Public Services Delivery
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Personal Protective Equipment (PPE) Respiratory Protective Equipment (RPE)

Executive Summary

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

Contents

Introduction

This literature review informs the Personal Protective Equipment – Respiratory Protective Equipment' content in the National Infection Prevention and Control Manual (NIPCM) and the Care Home Infection Prevention and Control Manual (CHIPCM). See section 2.4 'Personal Protective Equipment: Respiratory Protective Equipment (RPE)' in Chapter 2 of the NIPCM, Appendix 11 of the NIPCM, Appendix 15 of the NIPCM, section 4 'Personal Protective Equipment (PPE) ' in Chapter 2 of the CH IPCM,

There are three documents to note:

- **Literature review** which provides a comprehensive systematic review of the evidence
- **Considered judgement forms** which outline the evidence base and expert opinion used to develop the recommendations and good practice points for each literature review research question. Also detailed are the benefits, potential harms, feasibility of implementation, value judgements, intentional vagueness, and exceptions associated with the recommendations and good practice points
- **Evidence tables** which detail all the included studies and provide an assessment of the evidence for each research question of the literature review

Scope

Research questions

There are 21 research questions (RQs) in this literature review. The RQs were rephrased to assess evidence on all types of RPE, rather than limiting the evidence to FFP respirators. Nine RQs were removed and consolidated with other RQs to aid with readability. RQ 8 ‘When should RPE be worn by health and care staff?’ was added to assess indications for wearing RPE for infection prevention and control purposes. RQ 21 ‘How should RPE be disposed?’ was also added in relation to reusable RPE.

- RQ 1 defines RPE available for use in occupational settings.
- Legislative requirements and standards are described in RQ 2 and throughout the review, where applicable.
- The design features of disposable and powered RPE are discussed in RQ 3 and RQ 4, respectively.
- The definitions and indications of fit testing and fit checking and the steps involved following unsuccessful fit testing and fit checking are discussed in RQ 5, 6 and 7, respectively.
- RQ 8, 10 and 11 cover the indications for RPE by health and care staff, patients, and visitors, respectively.
- The use of valved or non-valved RPE are discussed under RQ 9.
- RQ 12 and 13 cover where and how disposable RPE should be donned and doffed respectively.
- RQ 14 covers when disposable RPE should be changed or removed.
- RQ 16 and 17 cover where and how powered RPE should be donned and doffed, respectively.
- RQ 18 and 19 covers how reusable RPE should be maintained and decontaminated of.
- RQ 20 and 21 cover how RPE should be stored and disposed of, respectively.

Changes to Practice

There has been a significant change to the transmission mode descriptors within the NIPCM; the historical ‘droplet’ and ‘airborne’ transmission mode descriptors have been replaced with the new term ‘air’ transmission following the outputs of the ARHAI Scotland literature review on the definitions for transmission-based precautions. Health and care staff will continue to wear RPE for ‘R2’ and ‘R3’ respiratory infectious agents, as per GGP8.2.

There is a new GPP that supports the use of RPE by health and care staff for ‘R1’ respiratory infectious agents if advised by occupational health, a GP or another medical practitioner, as per GPP8.3.

Staff may wear RPE instead of a surgical mask for R1 respiratory infectious agents based on personal choice which takes into consideration high-risk exposures, as defined by the TBP definitions literature review, or if advised by occupational health, a GP or other medical practitioner, as per GPP8.3 and GPP8.4. It is also no longer recommended that a risk assessment that considers the number of air changes per hour (ventilation rate) should direct the wearing of RPE. The associated Appendix (Appendix 1) of the literature review has also been removed because it is not possible to quantify parameters for risk in the context of ventilation rate, room size and the number of people emitting infectious virus. Appendix 17 of NIPCM on the Hierarchy of Controls has also been amended to reflect this.

There is no longer reference to ‘fallow times’ and ‘aerosol-generating procedures’ as per the outputs of the TBP definitions literature review. The associated Appendix within the literature review has also been removed.

It is now a GPP that reusable components of RPE should be decontaminated according to manufacturer instructions or in line with local policy or procedure, as per GPP19.1. This is to acknowledge the changes to the NIPCM when cleaning or disinfecting reusable equipment with a move away from recommending only chlorine-releasing agents

Recommendations within the previous version of this literature review regarding filtered respirators have been revised. This is because the previous of the literature review recommended the re-use of filters according to manufacturer instructions. It is

now a GPP that filters should be disposed of after use, to minimise the risk of transmission of infectious agents (GPP18.3).

There are no other significant changes to practice because of this literature review update. The other new Recommendations and GPPs are reflective of current practice.

Change to Recommendations and Good Practice Points

There are several good practice points that are ‘new’ in terms of appearing for the first time in this latest literature review update. The inclusion of these is supported by outputs of the literature review and expert opinion, where further information on their development can be found within the Considered Judgement Form. They do not reflect new practices but provide a rationale for the support of current practice.

The Recommendations and Good Practice Points refer to the use of ‘respiratory protective equipment’ to capture all types of RPE that may be worn by health and care staff.

