

**Standard Infection Control Precautions Literature Review:
Personal Protective Equipment (PPE)
Surgical Face Masks**

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Description:	This literature review examines the available professional literature on PPE (Surgical Face Masks) in the healthcare setting.
Purpose:	To inform the Standard Infection Control Precautions (SICP) section on Personal Protective Equipment (PPE) Surgical Face Masks in the National Infection Prevention and Control Manual.
Target audience:	All NHS staff involved in the prevention and control of infection in NHSScotland.
Circulation list:	Infection Control Managers, Infection Prevention and Control Teams, Public Health Teams
Update/review schedule:	Updated as new evidence emerges, with changes made to recommendations as required.
Cross reference:	National Infection Prevention and Control Manual http://www.hps.scot.nhs.uk/haiic/ic/guidelinedetail.aspx?id=49785 SBAR. Use of masks for invasive spinal procedures http://www.documents.hps.scot.nhs.uk/hai/infection-control/sbars/masks-invasive-spinal-procedures.pdf
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1. Objectives

The aim of this review is to examine the extant scientific literature regarding the use of surgical face masks as Personal Protective Equipment (PPE) for infection control purposes.

The specific objectives of the review are to determine:

- Are there any legislative requirements for the use of surgical face masks as PPE for standard infection control purposes?
- When/where should surgical face masks be used?
- What type(s) of surgical face masks should be used?
- When should surgical face masks be removed/changed?
- How should surgical face masks be removed?
- How should surgical face masks be disposed of?
- How should surgical face masks be stored?

N.B. The use of surgical masks as protection against either suspected or known specific infectious agents is considered as part of Transmission Based Precautions (TBPs), and therefore is not within the scope of this review.

Recommendations relating to surgical masks used as part of TBPs are outlined in the [Transmission Based Precautions: surgical masks literature review](#).

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. Recommendations

This review makes the following recommendations based on an assessment of the extant scientific literature on the use of surgical face masks as PPE for standard infection control purposes:

Are there any legislative requirements for the use of surgical face masks as PPE for infection control purposes?

There is no direct legislative requirement to wear surgical face masks for the purposes of the prevention and control of infection; however the Health and Safety at Work Act (1974),¹ Control of Substances Hazardous to Health (2002 as amended) regulations² and Personal Protective Equipment at Work Regulations 1992 (as amended)³ legislate that employers (i.e. NHSScotland) 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.

Specific standards relating to the quality and performance of masks are outlined in [Appendix 1](#).

When/where should surgical face masks be used?

Surgical face masks must be worn during any activities/procedures where there is a risk of splashing or spraying of blood, body fluids, secretions or excretions onto the respiratory mucosa.

(Grade D recommendation)

(AGREE rating: Recommend)

Surgical face masks must be worn during aerosol-generating procedures on patients who **are not** suspected of being infected with an agent for which extended respiratory protection is otherwise recommended.

(AGREE rating: Recommend)

Scrubbed members of the theatre surgical team should wear surgical face masks during all surgical procedures.

(Grade D recommendation)

Surgical face masks must be worn by non-scrubbed members of the theatre surgical team if deemed necessary following a risk assessment of exposure to blood and/or body fluids.

(Good Practice Point (GPP))

Surgical face masks should be worn when performing invasive spinal procedures such as myelography, lumbar puncture and spinal anaesthesia.

(AGREE rating: Recommend)

What type(s) of surgical face masks should be used?

Fluid-resistant (Type IIR) surgical face masks which fully cover the face and mouth should be used.

(Grade D recommendation)

Surgical face masks should be close fitting in order to prevent venting (exhaled air 'escaping' at the sides of the mask).

(Good Practice Point (GPP))

When should surgical face masks be removed/changed?

Surgical face masks are available in a variety of specifications but must be removed or changed:

- at the end of a clinical procedure/task;
- if the integrity of the mask is breached, for example from moisture build up after extended use or from gross contamination from a patient; and
- in accordance with manufacturer instructions.

(Good Practice Point (GPP))

How should surgical face masks be removed?

Surgical face masks should be removed by handling only the ties or elastic.

(Grade D recommendation)

(AGREE rating: Recommend)

How should surgical face masks be disposed of?

