Personal protective equipment selection for healthcare settings: COVID-19 evidence review to March 2020

Prepared by the **Health and Safety Executive** and **Public Health England**

ER001 (2020)
Evidence Report

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Prepared 2020

First published 2020

Re-issued with new covers 2022

This report was first published on 1 April 2020 and re-issued here on 31 March 2022 with additional front and back covers and an introduction.

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Scientific evidence about COVID-19 is vital to inform decision making by HSE and across Government. The national and global scientific evidence base about COVID-19 (SARS-CoV-2) continues to develop. Evidence reviews give the best available evidence on specific questions at the time of their preparation in order to inform the COVID-19 response. Subsequent HSE guidance, advice and involvement in the broader cross-government response to this public health emergency may therefore have been updated.

This evidence review considered three questions about selection of personal protective (PPE) equipment for use in healthcare settings during the COVID 19 pandemic. The summary was completed in March 2020. Scientists from HSE and Public Health England (PHE) carried out the review to inform decision making across Government. Part 1 of the report considers the first question, and Part 2 considers a further two.

Part 1: What is the evidence to support the use of either N95 or FFP2 disposable respirators in the UK as part of the PPE ensemble worn for aerosol generating procedures on patients with COVID-19?

Part 2: a) What is the evidence to support the use of either gowns or aprons in the UK as part of the PPE ensemble worn for caring for patients with COVID-19? b) What is the evidence for the use of eye protection?

The review gives conclusions about these questions only. Many other factors influence the risk of exposure of healthcare workers to SARS-CoV-2.

This report and the work it describes were funded by the Health and Safety Executive. Its contents, including any opinions and/or conclusions expressed, are those of the authors alone and do not necessarily reflect HSE policy.

Introduction

Scientists from the Health and Safety Executive (HSE) and Public Health England (PHE) carried out a rapid review of the evidence to March 2020 on the selection of personal protective equipment (PPE) for use in healthcare settings early in the COVID-19 pandemic. The rapid evidence review was published by HSE on 1 April 2020 to inform expert decision makers.

The review is re-issued here as the first in the HSE Evidence Report series used to inform decision making in relation to COVID-19. This Evidence Report has:

- the evidence review, unchanged from first publication on 1 April 2020 (pages 1 to 15);
- this new introduction providing the context for the review and dated March 2022 (pages iii to v); and
- additional front and back covers in the format for the HSE Evidence Reports series.

Background: personal protective equipment for use in healthcare settings

Types of PPE worn by healthcare workers

PPE worn by healthcare workers may include equipment to protect:

- the body, such as, gowns, aprons and gloves;
- the eyes, such as goggles and visors; and
- the respiratory tract using respirators.

Respirators

Respirators are respiratory protective equipment (RPE) which protects the wearer from inhaling hazardous microorganisms and other particles via the nose and mouth. The performance of respirators depends on achieving a tight fit between the wearer's skin and the face seal of the facepiece. The wearer must pass a face fit test for the particular size and model of respirator to be worn to demonstrate that an effective seal can be achieved.

Respirators are classified on the level of protection they provide to the wearer. In the UK and Europe the relevant categories are filtering facepiece FFP2 and FFP3 respirators; the latter provides the highest degree of protection. In the UK, the standards for FFP respirators are set by the British Standards Institute (BSI). In the United States the category of respirator comparable to FFP2 is classified as the N95.

UK and WHO guidance on PPE for healthcare workers early in the pandemic

On 3 March 2020, the UK Government published its action plan for dealing with the COVID-19 pandemic.

On 13 March 2020, the UK issued guidance for healthcare workers recommending that they use filtering facepiece FFP3 or FFP2 respirators for medical interventions that release airborne fluid droplets from infected patients. These interventions are called aerosol-generating procedures and create a high risk of exposure to COVID-19 for healthcare workers if they do not wear FFP3/FFP2 respirators. The guidance is *COVID-19: Guidance for infection prevention and control in healthcare settings: Version 1.0:* (accessed 22 March 2022.)

On 19 March 2020, the World Health Organisation (WHO) published interim guidance about healthcare workers using N95 respirators when undertaking procedures likely to release COVID-19 into the air. The interim guidance is *Infection Prevention and Control During Health Care When COVID-19 is Suspected: Interim Guidance* (accessed 22 March 2022.)

