass median aerodynamic diameters (MMAD) Exposure data - expressed as % of nebulised activity*. * Nebulized activity represented the difference between initial nebulizer charge and that remaining after nebulization Exposure data also expressed as simulated workplace protection factor (sWPF) defined as ratio of max exposure to actual exposure. “The protective effect of each intervention in

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
					reducing exposure is best illustrated by the magnitude of the sWPF." Mask filtration – radioactivity captured by each mask, reported as a % of activity exhaled at source Separation of 95% CIs indicated statistical significance.

Assessment of evidence

Experimental set-up:

- Two Resusci Anne CPR mannequin heads (no. 310200; Laerdal Medical, Wappingers Falls, NY) were placed in the enclosure, 3 ft apart.
- Both heads fitted with respiratory tubing and ventilated by a Harvard pump (Harvard Apparatus SN no. A52587; Millis, MA) simulating a tidal breathing pattern (volume of 500 mL, respiratory rate of 15 breathfs/min, and duty cycle of 0.5 sec).
- Source head was connected to an AeroTech II nebulizer (three devices used in rotation; Biodex, Shirley, NY) powered by an air tank with a flow of 10 L/min

Assessment of evidence

- nebulizer was filled with 3 mL of 0.9% normal saline labeled with technetium-99m and run to dryness over 10 min, producing radioactive wet aerosols
- Receiver head had no modifications and was ventilated through nose and mouth
- Exposure quantification by a filter (model no. 041B0522; PARI, Starnberg, Germany) was connected to receiver head to capture inhaled particles
- Aerosol exposure data – quantified by measuring radioactivity captured by receiver filter

Main findings:

- Particle distributions and MMAD (mass median aerodynamic diameters) (diameter vs probability):
- At the source, approx. 90% of particles were <2µm
- Average MMAD = 0.95µm (95% CI: + 0.119)
- The MMAD of particles reaching the vicinity of the receiver was 0.69µm (95% CI: + 0.0663).

Control: Maximum Exposure (Max Ex) (i.e. aerosol inhaled by receiver) average = 1.363% (95% CI: 0.912–1.81%). As this was the 'no protection' control, sWPF = 1.

SFM/N95 worn by source, i.e. patient:

- SFM naturally fitted: Exposure decreased to 0.000637% (95% 95% CI: 0.00163–0.01110%), SWPF = 214
- SFM tightly fitted: Exposure decreased to 0.00019% (0.00023% (95% CI: 0.00009–0.00038%), sWPF = 5,850
- N95 (no Vaseline): 0.00019% (95% CI: 0.00012– 0.00027%), sWPF = 7,174
- Compared to the control, these were deemed statistically significant reduction in aerosol exposure.

N95 sealed with Vaseline to mimic tight fit:

Assessment of evidence

- Source wearing N95 with Vaseline vs source wearing N95 without Vaseline: sWPF was 17,038 (exposure 0.00008%, 95% CI -0.00007, 0.00023) versus 7,174 (exposure 0.00019, 95% CI 0.00012, 0.00027), respectively.
- The difference in reduction of exposure when using a non-tightly fitted N95 vs a sealed N95s was not statistically significant due to overlapping 95% CIs (see bullet point above)

SFM/N95 worn by receiver, i.e. staff, visitor:

- SFM naturally fitted: 1.38% (95% CI: 0.992–1.77%), sWPF =0.99
- SFM tightly fitted: 0.669% (CI: 0.0641–1.27%), sWPF = 2.04
- N95 (no Vaseline): 0.181% (95% CI: 0.106–0.256), sWPF of 7.53
- Compared to the control, these results were not statistically significantly lower than the control.

N95 sealed with Vaseline to mimic tight fit:

- 0.0216% (95% CI -0.006, 0.0492), sWPF 63.1. This is significantly different when compared to the control, therefore the only PPE item to confer protection of the receiver. This is also significantly different compared to the receiver wearing a non-tightly fitted N95, indicating the importance of achieving a tight fit, i.e. performing a fit check.

Limitations:

- in-vitro
- set parameters of air flow, air changes and 3ft distancing between source and receiver
- “wet radioactive particles” unlikely to generalize behaviour of infectious particles
- Limited generalizability out with these conditions (use of manikins)
- No fit testing of respirators, only visual checking – confounding factor
- Use of Vaseline to seal respirator not applicable to real life scenario, may not fully represent a fit tested N95.

Assessment of evidence

- Use of N95, not recommended in UK
- One model of mask and one model of respirators used, specific to this
- Unknown no. of replicate of experiments to obtain an average
- Unclear if the source manikin wore a mask/respirator when the experiments involving source masking occurred. Therefore, any comparisons between receiver and source control are omitted from the conclusion.

Conclusion:

This in-vitro experimental study involved two mannequin heads which represented 3-foot distancing between a source and receiver. The study suggests a sealed N95 with Vaseline (attempting to mimic a fit tested N95) used as source control provides greatest reduction to exposure when compared with maximum exposure, where no masks were worn by either source or receiver mannequins. Significant reductions in exposure were seen when the source mannequin wore a SM naturally fitted (looped around ears), SM tightly fitted (stretched across mannequin head), and an unsealed N95. However, the difference in reduction between the N95s and SFMs when worn at the source (excluding the N95 tightly fitted using Vaseline) was non-significant. This indicates that in this experimental scenario, SFMs worn by the source, i.e. patient, provided sufficient protection to the receiver, i.e. staff, visitor.

The N95 respirator was assessed using two configurations: with and without Vaseline used to seal the respirator to the mannequin head. When the N95 respirator was sealed to the receiver, there was significant increase in sWPF when compared to the N95 being placed on the receiver head without the use of Vaseline. This indicates the importance of adequate N95 fit without face seal leakage, contributing to the evidence-base that a user seal check or fit test should be performed every time a respirator is donned by a staff member. Although the sealed N95 respirator conferred maximum protection when worn at the source, this was not statistically significant when compared to the use of a non-sealed N95 and SFMs, indicated by the overlapping 95 CIs.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
He, X., Reponen, T., Mckay, R. T and Grinshpun, S. A. Effect of Particle Size on the Performance of an N95 Filtering Facepiece Respirator and a Surgical Mask at Various Breathing Conditions, Aerosol Science and Technology. 2013a;47;1180-1187.	Simulation (manikin)	Level 3	Filtration efficiency and total inward leakage of N95 versus FRSM according to particle size, flow rate and breathing frequency.	Comparators: N95 respirator versus fluid-resistant surgical mask. Manufacturers are unclear. Authors reference previous study, but this study and the studies they cited are unclear. “SM model chosen for this study is expected to provide at least 95% filter efficiency for particles of 100 nm (according to its manufacturer, no flowrate is specified)”	Filter penetration (%) (“determined as the ratio of the corresponding size-specific number concentrations inside and outside of the [N95/FRSM] sealed to the headform”) Total inward leakage (%) (particle size specific) Most penetrating particle size (MPPS) (i.e. size of particle most able to pass through filter) (nm)
Assessment of evidence					
Methodology:					

Assessment of evidence

- Filtration efficiency of N95s and FRSMs assessed by placing them on a manikin head. N95/FRSMs replaced after 20 consecutive tests to minimise aerosol loading. The choice of this cut-off was not supported by literature.
- Experiments conducted in a 24.3 m3 respirator test chamber maintained at 17 - 22°C and 30 – 60% relative humidity
- NaCl particles (count median diameter (CMD): 125 nm; geometric standard deviation (GSD): 1.6) were generated using a particle generator (3054, TSI Inc.). The particle generator was operated for 1 hour prior to the start of experiments to ensure there was consistent NaCl concentration within the chamber. The particles were released into the test chamber, where the manikin was connected to a breathing recorder and simulation system (BRSS)
- A HEPA filter was placed between the manikin head and the BRSS to prevent particles from re-entering the respirator cavity during exhalation.
- N95 and FRSMs were both exposed to charge-equilibrated challenge particles (authors state that FRSMs are typically challenged against non-neutralised particles which is more conservative as “electrically charged particles have greater capture efficiency”).
- Mean inspiratory flow (MIF) rates assessed: 15, 30, 55 and 85 L/min. 10, 15, 20, 25 and 30 breaths/min also assessed. 20 total combinations of these variables.
- Nanoparticle spectrometer (“measures particles based on their electrical mobility so that the particle number concentration determined for each channel represent the mean electromobility particle diameter corresponding to this channel”) utilised to determine particle sizes inside/outside of N95/FRSM (sampling flow rate: 0.2 L/min). 6-minute sampling period used to determine particle-size specific concentration.
- The above process where the N95/FRSM were also placed on manikin head without sealing to the headform to assess TIL

Note: Charged-particle equilibrium: where the number of charged particles entering/leaving a volume are equal for each energy and type of particle.

Main findings:

Assessment of evidence

N95 filter penetration increased as MIF increased ($p < 0.05$). Particle size did not significantly affect total inward leakage of N95 ($p > 0.05$) for particles > 50 nm at any MIF or breathing frequency. Increased MIF was associated with decreased TIL of N95 ($p < 0.05$)

“Compared to the N95 FFR, the SM had a much higher filter penetration ($p < 0.05$), which is expected given its primary function to protect others from the aerosol exhaled by the wearer.”

Assessment of evidence:

In this study, the N95 had higher filtration efficiency when compare to SFMs ($p < 0.05$). Particle size did not affect total inward leakage of N95 when particles > 50 nm. Filter penetration of N95s significantly increased as MIF increased ($p < 0.05$).

Limitations:

- HEPA filtration rate not provided
- No independent experiment repeats
- Simulation study which has limited generalisability to real-life clinical settings
- Unclear if breathing rates and mean inspiratory flow chosen for the experiment are based on
- Authors suggest that experimental set-up and instruments used impacted the findings, in particular, most penetrating particle size for the N95/FRSM
- Only one N95 respirator and one FRSM brand assessed.
- Limited generalisability to NHS Scotland given use of N95s and no investigation of respirators with other filtration efficiencies e.g. FFP3s.
- Funding source and conflicts of interest not disclosed
- Use of manikin head lacks generalisability to real-life clinical settings
- Unclear how N95/FRSM were sealed to the manikin head to assess filtration efficiency accurately

Assessment of evidence
• Data presented in graphs, thus only possible to discuss p-values • N95/FRSMs were used for 20 consecutive tests. This may have impacted filtration efficiency. Direction of bias is unclear. This study suggests that N95s have greater filtration efficiency when compared to FRSMs, thus N95s are preferred when being used to protect the wearer from particles emitted by others. These findings should be considered as part of a wider evidence base given its limitations.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Patel RB. Skaria SD, Mansour MM, et al. Respiratory source control using a surgical mask: An in vitro study. J Occup Environ Hyg. 2016; 13(7); PP: 569-576	Observational with experimental setup	Level 3	The use of two manikins (a source and a receiver) with simulated breathing or coughing at 3ft apart to determine the degree of protection provided by a respirator (N95) and SM	Protection provided in three room conditions (zero ACH, six ACH, 12 ACH)	Aerosol particle distribution - MMAD (mass median aerodynamic diameter, µm) and GSD (Geometric standard deviation). Receiver protection factor (RPF) – defined as ratio of Max exposure (Max Ex) to actual exposure Mask capture efficiency

Assessment of evidence

Limitations:

- Funding not stated
- in-vitro nature
- set parameters of air flow and 3ft distancing between source and receiver
- “wet radioactive particles” unlikely to generalize behaviour of infectious particles
- Limited generalizability out with these conditions (use of manikins)
- No fit testing of respirators, only soap testing – confounding factor
- Use of Vaseline to seal respirator not applicable to real life scenario, may not fully represent a fit tested N95.
- Use of N95 limits generalisability to other RPE. Additionally online one model of mask and one model of respirators used.
- Unknown no. of repetitions of experiments to obtain an average

This in-vitro experimental study involved two manikin heads which represented 3-foot distancing between a source and receiver. The study suggests significant reduction to exposure of particles is seen, when comparing to max exposure (no mask worn on source or receiver) when the source is wearing a respirator in all three airflow conditions (no airflow, hospital room (6ACH) and negative pressure room (12 ACH)). A significant reduction in exposure is also seen when the receiver is wearing an N95 sealed with Vaseline in a no air flow room and an N95 both sealed and unsealed in a hospital room. However, this study is severely limited by its in-vitro nature, and potential lack of generalizability to real-life scenarios due to set parameters of air flow, and distancing between source and receiver.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Diaz KT and Smaldone GC. Quantifying exposure risk: surgical masks and respirators. American Journal of Infection Control. 2010;38(7):501-8.	Experimental simulation	3	Experimental set-ups assessed factors of exposure, dilution, deflection and filtrated of aerosols.	• No PPE • NIOSH-approved N95 respirator (No. 1860S size small; 3M) • Ear loop surgical mask (SM) (model No. GCFCXS; Crosstex International Inc). SMs were tested both loosely or tightly fitted on the source or receiver depending on experiment conditions. • N95s fitted with no	Maximum exposure (Max Ex): % of nebulised particles (i.e. inhaled particles) captured by the receiver – direct result of dilution, i.e. exhaled particles from the source mixing with ambient air. Ratio of Max Ex to actual exposure defined as the simulated workplace protection factor (sWPF) Results presented as means and 95% confidence intervals with “separation of confidence intervals defined statistical significance”.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
				obvious leaks. Additional experiments were performed with N95 sealed to face with Vaseline to prevent leaks.	Particle distribution and mass median aerodynamic diameters (MMAD) (uM) also presented.

Assessment of evidence

Methodology:

Chamber (5ft x 4.5ft x 6ft, 135 ft^3) with a fixed flow providing 0 or 6 air changes/hr within the chamber.

Nebuliser (AeroTech II) connected to an air tank with flow of 10L/min was used to create aerosols (3 devices used in rotation). Environmental flow within the chamber was regulated using an opening between the chamber and a hood. The nebuliser contained 3 ml 0.9% saline labelled with technetium-99m and run to dryness (approx. 10 minutes).

Source aerosols were exhaled via a manikin head (Brad CPR adult manikin head, no 2512, Simulaids) directed towards a receiver; a ventilated manikin head was also placed in the chamber to simulate the receiver. Manikin heads were both connected to Harvard pumps (Harvard Apparatus SN A52587) with a tidal volume of 500 mL, respiratory rate of 15 breaths/min and duty cycle of 0.5 to simulate a tidal breathing pattern.

Assessment of evidence

Manikin heads were placed 3 feet from each other (distance chosen in line with CDC recommendation to represent 2 individuals sitting in a room). The ventilators of the manikin heads were not synchronised and triggered randomly.

Aerodynamic distribution of particles expelled by source near the receiver measured in triplicate using an 8-stage cascade impactor. Aerosols near the receiver were also measured with and without masks placed on the source – a filter (model No. 041B0522; Pari, Starnberg, German) was placed on the receiver head to capture inhaled particles (capturing radioactivity using a calibrated well counter (≤10 µCi; Kemble Instruments, Hamden, Ct) or a calibrated Ratemeter (≥10 µCi; Ludlum Measurements Inc, Sweetwater, TX).)

Manikin heads were cleaned and the chamber was opened and flushed with a fan between experiments.

Smoke trace experiments were performed to define ambient air currents. Chamber flow (CFM) towards the hood that the chamber was connected to using a balometer (ft^3/min). Flow was measured at 14 CFM or 0 CFM (where 14 CFM is equivalent to 6 air changes/hour). Local linear velocity was 0.670 ft/sec. Temperature 20-22ºC and relative humidity 21-26%.

Main findings:

Note: Results from experiments with no airflow have been excluded due to lack of generalisability to real-life clinical settings.

Authors state that "particles leaving the source were similar to exhaled droplets in vivo because approximately 95% of the particles were less than 2 mm, with an average MMA9D of 1.046 mm (95% CI: 0.984-1.11)"

No masks worn by source or receiver (control): the authors described the particles near the receiver as significantly smaller (75% sub-micron and 0.633µm, [95% CI 0.506-0.757]) where air flow was 14CFM 6 air change per hour compared to when no airflow was used (MMAD was 0.905 [(95% CI: 0.909-0.991]). No value provided to the second set of figures. It is assumed these are 'µm' but this is not confirmed.

- Experiments with environmental flow, i.e. 6 air changes/hour:
    - Exposure (source manipulation vs receiver manipulation), illustrated as percentage of nebulised particles:

Applying a surgical mask or N95 respirator to the source resulted in reduction of the sWPFs of 172 to 317 (95% CI not provided). Applying a SM or respirator to the receiver did not reduce exposure when compared to the use of no masks (sWPF 1.37 – 2.21)

Assessment of evidence

- Mask filtration: % of nebulised particles:

An N95 respirator worn at the source resulted in greater average filtration efficiency (35.7%, 95% CI 27.7 – 43.7) when compared to a surgical mask tightly fitted to the source (14.8%, 95% CI 10.1 – 19.6) and a surgical mask loosely fit on the source (6.07%, 95% CI 5.43 – 6.72). However, this did not correlate with reduction in exposure by the receiver when compared with the use of a tightly fitting or loosely fitting surgical mask fit on the source. The authors suggest this means that deflection (particles not captured by mask and deflected away from receiver) was a dominant factor.

Filtration at the receiver did not significantly alter protection according to the receiver wearing a loose fitting surgical mask (0.0855%, 95% - 0.00564 – 0.177), tight surgical mask (0.107%, 95% CI 0.591 – 0.156) or N95 (0.252%, 95% CI 0.027-0.377 – sWPF 2.21 vs no mask sWPF 1.37).

When the N95 was tightly applied to the source using Vaseline to represent filtration plus deflection, sWPF was highest (4082); filtration captured 81.0% (95% CI 59.5 – 103) of particles. When the N95 was tightly applied to the receiver using Vaseline, sWPF was 118, capturing 0.453% (95% CI – 0.0200 – 0.926) particles on average.

- Deflection at source (receiver not wearing PPE):

sWPF decreased from 172 to 5.92 for loose fitting SMs, 288 to 129 for tight fitting surgical masks and 317 to 15.1 for N95s.

Limitations:

- Air flow towards receiver may not reflect real air flow (multiple persons in health settings, both inhalation and exhalation in progress during interactions). Flow towards receiver may overinflate source control results.
- Experimental study with simulation may not generalize to health and care settings.
  - No human participants and constant flow rate
  - Radiolabeled wet particles may not reflect infectious particles and may be affected by humidity (though controlled 22-26%)
  - Fit – may not generalize.

Assessment of evidence

- Represents exposure at 3 feet only.
- Unclear number of replications nor statistical power.
- Comparators limited (both source and control wearing surgical mask not assessed).
- 10 minutes of sampling and unclear replications – power calculations not provided – possible validity and reliability issues.

Within this specific experimental setting, an N95 respirator worn at the source (sealed using Vaseline) resulted in greater average filtration efficiency (35.7%, 95% CI 27.7 – 43.7) when compared to a surgical mask tightly fitted to the source (14.8%, 95% CI 10.1 – 19.6) and a surgical mask loosely fit on the source (6.07%, 95% CI 5.43 – 6.72).

Filtration at the receiver did not significantly alter protection according to the receiver wearing a loose-fitting surgical mask (0.0855%, 95% - 0.00564 – 0.177), tight surgical mask (0.107%, 95% CI 0.591 – 0.156) or N95 (0.252%, 95% CI 0.027-0.377 – sWPF 2.21 vs no mask sWPF 1.37). This result may have been impacted by the fact that the N95 respirator was not tightly sealed to the manikin head in this experimental condition. These findings suggest that at a distance of 3 feet, N95s and SFMs may be comparable when worn by a receiver. However, given that fit testing/checking of respirator to the manikin head was not performed, these findings should be treated with caution.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
He X, Reponen T, McKay R, et al. How Does Breathing Frequency Affect the Performance of an N95 Filtering	Simulation (manikin)	Level 3	The study aims to address the effects of breathing frequency and flow rate on filter efficiency and face seal leakage of a	Filter penetration and total inward leakage with varying levels of breathing frequency and flow rate	Effect of mean inspiratory flows (MIF) and breathing frequency on Filter penetration (PFilter)

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Facepiece Respirator and a Surgical Mask Against Surrogates of Viral Particles? J Occup Environ Hyg. 2013b;11;178-185			N95 FFR and a SM challenged with NaCl particles (sized between 0.02 and 0.5µm)		Effect of MIF and breathing frequency on TILs N95 Faceseal Leakage-to-Filter Ratio

Assessment of evidence

Methodology:

- Carried out in a room-size (24.3m3)
- Temp. 17°C – 22°C and relative humidity 30-60%
- Manikin connected to breathing recording and simulation system
- "Particle size independent (overall) concentrations inside and outside the FFR/SM were obtained using a condensation particle counter (Model 3007, TSI Inc.)"
    - Total sampling time of 3 min with a time resolution of 1 sec
- Experiments conducted at four cyclic breathing flows (MIF= 15, 30, 55, 95 L/min) and five different breathing frequencies (10, 15, 20, 25, and 30 breaths/min).

Main findings:

Filter Penetration (PFilter)

Assessment of evidence

N95s

Pfilter consistently increased with /increasing MIF.

Both MIF and breathing frequency had a significant effect on filter penetration ($p<0.0001$).

- MIFs: “Pairwise multiple comparison results (see Table I) show that the four MIFs produced four different Pfilter groups with the highest mean Pfilter (0.72%, Tukey grouping A) occurring at the highest MIF of 85 L/min, and the lowest mean Pfilter (0.05%, Tukey grouping D) occurring at the lowest MIF of 15 L/min.”
- Breathing frequency: “The breathing frequency comparisons show that 10 and 15 breaths/min produced higher values of Pfilter (0.39% and 0.38%, Tukey grouping I) than those observed at 20, 25, and 30 breaths/min (0.25%, 0.23%, and 0.26%, respectively, Tukey grouping II).”

