





Key information

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Personal Protective Equipment (PPE) – Footwear

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Contact

ARHAI Scotland Infection Control team:

Telephone: 0141 300 1175

Email: nss.hpsinfectioncontrol@nhs.scot

Document information

Purpose: To inform the Standard Infection Control Precaution (SICPs) and

Transmission Based Precautions (TBPs) sections on footwear within the National Infection Prevention and Control Manual in order to facilitate the prevention and control of healthcare associated infections in NHSScotland

health and care settings.

Target audience: All health and care staff involved in the prevention and control of infection

in Scotland.

Circulation list: Infection Control Managers, Infection Prevention and Control Teams,

Public Health Teams.

Description: This literature review examines the available professional literature on the

use of footwear as Personal Protective Equipment (PPE) for standard

infection control purposes in health and care settings.

Update/review schedule: Updated as new evidence emerges with changes made to

recommendations as required.

Review will be formally updated every 3 years with next review in

2024.

Cross reference: National Infection Prevention and Control Manual

Update level: Practice – No significant change to practice

Research – No significant change to research

Version History

This literature review will be updated as new evidence emerges

| Version | Date | Summary of changes | Changes marked |
|---------|--------------|--|-------------------|
| 3.0 | August 2021 | This literature review has been updated using two-person systematic review methodology. Five additional research questions were added and two existing research questions were modified. | |
| 2.0 | August 2015 | Updated after review of current literature | |
| 1.0 | January 2012 | Defined as final | |

Approvals

| Version | Date Approved | Name |
|---------|---------------|---|
| 3.0 | July 2021 | Steering (Expert Advisory) Group for SICPs and TBPs |
| 2.0 | August 2015 | Steering (Expert Advisory) Group for SICPs and TBPs |
| 1.0 | January 2012 | Steering (Expert Advisory) Group for SICPs and TBPs |

Linked Documentation

| Document title | Document Filepath | |
|-------------------------------|--|--|
| National Infection Prevention | National Infection Prevention and Control Manual | |
| and Control Manual | http://www.nipcm.hps.scot.nhs.uk/ | |

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1. Objectives

The aim of this review is to examine the extant professional literature regarding the use of footwear as Personal Protective Equipment (PPE) for standard infection control purposes in health and care settings.

The specific objectives of the review are to determine:

- Are there any legislative requirements for the use of footwear as PPE for infection control purposes?
- What types of footwear are suitable for health and other care settings?
- When should overshoes be used?
- When/Where should dedicated footwear be used?
- How should dedicated footwear be donned?
- How should dedicated footwear be doffed?
- When should footwear be cleaned?
- How should footwear be cleaned?
- How should dedicated footwear be stored?
- How/when should footwear be disposed of?

N.B. This review did not assess the use of footwear in certain health and care settings where there may be a health and safety requirement for wearing specialist footwear, for example in either estates or kitchen environments. Additionally, this review did not assess the use of footwear as PPE for high consequence infectious diseases (HCIDs). The <u>literature review that examines the extant professional literature regarding PPE for HCIDs</u> is available.

2. Methodology

This targeted literature review was produced using a defined methodology as described in the National Infection Prevention and Control Manual: Development Process.

3. Discussion

3.1 Implications for practice

Are there any legislative requirements for the use of footwear as PPE for infection control purposes?

There are no specific legislative requirements regarding the use of footwear as PPE for standard infection control purposes, although the use of PPE in health and care settings is covered by the <u>Health and Safety at Work etc. Act (1974),</u> Control of Substances Hazardous to <u>Health 2002 Regulations (as amended)</u>, and the <u>Personal Protective Equipment at Work Regulations 1992 (as amended)</u>.