N95 respirators are not approved for use in the UK. Decisions makers needed to consider the potential use of N95 respirators in the event of FFP2 shortages in the UK during the pandemic. To inform decision making, a review was needed of the level of protection offered to the wearer by N95 and FFP2 respirators.

The UK guidance of 13 March 2020 also recommends the use of aprons and gowns by healthcare workers for reducing contamination of clothing when caring for patients with COVID-19.

Evidence review aim and scope

This evidence review considers the selection of personal protective equipment (PPE) for use in healthcare settings early in the COVID-19 pandemic. The review was undertaken at the request of the Government Chief Scientific Adviser and considered evidence published until March 2020. The aim was to provide evidence to inform decision making across Government. The review considers three questions. Part 1 of the review considers the first question, and Part 2 considers a further two.

- Part 1: What is the evidence to support the use of either N95 or FFP2 disposable respirators in the UK as part of the PPE ensemble worn for aerosol generating procedures on patients with COVID-19?
- Part 2: a) What is the evidence to support the use of either gowns or aprons in the UK as part of the PPE ensemble worn for caring for patients with COVID-19?
  b) What is the evidence for the use of eye protection?

Evidence review key findings

The key findings are based on the limited studies available to March 2020, particularly qualitative research, and are intended to inform decisions on use of PPE in healthcare settings during the COVID-19 pandemic only. The key findings are:

- There is no material difference between N95 and FFP2 respirators in the protection they provide against inhalation of COVID-19 if the user has passed a face fit test to ensure the mask seal prevents inward leakage of the virus.
- The evidence that aprons and gowns offer effective protection is limited.
- Goggles and visors are necessary when there is a risk of contamination of the eyes from exhaled droplets containing COVID-19.
- The selection of appropriate PPE should be determined by local risk assessment and reference to the UK COVID-19 guidance for healthcare settings.

Evidence review – use to inform decision making

This evidence review was used to inform decisions on the selection of personal protective equipment (PPE) for use in healthcare settings early in the COVID 19 pandemic. This included decisions about the use of FFP2 and N95 respirators in the UK in the event, early in the pandemic, of an insufficient availably of FFP3 respirators for healthcare workers undertaking aerosol generating procedures.

During the pandemic and up to the present (March 2022), no N95 respirators were procured for national supply in the National Health Service (NHS).

PART ONE: Equivalence of N95 and FFP2 masks

ISSUE

What is the evidence to support the use of either N95 or FFP2 disposable respirators in the UK as part of the PPE ensemble worn for aerosol generating procedures on patients with COVID-19.

Current position

The Department of Health and Social Care (DHSC), Public Health Wales (PHW), Public Health Agency (PHA) Northern Ireland, Health Protection Scotland (HPS) and Public Health England have issued official guidance for healthcare workers 'COVID-19 Guidance for infection prevention and control in healthcare settings', adapted from 'Pandemic Influenza: Guidance for Infection prevention and control in healthcare settings 2020' https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file /874316/Infection_prevention_and_control_guidance_for_pandemic_coronavirus.pdf

The Personal Protective Equipment (PPE) ensemble for broad activities is provided at Table 1 in Section 6.4, page 24. A poster has also been produced; https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file /874411/When_to_use_face_mask_or_FFP3.pdf.

The guidance requires a filtering facepiece class 3 (FFP3) respirator, also referred to as an FFP3 respirator wherever there is risk of aerosol generating procedures (AGPs) and at all times in intensive care unit (ICU), intensive therapy unit (ITU), or high dependency unit (HDU) where COVID-19 patients are cohorted.

UK Legal Position

Biological Agents (such as SARS-CoV-2) are covered under the Control of Substances Hazardous to Health (COSHH) Regulations 2002. COSHH provides a framework of actions designed to control risk. from exposure to hazardous substances.

The Approved Code of Practice (ACOP) to COSHH Regulation 7 states that if employers cannot prevent exposure to a biological agent, they should take steps to ensure that it is controlled adequately and consider all the requirements set out in regulation 7(3), (4), (6) and (7). They should apply the principles of good practice and use each requirement where, and to the extent that:

- it is applicable;
- the assessment carried out under regulation 6 shows that it will lead to a reduction in risk.