To reflect current practice, the recommendation that fit testing should be performed annually has been removed. The extant evidence is inconclusive regarding an appropriate time period for repeat fit testing across all occupational settings. ARHAI Scotland have been commissioned by Scottish Government to consider potential options to support defining a set frequency of fit testing. It is now a GPP that fit testing should be performed on a regular basis to reflect the need for local management in the interim (GPP6.3).

It is now a GPP that, where feasible, reusable components of powered RPE should be personally issued. This is to reflect the challenges around the decontamination of reusable RPE (GPP15.1). Additionally, recommendations within the previous version of this literature review regarding how to don a powered respirator, and how to don a filtering facepiece respirator have been removed. The associated Appendix (Appendix 3) has also been removed. This is because the steps for donning RPE can differ according to the style of RPE. A GPP now highlights that powered RPE should be donned according to manufacturer instructions (GPP16.1). Summary of Recommendations (R) and Good Practice Points (GPP).

Summary of Recommendations (R) and Good Practice Points (GPP)

Research Question 1: What is respiratory protective equipment (RPE)?

This research aimed to outline how RPE suitable for health and care settings is currently described within the literature. It therefore does not have any associated Rs or GPPs.

Research 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?

R2.1	**Employers must provide RPE which affords adequate protection against the risks associated with the task being undertaken as per Health and Safety at Work Act (1974), Control of Substances Hazardous to Health (2002 as amended) regulations and Personal Protective Equipment at Work Regulations 1992 (as amended).**
R2.2	**Employers must provide clear instruction and information on how to use provided RPE.**
R2.3	**Health and care staff must ensure that suitable RPE is worn correctly and in line with manufacturer's instructions for the task being undertaken.**
GPP2.1	**RPE intended for use in health and care settings should meet the relevant standards as detailed in Appendix 1 of the literature review.**

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

GPP3.1	**RPE with design features that support achieving a tight seal, for example adjustable straps, should be used in health and care settings.**

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

There are no recommendations or good practice points proposed for this research question.

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

GPP5.1	**A fit test ensures that an FFP respirator can properly fit the wearers face shape, with no gaps between mask and face for unfiltered air to pass, and should be conducted by a competent fit test operator. British and International Standard BS ISO 16975-3: 2017 outlines the requirements for RPE fit testing.**
GPP5.2	**The wearer should be clean shaven and free of any jewellery or piercings to support effective fit testing by ensuring a smooth surface area for a seal.**
GPP5.3	**A record of fit testing including the style, model and size needed for each individual, or if unable to be fitted to any available RPE, should be held.**
GPP5.4	**Fit testing results should not be transferred across respirator styles, models and sizes.**
GPP5.5	**Fit checking should be performed every time a respirator is donned.**
GPP5.6	**A fit check should follow manufacturer instructions, which can recommend a positive or negative pressure fit check.**
GPP5.7	**A fit check should not replace or be a substitute for fit testing.**

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

GPP6.1	**Tight-fitting RPE, for example an FFP3 respirator, should be fit tested prior to first use.**
GPP6.2	**Fit testing should be performed if changing the brand, model or size of respirator used.**
GPP6.3	**Fit testing should be repeated on a regular basis.**

GPP6.4	**In addition to routine fit testing on a regular basis, fit testing should be repeated following reported or observed changes to the wearer's face that could impair the face seal with the mask (for example as a result of weight gain/ loss, dental or cosmetic work, piercing, surgery, or scarring).**
GPP6.5	**A fit check should be performed every time RPE is donned (put on).**

Research Question 7: What if a fit test or fit check is unsuccessful?

GPP7.1	**If a fit test/check is unsuccessful, the following should be considered, in this order:**

1. **Adjust the straps and face seal and repeat fit test/check**
2. **Repeat fit test with a different size or model of tight-fitting respirator (note: this is not applicable for fit checks)**
3. **If a tight seal cannot be achieved with an FFP respirator, other types of RPE that offer equivalent protection (for example a powered respirator with a hood or helmet) may be considered.**

GPP7.2	**A task that requires respiratory protection should not be undertaken if a fit test or check has failed and alternative RPE is unavailable.**

Research Question 8: When should RPE be worn by health and care staff?

GPP8.1	**When indicated for use, RPE with at least 99% filtration efficiency (FFP3 respirator or equivalent) should be selected.**
GPP8.2	**RPE should be worn by all staff providing care for a service user with a suspected or confirmed infection caused by a category R2 or R3 respiratory infectious agent (as defined in the TBP Definitions literature review).**
GPP8.3	**Health and care staff should wear RPE during provision of care for a patient with a suspected or confirmed infection caused by a category R1 respiratory infectious agent (as defined in the TBP**

	Definitions literature review) if advised by occupational health, a GP or another medical practitioner.
GPP8.4	**Where a surgical mask is indicated during provision of care for a service user with a suspected or confirmed infection with a category R1 respiratory infectious agent (as defined in the TBP Definitions literature review), health and care staff may choose to wear RPE as an alternative to a surgical mask. This decision can be based on personal choice. This personal choice may be informed by high-risk exposures that are discussed in the TBP Definitions literature review and will be made clear in final guidance regarding RPE use.**

Research Question 9: When should valved versus unvalved respirators be worn?