The Health and Safety at Work etc. Act is the generic health and safety legislation for the UK and broadly covers the use of PPE and risk, but is not healthcare specific. Control of Substances Hazardous to Health (COSHH) is more specific and provides details in relation to hazardous materials and the use of PPE, and can almost be viewed as a detailed schedule of the Health and Safety at Work etc. Act, which would include pathogens in health and care settings and the use of appropriate PPE. For example, the use of gloves to protect against blood borne viruses during venepuncture.² If an activity does not involve or is perceived not to involve contact with a hazardous material, then the Personal Protective Equipment at Work Regulations 1992 provide general guidance on the use of PPE;³ in health and care settings this could be the use of gloves to protect against glass fragments when cleaning up broken glass. However, if the glass contained a laboratory sample then the activity would be covered by COSHH.¹

UK legislation outlines responsibilities of the employer and employee. Employers are obligated to provide appropriate PPE for their employees when hazards within the workplace cannot be otherwise controlled.¹⁻³ Employers are also responsible for ensuring that PPE is suitable for the task undertaken, fits correctly and complies with PPE Regulations 2002.³ Furthermore, the PPE

provided should provide the maximum protection possible with minimum discomfort. If multiple items of PPE are worn together, the employer must ensure that they are compatible with each other and that the level of protection they offer is not reduced.^{2, 3}

It was previously a requirement that PPE was CE marked.⁴ Given the UK's exit from the EU, from 1st January 2021 PPE must now be UKCA marked.⁵ Where conformity assessments were performed by a UK conformity assessment body prior to 1st January 2021, PPE that is CE marked may still be used until 31st December 2021.⁵ If conformity assessments were performed by an EU notified body, manufacturers must continue to use CE marking for PPE products placed on the GB market. Again, CE-marked products can only be placed on the UK market until 31st December 2021.⁵

Legislation outlines that employers must provide sufficient instruction on the correct use of PPE.^{2, 3} Employees are then responsible for ensuring that they comply with these instructions and use PPE that is suitable for the task being undertaken.^{2, 3} Employers are responsible for ensuring that PPE is regularly checked and repaired or replaced before further use if damaged. Employees are responsible for ensuring that PPE is well-maintained and kept in a clean condition.^{2, 3}

PPE Regulations 2002, associated with the PPE (Enforcement Regulations) 2018 and the Regulation (EU) 2016/425, outline that PPE available on the market must be supplied with information on, "storage, use, maintenance, servicing, cleaning and disinfecting; the level of protection provided by the PPE; suitable PPE accessories and appropriate spare parts; limitations on use and the obsolescence period [expiry date] for the PPE or certain of its components".³

Specific standards relating to footwear in health and care settings is outlined in Appendix 1.

What types of footwear are suitable for health and care settings?

There is very limited evidence on this topic. Overall, there is consensus that the footwear types worn by healthcare personnel should be driven by health and safety requirements, i.e. minimising the risk of trips and falls, as well as risk of contamination from blood and other bodily fluids.^{6,7} Suitable footwear should therefore be closed toe with low heels and non-skid soles.⁶ This is further supported by the Scottish Government National Uniform Dress Code and Laundering Policy, which states that staff should wear soft-soled, closed toe shoes.⁸

Expert opinion guidelines recently developed for the use of PPE during the COVID-19 pandemic advises that footwear should be anti-static, resistant to penetration and washable. Guidelines developed by the World Health Organisation (WHO) on infection, prevention and control (IPC) measures for epidemic and pandemic-prone acute respiratory infections state that resistant closed-toe shoes be worn for heavy-duty tasks, such as environmental cleaning.

The majority of the literature identified was in relation to footwear in operating theatre settings, and was restricted to professional opinion. Footwear worn in theatre settings should be comfortable, well-fitting, anti-static, easily cleaned, and have impervious soles with good traction.^{7, 11, 12} In some instances, boots or clogs are recommended for use in theatre settings^{7, 12} if, for example, gross contamination is anticipated.⁷

When should overshoes be used?

The evidence-base for this topic is very limited, focussing predominantly on the use of overshoes in theatre settings. The Association of Perioperative Registered Nurses (AORN) and the American Association of Nurse Anaesthetists (AANA) have recommended that they should be worn when a high risk of splash contamination is anticipated.^{7, 13}

The remaining guidelines identified for this review advise against their use,^{11, 14, 15} citing shortcomings including lack of traction underfoot, potential increased risk of bacterial contamination on floors, and cross-contamination to hands when overshoes are doffed.¹⁵

When/where should dedicated footwear be used?

Again, the evidence base for this research question is very limited.