HSE guidance document HSG53 states 'when in an airborne state, micro-organisms can be classed as particles, so can usually be removed by filter-type Respiratory Protective Equipment (RPE). You should always use equipment fitted with the highest efficiency filter possible (protection factor of at least 20) to control exposure down to the lowest levels.' Therefore HSE recommends the use of an FFP3 for use against viruses. Whilst FFP3 is the usual recommended control measure, it may not be reasonably practicable to use these if global supplies of FFP3 masks are low during a pandemic. In this scenario, an FFP2 could be used as an alternative, as this is consistent with WHO guidance.

A specific risk assessment under COSHH would help to determine whether exposure is adequately controlled. This should include consideration of the type and extent of exposure, potential health effects and effectiveness of control measures other than RPE.

HSE RR619 (2008) https://www.hse.gov.uk/research/rrhtm/rr619.htm

This research report states in the introduction 'HSE's current stance is that where there is a respiratory risk of infection use of FFP3 devices represents best practice, and where these are not available then FFP2 may be an acceptable, pragmatic compromise.'

In the context of the COSHH Regulations, elimination, substitution, and physical separation are not possible in the healthcare setting as workers are exposed to infectious agents as a consequence of their work. Since physically preventing exposure of healthcare workers to the virus is not feasible, it is important to minimise the likelihood that they will become infected, as far as is reasonably practicable, whilst still ensuring they are able to undertake their duties effectively. What is both reasonable and practicable will change during a pandemic, although the duty of control will still be based upon applying protective measures appropriate to the activity and consistent with the risk assessment.

WHO Guidance https://www.who.int/publications-detail/infection-prevention-and-control-during-health-care-when-novel-coronavirus-(ncov) -infection-is-suspected-20200125

The World Health Organisation (WHO), recommends the use of N95, FFP2 respirator or equivalent for protection against coronavirus during aerosol generating procedures (AGP).

Comparison of FFP3, FFP2 and N95

Previously, the N95 could not be used in the UK as it hasn't been tested to the European standards and was not CE marked.. It is widely accepted by industry that the N95 is comparable to an FFP2. The 3M technical bulletin 'Comparison of FFP2, KN95, and N95 and other filtering facepiece respirator classes' suggest it is reasonable to consider N95 and FFP2 masks are equivalent for filtering non-oil-based particles including bioaerosols (e.g. viruses).

The respective test standards (European standard for filtering half masks EN 149:2001+A1:2009 and NIOSH 42CFR84) detail requirements ranging from the compatibility of materials to flammability. A review of the key requirements however is detailed in Table 1 which compares N95, FFP2, FFP3 respirators.

Table 1 Comparison of key requirements of N95, FFP2 and FFP3 respirators.

Requirement	N95 (NIOSH-42CFR84)	FFP2 (EN149:2001+A1:2009)	FFP3 (EN149:2001+A1:2009)
Assigned Protection factor (APF)	10	10	20
Filter efficiency	≥95% (85 l/min)	≥94% (95 l/min)	≥99% (95 l/min)
Test agent used	NaCl	NaCl and Paraffin oil	NaCl and Paraffin oil
Total inward leakage (TIL)	N/A	≤8%	≤2%
Inhalation resistance	≤343 Pa (85 l/min)	≤240 Pa (95 l/min)	≤300 Pa (95 l/min)
Exhalation resistance	≤245 Pa (85 l/min)	≤300 Pa (160 l/min)	≤300 Pa (160 l/min)

Rebreathed CO2	N/A	≤1%	≤1%

The requirements detailed above show the N95 to be comparable to an FFP2 in assigned protection factor (APF), filter efficiency and breathing resistance. The N95 is not tested against a number of requirements, the differences observed are considered to have the following impacts on performance:

A liquid oil particulate test agent- this is representative of oil-based particulates. The 3M technical bulletin (and subsequently verified by 3M Senior Respiratory Protection Research & Application Specialist) considers that the N95 and FFP2 are equivalent at filtering non-oil-based particles such as bioaerosols, and that the WHO guidance confirms N95 will provide adequate protection against the coronavirus.

Total Inward Leakage - this consists of face seal leakage, exhalation valve leakage (if fitted) and filter penetration, all while being worn by a human test subject and performing a series of exercises. The N95 mask is tested for exhalation valve leakage and filter penetration in a separate requirement. Provided that the N95 masks are fit tested prior to use, this would provide reassurance on face seal leakage during exercises.