SMs

“Compared to the N95 FFR, the SM had a much higher filter penetration.” “Increasing MIF frequently resulted in an increase in filter penetration, especially at the lowest breathing frequency.”

Both MIF and breathing frequency had a significant effect on filter penetration ($p<0.0143$)

- MIFs: “The pairwise multiple comparisons (see Table III) show the highest MIF (85 L/min) produced the highest mean Pfilter (9.65%, Tukey grouping A), whereas the lowest Pfilter (5.41%, Tukey grouping C) occurred at the lowest MIF (15 L/min).”
- Breathing frequency: “the mean Pfilter = 7.81% (Tukey grouping I) obtained at 30 breaths/min was significantly higher ($p <0.05$) than Pfilter = 6.67% (Tukey grouping II) obtained at 20 breaths/min. However, no consistent trend was identified throughout the frequency scale”

TIL

N95s

“MIF of 15 L/min produced the highest TILs”. “the TIL increased with increasing the breathing frequency”.

Assessment of evidence

Both MIF (=0.0019) and breathing frequency (p=0.0025) had a significant effect on TIL.

- MIF: “The pairwise multiple comparison results presented in Table II show that the lowest MIF (15 L/min) was associated with the highest mean TIL (1.93%, Tukey grouping A).”
- Breathing frequency: “. The highest breathing frequency (30 breaths/min) produced the highest mean TIL (1.73%, Tukey grouping I) compared to the lowest mean TIL (1.22%, Tukey grouping II) with the lowest breathing frequency (10 breaths/min). The highest and lowest breathing frequencies were significantly different (Tukey groups I and II).”

SM

Increasing MIF caused the mean TIL to decrease

“While ANOVA revealed that both MIF and breathing frequency had a significant effect on the TIL ($p<0.05$), no consistent trend of increase or decrease of TIL with breathing frequency was observed.”

Limitations:

- Model of N95 FFR and SM not provided
- Unknown why 20 tests was cut off for minimizing loading effect, no tests to establish this as sufficient
- Unknown how N95 and SM is sealed to manikin
- HEPA filtration rate not provided
- Simulation study which has limited generalisability to real-life clinical settings
- Unclear if breathing rates and mean inspiratory flow chosen for the experiment are based on
- Only one N95 respirator and one FRSM brand assessed.
- Limited generalisability to NHS Scotland given use of N95s and no investigation of respirators with other filtration efficiencies e.g. FFP3s.

Assessment of evidence
• Funding source and conflicts of interest not disclosed • Data presented in graphs, thus only possible to discuss p-values • Method to seal N95 not provided This simulation study involving manikins suggests that with increasing breathing frequency and increasing MIF, filter penetration of a sealed N95 significantly increased ($p<0.0001$). Filter penetration was higher for a sealed SM. TIL from a non sealed N95 significantly increased with increasing breathing frequency ($p=0.0025$), and significantly decreased with increasing MIF ($=0.0019$). This study is greatly limited by its experimental nature with use of manikins affecting its generalizability in real life scenarios.

Evidence from previous update(s):

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Siegel JD, Rhinehart E, Jackson M, Chiarello L. 2007 guideline for isolation precautions: preventing transmission of infectious agents in health care settings.	Expert opinion guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
American journal of infection control. 2007 Dec 1;35(10):S65-164. Last updated: September 2024 Accessed: 28 October 2024					

Assessment of evidence

Aim: To provide recommendations for healthcare settings embedded with infection prevention principles that can be sensibly modified depending on the setting.

Target audience: Infection control staff, health care epidemiologists, healthcare administrators, nurses, other health care providers and persons involved in infection control programs (developing, implementing and evaluating) for healthcare settings.

Methodology: Expert opinion by CDC and HIPAC (members listed). This guidance presents narrative synthesis summary of literature and how it contributes to IPC guidance. New emerging pathogens, rising concern for known pathogens, new therapy development and rising concern for bioterrorism prompt updates. Little detail is provided on the methodology for literature search and review process.

Consistent with the TBP review, this was AGREE Not Recommend based on lack of detail on review methods.

The reference list was screened for papers/guidance which may be relevant for RPE review. Unless otherwise stated, CDC guidance is cited to support these deadlines.

Relevant recommendations regarding when patients should wear RPE include:

- Under protective equipment:

Assessment of evidence

  - VI.E. (page 96): “During periods of construction, to prevent inhalation of respirable particles that could contain infectious spores, provide respiratory protection (eg, N95 respirator) to patients who are medically fit to tolerate a respirator when they are required to leave the PE.” (where PE stands for ‘protective equipment’)
- This recommendation is category II, meaning it’s being put forward based on clinical, epidemiological or theoretical studies.
- This recommendation cites an epidemiological investigation study which was excluded in the 2019 RPE review on aspergillosis in a leukaemia and bone marrow transplant unit (158 - Thio et al., 2000) and another which was not carried forward due to its’ relevance to surgical masks (944 - Raad et al., 2002)

- V1.E.1.b. (page 96): “No recommendation for use of particulate respirators when leaving the PE in the absence of construction.”

Under the heading “Protective Environment”:

- “To prevent inhalation of fungal spores during periods when construction, renovation, or other dust-generating activities that may be ongoing in and around the health care facility, it has been recommended that severely immunocompromised patients wear a high-efficiency respiratory protection device (eg, an N95 respirator) when they leave the PE. The use of masks or respirators by HSCT patients when they are outside of the PE for prevention of environmental fungal infections in the absence of construction has not been evaluated.” (page 96)
- This section cites CDC guidance (11 and 14) and another which was not carried forward due to its’ relevance to surgical masks (944 - Raad et al., 2002)

Question 11: When should a visitor wear RPE?

Evidence added to 2024 update:

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Lai J, Coleman KK, Tai SH, et al. Relative efficacy of masks and respirators as source control for viral aerosol shedding from people infected with SARS-CoV-2: a controlled human exhaled breath aerosol experimental study. EBioMedicine. 2024 May 28.	Observational	Level 3	No mask, N95, KN95, surgical mask, cloth mask use for source control	Exhaled breath aerosol	Viral load, defined as fraction of unmasked aerosol detected in masked samples. Source-control factor (similar to established definition for fit factor), defined as the percentage reduction in viral load realised in the environment (%) Relative efficacy of mask/respirator (%), calculated using ration of outward leakage.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
					Exhaled breath aerosols were considered in total (combined) and for coarse (>5 uM) and fine (≤5 uM) aerosol particles.

Assessment of evidence

Setting: University in USA

Methodology:

This controlled human experimental study involved paired samples (exhalations with and without a mask) from 44/106 participants who had one or more samples positive for SARS-CoV-2. The aim of this study was to analyze the efficacy of various face masks (surgical, cloth, KN95, N95) as source control (through a measure of reduction in total exhaled particles (both fine and coarse), fine particles and coarse particles) for SARS-CoV-2 positive persons.

The study took place un a US university between 2020 and 2022. There were some variations in the methods used depending on the type of mask, activities (saying the alphabet, shouting and saying happy birthday song loudly or breathing) based on symptoms, time the person took part. Generally, participants were asked to undertake speaking or shouting activities with and without a mask for up to 30 minutes. A particle counter (Gesundheit-II (G-II) human exhaled bioaerosol collector) was utilized to measure 'exhaled' particles. Outcomes were measured for total exhaled particles as well as fine (≤5 µm) or coarse (>5 µm) particles. Mask use compared to no mask use and efficacy between types of masks were considered within the analyses. The statistical analysis was based on a sample of 44 and it is not indicated by the authors if this met any conducted power calculation.

Assessment of evidence

Main findings:

44 participants provided 60 same-day paired exhaled breath aerosol (EBA) samples (SARS-CoV-2 detected in at least one sample). Of 44 participants, 16 provided two sample pairs on different days; the rest provided one pair on one day.

Paired samples: “The analysed paired samples included 8 with cloth masks, 26 with surgical masks (25 Kimtech™ M3 and 1 unknown brand), 13 with KN95 respirators (10 Powecom and 3 unknown brands), and 13 with N95 respirators”

Comparison: “Cloth and surgical mask pairs were mainly collected before the emergence of Delta and Omicron and from unvaccinated volunteers. Conversely, most KN95 and N95 pairs were collected during the Delta and Omicron waves from volunteers who had completed the initial vaccination series (fully vaccinated) and/or had received at least one booster dose”

Viral load in exhaled breath aerosols: Note that “Volunteers who provided paired samples for KN95 respirators shed a higher amount of viral RNA when they were not wearing a mask compared to the other three masked groups”. When compared to wearing no mask or respirator, wearing cloth masks, surgical masks, KN95 and N95 respirators reduced geometric mean of viral load in total exhaled breath aerosol ($p < 0.05$) in crude analysis.

Source control factors and improvement in source control for viral RNA in total exhaled breath: In paired modelling analysis, all mask/respirator types reduced viral RNA copies in fine, course and total exhaled breath aerosols when compared to wearing no mask (Fig. 3 – comparisons were not made between mask types. 95% CIs provided for comparisons, p-values not reported).

Controlling for number of coughs, age, sex, BMI and SARS-CoV-2 variant, viral load decreased by 98% (95% CI 97 – 99%) with use of N95 respirators. This percentage decrease in viral load was then followed by cloth masks (87% (95% CI 77 – 92)), surgical masks (74% (95% CI 65 – 81), KN95 respirators (71% (95% CI 59 – 79%) (increased to 76% (95% CI 64 – 84%) after excluding unknown KN95 respirator brands. The non-overlapping 95% CIs confidence intervals suggest this is statistically significant, although p-values not reported.

Cloth masks performed better than surgical masks ($p = 0.027$) and KN95 respirators (when including unknown brands) ($p = 0.014$) for source control factors for total RNA aerosol. When limiting analysis to fine and course aerosol fractions, the comparisons were not statistically significant.

Assessment of evidence

Limitations:

- Recruitment was from community testing facilities, it is unclear if there were other people (not within the 106) who were also tested but who chose not to participate. Differences between those eligible/ineligible, are not provided.
- Lack of replicability – unclear how far away the particle collector was from the participant and if this was standardized for all experiments. It was stated that participants had no prior training of wearing RPE. It is not clear if fit checking/testing was conducted.
- Participants were asked to wear their own or a supplied mask the brand/type of supplied mask is provided. It is not clear how many masks were brought by patients, it is stated “mostly cloth” indicating some SFM or RPE may have been supplied by the participants and it is not clear if these met minimum standards. The indication for use was reported as the researchers decided they were “well-fitted”.
- It is not clear how far away the particle counter was from the participant and it difficult to state with any certainty how this would impact a clinical interaction. It is also not clear how a mask (of any type) worn by the ‘receiver’ (in addition to the ‘source’) may impact the risk of transmission.
- Small sample (44 in total but under 27 per group of masks), unclear power.
- Variations in sampling time, activities undertaken (happy birthday, shouting), differences in level of illness (as demonstrated by some people being reported as too unwell to undertake the speaking activities). Impact (if any) of these differences are unclear.
- Variations in the type of mask (provided SFM are described but unclear how many if any were brought by the participant).
- Lack of replicability and applicability - room humidity, temperature, distance of counter from participant, ventilation in place and other persons in the room are unclear.
- It is unclear how this experimental setup may compare to real clinical interactions within health and care settings. • The true risk of transmission is unclear.

Assessment of evidence
This study highlights that the tested N95 respirators may provide statistically significant reductions in emitted particles compared to the tested surgical face masks but that this superiority may not be consistently reported with other respirator types (KN95). The clinical significance of these differences are unclear and the transmission risk is also not clear.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Onishi, K. and Nojima, M. Comparison of the inward leakage rate between N95 filtering facepiece respirators and modified surgical masks during the COVID-19 pandemic. Environmental Health and Preventative Medicine. 2024; 29(8), doi: 10.1265/ehpm.23-00303.	Observational simulation (human participants)	Level 3	The study assessed the inward leakage of an unadjusted surgical mask, and a surgical mask adjusted to improve fit. NaCl particles (particle size: 0.075 ± 0.02 uM) at 85 L/min flow rate were used to assess filtration-collection efficiency.	Inward leakage rate according to mask/respirator type	Inward leakage rate

Assessment of evidence

Setting: University hospital, Tokyo, Japan

Methodology:

Volunteers from the general population as well as healthcare workers ((HCWs)) including nursing students). N = 54 participants in total (20 men, 34 women; 31 from general population; 23 HCWs).

Leakage rates of included masks were assessed using various measurements:

- Measurement 1 - Mask B (surgical mask) worn with pleats spread out and the nose wire pressed down onto the nose
- Measurement 2 – Mask B (surgical mask) worn with nose wire adjusted to a 'W' shape prior to donning, according to the shape of the participants' noses. To standardise this approach, the researcher's bent the wire to the appropriate shape according to the participant's nose.
- Measure 5 – Mask D (N95) were put on by participants after the researchers taught them how to achieve a tight fit. A fit test was performed on some participants (n = 39) to validate fit.

The fit check was performed using an optical particle counter (MT-05U; SIBATA, Tokyo, Japan). Ambient particles (>0.3 uM in diameter) inside and outside of masks were counted. To validate these results, a CNC counter was used to count particles 0.15 – 1 uM in size (AccuFIT 9000 PRO 3000-J1. Kanomax Japan Ink, Osaka, Japan). Exercises were taken from the OSHA CNC QNFT protocol were used (29 CFR 1910.134, OSHA), namely: 1) normal breathing, 2) bending over, 3) moving head up and down, 4) turning head side to side, 5) talking (counting down from 100), 6) normal breathing.

NaCl particles (particle size: 0.075 ± 0.02 uM) at 85 L/min flow rate were used to assess filtration-collection efficiency and inhalation resistance.

Fit factor (FF; number of particles outside mask / number of particles inside of mask) was calculated using mean of FF for each exercise, then converted to inward leakage rate (ILR) based on the fine particular matter number in order to compare results.

Statistical analysis: Wilcoxon signed-rank test with Bonferroni correction used for paired comparisons of masks B and D.

Main findings:

Assessment of evidence

Median ILR (IQR) of N95 0.78 (0.29 – 2.55) versus surgical mask with nose-wire adjusted to W shape: 50.82 (35.36 – 76.82), p-value < 0.001, p-value with Bonferonni's correction < 0.001; and N95 versus a surgical mask with the filter wire pressed down onto nose: 96.44 (72-100), p-value <0.0001, p-value with Bonferonni's correction. <0.001.

In this observational study, inward leakage rate was significantly lower for participants wearing an N95 respirator when compared to a surgical mask with the noses wire pressed down, and with the nose-wire shaped into a 'W' according to the participant's nose shape and size.

Limitations:

- Small sample size
- Large proportion of participants were from the general population, thus lack relevant experience of wearing SFM and RPE in clinical settings.
- Single study site
- Only one respirator type included, where it is unclear if multiple brands of this type have been used. This limitation also applies to surgical masks.
- N95 duckbill type not typically used in NHSScotland, limiting generalisability of findings.
- Fit test only performed on 39 participants.
- Unclear if surgical mask if fluid resistant
- Optical particle counter measured ambient particles >0.3 uM in diameter. Particles smaller than this were not counted, which may impact the findings. It is unclear in which direction this would bias the findings.

Assessment of evidence
This study contributes to the evidence base that in a controlled, experimental setting, N95 respirators have higher filtration efficiency when compared to surgical masks. However, the methods used are not designed to assess the function of a surgical mask, and the findings do not translate to infection risk in a real-life clinical setting.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Pennington, E. R., Griffin, J. S., McInroe E. M. et al. Variation in the fitted filtration efficiency of disposable face masks by sex. Journal of Exposure Science & Environmental Epidemiology, 2024; doi: 10.1038/s41370-024-00697-4.	Cohort	Level 3	Filtration efficiency	N95 versus surgical mask	Mean fitted filtration efficiency (FFE) (%, s.d.)
Assessment of evidence					
Setting: North Carolina, USA					

Assessment of evidence

Methodology:

N = 100 healthy individuals recruited to participate (50% female, 50% male, predominantly Caucasian (n = 60). Participants were excluded if: BMI < 19.0, BMI > 33.4, history of cardiovascular disease, cancer, uncontrolled hypertension or diabetes. All participants were clean shaven.

A modified version of the OSHA QNFT was performed using NaCl. A particle counter was used to count particles in the breathing space and ambient air chamber.

Surgical mask: 3-ply (surgical mask (Hannah Linen, Portland, OR, USA) – unclear if fluid resistant. N95: tri-fold (3M N95 Aura 9205+).

The masks/RPE were fitted with an aluminium port for testing, and a study team member assisted with donning.

Main findings:

FFE according to use of ear loop clips have been excluded from this appraisal due to lack of applicability in NHSScotland.

N95s had highest FFE (97.8% ± 3.2) when compared to KN95s (69.4 ± 12.2), surgical masks (57.5 ± 9.9) and KF94 (55.2 ± 15.6); P < 0.001 for all comparisons. The difference between FFE between males (98.2 ± 2.9) and females (97.4 ±3.4) was not significantly different for N95s.

FFE was higher for males compared to females for KN95s and KF94s but this is not applicable to NHSScotland.

Assessment of evidence:

In this cohort study of healthy individuals based in the USA, FFE was significantly higher for N95s (97.8% ± 3.2) when compared to SFMs (57.5% ± 9.9).

Limitations:

- Cohort of health individuals
- Relatively small sample size

Assessment of evidence
• No power calculation • Unclear on recruitment methods • Unclear of the standards that SFM and N95 used in study met • No indication that a formal fit check was performed after donning RPE (perhaps because FFE was being assessed via QNFT) The above limitations limit generalisability of the findings but add to the evidence base regarding that RPE are potentially more effective at filtering particles when compared to surgical masks, KF94s and KFN95s, but does not give clear indication of how this translates infection risk amongst staff, patients or visitors.

Evidence from previous update(s):

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Munoz- Price LS, Banach DB, Bearman G, et al. Isolation Precautions for Visitors. Infect. Control Hosp. Epidemiol. 2015; 36(7); 747-758. Doi: 10.1017/ice.2015.67.	Guidance	**Level 4**	N/A	N/A	N/A

Assessment of evidence

This guidance is developed by The Society for Healthcare Epidemiology of America (SHEA) “based on a synthesis of limited evidence, theoretical rationale, practical considerations, a survey of SHEA membership and the SHEA Research Network, author opinion, and the consideration of potential harm, where applicable.” Recommendations are intended for endemic pathogens in non-outbreak situations and “primarily for acute facilities, similar considerations may apply to other healthcare settings (eg, post-acute care).” Due to a “lack of evidence required for a more formal guideline using a GRADE system” ... “no grading of the evidence level is provided”.

Recommendation H:

- “For visitors to patients on airborne precautions, we recommend the use of surgical masks. An alternative is an N95 respirator; however, this equipment is best used with training and fit testing. Visitors with extensive documented exposure to the symptomatic patient prior to hospitalization, such as household contacts, may be excluded from these precautions as they may be either immune to the infectious agent or already in the incubation period.”
- “In those instances in which prior extensive exposure is not documented and N-95 or higher respiratory protection is recommended for the patient, consideration should be given to limiting visitation for those who have not been fit tested. In these instances, education of visitors is important and facilities should clearly document these communications.”
- “With regard to airborne isolation, the use of N95 respirators among unfitted visitors is not warranted. If a visitor is considered at risk of an airborne pathogen and lacks previous exposure, then consideration should be given to limiting entrance.”

Limitations:

- No systematic process to literature review
- Use of a survey to obtain expert opinion, with no clear methods as to how guidelines were developed (i.e., no consensus process explained)
- No mention of planned updates, may be dated
- No description of “airborne precautions” or “airborne isolation”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The National Institute for Health and Care Excellence (NICE) Tuberculosis. NICE Guideline NG33. 2016. Accessed: 20th December 2022.	Guidance	AGREE: Recommend	N/A	N/A	N/A

Assessment of evidence

Guideline scope:

“This guideline covers preventing, identifying and managing latent and active tuberculosis (TB) in children, young people and adults.”

Update info:

“January 2016: This guideline was published. It is an update of NICE guideline CG117 (published March 2011) and replaces it. It also incorporates and adapts NICE guideline PH37 (published March 2012).

Through the scoping process we work with stakeholders to identify, prioritise and agree areas of the guideline to update. This means that areas outside the scope were not reviewed during this update and the recommendations may not reflect current practice. Areas that have not been reviewed in this update may be addressed 2 years after publication, when NICE next considers updating this guideline. NICE may undertake an update of discrete areas of the guideline if new and relevant evidence is published.”

Recommendations:

Assessment of evidence

“Multidrug-resistant TB Staff […] and visitors should wear filtering face piece (FFP3) masks during contact with a person with suspected or known multidrug resistant TB while the person is thought to be infectious. [2016]”* *”[2016] if the evidence has been reviewed but no change has been made to the recommended action”

Limitations:

- Update is due, checked in January 2022 and stated it will be updated with a focus on adherence.
- Screening process of evidence by NICE involved two persons independently, however this can be done on a % (as little as 10%) of articles retrieved. They do however set out a method to ensure agreement is >90% of the % of articles independently reviewed.

Question 12: Where and how should disposable respirators be donned?