GPP9.1	**Respirators with unshrouded valves are not considered to be fluid resistant. Where there is a risk of contamination with blood or body fluids additional PPE should be worn, such as full face shield/visor.**
GPP9.2	**Valved respirators should not be worn when a sterile field is required.**

Research Question 10: When should a patient wear RPE?

There are no recommendations or good practice points proposed for this research question.

Research Question 11: When should a visitor wear RPE?

GPP11.1	**Consideration should be given to providing visitors with RPE visiting a patient with a suspected or confirmed infection caused by a category R2 or R3 infectious agent[1].**

Research Question 12: Where and how should disposable respirators be donned?

R12.1	**Where two or more items of PPE are worn, these must be compatible with one another.**
GPP12.1	**RPE should be donned (put on) outside of the service user's room/care area, or within an ante room.**
GPP12.2	**RPE should be worn in accordance with manufacturer's instructions, including use within expiration dates.**
GPP12.3	**Hand hygiene should be performed before donning RPE, or all PPE when worn as part of an ensemble.**
GPP12.4	**RPE should be checked for any damage or defects prior to donning (putting on).**
GPP12.5	**When part of a PPE ensemble, RPE should be donned after aprons/gowns, and before eye/face protection. If eye/face protection is already being worn, these should be removed before donning RPE.**
GPP12.6	**Once donned (put on) the front of RPE should not be touched.**

Research Question 13: Where and how should disposable respirators be doffed?

R13.1	**RPE must be doffed (removed) after exiting the area in which the RPE was required.**
GPP13.1	**When RPE is worn as part of a PPE ensemble, RPE should be doffed (removed) last.**
GPP13.2	**RPE should be doffed in a manner that minimises contact with the front of the mask, using only the straps.**
GPP13.3	**Hand hygiene should be performed before and after doffing (removing) RPE.**

Research Question 14: When should RPE be changed or removed?

GPP14.1	**RPE should be changed or removed when a clinical procedure or task has been completed and/or there is no longer an exposure risk which indicates the need for RPE.**
GPP14.2	**RPE should be changed or removed** • **when they become moist** • **when they are visibly soiled or damaged** • **if contaminated by blood or body fluids**

Research Question 15: When should a powered respirator be worn?

GPP15.1	**Reusable powered RPE should be considered for use by individuals who cannot undertake or pass a fit test; where feasible, reusable components (for example, powered hoods and helmets) should be personally issued.**

Research Question 16: Where and how should powered respirators be donned?

GPP16.1	**Powered respirators should be configured according to manufacturer instructions, including correct airflow and choice of filter.**
GPP16.2	**Elastomeric (non-powered, reusable) RPE should be configured according to manufacturer instructions using the appropriate choice of filter.**

R12.1, GPP12.1, GPP12.2, GPP12.3, GPP12.4, GPP12.5 and GPP12.6 also apply to powered and non-powered reusable (elastomeric) RPE.

Research Question 17: Where and how should powered respirators be doffed?

R13.1, GPP13.1, GPP13.2 and GPP13.3 are applicable to powered RPE and reusable non-powered (elastomeric) RPE.

Research Question 18: How should reusable respirators be maintained?

R18.1	Users must report any damage or loss of RPE to employers.
R18.2	Reusable RPE should be visually inspected for damage, cleanliness, expiry dates and integrity at suitable intervals according to frequency of use, at a minimum monthly or as determined by the manufacturer (whichever is earlier/sooner).
GPP18.1	RPE and its reusable components, including filters, should be maintained according to manufacturer instructions.
GPP18.2	Where visitors or service users are required to don (put on) reusable RPE, staff should perform relevant maintenance requirements on their behalf according to manufacturer instructions.
GPP18.3	RPE filters/filter cartridges should be discarded after use.
GPP18.4	RPE filters/filter cartridges should be replaced if breathing becomes difficult, if they are visibly damaged or if they become visibly contaminated.

Research Question 19: How should reusable respirators be decontaminated?

R19.1	Employers must ensure that cleaning and/or disinfecting arrangements are in place for reusable RPE.
GPP19.1	Reusable RPE should be decontaminated according to manufacturer's instructions, or in line with local policy or procedure.
GPP19.2	Reusable RPE should be decontaminated following each use.

Research Question 20: How should RPE be stored?

R20.1	When not being used, RPE must be stored in a well-defined, accessible, safe storage place where it is protected from loss, contamination and damage, such as from sunlight, dust and moisture.

GPP20.1	**RPE should be stored within their original packaging in an appropriate dedicated room or allocated space that is accessible and near to the intended point of use, outside of service user rooms/zones.**

Research Question 21: How should RPE be disposed?

R21.1	**RPE should be disposed of as infectious waste within an appropriate waste receptacle. Please refer to the Safe Disposal of Waste Literature Review to determine the 'appropriate' disposal route for RPE.**
GPP21.1	**Single-use RPE should be disposed of immediately after use.**
GPP21.2	**Hand hygiene should be performed after disposing of used RPE.**