Rebreathed CO_2 - there is little concern with this as the size of the N95 masks are small and comparable to the FFP2 and therefore should have a similar rebreathed CO_2 result.

A further 3M technical bulletin 'Respiratory protection for airborne exposures to biohazards' shows the particle size range for six common N95 masks to be between 0.04 and 0.1 µm. This details the particle sizes of a range of microorganism, the smallest being Hepatitis B with a particle size of 0.042-0.047 µm and SARS with a particle size of 0.125 µm. The size distribution of droplet nuclei from a sneeze and a cough are much higher than the filtering efficiency measured for an N95 so will be easily filtered. This supports the N95 is suitable for filtering microorganisms.

Annex 1 provides a summary of UK and WHO guidance on PPE ensembles for primary care workers against COVID-19.

Fit testing

In order to protect health workers from contracting and spreading COVID-19 and to comply with the 'duty to adequately control' in COSHH Regulation 7(1) a face fit test is required where staff are wearing tight fitting disposable respirators to ensure that they are adequately protected whilst carrying out AGPs.

The performance of tight-fitting respirators depends on achieving a good contact between the wearer's skin and the face seal of the facepiece. Healthcare workers facial characteristics vary significantly in shape and size so it is unlikely that one model of respirator will fit everyone. Inadequate fit will significantly reduce the protection provided to the wearer.

There are two basic types of RPE fit testing – qualitative (where the wearer needs to detect a sweet or bitter tasting solution sprayed into a hood whilst they are wearing the respirator) and quantitative (using a particle counter which measures the ratio of particles inside and outside the respirator).

HSE produces guidance on its website in relation to the requirement for fit testing including INDG 479. This states that '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, also known as a fit check is not a substitute for fit testing.'

HSE produced a research report RR1029 'Review of fit test pass criteria for filtering facepiece FFP3 respirators'. Although not the main part of the research, the report found that subjective opinions on the fit of a mask, including the wearer fit check, were demonstrated to be of very little value as a substitute for a fit test.

The International Position

In undertaking this review, a number of national Health and Safety Laboratories provided their position on the question of equivalence between N95 and FFP2 masks.

NIOSH (USA)

A recent note from the FDA (dated 24 March 2020)[1] provided the following information regarding the use of non-NIOSH approved masks. It concluded that, based on the totality of scientific evidence available, that certain imported disposable FFRs are appropriate to protect the public health or safety (as described under section II Scope of Authorization) under section 564 of the Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. § 360bbb-3). This means that the respirators listed in the table below are authorized for use in healthcare settings by healthcare personnel (HCP) 2 when used in accordance with CDC recommendations to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages resulting from the Coronavirus Disease 2019 (COVID-19) outbreak.

Jurisdiction[6]	Performance Standard	Acceptable product classifications	Standards/ Guidance Documents	Protection Factor ≥ 10
Australia	AS/NZS 1716:2012	P3, P2	AS/NZS 1715:2009	YES
Brazil	ABNT/NBR 13698:2011	PFF3, PFF2	Fundacentro CDU 614.894	YES
Europe	EN 149-2001	FFP3, FFP2	EN 529:2005	YES
Japan	JMHLW-2000	DS/DL3 DS/DL2	JIS T8150: 2006	YES

Institut fur Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung (IFA)

The view from NIOSH is also supported by IFA. They point out that the N95s are not tested and approved for use in oil-based applications, while the FFP2s are. They also support fit-testing for the N95 for each employee individually, and agree with the CDC position that a positive test with NaCl is sufficient for use in the medical sector or for protection against corona virus.

The Federal Institute for Occupational Safety and Health (BauA, Germany)

[1] https://www.fda.gov/media/136403/download

If no CE-marked masks are available, the BAuA recommends the use of masks that comply at least with NIOSH standard N95 for medical and nursing staff until further notice.

Institut national de recherche et de sécurité (INRS, France)

Masks meeting the requirements of certain foreign standards can actually be used. The filtration performance of the filter material is very similar between FFP2 masks (European standard EN 149), N95 masks (American standard NIOSH 42C-FR84), Korea 1st Class masks (Korean standard KMOEL - 2017-64), masks KN95 (Chinese standard GB2626-2006), DS2 masks (Japanese standard JMHLW-2000) and P2 masks (Australian standard AS / NZS 1716: 2012).