Evidence added to 2024 update:

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Department of Health Infection Prevention and Control (IPC) National Clinical Guideline No. 30 Last updated: May 2023 Accessed: 03 February 2025	Guidance	Level 4	N/A	N/A	N/A
Assessment of evidence					
Target audience: “This National Clinical Guideline applies to all health and social care workers because the control of healthcare associated infection is everyone’s responsibility. It is particularly relevant to Infection Prevention and Control (IPC) Practitioners. IPC Practitioners are those health and social care workers with specific training and expertise in the prevention and control of infection and who provide training, guidance and leadership to others on IPC.” Recommendations: Information taken from infographic on donning, found within the guidance document.					

Assessment of evidence

Cup-shaped respirator:

“1. Separate the edges of the respirator mask to fully open it.

2. Slightly bend the nose wire to form a gentle curve.

3. Hold the respirator mask upside down to expose the two headbands.

4. Using your index fingers and thumbs, separate the two headbands.

5. While holding the headbands with your index fingers and thumbs, cup the respirator mask under your chin.

6. Pull the headbands up over your head.

7. Release the lower headband from your thumbs and position it at the base of your neck.

8. Position the remaining headband on the crown of your head.

9. Conform the nosepiece across the bridge of your nose by firmly pressing down your fingers.

10. Continue to adjust the respirator mask and secure the edges until you feel you have achieved a good facial fit. Now, perform a fit check.”

“Wearing an FFP 2 respirator

Considerations when using an FFP2 respirator include:

[…]

“respirator masks should not be touched while being worn

• respirator masks should never be reapplied after they have been removed

• respirator masks should not be left dangling around the neck”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Ministry of Health New Zealand. Infection prevention and control. 2022. Last updated: 01 November 2024. Accessed: 04 November 2024	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

“Infection Prevention and Control (IPC) refers to practical, evidence-based practices and procedures to protect patients, visitors, residents, clients and health workers from being harmed by avoidable infections in the healthcare setting. “

“Airborne Precautions

Airborne Precautions are required when interacting with people known or suspected to have diseases spread by very small particles that can suspend in the air and can be inhaled into the lungs.

The following Airborne Precautions apply for all interactions:

- Wear a P2/N95 particulate respirator that you have fit checked before room entry.”

No references are provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Australian Government National Health and Medical Research Council (NHMRC) Australian Guidelines for the Prevention and Control of Infection in Healthcare 2019 (revised 2024, v11.24) Accessed 11 October 2024	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

Funding: Guidance was co-funded by the NHMRC and Medical Research Council and Australian Commission on Safety and Quality in Health Care.

Aim of guidance (page 20): “By assisting healthcare workers to improve the quality of the care they deliver, these Guidelines aim to promote and facilitate the overall goal of infection prevention and control: the creation of safe healthcare environments through the implementation of evidence-based practices that minimise the risk of transmission of infectious agents.”

Assessment of evidence

Target audience (page 20): “The Guidelines are for use by all those working in acute health care settings —this includes healthcare workers, management and support staff. As some of the principles and recommendations described in this guideline may be applicable to other health care settings, individuals working in other health care settings may also find the guidelines useful.”

The introduction states that all recommendations are based on systematic reviews, however there is insufficient evidence within the guidance to support this claim.

Note: P2 respirators meet the relevant Australian standard (AS/NZS 1716:2012 and 1715:2009) and differs to NIOSH, which specifies N95 respirators.

Fitting instructions for one type of P2 respirators provided in Figure 9 (Based on one citation [178] – Australian Government Department of Health).

- “Position respirator over mouth and nose”
- “Position tapes above and below ears and back of head”
- “Fit snugly at bridge of nose and under chin by using the adjusters”

The guidance highlights: “Sequencing may differ across healthcare settings and any variations to sequencing should be based on a risk assessment relevant to the setting and task being undertaken. Note that for surgical procedures and dentistry, the sequence for putting on PPE differs. In these situations, masks and protective eyewear are applied first prior to hand preparation” [unclear from this text but image suggests that a ‘mask’ includes a particulate respirator].

- respirators should not be left dangling around the neck”

Use of P2 respirators by staff for airborne precautions:

“It is suggested that a correctly fitted P2 respirator is worn when entering the patient-care area when an airborne-transmissible infectious agent is known or suspected to be present. [Conditional recommendation]” (page 12)

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Association for Professionals in Infection Control and Epidemiology (APIC). Do's and Dont's for wearing N95 respirators in non-surgical healthcare settings, 2015. Accessed: 16th November 2022.	Infographic	**Level 4**	N/A	N/A	N/A

Assessment of evidence

Format: Poster that is endorsed by The American Nurses Association (ANA), Association of Occupational Health Professionals in Healthcare and the Association of PeriOperative Nurses (AORN).

Target audience: staff working in non-surgical settings

Setting: USA

Recommendations:

- "Follow manufacturer's instructions for donning and doffing of N95 respirator."
- "Ensure proper fit – making sure nose and mouth are completely covered. The N95 respirator must have a complete seal all around."

Assessment of evidence
• “Mould the respirator over the bridge of your nose when putting it on to help keep the N95 respirator on and fitting properly. It is also helpful to press all around the face to be sure it is tightly in place.” • “DON’T touch the front of the N95 respirator as it is contaminated after use.” • “DON’T leave an N95 respirator hanging around your neck.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Association of perioperative Registered Nurses (AORN). Guideline Quick View: Transmission-Based Precautions. AORN Journal; 109(4); 529-536. Doi: 10.1002/aorn.12675.	Guidance	Level 4	N/A	N/A	N/A
Assessment of evidence					
References not provided. Guidance developed for nursing staff working in the USA. • “Don the respirator in accordance with the manufacturer’s IFU”					

Assessment of evidence
• “Do not allow facial hair to cross under the seal of a fit tested N95 respirator.” • “Don a NIOSH-approved, fit-tested, surgical N95 respirator or higher-level respirator before entering the room of a patient with suspected or proven infections transmitted by the airborne route (eg, Mycobacterium tuberculosis [TB], rubeola virus [measles], varicella-zoster virus [chickenpox], disseminated herpes zoster).”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
I Australian Government. Infection Prevention and Control Expert Group. Guidance on the use of personal protective equipment for health workers in the context of COVID-19, 2022. Accessed: 28th November 2022	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

General notes:

- Guidance endorsed by the Australian Health Protection Principal Committee.
- Recommendations developed with advice from the National COVID-19 Clinical Evidence Taskforce Infection and Prevention and Control Panel (IPC Panel).
- Consensus recommendations based on the experience of the IPC panel and ICEG members.
- “They reflect emerging evidence concerning all potential modes of viral transmission and the increased transmissibility of SARS-CoV-2”
- “The recommendations contained in this document describe the minimum national standard for PPE for health workers in the context of COVID-19.”
- “Given the variability across and within health care settings, decisions around the use of PPE may require a nuanced and flexible approach, guided by evidence, contextual factors, and consideration of health worker preferences. This guidance is not meant to be exhaustive but aims to supplement detailed guidance available at a state, territory and institutional level.”

“When putting on a PFR:

- check for any defects.
- remove glasses/headwear.
- tie back long hair so it does not become tangled in the straps of the respirator.
- put the mask on the face, ensuring the nose piece is at the top of the mask.
- place the headband over the head and at the base of the neck.
- ensure mask fits comfortably on the nose and under the chin.
- compress the mask against the face to ensure a seal across the bridge of the nose.

Assessment of evidence

- compress the mask to ensure a seal across the cheeks and the face.
- conduct a fit check."

"PPE should be donned in the following order before entering the patient/client/resident zone:

- Perform hand hygiene
- Put on gown/apron7
- Put on surgical mask or PFR (whichever is applicable)
- Put on eye protection (see Protective eyewear, below)
- Put on disposable non-sterile gloves. (the cuff of the glove should extend over the sleeve of the gown)."

Care should be taken not to touch the mask whilst in use. If a health worker touches the front of a mask, hand hygiene should be performed immediately after removing the gloves, and the mask replaced."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centers for Disease Control and Prevention (CDC). How to Use Your N95 Respirator, 2022.	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Updated 16 May 2023. Accessed: 29 October 2024					

Assessment of evidence

Instructions apply to N95 respirators with 2 head straps (not ear loops).

“1. Wash Hands.

It is best to put on your N95 with clean, dry hands.

2. Check your N95 Respirator.

Always inspect the N95 for damage before use. If it appears damaged, dirty, or damp, do not use it.

3. Put on the N95 Respirator.

Hold the N95 respirator in your hand with the nose piece bar (or foam) at your fingertips.

If yours does not have a nose piece, use the text written on it to be sure the top end is at your fingertips.

Place the N95 respirator under your chin with the nose piece bar at the top.

Pull the top strap over your head, placing it near the crown. Then, pull the bottom strap over and place it at the back of your neck, below your ears. Do not crisscross the straps. Make sure the straps lay flat and are not twisted.

Place your fingertips from both hands at the top of the nose piece. Press down on both sides of the nose piece to mold it to the shape of your nose.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centers for Disease Control and Prevention (CDC). Sequence for putting on personal protective equipment, 2019a. Accessed: 11 November 2024	Poster	**Level 4**	N/A	N/A	N/A

Assessment of evidence

"The procedure for putting on and removing PPE should be tailored to the specific type of PPE"

Sequence:

1. Gown
2. Mask/respirator
    a. Secure ties or elastic bands at middle of head and neck
    b. Fit flexible band to nose bridge
    c. Fit snug to face and below chin
    d. Fit-check respirator
3. Goggles or face shield
4. Gloves

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Health Security Agency (UKHSA). Putting on (donning) personal protective equipment (PPE) for aerosol generating procedures (AGPs). Airborne Precautions – Gown version, 2020. Accessed: 13th December 2022	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

This COVID-19 guidance advises that, when wearing gowns as part of PPE for airborne precautions, the gown is donned first, followed by the respirator, then eye protection and gloves. It provides guidance for checks to be done before donning, that it is performed outside the patient room, and how respirators should be donned, including fit checks. This guidance also provides pictures to aid user understanding.

- Prior to donning, it is advised that healthcare workers should be hydrated, have their hair tied back, remove jewellery and check the correct size of PPE is available.
- “The order for putting on is gown, respirator, eye protection and gloves. This is undertaken outside the patient’s room.”
- Following donning the fluid repellent disposable gown, the respirator should be donned as such:

Assessment of evidence

- “Note: this must be the respirator that you have been fit tested to use. Where goggles or safety spectacles are to be worn with the respirator, these must be worn during the fit test to ensure compatibility.
- Position the upper straps on the crown of your head, above the ears and the lower strap at the nape of the neck. Ensure that the respirator is flat against your cheeks. With both hands mould the nose piece from the bridge of the nose firmly pressing down both sides of the nose with your fingers until you have a good facial fit. If a good fit cannot be achieved DO NOT PROCEED.
- Perform a fit check. The technique for this will differ between different makes of respirator. Instructions for the correct technique are provided by manufacturers and should be followed for fit checking.”

(**Note** that this guidance is the same as the UKHSA guidance for donning a respirator with coveralls)

Following this step, eye protection and gloves can be donned.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
European Centre for Disease Prevention and Control (ECDC). Guidance for wearing and removing personal protective equipment in healthcare settings for the care of patients with	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
suspected or confirmed COVID-19; 2020. Accessed: 14th December 2022					

Assessment of evidence

“Scope of this document

This document provides support to healthcare workers managing suspected or confirmed cases of novel coronavirus 2019 (COVID-19). The general objectives of the document are:

- to present the minimal set of personal protective equipment (PPE) required for managing suspected or confirmed COVID-19 cases;
- to make healthcare workers aware of the critical aspects of the donning and doffing of PPE; and
- to strengthen occupational safety in healthcare workers for patients suspected of, or confirmed with, COVID-19.
- This document is based on current COVID-19 knowledge and PPE best practices.

ECDC will update this document based on the evolving situation and if new relevant information arises.

Target audience:

Healthcare workers and infection prevention and control personnel in EU/EEA countries and in the United Kingdom.”

Donning PPE:

1. Hand hygiene using ABHR

Assessment of evidence
2. Gown 3. FFP2/3 a. “After wearing the gown, it is suggested to proceed with the respirator that protects from the inhalation of droplets and particles” b. “The metal nose clip needs to be adjusted (Figure 7) and the straps have to be tightened to have a firm and comfortable fit […]” 4. Eye protection 5. Gloves

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The British Standard Institution (BSI). BS ISO 16975-3:2017. Respiratory protective devices - Selection, use and maintenance Part 3: Fit-testing procedures.	British Standard	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Accessed: 12th July 2023.					
Assessment of evidence					
"All RPD wearers shall don and adjust their RPD in accordance with the manufacturer's instructions"					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Public Health Agency of Canada (PHAC). Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Healthcare Settings, 2017. Accessed: 20th December 2022	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

Setting: Canada

Guidance developed by the Public Health Agency of Canada, in which evidence-based IPC recommendations are provided.

Target audience: “This guideline is intended to assist infection prevention and control professionals and all other healthcare providers responsible for developing policies and procedures related to routine practices and additional precautions in all healthcare settings whether in acute or long-term care, ambulatory care, home care or prehospital care settings. This guideline is intended for settings where healthcare is provided”

Methodology: “The Guideline Working Group was composed of members representing paediatric and adult infectious disease, hospital epidemiologists, acute and long-term care infection prevention and control practitioners, and home care, public health, medical microbiology, occupational health, respiratory therapy and emergency response professionals”

The guidance is based on non-systematic review methodology, thus is based on expert opinion. Authors also highlight that where there was a paucity of evidence, expert consensus was used to formulate recommendations. Note that the guidance is relatively outdated given its publication year.

- “Hand hygiene should be performed prior to putting on a respirator.
- A seal check should be performed.
- Self-contamination should be avoided by not touching the respirator on its external surface during use.”
- A respirator should not dangle around the neck when not in use.

“Putting on PPE:

- Hand hygiene
- Gown
- Put on mask or N95 respirator
    - Place mask over nose and under chin

Assessment of evidence

- Secure ties, loops or straps
- Mould metal piece to your nose bridge
- For respirators, perform seal check

- Put on protective eyewear
- Put on gloves”

Grade for all recommendations: Weak “(Studies of low quality, regardless of study design or Contradictory results, regardless of study design or Case series/case reports or Expert opinion)

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Government of Canada. Updated guidance for infection prevention and control in health care settings when COVID-19 is suspected or confirmed – April 2024	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Accessed: 1 November 2024					
Assessment of evidence					
Recommendations for all care settings developed in light of the COVID-19 Omicron variant. To be considered in conjunction with setting-specific Canadian Government guidance for acute care, long term care, home care and ambulatory/outpatient care. The authors outline further COVID-19 IPC guidance for employers: “Information is provided to staff, visitors, and patients who are asked to wear a respirator or mask about the importance of performing hand hygiene prior to putting on, and after removing or touching their mask, to reduce risk of self-contamination.”					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
World Health Organization (WHO) Infection prevention and control in the context of coronavirus disease (COVID-19): a living guideline. 2023. Accessed: 29 October 2024	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

Target audience: “Policy and decision-makers, public health professionals, IPC professionals at the national and facility levels, health care facility administrators, managers and other health workers.” – health workers work across all health and care settings.

Relevant recommendations:

“A respirator or a medical mask should be worn by health workers along with other PPE– a gown, gloves and eye protection – before entering a room where there is a patient with suspected or confirmed COVID-19. This applies to any setting where regular care is provided to patients with suspected or confirmed COVID-19, including home care, long-term care facilities and community care settings.” (54, 55, 56, 57, 58, 59, 60, 61, 62, 63)

Relevant references cited to support the above recommendations:

- Citation 54 (Fletcher et al 2019): Excluded at first screen in the current review as study looked at outbreak investigation
- Citation 55 (Sims et al): Excluded at first screen in the current review as it looked at seropositive and asymptomatic rates
- Citation 56 (Piapan et al. 2020): Excluded at first screen as it is out of scope for current review. Outbreak investigation
- Citation 57 (Venugopal et al 2021): Excluded at first screen as it was outside scope of the current review. Outbreak investigation
- Citation 58 (Haller et al 2022): Excluded in current review due to: results from questionnaire subject to recall bias. Adherence to IPC measures estimated by investigators. Preferential use of FFPs reported, introducing bias. Seroconversion included in the analysis as indicator of infection.
- Citation 59 (Jefferson et al. 2021). Systematic review included in current review – Excluded from this update
- Citation 60 (Loeb et al 2009): Included in previous review – Excluded from this update
- Citation 61 (Long et al. 2020): Meta analysis included in current review – Excluded from this update
- Citation 62 (MacIntyre 2011): Included in previous review – Excluded from this update
- Citation 63 (MacIntyre 2013): Included in previous review – Excluded from this update

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). Personal protective equipment at work. The Personal Protective Equipment at Work Regulations 1992 (as amended). Guidance on Regulations. 2022.	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

This HSE document provides guidance on how to comply with the PPER legislation regarding when to remove (and discard) eye and face protection.

“This guidance provides practical advice on how you can comply with the requirements of the Personal Protective Equipment at Work Regulations 1992 as amended by the Personal Protective Equipment at Work (Amendment) Regulations 2022”

“Part 2 85 Part 2 provides guidance to employers to help them comply with their duties to select suitable PPE, ensure its proper use, and maintain it.”

Evidence from previous update(s):

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). Respiratory protective equipment at work: A practical guide. HSG53 (4th Ed.), 2013b. ISBN: 978 0 7176 6454 2.	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

About this guidance:

- This guide prepared by the HSE “in consultation with industry: employers, trade unions and trade associations”, is stated to support “the Approved Code of Practice (ACOP) to the Regulations that apply (see paragraphs 36–39)”.
- “The guide contains practical guidelines to help you select the correct RPE and manage its use in your workplace to ensure effective protection.”
- “As an employer, you have a legal responsibility under all the Regulations listed in paragraphs 36–39”

“8 In addition, users should remember that the RPE will only be effective if it is worn and used in accordance with the manufacturer’s instructions.”

Assessment of evidence

“79 Users should check their RPE every time they use it – this is known as a ‘preuse check’. The check will cover a variety of things, dependent on the type of RPE, so users should follow the manufacturer’s instructions. Common things to look out for include making sure that:

- the nose bridge on disposable RPE is adjusted to ensure a proper seal;
- all the straps are used;”

Non-powered respirators

“Dos

- Always use all the straps provided, making sure they are correctly positioned and adjusted. Follow the manufacturer’s instructions.
- Ensure the other PPE you need to wear is compatible with the respirator.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The Control of Substances Hazardous to Health (Amendment) Regulations 2004 No. 3386.	Legislation	Mandatory	N/A	N/A	N/A

Assessment of evidence

Introduction:

These regulations describe requirements to protect employees from substances hazardous to health in the workplace: “In these Regulations, a reference to an employee being exposed to a substance hazardous to health is a reference to the exposure of that employee to a substance hazardous to health arising out of or in connection with work at the workplace.”

Regulation 8 (1)

“Regulation 8 Use of control measures etc

(1) Every employer who provides any control measure, other thing or facility in accordance with these Regulations shall take all reasonable steps to ensure that it is properly used or applied as the case may be.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). The Control of Substances Hazardous to Health (COSHH) - Approved Code of Practice and guidance. Health and Safety	Expert opinion	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Executive. 6th edn, 2013a. ISBN: 9780717665822.					

Assessment of evidence

This document contains the “Approved Code of Practice (ACOP) to the Control of Substances Hazardous to Health Regulations 2002 (as amended) (COSHH) and covers all substances to which the Regulations apply.” “The ACOP describes the preferred or recommended methods that can be used (or the standards to be met) to comply with the Regulations and the duties imposed by the Health and Safety at Work etc Act 1974 (HSW Act). The accompanying guidance also provides advice on achieving compliance, or it may give information of a general nature, including explanation of the requirements of the law, more specific technical information or references to further sources of information.”

ACOP:

“168 Employees should use the control measures in the way they are intended to be used and as they have been instructed. In particular, they should:

- wear the PPE provided, including any RPE, correctly and in accordance with the manufacturer’s instructions;”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Coia JE, Ritchie L, Adisesh A, et al. Guidance on the use of respiratory and facial protection equipment. J. Hosp. Infect., 2013; 85;PP:170-182. DOI: 10.1016/j.jhin.2013.06.020.	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

Best practice guidance based on a non-systematic literature review published separately (Bunyan D, Ritchie L, Jenkins D, Coia JE. Respiratory and facial protection: a critical review of recent literature. J Hosp Infect 2013;85:165e169).

“The Scientific Development Committee of the Healthcare Infection Society established a short-life working group in May 2011 to develop appropriate guidance. The working group included representation from the Healthcare Infection Society, Public Health England, Health and Safety Executive (HSE), Association of National Health Occupational Physicians, Health Protection Scotland, Infection Prevention Society, Intensive Care Society, Clinical Virology Network and British Infection Association.”

“Follow these five steps to fit your respirator correctly

Tip: it may be helpful to look in the mirror when fitting your respirator.

Assessment of evidence

1. Hold the respirator in one hand and separate the edges to fully open it with the other hand. Bend the nose wire (where present) at the top of the respirator to form a gentle curve
2. Turn the respirator upside down to exposure the two headbands and then separate them using your index finger and thumb. Hold the headbands with your index finger and thumb and cup the respirator under your chin.
3. Position the upper headband on the crown of your head, above the ears, not over them. Position the lower strap at the back of your head below your ears.
4. Ensure that the respirator is flat against your cheeks.
5. Mould the nosepiece across the bridge of your nose by firmly pressing down until you have a good facial fit.