Expert opinion pieces recommend that dedicated footwear should be used in operating theatres.^{7, 14, 15} The Association of Anaesthetists (ANA) state that these should be donned when entering the theatre.¹⁵ Conversely, the Hospital Infection Society Working Party on Infection Control in Operating Theatres indicate that given the evidence on bacterial contamination on the floor of theatre corridors, dedicated footwear should be donned in the theatre department.¹⁴

Although there is consensus against the use of overshoes, if overshoes are used, it is recommended that they are removed before leaving the operating theatre.^{7, 16} AORN's

guidelines on surgical attire also state that dedicated footwear should be worn in support areas of operating theatres i.e. cleaning and storage areas.⁷

How should dedicated footwear be donned?

Only one piece of evidence relating to the donning of dedicated footwear was identified, developed in the context of anaesthesia care.¹³ The AANA recommend donning shoes and overshoes prior to donning gloves.¹³

Evidence on the donning of footwear in non-theatre and other care settings was not identified.

How should dedicated footwear be doffed?

Two expert opinion pieces discussed the doffing of dedicated footwear in theatre settings, however these focussed only on the doffing of overshoes.^{7, 13} AORN recommend that overshoes should be doffed and discarded immediately after use, after which hand hygiene should be performed.⁷ Similarly, the AANA state that overshoes should be doffed and disposed of while gloves are donned.¹³

Evidence relating to non-acute care settings was not identified. The remaining studies that were examined focussed on the doffing of footwear in the context of HCIDs, which is outside the scope of this literature review.

When should footwear be cleaned?

Two UK-based expert opinion documents that provide recommendations on the cleaning of theatre footwear were identified in this review.^{14, 15} There was consensus in the recommendation that theatre footwear should be cleaned after every use to remove bodily fluid and blood splashes.^{14, 15} The Association of Anaesthetists and Hospital Infection Society recommend that procedures should be in place to ensure that this occurs at the end of every session.¹⁴ However, this was not specified in the guidelines produced by the ANA.¹⁵

There is no evidence on cleaning requirements for footwear in non-theatre or non-acute care settings.

How should footwear be cleaned?

Two pieces of expert guidance discussed methods of cleaning footwear.^{7, 15} The recommendations made were relatively broad and relevant only to the cleaning of dedicated footwear used in theatre settings. Guidance from the ANA states that NHS trusts are responsible for ensuring that there is a system available for cleaning theatre footwear.¹⁵ This system must be implemented in each theatre suite.¹⁵ AORN guidelines state that any PPE contaminated with blood, bodily fluids or other infectious agents should be cleaned on-site. Scrub attire i.e. dedicated footwear for theatre settings, must be bagged/containerised at the location where it was used, rather than being rinsed or sorted.⁷

Evidence on the cleaning of footwear in non-theatre settings and other care settings were not identified.

How should dedicated footwear be stored?

UK Control of Substances Hazardous to Health (2002) legislation states that following use, PPE should be stored away from uncontaminated clothing and equipment, in a well-defined place.² Storage spaces for PPE must prevent external damage i.e. from sunlight, humidity or chemicals; prevent contamination; and reduce the likelihood of losing PPE.³

Evidence on the storage of dedicated footwear in health and other care settings were not identified.

How/when should footwear be disposed of?

Two pieces of expert opinion guidance relating to the disposal of footwear were identified.^{7, 13} The AANA recommend that shoe covers should be removed and disposed before exiting a care area.¹³ AORN guidelines state that any surgical attire (including footwear) should be removed if possibly contaminated with blood, bodily fluids or other infectious materials.⁷

3.2 Implications for Research

There is a lack of scientific evidence on the use of footwear in health and care settings. Of note, there was a lack of evidence in the context of non-acute care settings and the evidence examined focussed predominantly on the use of dedicated footwear in theatre settings. Furthermore, a number of studies relating to the use of footwear as an element of PPE for HCIDs were identified. Given the lack of generalisability of such evidence for standard infection control practices, this evidence base could not be used to form recommendations in this review.

Consensus is needed on the use of shoe covers in health and care settings. Expert opinion was both scant and inconsistent; where those against their use cited health and safety concerns, and the potential for increased risk of cross-contamination during doffing of PPE.