Conclusions

The group concluded that there was no material difference between the N95 and FFP2 masks, and both would provide comparable protection against coronavirus as long as the wearer was face-fit tested. These conclusions were supported by the international experts consulted.

Additional contextual considerations

In coming to these conclusions, the group also considered the following important contextual issues:

1. The choice of respirator should be driven by the risk assessment, with this risk assessment being developed by those delivering the work so they can consider the local context;
2. That it is important that these considerations are based on an understanding of the risks rather than the hazards, and that a better understanding of the hierarchy of aerosol generating procedures would help to inform the risk assessment process above;
3. That the information and guidance used in support of this process would be assisted by more visual communications which give consistent messages (could include posters, infographics, webinars and videos), and supported by both TU and professional bodies);
4. The communication would be best achieved through close cooperation between HSE, PHE and NHS comms teams;
5. That in all cases, appropriate fit testing would be required to assure the performance of the chosen respirator on the specific user.

Annex 1 – Comparison of UK and WHO guidance on PPE ensembles for primary care workers COVID-19 (as at 24 March 2020). Notes text highlighted in red denotes difference from 1. Grey shaded = AGP Yellow shaded = WHO guidance

Guidance (see references below	1 (Official UK Guidance for Infection prevention and control in healthcare settings 2020)				2 (PHE poster when to use a surgical face mask or FFP3 respirator on gov.uk)			3 (PHE posters including videos on gov.uk)	4 (PHE posters including videos on gov.uk)	5 (WHO Infection prevention and control during health care when COVID-19 is suspected)	
	Entry to cohort area (only if necessary) no patient contact*	Within 1 metre of a patient with possible/confirmed COVID-19*	High risk units where AGPs are being conducted e.g.: ICU/ITU/HDU	Aerosol generating procedures (any setting)	In cohorted area (but no patient contact) For example: Cleaning the room, equipment cleaning, discharge patient room cleaning, etc	Close patient contact (within one metre) For example: Providing patient care, direct home care visit, diagnostic imaging, phlebotomy services, physiotherapy, etc	When carrying out aerosol generating procedures (AGP) on a patient with possible or confirmed COVID-19 In high risk areas where AGPs are being conducted (e.g.: ICU)	Personal protective equipment (PPE) for aerosol generating procedures (AGPs)	Personal protective equipment (PPE) for non-aerosol generating procedures (non-AGPs)	Direct Care of Patients with COVID-19	Workers undertaking AGP
Mask/Respirator	FRSM	FRSM	FFP3	FFP3	FRSM	FRSM	FFP3	Respirator (type not specified)	FRSM	Surgical mask	FFP2, N95 or equivalent
Eye Protection	None	RA	Disposable	Disposable	As designated for cleaning[6]	Eye protection (if risk of contamination of eyes by splashes or droplets	Disposable	Disposable full-face visor or goggles	If required	Goggles or face shield	Eye Protection
Gloves	None	Yes	Yes	Yes	As designated for cleaning	Yes	Yes	Yes	Yes	Yes	Yes
Body Protection	None	Disposable Apron	Disposable Apron	Disposable Gown	As designated for cleaning	Apron	Long sleeved disposable gown	Long sleeved fluid repellent disposable gown	Apron	Gown	Long sleeved gowns (aprons should also be used if gowns are not fluid resistant)

References

1 COVID-19 Guidance for infection prevention and control in healthcare settings Adapted from Pandemic Influenza: Guidance for Infection prevention and control in healthcare settings 2020 Issued jointly by the Department of Health and Social Care (DHSC), Public Health Wales (PHW), Public Health Agency (PHA) Northern Ireland, Health Protection Scotland (HPS) and Public Health England as official guidance. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/874316/Infection_prevention_and_control_guidance_for_pandemic_coronavirus.pdf

2 When to use a surgical face mask or FFP3 respirator When caring for patients with suspected or confirmed COVID-19 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/874411/When_to_use_face_mask_or_FFP3.pdf

3 COVID-19: personal protective equipment use for aerosol generating procedures Guidance on the use of personal protective equipment (PPE) for aerosol generating procedures (AGPs). https://www.gov.uk/government/publications/covid-19-personal-protective-equipment-use-for-aerosol-generating-procedures

4. COVID-19: personal protective equipment use for non-aerosol generating procedures Guidance on the use of personal protective equipment (PPE) for non-aerosol generating procedures (APGs). https://www.gov.uk/government/publications/covid-19-personal-protective-equipment-use-for-non-aerosol-generating-procedures