Do not ‘fiddle with respirator’ while in position on the face

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
World Health Organization. Infection prevention and control of epidemic-and pandemic prone acute respiratory infections in health care, 2014.	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Accessed: 24th January 2023					

Assessment of evidence

Funding: “Financially supported by the United States Centers for Disease Control and Prevention (CDC), the United States Agency for International Development (USAID), the German Agency for International Cooperation (GIZ), and the French Ministry of Social Affairs and Health”

Aim of guidance: “The guidance is intended to help policy-makers, administrators and health-care workers to prioritize effective IPC measures”

Target audience: “Recommendations, best practices, and principles for non-pharmacological aspects of infection prevention and control (IPC) for acute respiratory infections (ARI) in health care” intended for policy-makers, administrators and health-care workers, including doctors, nurses, allied health professionals, auxiliary and community health workers, and others involved in provision of health care.

Recommendations:

- “avoid contamination during use” (158)

Citation 158 (Hannum et al. 1996). The effect of respirator training on the ability of healthcare workers to pass a qualitative fit test. This a dated reference particularly in regard to the scope of the current review.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Siegel JD, Rhinehart E, Jackson M, Chiarello L. 2007 guideline for isolation precautions: preventing transmission of infectious agents in health care settings. American journal of infection control. 2007 Dec 1;35(10): S65-164. Last updated: September 2024 Accessed: 28 October 2024	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

Target audience: Infection control staff, health care epidemiologists, healthcare administrators, nurses, other health care providers and persons involved in infection control programs (developing, implementing and evaluating) for healthcare settings.

Methodology:

Assessment of evidence

- Expert opinion by CDC and HIPAC (members listed). This guidance presents narrative synthesis summary of literature and how it contributes to IPC guidance. New emerging pathogens, rising concern for known pathogens, new therapy development and rising concern for bioterrorism prompt updates. Little detail is provided on the methodology for literature search and review process.
- Consistent with the TBP review, this was AGREE Not Recommend based on lack of detail on review methods.
- The reference list was screened for papers/guidance which may be relevant for RPE review. Unless otherwise stated, CDC guidance is cited to support these recommendations.

Recommendations:

Under the heading “Transmission-Based Precautions”:

- For airborne precautions, “HCWs caring for patients on Airborne Precautions wear a mask or respirator, depending on the disease-specific recommendations (see Section II.E.4, Table 2, and Appendix A), that is donned before room entry” (page S110)
    - This section cites the section on personal protective equipment, table 2 outlining transmission based precautions whilst waiting on confirmatory diagnosis and appendix A, an up to date list of infectious agents, their precautions and duration (relevant entries described below)
- Figure. Example of Safe Donning and Removal of Personal Protective Equipment (PPE) (page 132)

  “Donning PPE

  1. Gown […]
  2. Mask or Respirator
      - Secure ties or elastic band at middle of head and neck
      - Fit flexible band to nose bridge
      - Fit snug to face and below chin

Assessment of evidence

- Fit-check respirator

3. Goggles/face shield […]
4. Gloves [...]”

Question 13: Where and how should disposable respirators be doffed?

Evidence added to 2024 update:

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Department of Health Infection Prevention and Control (IPC) National Clinical Guideline No. 30 Last updated: May 2023 Accessed: 03 February 2025	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence
Target audience: “This National Clinical Guideline applies to all health and social care workers because the control of healthcare associated infection is everyone’s responsibility. It is particularly relevant to Infection Prevention and Control (IPC) Practitioners. IPC Practitioners are those health and social care workers with specific training and expertise in the prevention and control of infection and who provide training, guidance and leadership to others on IPC.” **Recommendations:** Removal of an FFP2 respirator

Assessment of evidence
Correct removal of an FFP2 respirator mask is important as there is a risk of contamination to the user if not removed correctly. Considerations when removing an FFP2 respirator include: • removal of respirator masks should be by the straps from the back of the head forwards • respirator masks should be removed outside the patient care area.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The National Institute for Occupational Safety and Health (NIOSH) Donning and Doffing PPE: Proper Wearing, Removal, and Disposal. Last updated: October 2022 Accessed: 6 January 2025	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence
“Doffing means removing PPE in a way that avoids self-contamination. For example, avoid skin and mucous membrane contact with potentially infectious materials, and chemical and biological agents.” Information regarding highly infectious diseases has been excluded as this is outside the scope of this literature review.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Australian Government National Health and Medical Research Council (NHMRC) Australian Guidelines for the Prevention and Control of Infection in Healthcare 2019 (revised 2024, v11.24) Accessed 11 October 2024	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

Funding: Guidance was co-funded by the NHMRC and Medical Research Council and Australian Commission on Safety and Quality in Health Care.

Aim of guidance (page 20): “By assisting healthcare workers to improve the quality of the care they deliver, these Guidelines aim to promote and facilitate the overall goal of infection prevention and control: the creation of safe healthcare environments through the implementation of evidence-based practices that minimise the risk of transmission of infectious agents.”

Target audience (page 20): “The Guidelines are for use by all those working in acute health care settings —this includes healthcare workers, management and support staff. As some of the principles and recommendations described in this guideline may be applicable to other health care settings, individuals working in other health care settings may also find the guidelines useful.” The introduction states that all recommendations are based on systematic reviews, however there is insufficient evidence within the guidance to support this claim.

Note: P2 respirators meet the relevant Australian standard (AS/NZS 1716:2012 and 1715:2009) and differs to NIOSH, which specifies N95 respirators.

Recommendations:

“Surgical or particulate masks should be removed outside of the patient room or >1 metre from symptomatic patients”

Sequence:

1. Remove gloves
2. Hand hygiene
3. Remove gown
4. Remove eye/face protection
5. Remove mask/respirator
6. Hand hygiene

Assessment of evidence

- “Removal of a P2 respirator Correct removal of a P2 respirator is important as there is a risk of contamination to the user if not removed correctly. Considerations when removing a P2 respirator include (see Figure 9):
    - removal of respirators should be by the straps from the back of the head
    - respirators should be removed outside the patient-care area and disposed of in a closed receptacle [263].” (page 124)

Citation 263 is considered expert opinion guidance and is included within the ARHAI Scotland RPE literature review: Siegel JD, Rhinehart E, Jackson M, Chiarello L : Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings (2007). Centers for Disease Control and Prevention: Health Care Infection Control Practices Advisory Committee 2007.

- “Hand hygiene should be performed upon touching or disposing of a used respirator.” (page 124)
- Figure 9 (page 124) states “With clean hands, grasp tapes at back of head and remove by only handling the tapes, then discard in appropriate waste. Wash hands.” One citation is used to support this recommendation (Citation 178). This citation is no longer available but was Australian Government advice on how to fit and remove a respirator.

Adapted from CDC Isolation Precautions (expert opinion guidance that is included in this ARHAI Scotland literature review):

- “Removal of PPE should be done at the doorway (just prior to leaving patient’s room) or immediately outside patient room.”
- “To remove a P2 respirator, remove gloves and gown, perform hand hygiene and step outside the room or into an anteroom. Remove protective eyewear or face shield before removing and disposing of the respirator in a closed container and performing hand hygiene again.”
- “At a minimum, hand hygiene should be performed […] after the removal of any other individual item of contaminated PPE.”
- The guidance highlights: “Sequencing may differ across healthcare settings and any variations to sequencing should be based on a risk assessment relevant to the setting and task being undertaken.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Association for Professionals in Infection Control and Epidemiology (APIC) Do's & Don't's for wearing N95 respirators in non-surgical healthcare settings, 2015. Accessed: 16th November 2022	Poster	Level 4	N/A	N/A	N/A

Assessment of evidence

Format: Poster that is endorsed by The American Nurses Association (ANA), Association of Occupational Health Professionals in Healthcare and the Association of Perioperative Nurses (AORN).

Target audience: staff working in non-surgical settings

Setting: USA

Recommendations:

- "Tilt head forward and remove the N95 respirator by pulling bottom strap over back of head, followed by the top strap without touching the front of mask. Keep straps tight during the removal process."
- "Discard an N95 respirator by touching straps only. Perform hand hygiene before and after use of an N95 respirator"

Assessment of evidence
• “DON’T snap the strap as that may spread germs”.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Association of perioperative Registered Nurses (AORN). Guideline Quick View: Transmission-Based Precautions. 2019.	Guidance	**Level 4**	N/A	N/A	N/A

Assessment of evidence
References not provided. Guidance developed for nursing staff working in the USA. **Recommendations**: • Remove the respirator after leaving the patient’s room and closing the door. • Remove the respirator last when it is worn in combination with other PPE (e.g, gown, gloves, eye protection). • Remove the surgical N95 respirator in accordance with the manufacturer’s written [instructions for use] IFU by touching only the ties and without touching the front of the respirator.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Infection Prevention and Control Expert Group, Australian Government. Guidance on the use of personal protective equipment for health workers in the context of COVID-19, 2019. Accessed: 28th November 2022.	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

General notes:

Guidance endorsed by the Australian Health Protection Principal Committee.

Recommendations developed with advice from the National COVID-19 Clinical Evidence Taskforce Infection and Prevention and Control Panel (IPC Panel).

Consensus recommendations based on the experience of the IPC panel and ICEG members.

“They reflect emerging evidence concerning all potential modes of viral transmission and the increased transmissibility of SARS-CoV-2”

Assessment of evidence

“The recommendations contained in this document describe the minimum national standard for PPE for health workers in the context of COVID-19.”

“Given the variability across and within health care settings, decisions around the use of PPE may require a nuanced and flexible approach, guided by evidence, contextual factors, and consideration of health worker preferences. This guidance is not meant to be exhaustive but aims to supplement detailed guidance available at a state, territory and institutional level.”

Recommendations:

“The following sequence is recommended but alternative sequences can be performed safely. Do not touch the front of the gown, eye protection or mask and perform hand hygiene between each step:

- Remove gloves without touching the outside of the glove and perform hand hygiene.
- Remove gown/apron, without touching the front of the gown, by folding it so that the external (exposed) side is inside; perform hand hygiene.
- Remove eye protection and perform hand hygiene. To take off eye protection, the wearer should remove them using the tip of the goggle arms or the elastic band/garter that secures them to the wearer’s head. Avoid touching the face near the eyes and perform hand hygiene following removal. Protective eyewear labelled single use, should be discarded.
- Remove surgical mask or PFR by only handling the ties or ear loops, then discard in appropriate waste and perform hand hygiene. Do not touch front of the mask.

Note:

Eye protection and surgical masks or PFRs should only be removed outside of the patient/client/resident zone.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centers for Disease Control and Prevention (CDC). Infection Control Guidance: SARS-CoV-2. 2023 Accessed: 30 October 2024	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

Note: “This interim guidance has been updated based on currently available information about COVID-19 and the current situation in the United States. Updates were made to reflect the high levels of vaccine-and infection-induced immunity and the availability of effective treatments and prevention tools. This guidance provides a framework for facilities to implement select infection prevention and control practices (e.g., universal source control) based on their individual circumstances (e.g., levels of respiratory virus transmission in the community). This guidance is applicable to all U.S. settings where healthcare is delivered (including nursing homes and home health).”

Recommendations:

Ambulance with isolated driver and patient compartments that can provide separate ventilation to each area:

“Before entering the isolated driver’s compartment, the driver (if they were involved in direct patient care) should remove and dispose of PPE and perform hand hygiene to avoid soiling the compartment.” NOT the case without an isolated driver compartment.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centers for Disease Control and Prevention (CDC). Sequence for putting on personal protective equipment, 2019a. Accessed: 11 November 2024	Poster	Level 4	N/A	N/A	N/A

Assessment of evidence

Detailed procedure for donning respirator

- “Front of mask/respirator is contaminated — DO NOT TOUCH!
- If your hands get contaminated during mask/respirator removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Grasp bottom ties or elastics of the mask/respirator, then the ones at the top, and remove without touching the front
- Discard in a waste container”

Image suggests non-powered respirator.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Health Security Agency (UKHSA). Removal of (doffing) personal protective equipment (PPE). Airborne Precautions for AGPs – Gown version, 2022. Accessed 20th December 2022.	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

This COVID-19 guidance advises the process by which FFP3 respirators should be doffed following AGPs whilst the healthcare worker is wearing a gown, and that this process should be outside a patient's room (in an anteroom, lobby or safe area) with a buddy observing.

Pictures are also provided to aid understanding.

The authors advise that:

- "The FFP3 respirator must always be removed outside the patient's room"
- "Where possible […] the process should be supervised by a buddy at a distance of 2 metres to reduce the risk of the healthcare worker removing PPE and inadvertently contaminating themselves while doffing"

Assessment of evidence

- “The FFP3 respirator should be removed in the anteroom/lobby. In the absence of an anteroom/lobby, remove FFP3 respirator in a safe area (e.g., outside the isolation room)”

Sequence

1. Gloves
2. Gown
3. Eye protection
4. “Respirator – in the absence of an anteroom/lobby remove FFP3 respirators in a safe area (e.g. outside the isolation room). Clean hands with alcohol hand rub.
    - Do not touch the front of the respirator as it will be contaminated
    - Lean forward slightly
    - Reach to the back of the head with both hands to find the bottom retaining strap and bring it up to the top strap
    - Lift straps over the top of the head
    - Let the respirator fall away from your face and place in bin”
5. Wash hands

(Note that this guidance is the same as the UKHSA guidance for donning a respirator with coveralls)

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Government Department of Health and Social Care Infection prevention and control (IPC) in adult social care: acute respiratory infection (ARI). 2024 Accessed: 17 October 2024	Guidance	**Level 4**	N/A	N/A	N/A
Assessment of evidence					
“FFP3 respirators should be removed and disposed of outside of the room where the AGP was carried out, or when leaving the house of a care recipient. For donning and doffing instructions for AGPs refer to the PPE guidance for AGPs.”					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
European Centres for Disease Prevention and Control (ECDC). COVID-19 infection prevention and control measures for primary care, including general practitioner practices, dental clinics and pharmacy settings: first update, 2020a. Accessed: 14th December 2022.	Technical report	Level 4	N/A	N/A	N/A

Assessment of evidence

“Scope of this document

This document provides guidance on infection prevention and control (IPC) measures to healthcare providers in the European Union/European Economic Area (EU/EEA) and the United Kingdom (UK) in order to prevent COVID-19 infection.

Target audience:

Assessment of evidence
Healthcare workers in general practitioner (GP) offices, primary care clinics, dental offices/clinics, and pharmacies in the EU/EEA and the UK." **Recommendation**: "Hand hygiene should be performed after doffing PPE which includes FFP2/3" (no references provided)

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
European Centres for Disease Prevention and Control (ECDC). Guidance for wearing and removing personal protective equipment in healthcare settings for the care of patients with suspected or confirmed COVID-19, 2020b.	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Accessed: 14th December 2022					

Assessment of evidence

“Scope of this document

This document provides support to healthcare workers managing suspected or confirmed cases of novel coronavirus 2019 (COVID-19). The general objectives of the document are:

- to present the minimal set of personal protective equipment (PPE) required for managing suspected or confirmed COVID-19 cases;
- to make healthcare workers aware of the critical aspects of the donning and doffing of PPE; and
- to strengthen occupational safety in healthcare workers for patients suspected of, or confirmed with, COVID-19.
- This document is based on current COVID-19 knowledge and PPE best practices.

ECDC will update this document based on the evolving situation and if new relevant information arises.

Target audience:

Healthcare workers and infection prevention and control personnel in EU/EEA countries and in the United Kingdom.”

Doffing procedure:

1. Gloves
2. Hand hygiene
3. New pair of gloves
4. Gown

Assessment of evidence
5. Goggles 6. Respirator 7. Gloves 8. Hand hygiene “The respirator should be removed next. In order to remove the respirator, a finger or thumb should be placed under the straps in the back and the respirator taken off as shown in Figure 21. […] It is important to avoid touching the respirator with the gloves (except for the elastic straps) during its removal.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Public Health Agency of Canada (PHAC). Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Healthcare Settings, 2017.	Report/guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Accessed: 20th December 2022.					

Assessment of evidence

Aim: To present evidence-based recommendations for monitoring, preventing and controlling healthcare associated infections.

Target audience: Infection prevention and control professionals and healthcare providers involved with developing policy and procedure for routine practices in healthcare settings (acute, long-term, ambulatory, home care or prehospital care settings)

Methods: These guidelines were produced by PHAC, advised by PHAC's Steering Committee on Infection Prevention and Control Guidelines Working Group, made up of professionals from different areas of healthcare who provided technical advice (list provided on page 2). They are described as "principles and recommendations" rather than strict standards.

A literature search was conducted for papers from 1999 (details of this search are available to request).

Recommendations were graded based on the strength of evidence

This guidance is based on scientific evidence and expert opinion where evidence was lacking but was graded as expert opinion due to limited methodological detail making it difficult to deduce how systematic methods were.

Part B.IV. includes recommendations for additional precautions, and in subsection iii for patients with known or suspected infections requiring airborne precautions (examples of these include tuberculosis, measles and disseminated zoster):

- Also under personal protective equipment (page 102), the authors state the following for "appropriate respirator use" (CII - weak):
- "Self-contamination should be avoided by not touching the respirator on its external surface during use and disposal.
- Respirators should be carefully removed by the straps.
- The respirator should be discarded immediately after its use (i.e., dispose of when removed from the face) into a no-touch waste receptacle, followed by hand hygiene."

Assessment of evidence

Appendix X provides the steps for donning and doffing PPE, including respirators (page 187):

Doffing:

1. Gloves
2. Gown
3. Hand hygiene
4. Eye protection
5. “Remove mask or N95 respirator:
    a. Ties or ear loops or straps are considered to be ‘clean’ and may be touched with the hands
    b. The front of the mask or respirator is considered to be contaminated
    c. Untie bottom tie then top tie, or grasp straps or ear loops
    d. Pull forward off the head, bending forward to allow mask or respirator to fall away from the face
    e. Discard immediately into waste receptacle”
6. Hand hygiene

These instructions were reproduced from the Ontario Ministry of Health and Long-Term Care

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Government of Canada. Updated guidance for infection prevention and control in health care settings when COVID-19 is suspected or confirmed – April 2024. Accessed: 1 November 2024	Guidance	Level 4	N/A	N/A	N/A
Assessment of evidence					
Recommendations for all care settings developed in light of the COVID-19 Omicron variant. To be considered in conjunction with setting-specific Canadian Government guidance for acute care, long term care, home care and ambulatory/outpatient care. The authors outline further COVID-19 IPC guidance for employers: • "Information is provided to staff, visitors, and patients who are asked to wear a respirator or mask about the importance of performing hand hygiene prior to putting on, and after removing or touching their mask, to reduce risk of self-contamination".					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution (BSI) PD ISO/TS 16975-1:2016 Respiratory protective devices: selection, use and maintenance establishing and implementing a respiratory protective device programme Accessed: 11th July 2023.	International Standard	Level 4	N/A	N/A	N/A

Assessment of evidence

"This part of ISO 16975 specifies detailed information to assist persons responsible for establishing and implementing a programme for respiratory protective devices (RPD) that meet the performance requirements of the performance standards."

"Where more than one item of personal protection is needed, the sequence of doffing should be considered to ensure that respiratory protection is maintained where required"

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centres for Disease Control and Prevention (CDC). CDC's Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings. 2022c. Last updated: 12 April 2024 Accessed: 01 November 2024	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

Appropriate use of PPE:

"Remove and discard PPE, other than respirators, upon completing a task before leaving the patient's room or care area. If a respirator is used, it should be removed and discarded (or reprocessed if reusable) after leaving the patient room or care area and closing the door"

Expert opinion guidance with a small number of resources listed.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centers for Disease Control and Prevention (CDC). How to Use Your N95 Respirator, 2022d. Updated 16th May 2023. Accessed: 29th October 2024	Guidance	Level 4	N/A	N/A	N/A
Assessment of evidence					
Instructions apply to N95 respirators with 2 head straps (not ear loops). 5. Remove the N95 respirator After you remove your N95, wash your hands. Image indicates the N95 is removed by pulling the straps on the back of the head.					

Evidence from previous update(s):

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Siegel JD, Rhinehart E, Jackson M, Chiarello L. 2007 guideline for isolation precautions: preventing transmission of infectious agents in health care settings. American journal of infection control. 2007 Dec 1;35(10):S65-164. Last updated: September 2024 Accessed: 28 October 2024	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

- Figure. Example of Safe Donning and Removal of Personal Protective Equipment (PPE) (page 132)

Assessment of evidence

1. Gloves […]
2. Goggles/face shield […]
3. Gown […]
4. Mask or respirator

- Front of mask/respirator is contaminated – DO NOT TOUCH!
- Grasp ONLY bottom then top ties/elastics and remove
- Discard in waste container

Hand Hygiene Perform hand hygiene immediately after removing all PPE!”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Coia JE, Ritchie L, Adisesh A, et al. Guidance on the use of respiratory and facial protection equipment. Journal of Hospital Infection. 2013; 85;PP:170-182. DOI: 10.1016/j.jhin.2013.06.020.	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

“Respiratory and facial protection is used in conjunction with other types of PPE.

All PPE should be put on and removed in an order that minimizes the potential for cross-contamination.