Surgical face masks are single-use items and must be disposed of as healthcare (including clinical) waste immediately after removal.

(Good Practice Point (GPP))

How should surgical face masks be stored?

Surgical face masks should be stored in their original containers and should be stored away from direct sunlight, heat sources and liquids, including chemicals. The area should be clean and should protect the masks from contamination.

(Good Practice Point (GPP))

4. Discussion

4.1 Implications for practice

Are there any legislative requirements for the use of surgical face masks as PPE for infection control purposes?

There are no specific legislative requirements regarding the use of surgical face masks as PPE for infection control purposes, that is, to prevent the spread of healthcare associated infection. The wearing of PPE is covered by the Health and Safety at Work Act (1974),¹ Control of Substances Hazardous to Health 2002 (as amended)² regulations, and the Personal Protective Equipment at Work Regulations 1992 (as amended).³

The Health and Safety at Work 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. The 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 Act, which would include pathogens in the hospital environment and the use of appropriate PPE – for example the use of gloves to protect against blood borne viruses during venepuncture. 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; in the healthcare environment 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 the Control of Substances Hazardous to Health.

All of the UK legislation and regulations outline the responsibilities of the employer and employee and also cover the unnecessary exposure to risk of service users, i.e. they cover NHSScotland employees and patients.

Specific standards relating to surgical face masks are outlined in [Appendix 1](#) of this document.

When/where should surgical face masks be used?

The rationale for the use of surgical face masks is twofold; to protect the wearer from sources of infection e.g. splashing or spraying of blood, and to protect others from the wearer as a source of infection.⁴⁻¹⁰

It has, however, been observed that surgical face masks are not designed specifically to protect the wearer from infection⁶ but to protect the wearer (i.e. the healthcare worker), during any activities/procedures where there is a risk of splashing or spraying of blood, body fluids, secretions or excretions.^{7;11-17}

(Grade D recommendation)

(AGREE rating: Recommend)

It has also been recommended that a surgical face mask with attached face shield or a surgical face mask and goggles should be used for the protection of the wearer during aerosol generating procedures in patients who are not suspected of being infected with an agent for which respiratory protection is otherwise recommended.^{4;5;9;11}

(AGREE rating: Recommend)

There is ongoing debate in the literature regarding the use of surgical face masks by surgical teams to protect patients during surgical procedures.^{6;7;10;14;18-26} Due to lack of available evidence, a Cochrane systematic review on the use of face masks by surgical teams during clean surgery was unable to draw conclusions on whether their use had an impact on rates of surgical wound infections.¹⁸

Despite the lack of evidence, there is a majority consensus of opinion in the literature that scrubbed members of the surgical team should routinely wear surgical face masks during all surgical procedures for the protection of patients.^{6;7;10;18;20-25}

Opinion is divided on the use of surgical face masks by non-scrubbed members of the surgical team for the protection of patients. While the majority of the literature advocates the use of surgical face masks by all members of the surgical team, whether scrubbed or non-scrubbed^{7;14;20;21;24;25}, there is also support for the view that it is not necessary for non-scrubbed staff to wear surgical face masks.^{23;26} A recent randomised controlled trial demonstrated that rates of surgical site infection in a general surgical cohort were not significantly different

between the trial group, where non-scrubbed staff wore surgical face masks, and the trial group, where they did not.¹⁹ Although this trial lends support to the view that surgical face masks are not necessary for non-scrubbed staff, the evidence overall is limited and there is no consensus on the issue.

(Grade D recommendation)

Surgical face masks must be worn by non-scrubbed members of the theatre surgical team if deemed necessary following a risk assessment of exposure to blood and/or body fluids.^{8;9}

(Good Practice Point (GPP))

There is strong evidence implicating droplet contamination with microorganisms from the operator's nasopharynx/oropharynx in cases of meningitis following invasive spinal procedures such as myelography, lumbar puncture and spinal anaesthesia.^{16;27-31} Although the risk of this infectious complication is believed to be low, the consequences are serious. It is therefore recommended that operators wear a mask when performing such procedures to minimise the risk of infection to patients.^{16;29}

(AGREE rating: Recommend)

What type(s) of surgical face masks should be used?