5. Infection prevention and control during health care when novel coronavirus (nCoV) infection is suspected https://www.who.int/publications-detail/infection-prevention-and-control-during-health-care-when-novel-coronavirus-(ncov)-infection-is-suspected-20200125

6. COVID-19: interim guidance for primary care https://www.gov.uk/government/publications/wn-cov-guidance-for-primary-care/wn-cov-interim-guidance-for-primary-care#environmental-cleaning-following-a-possible-case

Annex 2 Published Guidance on Aerosol Generating Procedures

WHO guidance on AGP

Tracheal intubation, non-invasive ventilation, tracheostomy, cardiopulmonary resuscitation, manual ventilation before intubation,

bronchoscopy **WHO guidance on additional controls for AGP**

- Ensure that HCWs performing aerosol-generating procedures: perform procedures in an adequately ventilated room – that is, natural ventilation with air flow of at least 160 L/s per patient or in negative- pressure rooms with at least 12 air changes per hour and controlled direction of air flow when using mechanical ventilation;10
- Limit the number of persons present in the room to the absolute minimum required for the patient's care and support.

UK guidance on AGP

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/874316/Infection_prevention_and_control_guidance _for_pandemic_coronavirus.pdf#page=27

The following procedures are considered to be potentially infectious AGPs:

- Intubation, extubation and related procedures;
- Tracheotomy/tracheostomy procedures;
- Manual ventilation;
- Open suctioning;
- Bronchoscopy;
- Non-invasive ventilation (NIV) e.g. Bi-level Positive Airway Pressure (BiPAP) and Continuous Positive Airway Pressure ventilation (CPAP);
- Surgery and post-mortem procedures in which high-speed devices are used;
- High-frequency oscillating ventilation (HFOV);

● High-flow Nasal Oxygen (HFNO)

● Induction of sputum (see glossary);

● Some dental procedures (e.g. high speed drilling).

Certain other procedures/equipment may generate an aerosol from material other than patient secretions but are not considered to represent a significant infectious risk. Procedures in this category include:

● administration of pressurised humidified oxygen;

● administration of medication via nebulisation.

Note: During nebulisation, the aerosol derives from a non-patient source (the fluid in the nebuliser chamber) and does not carry patient-derived viral particles. If a particle in the aerosol coalesces with a contaminated mucous membrane, it will cease to be airborne and therefore will not be part of an aerosol. Staff should use appropriate hand hygiene when helping patients to remove nebulisers and oxygen masks.

Additional UK Control Guidance for AGP

- For patients with suspected/confirmed COVID-19, any of these potentially infectious AGPs should only be carried out when essential.
- Where possible, these procedures should be carried out in a single room with the doors shut.
- Only those healthcare staff who are needed to undertake the procedure should be present.

PART TWO: Aprons, Gowns and eye protection

ISSUE

- **What is the evidence to support the use of either gowns or aprons in the UK as part of the PPE ensemble worn for caring for patients with COVID-19?**
- **What is the evidence for the use of eye protection?**

UK legal position

Biological Agents (such as SARS-CoV-2) are covered under the Control of Substances Hazardous to Health (COSHH) Regulations 2002. COSHH provides a framework of actions designed to control risk. from exposure to hazardous substances.

As of 19 March 2020, COVID-19 is no longer considered to be a high consequence infectious disease (HCID) in the UK.

The Approved Code of Practice (ACOP) to COSHH Regulation 7 states that if employers cannot prevent exposure to a biological agent, they should take steps to ensure that it is controlled adequately and consider all the requirements set out in regulation 7(3), (4), (6) and (7). They should apply the principles of good practice and use each requirement where, and to the extent that:

- it is applicable;
- the assessment carried out under regulation 6 shows that it will lead to a reduction in risk.

Risk assessment

It is important to note that no PPE is 100% effective and that the level of protection offered is dependent on the outcome of a thorough risk assessment based on the inherent characteristics of the hazard, including routes of transmission and the type(s) of activities being performed as well as the correct:

- selection;
- training;
- donning;
- use;
- doffing;
- storage;
- decontamination (of reusable items); and
- waste disposal.