- Before leaving the relevant work area Gloves, gown/apron and eye protection should be removed (in that order, where worn) and disposed of as healthcare waste.
- On removal of eye protection, it should be handled by the headband or earpieces only.
- Where non-disposable eye protection has been used, appropriate measures for decontamination between uses needs to be in place
- Hand hygiene must be performed after removal and disposal.
- After leaving the area:
    - The respirator or surgical mask can be removed and disposed of as healthcare waste. Untie or break the bottom ties first, followed by top ties or elastic, and remove by handling ties only.
    - Hand hygiene must be performed after disposal.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Loveday HP, Wilson JA, Pratt RJ, et al. epic3: National Evidence-Based Guidelines for Preventing Healthcare-	Guidance	AGREE: Recommend (with provisos)	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Associated Infections in NHS Hospitals in England, 2014. Journal of Hospital Infection. 2014;86 Suppl 1:S1-S70. doi:10.1016/S0195-6701(13)60012-2					

Assessment of evidence

These guidelines were commissioned by The Department of Health (England) for preventing HCAI in hospital or other acute heal and care settings. It is unclear how the evidence/ expert opinion formulated the following recommendations: this document is also outdated as an update was due to be published in 2017. The guideline development team was comprised of individuals with varied specialties within IPC including, nursing, microbiology, infectious diseases. The guideline advisory team was formed of consultants, trust, and lay members amongst others.

“Personal protective equipment should be removed in the following sequence to minimise the risk of cross/self-contamination:

- gloves.
- Apron.
- eye protection (when worn); and
- mask/respirator (when worn). Hands must be decontaminated following the removal of personal protective equipment.

New recommendation Class D/GPP/H&S”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Occupational Safety and Health Administration (OSHA). Guidance on Preparing Workplaces for an Influenza Pandemic. OSHA 3327-05, 2009.	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

Avoid self-contamination when doffing:

“Once worn in the presence of an infectious patient, the respirator should be considered potentially contaminated with infectious material, and touching the outside of the device should be avoided to prevent self-inoculation (touching the contaminated respirator and then touching one’s eyes, nose, or mouth). It should be noted that a once-worn respirator will also be contaminated on its inner surface by the microorganisms present in the exhaled air and oral secretions of the wearer”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The Control of Substances Hazardous to Health (Amendment) Regulations 2004. UK Statutory Instruments 2002. No. 3386.	Legislation	Level 4	N/A	N/A	N/A

Assessment of evidence

Introduction:

These regulations describe requirements to protect employees from substances hazardous to health in the workplace: “In these Regulations, a reference to an employee being exposed to a substance hazardous to health is a reference to the exposure of that employee to a substance hazardous to health arising out of or in connection with work at the workplace.”

“Regulation 9 Maintenance, examination and testing of control measures”:

“Personal protective equipment which may be contaminated by a substance hazardous to health shall be removed on leaving the working area and kept apart from uncontaminated clothing and equipment. “

Question 14: When should RPE be changed or removed?

Evidence added to 2024 update:

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive. COSHH essentials: Respiratory protective equipment. UK Standard Assigned Protection Factor 4 (APF 4). Supplementary advice, 2006a. Accessed 15th February 2022.	Expert Opinion	Level 4	N/A	N/A	N/A

Assessment of evidence
This supplementary advice provided by HSE states “This information will help employers comply with the Control of Substances Hazardous to Health Regulations 2002 (COSHH), as amended, to control exposure to chemicals and protect workers’ health.” “Training: instruct users to throw away disposable RPE after one use.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). COSHH essentials: Respiratory protective equipment. UK Standard Assigned Protection Factor 10 (APF 10). Supplementary advice, 2006b. Available from: COSHH Essential: Respiratory protective equipment (RPE) - R2 (hse.gov.uk). Accessed 15th February 2022.	Guidance	Level 4	N/A	N/A	N/A
Assessment of evidence					
This supplementary advice provided by HSE states “This information will help employers comply with the Control of Substances Hazardous to Health Regulations 2002 (COSHH), as amended, to control exposure to chemicals and protect workers’ health.”					

Assessment of evidence
“Training Instruct users to throw away disposable RPE after one use.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). COSHH essentials: Respiratory protective equipment. UK Standard Assigned Protection Factor 20 (APF 20) Supplementary advice, 2006c. Available from: COSHH Essential: Respiratory protective equipment (RPE) - R3 (hse.gov.uk).	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Accessed 15th February 2022.					

Assessment of evidence

This supplementary advice provided by HSE states “This information will help employers comply with the Control of Substances Hazardous to Health Regulations 2002 (COSHH), as amended, to control exposure to chemicals and protect workers’ health.”

“Throw away disposable RPE after one use.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). COSHH essentials: Respiratory protective equipment. UK Standard Assigned Protection Factor 40 (APF 40). Supplementary advice. 2006d.	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Available from: COSHH essentials RPE (hse.gov.uk). Accessed 15th February 2022.					
Assessment of evidence					
This supplementary advice provided by HSE states “This information will help employers comply with the Control of Substances Hazardous to Health Regulations 2002 (COSHH), as amended, to control exposure to chemicals and protect workers’ health.” “Throw away disposable RPE after one use.”					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Department of Health Infection Prevention and Control (IPC) National Clinical Guideline No. 30 Last updated: May 2023	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Accessed: 03 February 2025					

Assessment of evidence

Target audience: “This National Clinical Guideline applies to all health and social care workers because the control of healthcare associated infection is everyone’s responsibility. It is particularly relevant to Infection Prevention and Control (IPC) Practitioners. IPC Practitioners are those health and social care workers with specific training and expertise in the prevention and control of infection and who provide training, guidance and leadership to others on IPC.”

“HELPFUL TIPS:

The wearer should remove the respirator mask if:

• The respirator mask becomes uncomfortable

• Breathing becomes difficult

• The respirator mask is damaged or distorted

• The respirator mask becomes obviously contaminated by respiratory secretions, blood or bodily fluids.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Australian Government National Health and	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Medical Research Council (NHMRC) Australian Guidelines for the Prevention and Control of Infection in Healthcare 2019 (revised 2024, v11.24) Accessed 11 October 2024					

Assessment of evidence

Funding: Guidance was co-funded by the NHMRC and Medical Research Council and Australian Commission on Safety and Quality in Health Care.

Aim of guidance (page 20): “By assisting healthcare workers to improve the quality of the care they deliver, these Guidelines aim to promote and facilitate the overall goal of infection prevention and control: the creation of safe healthcare environments through the implementation of evidence-based practices that minimise the risk of transmission of infectious agents.”

Target audience (page 20): “The Guidelines are for use by all those working in acute health care settings —this includes healthcare workers, management and support staff. As some of the principles and recommendations described in this guideline may be applicable to other health care settings, individuals working in other health care settings may also find the guidelines useful.”

Assessment of evidence

The introduction states that all recommendations are based on systematic reviews, however there is insufficient evidence within the guidance to support this claim.

Note: P2 respirators meet the relevant Australian standard (AS/NZS 1716:2012 and 1715:2009) and differs to NIOSH, which specifies N95 respirators.

Recommendations:

- "Considerations when using a P2 respirator include [176]: […]
- respirators should not be touched while being worn
- respirators should be changed when they become moist
- respirators should never be reapplied after they have been removed

The information was based on one piece of expert opinion guidance (Coia JE, Ritchie L, Adisesh A, Booth CM, Bradley C, Bunyan D, et al. Guidance on the use of respiratory and facial protection equipment. Journal of Hospital Infection 2013;85 170-182) which is included in the ARHAI Scotland review.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Australian Government Infection Prevention and Control Expert Group. Guidance on the use of personal	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
protective equipment for health workers in the context of COVID-19, 2022. Accessed 28th November 2022.					

Assessment of evidence

General notes:

Guidance endorsed by the Australian Health Protection Principal Committee.

Recommendations developed with advice from the National COVID-19 Clinical Evidence Taskforce Infection and Prevention and Control Panel (IPC Panel).

Consensus recommendations based on the experience of the IPC panel and ICEG members.

“They reflect emerging evidence concerning all potential modes of viral transmission and the increased transmissibility of SARS-CoV-2”

“The recommendations contained in this document describe the minimum national standard for PPE for health workers in the context of COVID-19.”

“Given the variability across and within health care settings, decisions around the use of PPE may require a nuanced and flexible approach, guided by evidence, contextual factors, and consideration of health worker preferences. This guidance is not meant to be exhaustive but aims to supplement detailed guidance Available from a state, territory, and institutional level.”

Recommendations:

Assessment of evidence
• "Surgical masks and PFRs do not need to be removed between each patient. These masks can remain in place until they become damp with the wearer's respirations, or they are visibly soiled • "All PPE is required to be changed when leaving the COVID-19 clinical area or moving between COVID-19 clinical areas and non-COVID-19 areas."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centers for Disease Control and Prevention (CDC) Infection Control Guidance: SARS-CoV-2. 2023 Accessed: 30 October 2024	Guidance	Level 4	N/A	N/A	N/A
Assessment of evidence					
Note: "This interim guidance has been updated based on currently available information about COVID-19 and the current situation in the United States. Updates were made to reflect the high levels of vaccine-and infection-induced immunity and the availability of effective treatments and prevention tools. This guidance provides a framework for facilities to implement select infection prevention and control practices (e.g., universal source control) based on their individual circumstances (e.g., levels of respiratory virus transmission in					

Assessment of evidence
the community). This guidance is applicable to all U.S. settings where healthcare is delivered (including nursing homes and home health)." "When used solely for source control, any of the options [including NIOSH-approved particular respirator with N95 filters or higher, or a respirator approved under standards used in other countries that are similar to NIOSH-approved N95 filtering facepiece respirators (Note: These should not be used instead of a NIOSH-approved respirator when respiratory protection is indicated); listed above could be used for an entire shift unless they become soiled, damaged, or hard to breathe through. If they are used during the care of patient for which a NIOSH-approved respirator or facemask is indicated for personal protective equipment (PPE) (e.g., NIOSH-approved particulate respirators with N95 filters or higher during the care of a patient with SARS-CoV-2 infection, facemask during a surgical procedure or during care of a patient on Droplet Precautions), they should be removed and discarded after the patient care encounter and a new one should be donned.(See CDC (2022) Clinical Questions Q+A) "Source control devices (including respirator) should be changed if they become visibly soiled, damaged, or hard to breathe through."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centers for Disease Control and Prevention (CDC) Understanding the difference. 2019. Accessed 5th Dec 2022.	Poster	Level 4	N/A	N/A	N/A

Assessment of evidence
N95 Respirator “Ideally should be discarded after each patient encounter and after aerosol-generating procedures. It should also be discarded when it becomes damaged or deformed; no longer forms an effective seal to the face; becomes wet or visibly dirty; breathing becomes difficult; or if it becomes contaminated with blood, respiratory or nasal secretions, or other bodily fluids.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Public Health Agency of Canada (PHAC). Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Healthcare Settings, 2017. Accessed 20th December 2022.	Recommendations Report	Level 4	N/A	N/A	N/A
Assessment of evidence					
Aim: To present evidence-based recommendations for monitoring, preventing and controlling healthcare associated infections.					

Assessment of evidence

Target audience: Infection prevention and control professionals and healthcare providers involved with developing policy and procedure for routine practices in healthcare settings (acute, long-term, ambulatory, home care or prehospital care settings)

Methods: These guidelines were produced by PHAC, advised by PHAC's Steering Committee on Infection Prevention and Control Guidelines Working Group, made up of professionals from different areas of healthcare who provided technical advice (list provided on page 2). They are described as "principles and recommendations" rather than strict standards.

A literature search was conducted for papers from 1999 (details of this search are available to request).

Recommendations were graded based on the strength of evidence

This guidance is based on scientific evidence and expert opinion where evidence was lacking, but was graded as expert opinion due to limited methodological detail making it difficult to deduce how systematic methods were.

Recommendations:

Part B.IV. includes recommendations for additional precautions, and in subsection iii for patients with known or suspected infections requiring airborne precautions (examples of these include tuberculosis, measles and disseminated zoster):

Under personal protective equipment (page 102), the authors state the following for "appropriate respirator use" (CII - weak):

- "The respirator should be changed if it becomes wet or soiled (from the wearer's breathing or an external splash)."
- "The respirator should be changed if breathing becomes difficult."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Government of Canada. Infection prevention and control for COVID-19: Interim guidance for long-term care homes. Updated and re-posted 16 June 2021a. Last modified 25 January 2022 Accessed 17th April 2023.	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

Setting: Canada, long-term care homes

This Canadian interim guidance aimed to provide interim COVID-19 guidance related to IPC, to be considered in conjunction with the Canadian Government's Omicron variant guidance. It is specific to long term care homes. The guidance is broadly in line with acute care, ambulatory and outpatient settings guidance. Recommendations:

"Masks or N95 or equivalent respirators and eye protection should be replaced when they become damaged, wet, damp, or soiled (from the wearer's breathing or external splash), or when they come in direct contact with a resident."

Assessment of evidence
Minimum of droplet and contact precautions are advised for residents with potential COVID-19 (i.e. contacts, confirmed diagnosis or symptomatic): • "After seeing a resident on Droplet and Contact Precautions: ▪ Masks and N95 or equivalent respirators should be removed and replaced ▪ Medical masks or N95 or equivalent respirators and eye protection should always be removed if there is concern about possible contamination via splash or spray, if they have come into direct contact with a resident, or if they have been damaged."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Government of Canada Infection prevention and control for COVID-19: Interim guidance for acute healthcare settings. Updated and re-posted 16 June 2021b. Last modified 25 January 2022	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Accessed 17th April 2023.					

Assessment of evidence

This Canadian interim guidance aimed to provide interim COVID-19 guidance related to IPC, to be considered in conjunction with the Canadian Government's Omicron variant guidance. It is specific to acute care settings. The guidance is broadly in line with long term care homes, ambulatory and outpatient settings guidance.

"Masks or N95 or equivalent respirators and eye protection should be replaced when they become damaged, wet, damp, or soiled (from the wearer's breathing or external splash), or when they come in direct contact with a patient. Staff should be informed of how to access additional masks or N95 or equivalent respirators and eye protection when needed."

Sessional use of N95 respirator is not recommended. They recommend substituting a surgical mask for an N95 or equivalent respirator based on a point-of-care risk (PCRA) assessment, prior to interacting with a resident and/or the environment.

Additional precautions:

"A minimum of Droplet and Contact Precautions should be implemented for all patients who are considered exposed to, diagnosed with, or who are presenting with signs or symptoms of COVID-19":

- "After seeing a patient on Droplet and Contact Precautions:"
- "Masks and N95 or equivalent respirators should be removed and replaced"

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Government of Canada. Infection prevention and control for COVID-19: Interim guidance for outpatient and ambulatory care settings. 2022 Accessed 17th April 2023.	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

This Canadian interim guidance aimed to provide interim COVID-19 guidance related to IPC, to be considered in conjunction with the Canadian Government's Omicron variant guidance. It is specific to outpatient and ambulatory care. The guidance is broadly in line with acute care and long-term care homes guidance.

"Masks or N95 or equivalent respirators and eye protection should be replaced when they become damaged, wet, damp, or soiled (from the wearer's breathing or external splash), or when they come in direct contact with a patient."

Additional precautions:

"Medical masks or N95 or equivalent respirators and eye protection should always be removed if there is concern about possible contamination via splash or spray, if they have come into direct contact with a patient, or if they have been damaged. Local and facility IPC policies regarding other indications for changing extended-use medical masks, N95 or equivalent respirators, and eye protection should be followed"

Evidence from previous update(s):

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Coia J. E., Ritchie L., Adisesh, A. et al. Guidance on the use of respiratory and facial protection equipment, 2013. Journal of Hospital Infection, 2013; 85;170-182; doi: 10.1016/j.jhin.2013.06.020.	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

Best practice guidance based on a non-systematic literature review published separately (Bunyan D, Ritchie L, Jenkins D, Coia JE. Respiratory and facial protection: a critical review of recent literature. J Hosp Infect 2013; 85:165e169).

“The Scientific Development Committee of the Healthcare Infection Society established a short-life working group in May 2011 to develop appropriate guidance. The working group included representation from the Healthcare Infection Society, Public Health England, Health and Safety Executive (HSE), Association of National Health Occupational Physicians, Health Protection Scotland, Infection Prevention Society, Intensive Care Society, Clinical Virology Network and British Infection Association.”

“Can keep same respirator in use for the duration of the specified activity. Should be changed:

- after each use;

Assessment of evidence
• if breathing becomes difficult; • if respirator is damaged; or • if obviously contaminated with respiratory secretions or other body fluids” “FFP3 respirators should be changed after each use, if breathing becomes difficult, if it is damaged, or if it becomes obviously contaminated with respiratory secretions or other body fluids. Single-use respirators should be worn once […]” “Ensure that the eye protection, surgical face mask or FFP respirator is removed at the end of a clinical procedure or task”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The World Health Organization (WHO). Infection prevention and control of epidemic-and pandemic prone acute respiratory infections in health care, 2014. Accessed 24th January 2023.	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

"The development of the guidelines followed the process established in the WHO handbook for guideline development, which involved active participation of the Global Infection Prevention and Control Network (GIPCN). The resulting recommendations were peer reviewed by internal and external experts." This guidance is deemed expert opinion as it is unclear the edition of the "WHO handbook for guideline development" that was used. Further to this, the elements of the systematic review process, such as the search strategies, are not provided.

Funding: "Financially supported by the United States Centres for Disease Control and Prevention (CDC), the United States Agency for International Development (USAID), the German Agency for International Cooperation (GIZ), and the French Ministry of Social Affairs and Health"

Aim of guidance: "The guidance is intended to help policy-makers, administrators and health-care workers to prioritize effective IPC measures"

Target audience: "Recommendations, best practices, and principles for non-pharmacological aspects of infection prevention and control (IPC) for acute respiratory infections (ARI) in health care" intended for policymakers, administrators and health-care workers, including doctors, nurses, allied health professionals, auxiliary and community health workers, and others involved in provision of health care.

Recommendations:

- "Particulate respirators should be changed after each use or if they become wet or dirty" (No reference from the document)

References:

Citation 158 (Hannum et al. 1996). The effect of respirator training on the ability of healthcare workers to pass a qualitative fit test. This a dated reference particularly in regard to the scope of the current review.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Occupational Safety and Health Administration (OSHA). Guidance on Preparing Workplaces for an Influenza Pandemic, 2009. OSHA 3327-05R	Guidance	**Level 4**	N/A	N/A	N/A

Assessment of evidence

Guidance document produced by The Occupational Safety and Health Administration is an agency of the United States Department of Labor. Influenza pandemic guidance.

Filtering facepiece respirators: “discarded when it becomes unsuitable for further use due to excessive breathing resistance (e.g., particulate clogging the filter), unacceptable contamination/soiling, or physical damage.”

“Disposable respirators are designed to be used once and are then to be properly disposed of”

Recommend against re-use in normal settings:

- “If a sufficient supply of respirators is not available during a pandemic, employers and employees may consider reuse as long as the device has not been obviously soiled or damaged (e.g., creased or torn), and it retains its ability to function properly. This practice is not acceptable under normal circumstances and should only be considered under the most dire of conditions. Data on

Assessment of evidence
decontamination and/or reuse of respirators for infectious diseases are not available. Reuse may increase the potential for contamination; however, this risk must be balanced against the need to provide respiratory protection” **Note** that PPE shortages are outside the scope of the RPE review, thus only the recommendations for conventional settings have been considered for inclusion.

Question 15: When should a powered respirator be worn?

Evidence added to 2024 update:

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centres for Disease Control and Prevention (CDC) The National Personal Protective Technology Library (NPPTL) The Respiratory Protection Information Trusted Source. Healthcare Setting Specific FAQs. Last updated: 5 July 2022 Accessed: 6 January 2025	British Standard	Level 4	N/A	N/A	N/A

Assessment of evidence

“Can I use a powered air-purifying respirator (PAPR) in the operating room?

Studies on PAPRs are ongoing at this time. Professional judgement suggests PAPRs as an alternative for operating room staff who cannot pass a fit test with an N95 respirator. The PAPR should vent under the shroud in which exhalation gases vent underneath the gown. Ensure you can wear the PAPR shroud in this fashion (under the gown) by checking the manufacturer’s instructions. PAPRs venting to the rear of the PAPR wearer likely provide less contamination to the surgical field. PAPRs venting to the front may contaminate the surgical field.

For PAPRs used in operating rooms, we suggest the following approach:

Identify a NIOSH-approved filtering facepiece respirator (e.g., N95) for which you successfully passed a fit test.

If (1) is not possible, choose a PAPR model capable of venting under the gown. First check the PAPR manufacturer’s instructions to verify they permit such use for that particular model. In addition, direct the PAPR blower/exhaust away from the sterile field.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Australian Government National Health and Medical Research Council (NHMRC) Australian Guidelines for the Prevention and	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Control of Infection in Healthcare 2019 (revised 2024, v11.24) Accessed 11 October 2024					

Assessment of evidence

Funding: Guidance was co-funded by the NHMRC and Medical Research Council and Australian Commission on Safety and Quality in Health Care.

Aim of guidance (page 20): “By assisting healthcare workers to improve the quality of the care they deliver; these Guidelines aim to promote and facilitate the overall goal of infection prevention and control: the creation of safe healthcare environments through the implementation of evidence-based practices that minimise the risk of transmission of infectious agents.”

Target audience (page 20): “The Guidelines are for use by all those working in acute health care settings —this includes healthcare workers, management and support staff. As some of the principles and recommendations described in this guideline may be applicable to other health care settings, individuals working in other health care settings may also find the guidelines useful.”

The introduction states that all recommendations are based on systematic reviews, however there is insufficient evidence within the guidance to support this claim.