No standard definition of a surgical face mask was identified in the literature. Surgical masks must be fluid-resistant, compliant with Medical Device Directive (MDD/93/42/EEC) and be 'CE' marked.^{4;5} Surgical masks are tested against the safety standard BS EN 14683; this series of tests measures the performance of a surgical mask in bacterial filtration efficiency, breathing resistance and splash resistance. Type II and Type IIR surgical masks are both tested against this standard; however only Type IIR masks must pass the splash resistance test with a resistance of at least 120mmHg. The terms 'fluid resistant' and 'fluid repellent' are often used interchangeably to denote a Type IIR surgical mask, however, terminology may vary internationally and a 'fluid repellent' mask may occasionally describe a mask that does not meet the BS EN 14683 splash resistance standard and which is not suitable for protection against splash or spray i.e. a Type II surgical mask..

When recommended for infection control purposes a 'surgical mask' will be a fluid-resistant (Type IIR) surgical mask.

Further details on the standards relating to quality and performance of surgical masks are provided in [Appendix 1](#).

There appears to be a wide variation in design and quality of masks in use. In terms of design, it is recommended that masks should fully cover the nose and mouth of the wearer.^{8;15;20;26;32}

(Grade D recommendation)

It has also been advised that surgical face masks should be close fitting in order to prevent venting (exhaled air 'escaping' at the sides of the mask).^{7;8;20;33}

(Good Practice Point (GPP))

When should surgical face masks be removed/changed?

It has been recommended that masks, when used, are changed after every patient contact or operation.^{4;5;26;34} Surgical masks should be changed if they become damaged, damp or contaminated.^{4;5;8;12;26;33}

(Good Practice Point (GPP))

How should surgical face masks be removed?

The front of masks is considered to be contaminated after use.^{7;11;34} As such, it has been recommended that masks are removed by handling only the side ties or elastic.^{4;5;7;9;12;16;34;35}

(Grade D recommendation)

(AGREE rating: Recommend)

How should surgical face masks be disposed of?/How should surgical face masks be stored?

Surgical masks should be disposed of immediately after use in accordance with local policy (See National Infection Prevention and Control Manual ['Safe Management of Waste'](#)).³⁶

(Good Practice Point (GPP))

This review identified insufficient evidence on the correct storage of surgical face masks to enable a graded recommendation to be made. However, it is recommended that surgical face masks should be stored in their original containers and should be stored away from direct sunlight, heat sources and liquids, including chemicals. The area should be clean and should protect the masks from contamination.

(Good Practice Point (GPP))

4.2 Implications for research

In their systematic review, Lipp and Edwards recommended that further research on this topic should be in the form of well-conducted randomised trials that compare the effect of surgical face mask use by surgical teams with non-use of surgical face masks in relation to rates of surgical wound infection in patients.¹⁸ They also recommend that a focus for further research should be the use of disposable surgical face masks by surgical teams compared with other forms of face protection such as visors and helmets for the protection of both patients and staff.¹⁸ Given the frequency with which surgical face masks are routinely used across the healthcare environment, further research should also seek to examine the use and efficacy of surgical face masks in non-surgical settings by both healthcare workers and patients. Furthermore, there may be a need to clarify or expand existing legislation relating to the use of appropriate PPE in the healthcare setting. At present much of the legislation relates to the handling and management of dangerous substances and/or chemicals with no specific regulation for pathogens in a non-laboratory clinical environment.

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Appendix 1

<u>Standards pertaining to surgical face mask as PPE</u>			
Standard	Title	Description	Publication date
BS EN 14683:2005	Surgical masks. Requirements and test methods.	This standard outlines the Hygiene, Performance, Classification systems, Environmental cleanliness, Contamination, Biological hazards, Performance testing, Permeability measurement for surgical face masks.	January 2006.
ISO22609 : 2004 EDTN1 (R08)	Clothing for protection against infectious agents - Medical face masks - Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected).	This standard outlines the test method for surgical face masks in relation to synthetic blood penetration.	December 2004.
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.
Statutory Instrument 2002 No. 1144	Health and Safety – Personal Protective Equipment Regulations 2002	This instrument sets out the standards for PPE in the UK. Schedule 4 sets out the standards for conformity across the UK (and the EU) and requires that all PPE is CE marked . 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.	May 2002.

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 (www.cen.eu)

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 ... or BS EN ... or 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.