Aprons

Aprons are required to conform to British Standard (BS) 3314:1982: Aprons for wet work. This covers material composition, referencing BS 3546: Coated fabrics for water resistant clothing. It also covers allowable minimum dimensions:

- not less than 900 mm long and 750 mm wide across the skirt;
- bib top not less than 250 mm wide extending to full width of the apron;
- bib top depth not less than 200 mm and not more than 300 mm.

There are different styles of aprons available as noted in a recent personal protective equipment (PPE) study lead by HSE as part of the High Consequence Infectious Diseases programme. Aprons

with integral sleeves will confer increased droplet/splash protection to the wearer compared with those without.

Gowns

It is important to note that surgical gowns were originally designed and are largely used to protect the patient from clinical staff, as well as conferring protection to the Health Care Worker (HCW) from infective agents.

Gowns are required to conform to *BS EN 13795-1 2019: Surgical clothing and drapes*. *Requirements and test methods*; and *BS EN ISO 22610: 2006/2018: Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment. Test method to determine the resistance to wet bacterial penetration.* BS EN 13795-1 notes that *"The performance required of coverings for patients, clinical staff and equipment varies with, for example, the type and duration of the procedure, the degree of wetness of the operation field, the degree of mechanical stress on the materials and the susceptibility of the patient to infection. The use of surgical gowns with resistance to the penetration of liquids can also diminish the risk to the operating staff from infective agents carried in blood or body fluids."*

In many cases, aprons are worn over surgical gowns often as additional protection in response to specific circumstances (e.g. patient may be vomiting).

Current UK Guidance

Current UK guidance on PPE includes COVID-19 Guidance for infection prevention and control in healthcare settings. Version 1.0. This guidance was adapted from the pandemic flu guidance. This guidance stipulates the following in relation to aprons and gowns:

"Disposable plastic aprons must be worn to protect staff uniform or clothes from contamination when providing direct patient care and during environmental and equipment decontamination.

Fluid-resistant gowns must be worn when a disposable plastic apron provides inadequate cover of staff uniform or clothes for the procedure/task being performed and when there is a risk of extensive splashing of blood and/or other body fluids e.g. during aerosol generating procedures (AGPs).

Disposable aprons and gowns must be changed between patients and immediately after completion of a procedure/task."

Interim WHO Guidance

Infection prevention and control during health care when COVID-19 is suspected: interim guidance produced by the WHO stipulates that HCWs should wear long sleeved surgical gowns for caring for patients suspected of having COVID-19. It also stipulates that the use of boots, coverall and apron are not required during routine care. For Aerosol Generating Procedures (AGPs) it also stipulates that if gowns are not fluid-resistant, HCWs should use a waterproof apron for procedures expected to create high volumes of fluid that might penetrate the gown. It does not specify whether this should be long-sleeved

Published Literature

This review assessed readily available peer review published evidence, and did not assess grey literature or unpublished data. Similarly, qualitative studies were not identified in the time available.

Public Health Scotland produced a literature review on PPE used in healthcare (Standard Infection Control Precautions (SICPs) Literature Review: Personal Protective Equipment (PPE) – Aprons or Gowns. 2015), the outcome of which determined that aprons or gowns should be worn:

- "*when it is anticipated that there may be exposure to blood, body fluids, secretions or excretions through close contact with a patient or any activity/procedure*"; and
- *"during aerosol-generating procedures in patients who are not suspected of being infected with an agent for which respiratory protective equipment is otherwise recommended".*

This review also determined that:

- *"Plastic aprons and/or fluid repellent gowns should be used in health and social care settings";*
- *"Full-body fluid repellent gowns must be used when there is a risk of extensive splashing of blood, body fluids, secretions or excretions."*

An article by Tomas *et al* (2015) determined that "*Contamination of the skin and clothing of health care personnel occurs frequently during removal of contaminated gloves or gowns. Educational interventions that include practice with immediate visual feedback on skin and clothing contamination can significantly reduce the risk of contamination during removal of PPE."*

A Cochrane systematic review (2019) evaluated the evidence regarding which type of full body PPE, and which method of donning or doffing PPE have the least risk of self-contamination or infection for health care workers exposed to highly infectious diseases, and which training methods increase compliance with PPE protocols. The Cochrane review considered a relatively small number of studies (n=17) dealing with PPE efficacy after applying their exclusion criteria. Evidence was thought to be of "very low" quality because of the "limitations of the studies". On the question of gowns vs aprons, the review concluded that:

- Gowns may protect better against contamination than aprons;
- Some types of training appeared more effective than others (video/computer/face-to-face)

However, in general the authors judged the quality of the evidence to be very low because of limitations in the studies, indirectness, and small number of participants, with more studies being required to provide a robust evidence base. There may be an opportunity to collect data during the current pandemic to help develop this evidence base at a more rapid pace.