Note: P2 respirators meet the relevant Australian standard (AS/NZS 1716:2012 and 1715:2009) and differs to NIOSH, which specifies N95 respirators.

Recommendations:

Assessment of evidence

“If a good facial seal cannot be achieved (e.g., the intended wearer has a beard or long moustache), an alternative respirator such as a powered air-purifying respirator (PAPR) should be used”

This consideration is based on one citation [Citation 176]: Coia JE, Ritchie L, Adisesh A, Booth CM, Bradley C, Bunyan D, et al. : Guidance on the use of respiratory and facial protection equipment. Journal of Hospital Infection 2013;85 170-182 Journal Website

This UK expert opinion guidance (level 4) is included within the ARHAI Scotland review. The document states that adequate seal may not be achieved due to facial hair and that a PAPR hood may be the only option for some HCWs – see appraisal of this guidance document for further information.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
American Society of Anaesthesiologists (ASA). Anaesthesia Patient Safety Foundation (APSF), American Academy of Anaesthesiologist Assistants (AAAA) and American Association of Nurse Anaesthetists (AANA).	Joint Position Statement	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Revised: The Use of Personal Protective Equipment by Anaesthesia Professionals during the COVID-19 Pandemic Joint Position Statement. 2020. Accessed 17th Nov 2022.					

Assessment of evidence

Position statement for the safety of anaesthesia professionals in the context of the COVID-19 pandemic in the USA.

Recommendations:

- “PAPRs should be used by individuals who are not N95 fit-tested, have facial hair, or fail N95 fit-testing.”
- Appropriate PPE should be used for all patients during aerosol generating procedures (AGPs). This has been recommended given the incubation time of SARS-CoV-2, potential asymptomatic patients, and lack of sensitivity of the test used to detect infection. List of AGPs are not provided.
    - Note that appropriate PPE includes: fitted N95 respirator, PAPRs, or other CDC or NIOSH-approved respirator.

Limitations:

- Specific to pandemic setting (COVID-19)

Assessment of evidence
• Potentially outdated, early in pandemic (June 2020)

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Infection Prevention and Control Expert Group, Australian Government. Guidance on the use of personal protective equipment for health workers in the context of COVID-19, 2022. Accessed 28th November 2022.	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence
Guidance context: Guidance endorsed by the Australian Health Protection Principal Committee. Recommendations developed with advice from the National COVID-19 Clinical Evidence Taskforce Infection and Prevention and Control Panel (IPC Panel). Consensus recommendations based on the experience of the IPC panel and ICEG members.

Assessment of evidence
“They reflect emerging evidence concerning all potential modes of viral transmission and the increased transmissibility of SARS-CoV-2” “The recommendations contained in this document describe the minimum national standard for PPE for health workers in the context of COVID-19.” “Given the variability across and within health care settings, decisions around the use of PPE may require a nuanced and flexible approach, guided by evidence, contextual factors, and consideration of health worker preferences. This guidance is not meant to be exhaustive but aims to supplement detailed guidance available at a state, territory and institutional level.” **Recommendations**: • “A PAPR may be considered as an alternative to a PFR in some circumstances (e.g., when the fit of a PFR is compromised or when extended use is required). The following should be considered: ▪ The use of a PAPR may not provide additional protection compared to a well-sealed PFR. ▪ If a health worker is required to remain in the patient’s room continuously for a long period, the use of a PAPR may be considered for additional comfort and visibility. ▪ PAPRs used during sterile procedures should be suitable for use to maintain sterile field.”

Evidence from previous update(s):

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). Respiratory protective equipment at work:	Expert opinion	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
A practical guide. HSG53 (4th Ed.) 2013. ISBN: 978 0 7176 6454 2.					

Assessment of evidence

About this guidance:

- This guide prepared by the HSE “in consultation with industry: employers, trade unions and trade associations”, is stated to support “the Approved Code of Practice (ACOP) to the Regulations that apply (see paragraphs 36–39)”.
- “The guide contains practical guidelines to help you select the correct RPE and manage its use in your workplace to ensure effective protection.”
- “As an employer, you have a legal responsibility under all the Regulations listed in paragraphs 36–39”

Recommendations:

“8 Filters are additionally marked:

- NR = Not reusable – Designed for a single work shift (eight hours) and must be disposed of safely at the end.

R = Reusable.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). Respiratory protective equipment at work. A practical guide. HSG53 (4th Ed.), 2013.	Expert opinion	Level 4	N/A	N/A	N/A

Assessment of evidence

"Where RPE is required to be worn continuously for long periods, powered respirators or airline BA, for example a loose-fitting facepiece such as a hood or helmet, are better options."

Use of powered RPE or loose-fitting facepieces to "minimise fatigue and discomfort". Similarly, use of powered respirators/airline breathing apparatus are recommended in hot/humid conditions.

Powered respirator:

- "Where possible, choose equipment where the different forms of protection required are combined (often referred to as integrated or combined PPE), e.g., eye, face, head and respiratory protection provided by a powered helmet respirator."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Occupational Safety and Health Administration (OSHA). Guidance on Preparing Workplaces for an Influenza Pandemic. OSHA 3327-05R, 2009.	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

Guidance document produced by The Occupational Safety and Health Administration is an agency of the United States Department of Labor. Influenza pandemic guidance.

Explanation provided on the spread of influenza:

“Influenza is thought to be primarily spread through large droplets (droplet transmission) that directly contact the nose, mouth or eyes. These droplets are produced when infected people cough, sneeze or talk, sending the relatively large infectious droplets and very small sprays (aerosols) into the nearby air and into contact with other people. Large droplets can only travel a limited range; therefore, people should limit close contact (within 6 feet) with others when possible. To a lesser degree, human influenza is spread by touching objects contaminated with influenza viruses and then transferring the infected material from the hands to the nose, mouth or eyes. Influenza may also be spread by very small infectious particles (aerosols) traveling in the air. The contribution of each route of exposure to influenza transmission is uncertain at this time and may vary based upon the characteristics of the influenza strain.”

Assessment of evidence

PPE recommendations according to exposure level to pandemic influenza – recommendations are not healthcare specific – applied to non-health settings also:

- Very high/high exposure risk (contact with known/suspected infected persons; contact within 6 feet) – “Supplied air respirator (SAR) or powered air purifying respirator (PAPR) for certain high risk medical or dental procedures likely to generate bioaerosols”
- Then goes on to state “The appropriate form of respirator will depend on the type of exposure and on the transmission pattern of the particular strain of influenza” and links to NIOSH respirator selection logic (Ref XX. CDC (2004) NIOSH selection logic)

Question 16: Where and how should powered respirators be donned?

Evidence added to 2024 update: No evidence identified

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
N/A	N/A	N/A	N/A	N/A	N/A
Assessment of evidence					
N/A					

Evidence from previous update(s):

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). Respiratory protective equipment at work: A practical guide. HSG53 (4th Ed.). 2013b.	Expert opinion	Level 4	N/A	N/A	N/A

Assessment of evidence

About this guidance:

- This guide prepared by the HSE “in consultation with industry: employers, trade unions and trade associations”, is stated to support “the Approved Code of Practice (ACOP) to the Regulations that apply (see paragraphs 36–39)”.
- “The guide contains practical guidelines to help you select the correct RPE and manage its use in your workplace to ensure effective protection.”
- “As an employer, you have a legal responsibility under all the Regulations listed in paragraphs 36–39”

Recommendations:

- “Where possible, choose equipment where the different forms of protection required are combined (often referred to as integrated or combined PPE), eg eye, face, head and respiratory protection provided by a powered helmet respirator.”
- “In addition, users should remember that the RPE will only be effective if it is worn and used in accordance with the manufacturer’s instructions.”
- “Users should check their RPE every time they use it – this is known as a ‘preuse check’. The check will cover a variety of things, dependent on the type of RPE, so users should follow the manufacturer’s instructions. Common things to look out for include making sure that:
    - the nose bridge on disposable RPE is adjusted to ensure a proper seal;
    - all the straps are used;
    - any hoses are connected properly;
    - battery-powered RPE is fully charged”

Powered respirators

- “Always ensure the respirator is in good working order before putting it on, even when new.

Assessment of evidence

- Always use all the straps provided, making sure they are correctly positioned and adjusted. Follow the manufacturer's instructions.
- Always check the fan is providing enough airflow before you use the device.
- Always fit identical filters to a multi-filter unit.
- Always change all the filters on a multi-filter unit together.
- Ensure the other PPE you need to wear is compatible with the respirator."

Question 17: Where and how should powered respirators be doffed?

Evidence added to 2024 update:

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Australian Government National Health and Medical Research Council (NHMRC) Australian Guidelines for the Prevention and Control of Infection in Healthcare 2019 (revised 2024, v11.24) Accessed 11 October 2024	Guidance	Level 4	N/A	N/A	N/A
Assessment of evidence					
Aim of guidance (page 20): "By assisting healthcare workers to improve the quality of the care they deliver, these Guidelines aim to promote and facilitate the overall goal of infection prevention and control: the creation of safe healthcare environments through the implementation of evidence-based practices that minimise the risk of transmission of infectious agents."					

Assessment of evidence

Target audience (page 20): “The Guidelines are for use by all those working in acute health care settings —this includes healthcare workers, management and support staff. As some of the principles and recommendations described in this guideline may be applicable to other health care settings, individuals working in other health care settings may also find the guidelines useful.”

The introduction states that all recommendations are based on systematic reviews, however there is insufficient evidence within the guidance to support this claim.

“Hand hygiene should be performed upon touching or disposing of a used respirator.” (page 124)

Adapted from CDC Isolation Precautions (expert opinion guidance that is included in this ARHAI Scotland literature review):

- “Removal of PPE should be done at the doorway (just prior to leaving patient’s room) or immediately outside patient room.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centres for Disease Control and Prevention (CDC). Infection Control Guidance: SARS-CoV-2. 2023 Accessed: 30 October 2024	Expert opinion	Level 4	N/A	N/A	N/A

Assessment of evidence

Note: “This interim guidance has been updated based on currently available information about COVID-19 and the current situation in the United States. Updates were made to reflect the high levels of vaccine-and infection-induced immunity and the availability of effective treatments and prevention tools. This guidance provides a framework for facilities to implement select infection prevention and control practices (e.g., universal source control) based on their individual circumstances (e.g., levels of respiratory virus transmission in the community). This guidance is applicable to all U.S. settings where healthcare is delivered (including nursing homes and home health).”

Ambulance with isolated driver and patient compartments that can provide separate ventilation to each area:

“Before entering the isolated driver’s compartment, the driver (if they were involved in direct patient care) should remove and dispose of PPE and perform hand hygiene to avoid soiling the compartment.” NOT the case without an isolated driver compartment.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Association of perioperative Registered Nurses (AORN). Guideline Quick View: Transmission-Based Precautions, 2019. Doi: 10.1002/aorn.12675.	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence
References not provided. Guidance developed for nursing staff working in the USA. “Remove the respirator after leaving the patient’s room and closing the door. Remove the respirator last when it is worn in combination with other PPE (e.g, gown, gloves, eye protection).”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centres for Disease Control and Prevention (CDC). CDC’s Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings. 2022c.Last updated: 12 April 2024 Accessed 01 November 2024	Guidance	Level 4	N/A	N/A	N/A
Assessment of evidence					
Context: “The core practices in this document should be implemented in all settings where healthcare is delivered. These venues include both inpatient settings (e.g., acute, long-term care) and outpatient settings (e.g., clinics, urgent care, ambulatory surgical					

Assessment of evidence
centres, imaging centres, dialysis centres, physical therapy and rehabilitation centres, alternative medicine clinics). In addition, these practices apply to healthcare delivered in settings other than traditional healthcare facilities, such as homes, assisted living communities, pharmacies, and health fairs." Healthcare personnel (HCP) referred to in this document include all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances, contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air." Appropriate use of PPE "Remove and discard PPE, other than respirators, upon completing a task before leaving the patient's room or care area. If a respirator is used, it should be removed and discarded (or reprocessed if reusable) after leaving the patient room or care area and closing the door" Expert opinion guidance with a small number of resources listed.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution (BSI) PD ISO/TS 16975-1:2016 Respiratory protective devices: selection, use and maintenance	International standard	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
establishing and implementing a respiratory protective device programme. Accessed: 11th July 2023.					
Assessment of evidence					
"This part of ISO 16975 specifies detailed information to assist persons responsible for establishing and implementing a programme for respiratory protective devices (RPD) that meet the performance requirements of the performance standards." "Where more than one item of personal protection is needed, the sequence of doffing should be considered to ensure that respiratory protection is maintained where required"					

Evidence from previous update(s):

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Loveday HP, Wilson JA, Pratt RJ, et al. epic3: National Evidence-Based	Guidance	AGREE: Recommend (with provisos)	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Guidelines for Preventing Healthcare-Associated Infections in NHS Hospitals in England, 2014. Journal Hospital Infection;86(1);pp:1-70.					

Assessment of evidence

These guidelines were commissioned by The Department of Health (England) for preventing HCAI in hospital or other acute heal and care settings. It is unclear how the evidence/ expert opinion formulated the following recommendations; this document is also outdated as an update was due to be published in 2017. The guideline development team was comprised of individuals with varied specialties within IPC including, nursing, microbiology, infectious diseases. The guideline advisory team was formed of consultants, trust and lay members amongst others.

“Personal protective equipment should be removed in the following sequence to minimise the risk of cross/self-contamination:

- gloves;
- apron;
- eye protection (when worn); and
- mask/respirator (when worn). Hands must be decontaminated following the removal of personal protective equipment.

Assessment of evidence
New recommendation Class D/GPP/H&S”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Occupational Safety and Health Administration (OSHA). Guidance on Preparing Workplaces for an Influenza Pandemic. OSHA 3327-05R, 2009.	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence
Avoid self-contamination when doffing: “Once worn in the presence of an infectious patient, the respirator should be considered potentially contaminated with infectious material, and touching the outside of the device should be avoided to prevent self-inoculation (touching the contaminated respirator and then touching one’s eyes, nose, or mouth). It should be noted that a once-worn respirator will also be contaminated on its inner surface by the microorganisms present in the exhaled air and oral secretions of the wearer”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The Control of Substances Hazardous to Health (Amendment) Regulations 2004. UK Statutory Instruments No. 3386.	Legislation	Level 4	N/A	N/A	N/A

Assessment of evidence

Introduction:

These regulations describe requirements to protect employees from substances hazardous to health in the workplace: “In these Regulations, a reference to an employee being exposed to a substance hazardous to health is a reference to the exposure of that employee to a substance hazardous to health arising out of or in connection with work at the workplace.”

“Regulation 9 Maintenance, examination and testing of control measures”:

“Personal protective equipment which may be contaminated by a substance hazardous to health shall be removed on leaving the working area and kept apart from uncontaminated clothing and equipment. “

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The Control of Substances Hazardous to Health (Amendment) Regulations 2004. UK Statutory Instruments 2002. No. 3386.	Legislation	Level 4	N/A	N/A	N/A

Assessment of evidence

Introduction:

These regulations describe requirements to protect employees from substances hazardous to health in the workplace: “In these Regulations, a reference to an employee being exposed to a substance hazardous to health is a reference to the exposure of that employee to a substance hazardous to health arising out of or in connection with work at the workplace.”

“Regulation 9 Maintenance, examination and testing of control measures”:

“Personal protective equipment which may be contaminated by a substance hazardous to health shall be removed on leaving the working area and kept apart from uncontaminated clothing and equipment. “

Question 18: How should reusable respirators be maintained?

Evidence added to 2024 update:

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Government The Personal Protective Equipment at Work (Amendment) Regulations 2022. UK statutory instruments No. 8. Came into force 6th April 2022	Legislation	Mandatory	N/A	N/A	N/A

Assessment of evidence

Note: Below information taken from both the 1992 regulations and 2022 amendment. Reference to 2022 amendment required in the review.

Maintenance and replacement of PPE:

Regulation 7:

“(1) Every employer shall ensure that any personal protective equipment provided to his workers is maintained (including replaced or cleaned as appropriate) in an efficient state, inefficient working order and in good repair.

Assessment of evidence
(2) Every self-employed person shall ensure that any personal protective equipment provided to him is maintained (including replaced or cleaned as appropriate) in an efficient state, in efficient working order and in good repair." Reporting loss or defect: Regulation 11: "Every worker who has been provided with personal protective equipment by virtue of regulation 4(1) shall forthwith report to his employer any loss of or obvious defect in that personal protective equipment." 2022 Amendment: The term 'employer' replaced with 'worker'; definition below: ""worker" means an individual who has entered into or works under— (a) a contract of employment; (b) any contract, whether express or implied and (if it is express) whether oral or in writing, whereby the individual undertakes to do or perform personally any work or services for another party to the contract whose status is not by virtue of the contract that of a client or customer of any profession or business undertaking carried on by the individual; and any reference to a worker's contract shall be construed accordingly."" "These Regulations amend the Personal Protective Equipment at Work Regulations 1992 ("PPER 1992") to extend the duties contained in regulations 4 to 11 of the PPER 1992 from employees to workers, and to update cross-references to other legislation."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE) The Personal Protective Equipment at Work Regulations 1992 (as amended). Guidance on Regulations Accessed 12th April 2023.	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

"This guidance provides practical advice on how you can comply with the requirements of the Personal Protective Equipment at Work Regulations 1992 as amended by the Personal Protective Equipment at Work (Amendment) Regulations 2022 (hereafter referred to as "the Regulations")"

"Following the guidance is not compulsory, unless specifically stated, and you are free to take other action. But if you do follow the guidance, you will normally be doing enough to comply with the law. Health and safety inspectors seek to secure compliance with the law and may refer to this guidance." Not specific to health/care settings.

"The PPE at Work Regulations do not apply to hearing protectors and most respiratory protective equipment (RPE). For example, a person working with asbestos would, where necessary, have to use RPE and protective clothing under the Control of Asbestos Regulations 2012,10 rather than these Regulations. However, even if the Regulations do not apply, the advice given in this guidance

may still be useful, as the general principles of selecting and maintaining suitable PPE and the training in its use are common to all regulations which refer to PPE."

"The Regulations do not apply to respiratory protection other than it must be compatible with any other PPE provided. Full guidance on the selection, use and maintenance of RPE is given in HSG53 Respiratory protective equipment at work: A practical guide. If using RPE you should refer to this document. Respiratory protection should only be used where risks remain despite the implementation of other measures to control the risks, or while those other measures are being developed or put in place."

Recommendations:

An employer should ensure that PPE continues to provide protection; they can do this by

putting in place an effective maintenance system that should include the following:

(a) examination – checking for faults, damage, wear and tear, dirt etc;

(b) testing – to ensure PPE is operating as intended;

(c) ready for use – for example, the PPE may lose effectiveness if it is wet internally from sweating either due to the temperature (if you're working in hot environments) or the amount of activity or exertion; you may need to provide somewhere for drying the PPE so it retains its insulating properties;

(d) cleaning – including disinfection if appropriate;

(e) repair;

(f) replacement

"Simple repairs can be carried out by a trained wearer (for example, replacing broken laces on safety shoes), but more intricate repairs should be done by staff with the required skills and technical knowledge. Only the correct spare parts, as recommended by the manufacturer, should be used. It may be a good idea to keep a stock of spare parts"

Assessment of evidence
“80 Employers should make arrangements to ensure that their workers can report to them (or their representative) the loss of or defects in PPE. These arrangements should also ensure that defective PPE is repaired or replaced before the worker concerned restarts work. 81 Workers must take reasonable care of the PPE provided and report to their employer any loss or obvious defect or damage as soon as possible. If workers have any concerns about the serviceability of the PPE, they should immediately consult their employer or the employer’s representative.” “You, or your workers, must not: […] use PPE if it is damaged, heavily worn, unfit for use, or past its usable protective life. You should dispose of it properly and replace it.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Australian Government Infection Prevention and Control Expert Group. Guidance on the use of personal protective equipment for health workers in the context of COVID-19.	Guidance	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Last updated: 15 December 2022. Accessed: 20th February 2023					

Assessment of evidence

General notes:

- Guidance endorsed by the Australian Health Protection Principal Committee.
- Recommendations developed with advice from the National COVID-19 Clinical Evidence Taskforce Infection and Prevention and Control Panel (IPC Panel).
- Consensus recommendations based on the experience of the IPC panel and ICEG members.
- “They reflect emerging evidence concerning all potential modes of viral transmission and the increased transmissibility of SARS-CoV-2”
- “The recommendations contained in this document describe the minimum national standard for PPE for health workers in the context of COVID-19.”
- “Given the variability across and within health care settings, decisions around the use of PPE may require a nuanced and flexible approach, guided by evidence, contextual factors, and consideration of health worker preferences. This guidance is not meant to be exhaustive but aims to supplement detailed guidance available at a state, territory and institutional level.”

Recommendations:

- “Manufacturers’ instructions for reprocessing of reusable PAPR components and management of filters, should strictly be followed”

Assessment of evidence
• “PAPRs should be used according to the manufacturer’s instructions including battery use, filter position and reprocessing of re-usable components”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The British Standards Institute (BSI). PD ISO/TS 16975-1:2016 Respiratory protective devices: selection, use and maintenance establishing and implementing a respiratory protective device programme. Available from: 11th July 2023.	International Standard	Level 4	N/A	N/A	N/A

Assessment of evidence

Wearers are responsible for reporting “damage, defects or non-function of the RPE provided”

Filters:

- “Filters marked for single shift use only or that have time limitations shall be replaced in accordance with the manufacturer’s instructions for use.”
- “Filter(s) shall be replaced with new filter(s) of the same type and class. When more than one filter is used on an RPD, all filters shall be replaced at the same time.”