Two observational studies assessed the use of decontaminating mats used to remove contaminants from shoe soles; however, the studies had limitations that impacted the validity of their findings.^{17, 18} Further rigorous research should be performed in this area to assess whether the use of decontaminating mats for footwear are beneficial and should be incorporated into standard infection control practices.

Overall, the majority of recommendations proposed regarding the use of footwear in health and care settings are led by mandatory legislation. It is generally accepted that the use of overshoes is no longer appropriate and that all other footwear is kept clean and in good condition. The need for further research in this area should not be considered a priority.

4. Recommendations

This review makes the following recommendations based on an assessment of the extant professional literature on footwear as PPE for standard infection control purposes in health and care settings:

Are there any legislative requirements for the use of footwear as PPE for infection control purposes?

The Health and Safety at Work etc. Act (1974),¹ Control of Substances Hazardous to Health 2002 Regulations (as amended)² and Personal Protective Equipment at Work Regulations 1992 (as amended)³ legislate that employers (i.e. NHS Scotland) must provide PPE which affords adequate protection against the risks associated with the task being undertaken. Employees (i.e. healthcare workers) have a responsibility to comply by ensuring that suitable PPE is worn correctly for the task being carried out.

(Mandatory)

PPE must fit the wearer and if being worn with other items of PPE, the employer must ensure that these are compatible with each other and do not reduce the level of protection provided if worn together.

(Mandatory)

Employers must check PPE regularly and if found to be defective, repair or replace items before further use.

(Mandatory)

From 1st January 2021, PPE must be UKCA marked. Where conformity assessments were performed by a UK conformity assessment body prior to 1st January 2021, PPE that is CE marked may still be used if placed on the market before 31st December 2021.

(Mandatory)

Specific standards relating to the quality and performance of footwear are outlined in Appendix

<u>1.</u>

(Mandatory)

| What types of footwear are suitable for health and other care settings? | | | |
|---|-------------------------------------|--|--|
| Theatre footwear should: | | | |
| • ha | ve closed toes; | | |
| • be | clean and well maintained; | | |
| • be | easy to clean; | | |
| • be | impervious | | |
| • be | non-slip/have good traction; | | |
| • coi | mfortable and well-fitting | | |
| (Grade C recommendation) | | | |
| Footwe | ear in non-theatre settings should: | | |
| • ! | be soft-soled and have closed toes; | | |
| (Manda | atory) | | |
| • | have low heels | | |
| (Grade C recommendation) | | | |
| • | be clean and well maintained; | | |
| (Mandatory) | | | |
| | | | |

When should overshoes be used?

Overshoes/shoe covers should not be used in the general health and care environment.

(Grade C recommendation)

When/Where should dedicated footwear be used?

Dedicated footwear should be worn in the theatre environment.

(Grade C recommendation)

How should dedicated footwear be donned?

There is insufficient evidence to form a recommendation regarding this research question.

How should dedicated footwear be doffed?

There is insufficient evidence to form a recommendation regarding this research question.

When should footwear be cleaned?

Employees are responsible for ensuring that PPE is well-maintained and kept in a clean condition.

(Mandatory)

Dedicated footwear for use in theatre settings should be removed when leaving the theatre work area and must be subsequently cleaned and decontaminated.

(Mandatory)

Dedicated footwear used in theatre settings should be cleaned between procedures if visibly contaminated with blood or bodily fluid.

(Grade C recommendation)

How should footwear be cleaned?

Any PPE on the market must be supplied with information on methods for cleaning and disinfection.

(Mandatory)

How should dedicated footwear be stored?

PPE, including dedicated footwear, should be stored in a designated place.

(Mandatory)

Storage spaces for PPE must prevent external damage from sunlight, humidity or chemicals; prevent contamination, and reduce the likelihood of losing the PPE.

(Mandatory)

How/when should footwear be disposed of?

Footwear found to be defective should be repaired or replaced before further use.