Eye protection

Eye *protection provides a barrier to droplets and splashes, and includes* safety spectacles, full-face visors or an integral transparent panel on the top of a surgical face mask. Some of these items may be produced by additive manufacture (3-D printing). For visors, each manufacturer would need to demonstrate that they are complying with the appropriate standards and have documentation in support. BS EN ISO 18526-3: 2020 is the International Standard for eye and face protection. Eye protection should always be worn by all those present in the room during potentially infectious aerosol-generating procedures (AGPs). Disposable, single-use eye protection is recommended;

however, if this is re-usable, appropriate decontamination between uses is required." (Coia *et al.* 2013)

Ordinarily, eye protection would be considered as PPE so should be CE marked and fall into the most stringently checked category. However, the Office of Product Safety and Supply have recently issued new guidance on derogation of PPE requirements subject to meeting the essential safety requirements.

There are no published studies on the effectiveness of goggles or face shields (Verbeek et al 2019)

Conclusions

There are pros and cons to the selection, donning, use and doffing of aprons and gowns. The following table summarises these pros and cons.

	Pros	**Cons**
Non-sleeved aprons	• Easy to don, use and doff • Easy waste disposal • Common use • Fluid repellent	• Reduced coverage compared with gowns • Need to ensure top of bib is positioned high up at the neck
Gowns	• Offers extra coverage for Covers the whole torso and arms	• More difficult to doff • Not necessarily fluid repellent

Whilst both aprons and gowns appear suitable for caring for patients with suspected COVID-19 there is weak evidence to suggest that gowns appear to offer more protection. A critical element in the selection of the appropriate PPE is the context in which the work activity is being delivered. Specifically, this would include:

- The nature of the task(s) being performed;
- The training status and experience of the wearer;
- Practicability in the clinical setting;
- The clinical context, and culture.

Any novel manufacturing process employed during exceptional circumstances should still comply with the required standards to ensure appropriate protection.

Eye protection is necessary when there is a risk of contamination of the eyes from splashing such as during the performance or AGPs, but there are no published studies in this area.

Additional contextual considerations

In coming to these conclusions, the group also considered the following important contextual issues:

1. The choice of gown and/or apron should be driven by the risk assessment, with this risk assessment being developed by those delivering the work so they can consider the local context;

2. That it is important that these considerations are based on an understanding of the risks rather than the hazards, and that a better understanding of the hierarchy of aerosol generating procedures would help to inform the risk assessment process above;
3. That the information and guidance used in support of this process would be assisted by more visual communications which give consistent messages (could include posters, infographics, webinars and videos), and supported by both TU and professional bodies);
4. The communication would be best achieved through close cooperation between HSE, PHE and NHS comms teams;

References

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Scientific evidence about COVID-19 is vital to inform decision making by HSE and across Government. The national and global scientific evidence base about COVID-19 (SARS-CoV-2) continues to develop. Evidence reviews give the best available evidence on specific questions at the time of their preparation in order to inform the COVID-19 response. Subsequent HSE guidance, advice and involvement in the broader cross-government response to this public health emergency may therefore have been updated.

This evidence review considered three questions about selection of personal protective (PPE) equipment for use in healthcare settings during the COVID 19 pandemic. The summary was completed in March 2020. Scientists from HSE and Public Health England (PHE) carried out the review to inform decision making across Government. Part 1 of the report considers the first question, and Part 2 considers a further two.

Part 1: What is the evidence to support the use of either N95 or FFP2 disposable respirators in the UK as part of the PPE ensemble worn for aerosol generating procedures on patients with COVID-19?

Part 2: a) What is the evidence to support the use of either gowns or aprons in the UK as part of the PPE ensemble worn for caring for patients with COVID-19? b) What is the evidence for the use of eye protection?

The review gives conclusions about these questions only. Many other factors influence the risk of exposure of healthcare workers to SARS-CoV-2.

First published by the Health and Safety Executive 04/2020
Re-issued with additional covers and an introduction 03/2022