RPD that have undergone decontamination, reconditioning, leak testing and/or reassembly shall be inspected and recommended for reuse.” (Page 29)

Maintenance procedures (page 37):

“The RPD maintenance procedures shall address the following, as appropriate:

a) inspection.

b) decontamination.

c) cleaning and/or disinfecting.

d) routine maintenance (including performance checking);

e) filling of breathable gas cylinders.

f) repair.

g) disposal.

These procedures shall be established and carried out by competent persons in accordance with the manufacturer’s instructions. The frequency of inspection shall be at least monthly or in accordance with national or local regulations”

Assessment of evidence

Maintenance records should be retained

“Repairs or adjustments to RPD ~~shall be made only by competent persons and~~ shall use only the RPD manufacturer’s parts designed for the RPD”

Annex F contains detail on maintenance (page 59):

Inspection: “Regular inspection of RPD should be carried out in accordance with the manufacturer’s instructions. These could include a check for integrity of connections — for the condition of the respiratory interfaces, head harness, valves, harness assemblies, hoses, filters, end-of-service life indicator (if present), electrical components and shelf-life date(s) and for the proper function of regulators, alarms and other warning systems. Each rubber or other elastomeric part should be inspected for continuing pliability and any signs of deterioration.”

Routine maintenance and repair: “The maintenance and repair procedures should be designed to ensure that the RPD will continue to perform as intended by the manufacturer. A thorough maintenance programme should include

- fault-finding routines,
- replacement of parts, as necessary,
- performance checking, and
- servicing as recommended by the manufacturer.”

“As a filter is used, it becomes loaded with the contaminant and eventually clogs. This makes it difficult for the air to flow through the filter indicating that the filter should be replaced.”

Pre-use checks:

“All pre-use checks shall be carried out in accordance with the manufacturer’s instructions and the training received.

Pre-use checks shall include the following, where applicable:

a) inspect the RPD integrity;

Assessment of evidence
b) where filters are used, check that the filters are the right type and class, fitted correctly, not damaged, are within shelf life and have not reached the end of their service life; c) for assisted RPD, check that the manufacturer's minimum design flow rate is supplied and/or the manufacturer's minimum design condition is fulfilled; d) for supplied breathable gas RPD, check for the correct supply pressure and/or flow rate; e) where the RPD has integrated communication equipment, check for correct operation. RPD shall only be used when all pre-use checks are satisfactory." Wearer is responsible for reporting damage/defects

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The British Standards Institute (BSI). BS ISO 16975-3:2017 Respiratory protective devices – Selection, use and maintenance. Part 3: Fit-testing procedures.	British standard	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Available from: 12th July 2023.					
Assessment of evidence					
“RPD used for fit testing shall be properly inspected, tested and maintained according to the RPD manufacturer’s recommendations.”					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). COSHH essentials: Respiratory protective equipment. UK Standard Assigned Protection Factor 4 (APF 4) Supplementary advice, 2006a. Available from: COSHH Essential: Respiratory	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
protective equipment (RPE) - R1 (hse.gov.uk) Accessed: 15 February 2022					

Assessment of evidence

This supplementary advice provided by HSE states “This information will help employers comply with the Control of Substances Hazardous to Health Regulations 2002 (COSHH), as amended, to control exposure to chemicals and protect workers’ health.”

“Using RPE

- Change the filters on respirators regularly – your supplier may be able to advise you.”

Maintenance:

- Keep RPE clean and in good working order – follow the manufacturers’ instructions.
- Maintain RPE at least once every three months. Replace valves, face seals and worn or damaged parts on respirators.
- Remember to check the expiry dates on RPE and filters.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). COSHH essentials: Respiratory protective equipment. UK Standard Assigned Protection Factor 10 (APF 10) Supplementary advice, 2006b. Accessed: 15 February 2022	Expert Opinion	Level 4	N/A	N/A	N/A

Assessment of evidence

This supplementary advice provided by HSE states “This information will help employers comply with the Control of Substances Hazardous to Health Regulations 2002 (COSHH), as amended, to control exposure to chemicals and protect workers’ health.”

“Using RPE

- Change the filters on respirators regularly – your supplier may be able to advise you.”

Maintenance:

- Keep RPE clean and in good working order – follow the manufacturers’ instructions.

Assessment of evidence
• Maintain RPE at least once every three months. Replace valves, face seals and worn or damaged parts on respirators. • Remember to check the expiry dates on RPE and filters.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). COSHH essentials: Respiratory protective equipment. UK Standard Assigned Protection Factor 20 (APF 20). Supplementary advice, 2006c. Accessed: 15 February 2022	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence
This supplementary advice provided by HSE states “This information will help employers comply with the Control of Substances Hazardous to Health Regulations 2002 (COSHH), as amended, to control exposure to chemicals and protect workers’ health.”

Assessment of evidence
"Using RPE • Change the filters on respirators regularly – your supplier may be able to advise you." **Maintenance**: • Keep RPE clean and in good working order – follow the manufacturers' instructions. • Maintain RPE at least once every three months. Replace valves, face seals and worn or damaged parts on respirators. • Keep a small stock of replaceable parts. • Remember to check the expiry dates on RPE and filters.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). COSHH essentials: Respiratory protective equipment. UK Standard Assigned Protection Factor 40 (APF 40). Supplementary advice, 2006d.	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Accessed: 15 February 2022					

Assessment of evidence

This supplementary advice provided by HSE states “This information will help employers comply with the Control of Substances Hazardous to Health Regulations 2002 (COSHH), as amended, to control exposure to chemicals and protect workers’ health.”

“Using RPE

- Change the filters on respirators regularly – your supplier may be able to advise you.”

Maintenance:

- Keep RPE clean and in good working order – follow the manufacturers’ instructions.
- Maintain RPE at least once every three months. Replace valves, face seals and worn or damaged parts on respirators.
- Remember to check the expiry dates on RPE and filters.”

Evidence from previous update(s):

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The Control of Substances Hazardous to Health (Amendment) Regulations, 2004.	Regulation	Mandatory	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK statutory instrument No. 3386.					

Assessment of evidence

Introduction:

- These regulations describe requirements to protect employees from substances hazardous to health in the workplace: “In these Regulations, a reference to an employee being exposed to a substance hazardous to health is a reference to the exposure of that employee to a substance hazardous to health arising out of or in connection with work at the workplace.”
- A hazard includes biological agents – ““biological agent” means a micro-organism, cell culture, or human endoparasite, whether or not genetically modified, which may cause infection, allergy, toxicity or otherwise create a hazard to human health;”

“Regulation 8 Use of control measures etc

- Every employee shall make full and proper use of any control measure, other thing or facility provided in accordance with these Regulations and, where relevant, shall— […]

(b) if he discovers a defect therein, report it forthwith to his employer.”

“Regulation 9 Maintenance, examination and testing of control measures

“Every employer who provides any control measure to meet the requirements of regulation 7 shall ensure that—

[…] in the case of plant and equipment, including engineering controls and personal protective equipment, it is maintained in an efficient state, in efficient working order, in good repair and in a clean condition;”

Assessment of evidence

"Where respiratory protective equipment (other than disposable respiratory protective equipment) is provided to meet the requirements of regulation 7, the employer shall ensure that thorough examination and, where appropriate, testing of that equipment is carried out at suitable intervals."

"Every employer shall ensure that personal protective equipment, including protective clothing, is:

- checked at suitable intervals; and
- when discovered to be defective, repaired or replaced before further use."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). 2013. Respiratory protective equipment at work: A practical guide. HSG53 (4th Ed.) 2013.	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

About this guidance:

Assessment of evidence

- This guide prepared by the HSE “in consultation with industry: employers, trade unions and trade associations”, is stated to support “the Approved Code of Practice (ACOP) to the Regulations that apply (see paragraphs 36–39)”.
- “The guide contains practical guidelines to help you select the correct RPE and manage its use in your workplace to ensure effective protection.”

Recommendations:

- “RPE at work should […] be properly stored, cleaned and checked regularly to ensure it remains effective.”
- “29 In addition, you must ensure that reusable RPE undergoes thorough examination and, where appropriate, testing at suitable intervals. This should be monthly, or every three months if used less frequently. This will not only make sure the RPE protects the wearer but will also extend the life of the equipment and so maximise your investment.”
- “You should also ensure that RPE is used according to the manufacturer’s instructions, as poor working practices or improper use can significantly reduce its effectiveness.”
- “battery-powered RPE is fully charged.”
- “Change filters as instructed by the manufacturer.”
- “Always clean and store the RPE properly, paying special attention to the valves. Change filters as instructed by the manufacturer.”
- “Maintenance is a requirement for all RPE, except for disposable (single use) RPE, and should be carried out by properly trained personnel. Thorough maintenance, examination and tests should be carried out at least once a month. However, if the RPE is used only occasionally, an examination and test should be carried out before use and, in any event, the interval should not exceed three months. Emergency escape-type RPE should be examined and tested in accordance with the manufacturer’s instructions.

Powered respirator:

Assessment of evidence

“Always ensure the respirator is in good working order before putting it on, even when new. “

- Always fit identical filters to a multi-filter unit.
- Always change all the filters on a multi-filter unit together.

91 There are five key points you should follow when carrying out RPE maintenance:

- Follow the manufacturer’s instructions.
- A competent person should carry out the work.
- Keep records (see Figure 7 for an example).
- Ensure the intervals for maintenance are appropriate.
- The maintenance programme should reflect the complexity of maintaining the RPE.

92 Ideally, any parts that require replacing will be sourced from the original manufacturer of the RPE.”

“You must keep records of examination and testing, and any repairs made, for at least five years.

94 Key maintenance tasks include:

- changing any replaceable filters;
- cleaning the device;
- valve maintenance and replacement;
- checking the straps for damage;
- checking the battery charge and flow rate for powered devices.”

“When to change filters

Particle filters

Assessment of evidence

- 17 The following is recommended:
- For TH and TM type filters for fan-assisted respirators, change as instructed by the manufacturer.

For replaceable filters, it would be good practice to mark the filter visibly with the date it was taken out of the packaging and fitted to the RPE; an in-house replacement date can be added to this marking.

18 Changing particle filters – hints and tips:

- Do not use if the shelf-life expiry date on the filters has passed.
- Change when filters are damaged or visibly contaminated.
- Change when they become harder to breathe through. This can happen quickly if the wearer is exposed to very high dust concentrations.

Question 19: How should reusable respirators be decontaminated?

Evidence added to 2024 update:

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE) The Personal Protective Equipment at Work Regulations 1992 (as amended). Guidance on Regulations. 2022. Accessed 12th April 2023.	Guidance	Level 4	N/A	N/A	N/A
Assessment of evidence					
"This guidance provides practical advice on how you can comply with the requirements of the Personal Protective Equipment at Work Regulations 1992 as amended by the Personal Protective Equipment at Work (Amendment) Regulations 2022 (hereafter referred to as "the Regulations")"					

Assessment of evidence

“Following the guidance is not compulsory, unless specifically stated, and you are free to take other action. But if you do follow the guidance you will normally be doing enough to comply with the law. Health and safety inspectors seek to secure compliance with the law and may refer to this guidance.”

Not specific to health/care settings.

“The PPE at Work Regulations do not apply to hearing protectors and most respiratory protective equipment (RPE). For example, a person working with asbestos would, where necessary, have to use RPE and protective clothing under the Control of Asbestos Regulations 2012,10 rather than these Regulations. However, even if the Regulations do not apply, the advice given in this guidance may still be useful, as the general principles of selecting and maintaining suitable PPE and the training in its use are common to all regulations which refer to PPE.”

“The Regulations do not apply to respiratory protection other than it must be compatible with any other PPE provided. Full guidance on the selection, use and maintenance of RPE is given in HSG53 Respiratory protective equipment at work: A practical guide. If using RPE you should refer to this document. Respiratory protection should only be used where risks remain despite the implementation of other measures to control the risks, or while those other measures are being developed or put in place.”

Recommendations:

“When PPE becomes contaminated during use, it should be cleaned and decontaminated before storage, otherwise the storage accommodation may itself become contaminated and will also require suitable cleaning and decontamination. PPE which is ready for use should be clearly segregated from that which is awaiting repair or maintenance, and clearly labelled as such so that the correct PPE is chosen.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Australian Government Infection Prevention and Control Expert Group. Guidance on the use of personal protective equipment for health workers in the context of COVID-19. Last updated: 15 December 2022. Accessed: 20th February 2023.	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

General notes:

- Guidance endorsed by the Australian Health Protection Principal Committee.
- Recommendations developed with advice from the National COVID-19 Clinical Evidence Taskforce Infection and Prevention and Control Panel (IPC Panel).
- Consensus recommendations based on the experience of the IPC panel and ICEG members.
- “They reflect emerging evidence concerning all potential modes of viral transmission and the increased transmissibility of SARS-CoV-2”

Assessment of evidence

- "The recommendations contained in this document describe the minimum national standard for PPE for health workers in the context of COVID-19."
- "Given the variability across and within health care settings, decisions around the use of PPE may require a nuanced and flexible approach, guided by evidence, contextual factors, and consideration of health worker preferences. This guidance is not meant to be exhaustive but aims to supplement detailed guidance available at a state, territory and institutional level."

Recommendations:

"Manufacturers' instructions for reprocessing of reusable PAPR components and management of filters, should strictly be followed"

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The National Institute for Occupational Safety and Health (NIOSH) A guide to Air-Purifying Respirators, 2018. Accessed: 2nd December 2022	Infographic	Level 4	N/A	N/A	N/A

Assessment of evidence

Setting: USA

Assessment of evidence

Target audience: Unclear, found on CDC website but not healthcare specific

Elastomeric Half Facepiece Respirators Recommendations:

- "The attached filters and cartridges are replaceable and can be easily changed"
- "When cleaning and sanitizing a respirator, the manufacturer's guidelines should always be followed. Check the manufacturer's website if guidance is not included with the packaging of the respirator. If guidance isn't available, OSHA provides general cleaning and sanitizing guidelines."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centers for Disease Prevention and Control (CDC). Understanding the difference, 2019. Accessed: 5th Dec 2022	Poster	Level 4	N/A	N/A	N/A

Assessment of evidence

Setting: USA

Target audience and context: "This information provides clarification regarding respirator and mask use in workplaces in which employees are exposed to respiratory hazards, it is not specific for the COVID-19 pandemic."

Elastomeric Half Facepiece Respirator Recommendation:

Assessment of evidence
“Reusable and must be cleaned/ disinfected and stored between each patient interaction”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The British Standards Institute (BSI). PD ISO/TS 16975-1:2016 Respiratory protective devices: selection, use and maintenance establishing and implementing a respiratory protective device programme. Accessed: 11th July 2023.	International standard	Level 4	N/A	N/A	N/A

Assessment of evidence
Maintenance procedures:

Assessment of evidence
"RPD, other than those designated for single shift use only, shall be cleaned and disinfected at the following intervals. • RPD for the exclusive use of an individual shall be cleaned and disinfected as often as necessary to be maintained in a sanitary condition. • RPD used by more than one individual shall be cleaned and disinfected before being worn by different individuals. • RPD used in fit testing and training shall be cleaned and disinfected after each fit test. RPD that have undergone decontamination, reconditioning, leak testing and/or reassembly shall be inspected and recommended for reuse." (page 29) Annex F provides detail on maintenance (page 59): **Cleaning and disinfecting**: "RPD should be thoroughly cleaned and disinfected following the manufacturer's instructions. RPD should be appropriately disassembled and non-reusable parts should be disposed. Delicate parts, e.g. exhalation valves, require particular care and attention during cleaning."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standard Institution (BSI) BS ISO 16975-3:2017 Respiratory protective devices – Selection, use and maintenance. Part 3:	British standard	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Fit-testing procedures. Accessed: 12th July 2023.					
Assessment of evidence					
"RPD shall be cleaned and disinfected before being donned by different individuals. See the RPD manufacturer's instructions for recommended practices. Surrogate RI that cannot be sanitized (e.g. filtering facepiece) shall not be used by more than one individual."					

Evidence from previous update(s):

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The Control of Substances Hazardous to Health (Amendment) Regulations 2004. UK Statutory instrument No. 3386.	Regulation	Mandatory	N/A	N/A	N/A

Assessment of evidence

Introduction:

These regulations describe requirements to protect employees from substances hazardous to health in the workplace: “In these Regulations, a reference to an employee being exposed to a substance hazardous to health is a reference to the exposure of that employee to a substance hazardous to health arising out of or in connection with work at the workplace.”

A hazard includes biological agents – ““biological agent” means a micro-organism, cell culture, or human endoparasite, whether or not genetically modified, which may cause infection, allergy, toxicity or otherwise create a hazard to human health;”

Regulation 9 (5), (6), and (7)

“Regulation 9 Maintenance, examination and testing of control measures

Every employer shall ensure that personal protective equipment, including protective clothing, is:

- properly stored in a well-defined place;
- checked at suitable intervals; and
- when discovered to be defective, repaired or replaced before further use.

Personal protective equipment which may be contaminated by a substance hazardous to health shall be removed on leaving the working area and kept apart from uncontaminated clothing and equipment.

The employer shall ensure that the equipment referred to in paragraph (6) is subsequently decontaminated and cleaned or, if necessary, destroyed”

Regulation 7 Prevention or control of exposure to substances hazardous to health

(6) Without prejudice to the generality of paragraph (1), where it is not reasonably practicable to prevent exposure to a biological agent, the employer shall apply the following measures in addition to those required by paragraph (3)—

[…] (b) specifying appropriate decontamination and disinfection procedures”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). The Control of Substances Hazardous to Health (COSHH) - Approved Code of Practice and guidance, 6th Edition. 2013a.	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

This document contains the “Approved Code of Practice (ACOP) to the Control of Substances Hazardous to Health Regulations 2002 (as amended) (COSHH) and covers all substances to which the Regulations apply.” “The ACOP describes the preferred or recommended methods that can be used (or the standards to be met) to comply with the Regulations and the duties imposed by the Health and Safety at Work etc Act 1974 (HSW Act). The accompanying guidance also provides advice on achieving compliance, or it may give information of a general nature, including explanation of the requirements of the law, more specific technical information or references to further sources of information.”

ACOP:

“Suitable arrangements should be made to ensure that no employee uses RPE previously used by another person, unless it has been thoroughly washed and cleaned in accordance with the manufacturer’s instructions.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). Respiratory protective equipment at work: A practical guide. HSG53 (4th Ed.), 2013b.	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

About this guidance:

- This guide prepared by the HSE “in consultation with industry: employers, trade unions and trade associations”, is stated to support “the Approved Code of Practice (ACOP) to the Regulations that apply (see paragraphs 36–39)”.
- “The guide contains practical guidelines to help you select the correct RPE and manage its use in your workplace to ensure effective protection.”
- “As an employer, you have a legal responsibility under all the Regulations listed in paragraphs 36–39”

“96 Cleaning a reusable facepiece is required to remove contamination, moisture build-up and microbes. The manufacturer should provide advice on cleaning and inspection of the RPE, including on the appropriate cleaning materials and disinfectants to use. The use of cleaning products other than those recommended by the manufacturer may cause problems with the RPE.”

“97 Cleaning and drying should be carried out in a clean area to avoid contamination of the RPE.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Coia J. E., Ritchie L., and Adisesh, A. et al. Guidance on the use of respiratory and facial protection equipment, 2013. Journal of Hospital Infection, 2013; 85;170-182; doi: 10.1016/j.jhin.2013.06.020.	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

Setting: UK

“Re-usable devices will require appropriate decontamination. The manufacturer of the respirator should provide clear instructions on the method of decontamination to be used between uses.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution. BS EN 149-2001	British Standard	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Respiratory protective devices – Filtering half masks to protect against particles – Requirements, testing, marking. 149:2001+A1:2009					

Assessment of evidence

Recommendation:

“If the particle filtering half mask is designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Occupational Safety and Health Administration (OSHA). Guidance on Preparing Workplaces for an	Expert opinion	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Influenza Pandemic, 2009. OSHA 3327-05R					

Assessment of evidence

Guidance document produced by The Occupational Safety and Health Administration is an agency of the United States Department of Labor. Influenza pandemic guidance.

PAPR recommendation:

“Information on proper cleaning and maintenance of respirators (both elastomeric air-purifying respirators and PAPRs) is model-specific and is provided by the manufacturer as part of the NIOSH-certified user instructions”

“In the case of elastomeric air-purifying respirators and PAPRs, the respirator body and PAPR case is designed to be decontaminated and reused in accordance with the manufacturer’s use instructions.”

Question 20: How should RPE be stored?

Evidence added to 2024 update:

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centres for Disease Control and Prevention (CDC) The National Personal Protective Technology Library (NPPTL) The Respiratory Protection Information Trusted Source. Healthcare Setting Specific FAQs. Last updated: 5 July 2022 Accessed: 6 January 2025	British Standard	Level 4	N/A	N/A	N/A

Assessment of evidence
“How should I store my N95 between patient encounters? Manufacturers provide guidance for cleaning, sanitizing, repairing, inspecting, and storing their respirators. Refer to the manufacturer’s guidance. Pack or store the respirators so that they do not become damaged or deformed. Never store disposable respirators in pockets, plastic bags, or other confined areas.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE) The Personal Protective Equipment at Work Regulations 1992 (as amended). Guidance on Regulations. 2022. Accessed 12th April 2023.	Guidance	Level 4	N/A	N/A	N/A
Assessment of evidence					
“This guidance provides practical advice on how you can comply with the requirements of the Personal Protective Equipment at Work Regulations 1992 as amended by the Personal Protective Equipment at Work (Amendment) Regulations 2022 (hereafter referred to as “the Regulations”)”					

Assessment of evidence

“Following the guidance is not compulsory, unless specifically stated, and you are free to take other action. But if you do follow the guidance you will normally be doing enough to comply with the law. Health and safety inspectors seek to secure compliance with the law and may refer to this guidance.”