(Mandatory)

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Appendix 1: Specific standards relating to the quality and performance of footwear

| Standard | Title | Description | Publication date |
|----------------------|---|---|------------------|
| BS EN ISO 20344:2011 | Personal protective equipment. Test methods for footwear. | This standard outlines performance testing, mechanical testing, thermal testing, electrical testing, water-resistance tests, water-absorption tests, oil-resistance tests, and testing conditions for footwear. | January 2011. |
| BS EN ISO 13287:2019 | Personal protective equipment. Footwear. Test method for slip resistance. | This standard outlines slip tests, friction tests and physical testing for footwear. | November 2019. |
| BS EN 13921:2007 | Personal protective equipment. Ergonomic principles. | This standard provides guidance on the generic ergonomic characteristics related to personal protective equipment (PPE) – it does not however cover the requirements which relate to specific hazards that PPE may be designed. | September 2007. |

| Standard | Title | Description | Publication date |
|--|---|---|---|
| Statutory Instrument 2018 No. 390 and The Product Safety and Statutory Instrument 2019 No. 696 | Consumer Protection Health and Safety – The Personal Protective Equipment (Enforcement) Regulations 2018 and The Product Safety and The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 | Statutory instrument No. 390-sets out the standards for PPE in the UK. Schedule 35 of Statutory Instrument No. 696 sets out the amendments made to Statutory Instrument No. 390 due to the UK's withdrawal from the EU and requires that all PPE is UKCA marked. As it was previously a requirement that PPE was CE marked, CE marking is still valid until 31st December 2021 if items are assessed by EU recognised Notified Bodies. UKCA and CE marking demonstrates that an item has been manufactured to a particular standard and passed the appropriate tests for the PPE type and intended use/purpose. | Instrument No. 390: April 2018; Instrument No. 696: March 2019. |
| BS EN 20347:2011 | Personal protective equipment. Occupational footwear. | This standard outlines basic and additional optional requirements for occupational footwear that is not exposed to any mechanical risks i.e. impact or compression. | February 2012. |

Legend:

BS = British Standards produced by the British Standard Institution (www.bsigroup.co.uk)

EN = European Standards (European Norm) produced by the European Committee for Standardisation (<u>www.cen.eu</u>)

ISO = International Standards produced by the International Standards Organization (www.iso.org)

EN standards are gradually being replaced by ISO standards – when these are adopted in the UK they are prefixed with BS (e.g. BS EN; BS EN; BS EN ISO). This is usually to accommodate UK legislative or technical differences or to allow for the inclusion of a UK annex or foreword

Appendix 2: Grading of Recommendations

| Grade | Descriptor | Levels of Evidence |
|-------------------|--|---|
| Mandatory | 'Recommendations' that are directives from government policy, regulations or legislation | N/A |
| Category A | Based on high to moderate quality evidence | SIGN level 1++, 1+, 2++, 2+, AGREE strongly recommend |
| Category B | Based on low to moderate quality of evidence which suggest net clinical benefits over harm | SIGN level 2+, 3, 4, AGREE recommend |
| Category C | Expert opinion, these may be formed by the NIPC groups when there is no robust professional or scientific literature available to inform guidance. | SIGN level 4, or opinion of NIPC group |
| No recommendation | Insufficient evidence to recommend one way or another | N/A |

Appendix 3: Search Strategy

EMBASE and **MEDLINE** search 2000 to current

- 1. Shoes/
- 2. (shoe* adj3 cover*).mp
- 3. overshoe*.mp
- 4. over shoe*.mp
- 5. footwear.mp
- 6. shoe*.mp
- 7. 1 or 2 or 3 or 4 or 5 or 6
- 8. Exp Hospitals/
- 9. Exp Infections/
- 10. Exp Infection Control/
- 11. Exp Disease Transmission, Infectious/
- 12. 8 or 9 or 10 or 11
- 13. 7 and 12

Limit 13 to English language and human

CINAHL search 2000 to current

- S14 S7 and S12 (English language)
- S13 S7 and S12
- S12 S8 or S9 or S10 or S11
- S11 (MH "Disease Transmission+")
- S10 (MH "Infection Control+")
- S9 (MH "Infection+")
- S8 (MH "Hospitals+")
- S7 S1 or S2 or S3 or S4 or S5 or S6
- S6 shoe*
- S5 footwear
- S4 over shoe*
- S3 overshoe*
- S2 shoe* n3 cover*
- S1 (MH "Shoes")