Not specific to health/care settings.

“The PPE at Work Regulations do not apply to hearing protectors and most respiratory protective equipment (RPE). For example, a person working with asbestos would, where necessary, have to use RPE and protective clothing under the Control of Asbestos Regulations 2012,10 rather than these Regulations. However, even if the Regulations do not apply, the advice given in this guidance may still be useful, as the general principles of selecting and maintaining suitable PPE and the training in its use are common to all regulations which refer to PPE.”

“The Regulations do not apply to respiratory protection other than it must be compatible with any other PPE provided. Full guidance on the selection, use and maintenance of RPE is given in HSG53 Respiratory protective equipment at work: A practical guide. If using RPE you should refer to this document. Respiratory protection should only be used where risks remain despite the implementation of other measures to control the risks, or while those other measures are being developed or put in place.”

Recommendations:

“Storage is required to:

- prevent damage from chemicals, sunlight, high humidity, heat and accidental knocks;
- prevent contamination from dirt and harmful substances;
- reduce the possibility of losing the PPE;
- enable the sufficient drying of PPE to ensure its effectiveness is maintained; for example, retaining its insulating capabilities if used in damp, hot or cold environments.”

“Accommodation can be simple (for example, pegs for weatherproof clothing, safety helmets or hard hats). It does not have to be fixed; for example, safety spectacles could be kept by the user in a suitable carrying case […]”

Assessment of evidence
“You, or your workers, must not: […] store PPE in direct sunlight or in hot humid places as this can cause damage to some PPE”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Government 2022 No. 8 Health and Safety The Personal Protective Equipment at Work (Amendment) Regulations 2022. Came into force on 6th April 2022	Legislation	Mandatory	N/A	N/A	N/A

Assessment of evidence
Note: Below information taken from both the 1992 regulations and 2022 amendment. Reference to 2022 amendment required in the review. **Accommodation for PPE**: Regulation 8: “Where an employer or self-employed person is required, by virtue of regulation 4, to ensure personal protective equipment is provided, he shall also ensure that appropriate accommodation is provided for that personal protective equipment when it is not being used.”

Assessment of evidence

2022 Amendment:

The term ‘employer’ replaced with ‘worker’; definition below:

““worker” means an individual who has entered into or works under

a. a contract of employment

b. any contract, whether express or implied and (if it is express) whether oral or in writing, whereby the individual undertakes to do or perform personally any work or services for another party to the contract whose status is not by virtue of the contract that of a client or customer of any profession or business undertaking carried on by the individual; and any reference to a worker’s contract shall be construed accordingly.”

“These Regulations amend the Personal Protective Equipment at Work Regulations 1992 (“PPER 1992”) to extend the duties contained in regulations 4 to 11 of the PPER 1992 from employees to workers, and to update cross-references to other legislation.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centers for Disease Control and Prevention (CDC). Understanding the difference, 2019. Accessed: 5th Dec 2022	Poster	Level 4	N/A	N/A	N/A

Assessment of evidence

Setting: USA

Context: “This information provides clarification regarding respirator and mask use in workplaces in which employees are exposed to respiratory hazards, it is not specific for the COVID-19 pandemic”

Recommendation (Elastomeric Half Facepiece Respirator): “Reusable and must be cleaned/disinfected and stored between each patient interaction”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The British Standards Institution (BSI). BS EN 529 2005 Respiratory protective devices — Recommendations for selection, use, care and maintenance — Guidance document.	British Standard	Level 4	N/A	N/A	N/A

Assessment of evidence

Storage (page 17):

Assessment of evidence
Employer responsibility – “The employer is required (89/656/EEC) to provide suitable storage accommodation for respiratory protective devices as recommended in the user instructions supplied by the manufacturer. The employer should provide facilities/administrative systems for segregating dirty and clean respiratory protective devices for safely disposing of contaminated respiratory protective devices or their components.” Employee responsibility – “The individual wearers involved in the programme should store the devices safely in the accommodation provided.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution. PD ISO/TS 16975-1:2016 Respiratory protective devices: selection, use and maintenance establishing and implementing a respiratory protective device programme.	International standard	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Accessed: 12th July 2023.					

Assessment of evidence

Storage (page 30):

"All RPD shall be stored in accordance with the information supplied by the manufacturer in order to prevent contamination, damage and deterioration of the RPD."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Government of Canada. Infection prevention and control for COVID-19: Interim guidance for long-term care homes,2021a. Last modified 25 January 2022. Accessed: 17 April 2023.	Canadian Government COVID-19 guidance	Level 4	N/A	N/A	N/A

Assessment of evidence
Setting and context: This Canadian interim guidance aimed to provide interim COVID-19 guidance related to IPC, to be considered in conjunction with the Canadian Government's Omicron variant guidance. It is specific to long term care homes. The guidance is broadly in line with acute care, ambulatory and outpatient settings guidance. "All PPE (e.g., gloves, gowns, medical masks, N95 or equivalent respirators, eye protection) should be […] placed so it is readily accessible at the point-of-care for all staff and visitors. Additional supplies of PPE should be stored in clean supply rooms that are clearly separated from any soiled utility areas."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Government of Canada. Infection prevention and control for COVID-19: Interim guidance for acute healthcare settings, 2021b. Last modified 25 January 2022. Accessed: 17 April 2023	Canadian Government COVID-19 guidance	Level 4	N/A	N/A	N/A

Assessment of evidence
Setting and context: This Canadian interim guidance aimed to provide interim COVID-19 guidance related to IPC, to be considered in conjunction with the Canadian Government's Omicron variant guidance. It is specific to acute care settings. The guidance is broadly in line with long term care home, ambulatory and outpatient settings guidance. **Personal protective equipment**: "All PPE (e.g., gloves, gowns, medical masks, N95 or equivalent respirators, eye protection) should be […] stored so it is readily accessible at the point-of-care for all HCWs and permitted visitors."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Government of Canada. Infection prevention and control for COVID-19: Interim guidance for outpatient and ambulatory care settings,2021c. 2022. Accessed: 17th April 2023.	Canadian Government COVID-19 guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

Setting and context: This Canadian interim guidance aimed to provide interim COVID-19 guidance related to IPC, to be considered in conjunction with the Canadian Government's Omicron variant guidance. It is specific to outpatient and ambulatory settings. The guidance is broadly in line with long term care home and acute care settings guidance.

PPE:

"All PPE (e.g., gloves, gowns, medical masks, N95 or equivalent respirators, eye protection) should be […] placed so it is readily accessible at the point-of-care for all staff. Additional supplies of PPE should be stored in clean supply rooms that are clearly separated from any soiled utility areas."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive. COSHH essentials: Respiratory protective equipment. UK Standard Assigned Protection Factor 4 (APF 4) Supplementary advice,2006a.	Expert Opinion	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Accessed: 15 February 2022					

Assessment of evidence

This supplementary advice provided by HSE states “This information will help employers comply with the Control of Substances Hazardous to Health Regulations 2002 (COSHH), as amended, to control exposure to chemicals and protect workers’ health.”

Maintenance:

Store RPE in a safe place, away from contamination”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive. COSHH essentials: Respiratory protective equipment. UK Standard Assigned Protection Factor 10 (APF 10) Supplementary advice, 2006b.	Expert Opinion	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Accessed: 15 February 2022					

Assessment of evidence

This supplementary advice provided by HSE states “This information will help employers comply with the Control of Substances Hazardous to Health Regulations 2002 (COSHH), as amended, to control exposure to chemicals and protect workers’ health.”

Maintenance:

Store RPE in a safe place, away from contamination”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive. COSHH essentials: Respiratory protective equipment. UK Standard Assigned Protection Factor 20 (APF 20) Supplementary advice, 2006c.	Expert Opinion	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Accessed: 15 February 2022					

Assessment of evidence

This supplementary advice provided by HSE states “This information will help employers comply with the Control of Substances Hazardous to Health Regulations 2002 (COSHH), as amended, to control exposure to chemicals and protect workers’ health.”

Maintenance:

Store RPE in a safe place, away from contamination”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive. COSHH essentials: Respiratory protective equipment. UK Standard Assigned Protection Factor 40 (APF 40) Supplementary advice, 2006d.	Expert Opinion	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Accessed: 15 February 2022					
Assessment of evidence					
This supplementary advice provided by HSE states “This information will help employers comply with the Control of Substances Hazardous to Health Regulations 2002 (COSHH), as amended, to control exposure to chemicals and protect workers’ health.” **Maintenance**: Store RPE in a safe place, away from contamination”					

Evidence from previous update(s):

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The Control of Substances Hazardous to Health (Amendment) Regulations 2004 UK statutory instrument No. 3386.	Regulation	Mandatory	N/A	N/A	N/A

Assessment of evidence

This document contains the “Approved Code of Practice (ACOP) to the Control of Substances Hazardous to Health Regulations 2002 (as amended) (COSHH) and covers all substances to which the Regulations apply.” “The ACOP describes the preferred or recommended methods that can be used (or the standards to be met) to comply with the Regulations and the duties imposed by the Health and Safety at Work etc Act 1974 (HSW Act). The accompanying guidance also provides advice on achieving compliance, or it may give information of a general nature, including explanation of the requirements of the law, more specific technical information or references to further sources of information.”

Regulation 9 (5), (6), and (7)

“Regulation 9 Maintenance, examination and testing of control measures

Every employer shall ensure that personal protective equipment, including protective clothing, is:

- properly stored in a well-defined place”

Personal protective equipment which may be contaminated by a substance hazardous to health shall be removed on leaving the working area and kept apart from uncontaminated clothing and equipment.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). The Control of Substances Hazardous to Health (COSHH) - Approved Code of	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Practice and guidance. Health and Safety Executive, 2013.					

Assessment of evidence

This document contains the “Approved Code of Practice (ACOP) to the Control of Substances Hazardous to Health Regulations 2002 (as amended) (COSHH) and covers all substances to which the Regulations apply.” “The ACOP describes the preferred or recommended methods that can be used (or the standards to be met) to comply with the Regulations and the duties imposed by the Health and Safety at Work etc Act 1974 (HSW Act). The accompanying guidance also provides advice on achieving compliance, or it may give information of a general nature, including explanation of the requirements of the law, more specific technical information or references to further sources of information.”

Guidance:

“Employers should ensure that accommodation is provided for PPE so that it can be safely stored or kept when it is not in use... The storage should be adequate to protect the PPE from contamination, loss or damage by, for example, harmful substances, damp or sunlight.”

[Expert Opinion]

Question 21: How should RPE be disposed?

Evidence added to 2024 update:

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Department of Health Infection Prevention and Control (IPC) National Clinical Guideline No. 30 Last updated: May 2023 Accessed: 03 February 2025	Guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

Target audience: “This National Clinical Guideline applies to all health and social care workers because the control of healthcare associated infection is everyone’s responsibility. It is particularly relevant to Infection Prevention and Control (IPC) Practitioners. IPC Practitioners are those health and social care workers with specific training and expertise in the prevention and control of infection and who provide training, guidance and leadership to others on IPC.”

Recommendations:

• respirator masks should be removed outside the patient care area and disposed of in a closed receptacle.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Australian Government National Health and Medical Research Council (NHMRC) Australian Guidelines for the Prevention and Control of Infection in Healthcare 2019 (revised 2024, v11.24) Accessed 11 October 2024	Expert opinion guidance, Canberra: Commonwealth of Australia	Level 4	N/A	N/A	N/A

Assessment of evidence

Setting: Australia

Funding: Guidance was co-funded by the NHMRC and Medical Research Council and Australian Commission on Safety and Quality in Health Care.

Aim of guidance (page 20): “By assisting healthcare workers to improve the quality of the care they deliver, these Guidelines aim to promote and facilitate the overall goal of infection prevention and control: the creation of safe healthcare environments through the implementation of evidence-based practices that minimise the risk of transmission of infectious agents.”

Assessment of evidence

Target audience (page 20): “The Guidelines are for use by all those working in acute health care settings —this includes healthcare workers, management and support staff. As some of the principles and recommendations described in this guideline may be applicable to other health care settings, individuals working in other health care settings may also find the guidelines useful.”

Relevant recommendation:

“Respirators should be removed outside the patient-care area and disposed of in a closed receptacle [263].” (page 124).

Citation 263 (Siegel JD, Rhinehart E, Jackson M, Chiarello L : Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings (2007). Centers for Disease Control and Prevention: Health Care Infection Control Practices Advisory Committee 2007) is expert opinion guidance which is included in the ARHAI RPE literature review.

The introduction states that all recommendations are based on systematic reviews, however there is insufficient evidence within the guidance to support this claim. Note: P2 respirators meet the relevant Australian standard (AS/NZS 1716:2012 and 1715:2009) and differs to NIOSH, which specifies N95 respirators.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centers for Disease Control and Prevention (CDC). Sequence for putting on personal protective equipment, 2019a.	Expert opinion Poster, USA	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Accessed 11 November 2024					

Assessment of evidence

Setting: USA

Target audience: Healthcare professionals applying transmission-based precautions.

Recommendation: Respirator should be disposed of in a waste container as a last step of the doffing procedure.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The British Standards Institute (BSI). PD ISO/TS 16975-1:2016 Respiratory protective devices: selection, use and maintenance establishing and implementing a respiratory	International standard	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
protective device programme. Accessed: 11th July 2023.					
Assessment of evidence					
Annex F provides detail on maintenance (page 59): “Arrangements will need to be made for safe disposal of contaminated filters and other parts which cannot be safely decontaminated. Relevant national or local regulations should be followed”					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). COSHH essentials: Respiratory protective equipment. UK Standard Assigned Protection Factor 4 (APF 4).	Expert Opinion	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Supplementary advice, 2006a. Accessed: 15th February 2022					
Assessment of evidence					
This supplementary advice provided by HSE states “This information will help employers comply with the Control of Substances Hazardous to Health Regulations 2002 (COSHH), as amended, to control exposure to chemicals and protect workers’ health.” **Training**: Instruct users to throw away disposable RPE after one use.”					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The British Standards Institute (BSI). BS EN 529 2005 Respiratory protective devices — Recommendations for selection, use,	British Standard	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
care and maintenance — Guidance document. BSI Standards Publication 529:2005. Accessed: 11th July 2023.					
Assessment of evidence					
"The employer should provide facilities/administrative systems for segregating dirty and clean respiratory protective devices for safely disposing of contaminated respiratory protective devices or their components."					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Health Security Agency (UKHSA). Removal of (doffing) personal protective equipment (PPE). Airborne Precautions for	Guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
AGPs – Gown version, 2022. Accessed 20th December 2022.					

Assessment of evidence

This COVID-19 guidance advises the process by which FFP3 respirators should be doffed following AGPs whilst the healthcare worker is wearing a gown, and that this process should be outside a patient's room (in an anteroom, lobby or safe area) with a buddy observing.

Pictures are also provided to aid understanding.

"Respirator – in the absence of an anteroom/lobby remove FFP3 respirators in a safe area (e.g. outside the isolation room). Clean hands with alcohol hand rub.

- Do not touch the front of the respirator as it will be contaminated
- Lean forward slightly
- Reach to the back of the head with both hands to find the bottom retaining strap and bring it up to the top strap
- Lift straps over the top of the head
- Let the respirator fall away from your face and place in bin"

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Public Health Agency of Canada (PHAC). Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Healthcare Settings, 2017. Accessed: 20th December 2022.	Report/guidance	Level 4	N/A	N/A	N/A

Assessment of evidence

Aim: To present evidence-based recommendations for monitoring, preventing and controlling healthcare associated infections.

Target audience: Infection prevention and control professionals and healthcare providers involved with developing policy and procedure for routine practices in healthcare settings (acute, long-term, ambulatory, home care or prehospital care settings)

Methods: These guidelines were produced by PHAC, advised by PHAC's Steering Committee on Infection Prevention and Control Guidelines Working Group, made up of professionals from different areas of healthcare who provided technical advice (list provided on page 2). They are described as "principles and recommendations" rather than strict standards.

A literature search was conducted for papers from 1999 (details of this search are available to request).

Assessment of evidence

Recommendations were graded based on the strength of evidence

This guidance is based on scientific evidence and expert opinion where evidence was lacking, but was graded as expert opinion due to limited methodological detail making it difficult to deduce how systematic methods were.

Part B.IV. includes recommendations for additional precautions, and in subsection iii for patients with known or suspected infections requiring airborne precautions (examples of these include tuberculosis, measles and disseminated zoster):

- Also under personal protective equipment (page 102), the authors state the following for “appropriate respirator use” (CII - weak):
- “Self-contamination should be avoided by not touching the respirator on its external surface during use and disposal.
- Respirators should be carefully removed by the straps.
- The respirator should be discarded immediately after its use (i.e., dispose of when removed from the face) into a no-touch waste receptacle, followed by hand hygiene.”

Appendix X provides the steps for donning and doffing PPE, including respirators (page 187):

Doffing:

1. Gloves
2. Gown
3. Hand hygiene
4. Eye protection
5. “Remove mask or N95 respirator:
    a. Ties or ear loops or straps are considered to be ‘clean’ and may be touched with the hands
    b. The front of the mask or respirator is considered to be contaminated
    c. Untie bottom tie then top tie, or grasp straps or ear loops

Assessment of evidence
d. Pull forward off the head, bending forward to allow mask or respirator to fall away from the face e. Discard immediately into waste receptacle” 6. Hand hygiene These instructions were reproduced from the Ontario Ministry of Health and Long-Term Care

Evidence from previous update(s):

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Coia J. E., Ritchie L., Adisesh, A. et al. Guidance on the use of respiratory and facial protection equipment, 2013. Journal of Hospital Infection, 2013; 85;170-182; doi: 10.1016/j.jhin.2013.06.020.	Expert opinion guidance, UK	Level 4	N/A	N/A	N/A

Assessment of evidence

Best practice guidance based on a non-systematic literature review published separately (Bunyan D, Ritchie L, Jenkins D, Coia JE. Respiratory and facial protection: a critical review of recent literature. J Hosp Infect 2013;85:165e169).

"The Scientific Development Committee of the Healthcare Infection Society established a short-life working group in May 2011 to develop appropriate guidance. The working group included representation from the Healthcare Infection Society, Public Health England, Health and Safety Executive (HSE), Association of National Health Occupational Physicians, Health Protection Scotland, Infection Prevention Society, Intensive Care Society, Clinical Virology Network and British Infection Association."

Recommendations:

- "Single-use respirators should be worn once and disposed of as healthcare waste."
- "Dispose of single-use eye protection, surgical face mask or FFP respirator immediately after removal and in accordance with local policy."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). Respiratory protective equipment at work: A practical guide. HSG53 (4th Ed.), 2013b.	Expert opinion	Level 4	N/A	N/A	N/A

Assessment of evidence

About this guidance:

- This guide prepared by the HSE “in consultation with industry: employers, trade unions and trade associations”, is stated to support “the Approved Code of Practice (ACOP) to the Regulations that apply (see paragraphs 36–39)”.
- “The guide contains practical guidelines to help you select the correct RPE and manage its use in your workplace to ensure effective protection.”
- “As an employer, you have a legal responsibility under all the Regulations listed in paragraphs 36–39”

Recommendation:

“Contaminated RPE, or components, or any of the materials used to clean or disinfect the RPE, may need to be considered as hazardous waste. This will depend on the specific substances and the amounts involved. In some cases, specific legislation may apply. If in doubt, seek specialist help.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The Control of Substances Hazardous to Health (Amendment) Regulations, 2004. UK Statutory Instrument No. 3386	Regulation	Mandatory	N/A	N/A	N/A

Assessment of evidence

“Regulation 9 Maintenance, examination and testing of control measures:

Assessment of evidence
The employer shall ensure that the equipment referred to in paragraph (6) is subsequently decontaminated and cleaned or, if necessary, destroyed” “Employers must implement the following measure if exposure to a biological agent cannot be prevented: […]Instituting means for the safe collection, storage and disposal of contaminated waste, including the use of secure and identifiable containers, after suitable treatment where appropriate”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
European Centre for Disease Prevention and Control (ECDC). Guidance for wearing and removing personal protective equipment in healthcare settings for the care of patients with suspected or confirmed COVID-19, 2020.	Expert opinion guidance	Level 4	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Accessed: 14th December 2022					

Assessment of evidence

Scope of this document:

This document provides support to healthcare workers managing suspected or confirmed cases of novel coronavirus 2019 (COVID-19). The general objectives of the document are:

- to present the minimal set of personal protective equipment (PPE) required for managing suspected or confirmed COVID-19 cases;
- to make healthcare workers aware of the critical aspects of the donning and doffing of PPE; and
- to strengthen occupational safety in healthcare workers for patients suspected of, or confirmed with, COVID-19.

This document is based on current COVID-19 knowledge and PPE best practices.

ECDC will update this document based on the evolving situation and if new relevant information arises.

Target audience:

Healthcare workers and infection prevention and control personnel in EU/EEA countries and in the United Kingdom."

Recommendation:

"The respirator (or the surgical mask) should be disposed of after removal."