

**Transmission Based Precautions Literature Review:  
Surgical Masks**

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Version History:			
This literature review will be updated in real time if any significant changes are found in the professional literature or from national guidance/policy.			
Version	Date	Summary of changes	Changes marked
2.0	October 2017	Added: mask should be 'well fitting and fit for purpose covering the mouth and nose' (page 7/11)  'Surgical mask replaced' with 'FRSM' throughout document  DOH recommendations edited (page 8)  When should patients wear a surgical mask: Wording clarifying around patient transportation	
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Approvals – this document requires the following approvals (in cases where signatures are required add an additional 'Signatures' column to this table)::				
Version	Date Approved	Name	Job Title	Division
2.0	October 2017	NPGO Steering Group		
1.1		Steering (Expert Advisory) Group for SICPs and TBPs		

HPS ICT Document Information Grid	
<b>Purpose:</b>	To inform the Transmission Based Precautions (TBPs) section on the use of surgical masks in the National Infection Prevention and Control Manual.
<b>Target audience:</b>	All NHS Scotland staff involved in the prevention and control of infection in the hospital setting.
<b>Circulation list:</b>	Infection Control Managers, Infection Prevention and Control Teams, Public Health Teams
<b>Description:</b>	This literature review examines the available scientific literature on the use of surgical masks in the healthcare setting.
<b>Update/review schedule:</b>	Updated as new evidence emerges, with changes made to recommendations as required.
<b>Cross reference:</b>	National Infection Prevention and Control Manual  Standard Infection Control Precautions Literature Review: Surgical Face Masks  Transmission Based Precautions Literature Review: Respiratory Protective Equipment (RPE)
<b>Update level:</b>	Practice – <b>No significant change to practice</b>  Research – <b>No significant change</b>

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## 1. Objectives

The aim of this review is to examine the extant scientific literature regarding the use of surgical masks in the hospital setting to form the basis for evidence-based recommendations for practice. The specific objectives of the review are to determine:

- What type of surgical mask should be used?
- Are there legislative requirements for healthcare workers to wear a fluid repellent surgical mask (FRSM)?
- When should healthcare workers wear a FRSM?
- When should patients wear a FRSM?
- When should visitors wear a FRSM?
- When should a FRSM be removed/changed?

### **N.B.**

Transmission Based Precautions (TBPs) are measures that may be required in addition to Standard Infection Control Precautions (SICPs). It is assumed, for the purpose of this literature review that all SICPs are adhered to.

This review is focused on additional questions for TBPs and supplements the SICPs Personal Protective Equipment (PPE) literature review [Surgical Face Masks](#).

## 2. Recommendations

This review makes the following recommendations based on an assessment of the extant scientific literature on the use of surgical masks for Transmission Based Precautions in the healthcare setting.

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

A fluid resistant (Type IIR) surgical mask (FRSM) which fully covers the nose and mouth should be used.

#### **(Grade D recommendation)**

FRSMs should be well fitting and fit for purpose, covering the mouth and nose in order to prevent venting (exhaled air 'escaping' at the sides of the mask.)

#### **(Good Practice Point (GPP))**

### Are there legislative requirements for healthcare workers to wear a FRSM?

There is no direct legislative requirement for healthcare workers to wear a FRSM when delivering care, however, UK legislation does require employers to provide PPE that affords adequate protection against the risks associated with the task being undertaken. Healthcare workers have a responsibility to ensure that suitable PPE is worn correctly for the task being undertaken.

#### **(Mandatory)**

#### When should healthcare workers wear a FRSM?

Healthcare workers should wear a FRSM during any activities/procedures where there is a risk of blood, body fluids, secretions or excretions splashing or spraying onto their nose or mouth and when caring for a patient known or suspected to be infected with a microorganism spread by the droplet route.

**(AGREE rating: Recommend)**

A FRSM should be donned by healthcare workers before entry into the patient room/ area.

**(AGREE rating: Recommend)**

#### When should patients wear a FRSM?

If it can be tolerated, a FRSM may be worn by a patient known or suspected to be infected with a microorganism spread by the droplet route during patient transportation from one clinical area to another.

**(AGREE rating: Recommend)**

#### When should a visitor wear a FRSM?

The use of a FRSM may be offered to those visiting patients known or suspected to be infected with a microorganism spread by the droplet route; this should be based on a risk assessment by the clinical staff managing the patient.

**(Good Practice Point (GPP))**

#### When should a FRSM masks be removed/changed?

FRSMs 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))**

### 3. Discussion

#### 3.1 Implications for practice

The mucous membranes of the nose and mouth are susceptible entry points for infectious agents spread by the droplet route. A comprehensive review of the evidence for the protective effect of masks was conducted to inform recommendations for the 2007 CDC Guideline for Isolation Precautions. A more recent Cochrane systematic review of physical interventions to prevent the transmission of respiratory viruses (including isolation, quarantine, social distancing, hand hygiene and PPE) reported that use of FRSMs was the measure with the most consistent and comprehensive evidence of effectiveness.

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

A surgical mask is an item of PPE worn over the nose and mouth as a physical barrier to prevent droplets and splashes reaching the wearer's nose, mouth and respiratory tract.<sup>1</sup> Surgical masks do not provide protection against airborne (aerosol) particles and are not classified as respiratory protective devices. They are not regarded as respiratory protective equipment (RPE) under the European Directive 89/686/EEC (PPE Regulation 2002 SI 2002 No.1144).<sup>2</sup> Fluid repellent surgical masks can be worn as a physical barrier to prevent exposure to infectious agents transmissible by the droplet route.<sup>1</sup>

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.<sup>3;4</sup> 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 (FRSM).

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.<sup>5-9</sup>

**(Grade D recommendation)**

It has also been advised that FRSMs should be well fitting and fit for purpose, covering the mouth and nose in order to prevent venting (exhaled air 'escaping' at the sides of the mask).

5;7;10;11

**(Good Practice Point (GPP))**

**Are there legislative requirements for healthcare workers to wear a FRSM?**

In the UK, the Health and Safety at Work etc. Act (HSWA) requires a safe working environment and sets the precedence from which all other health and safety regulations follow. The Management of Health and Safety at Work Regulations (MHSWR) place the legal responsibility for health and safety primarily with the employer.<sup>12</sup>

Under Control of Substances Hazardous to Health (COSHH) Regulations, where it is not reasonably practicable to prevent exposure to a substance hazardous to health via elimination or substitution (as is the case where healthcare workers are caring for individuals known, or suspected, to be infected with a microorganism spread by the droplet route), then the hazard must be adequately controlled by "applying protection measures appropriate to the activity and consistent with the risk assessment".<sup>13</sup>

This includes the following controls listed in order of priority:

1. "The design and use of appropriate work processes, systems and engineering controls and the provision and use of suitable work equipment and materials.
2. The control of exposure at source, including adequate ventilation systems and appropriate organisational measures; and

3. Where adequate control of exposure cannot be achieved by other means, the provision of suitable personal protective equipment".<sup>13</sup>

COSHH requires that employees use the control measures provided, including PPE, appropriately. Therefore all reasonable steps should be undertaken by employers to make sure that control measures are used.<sup>13</sup>

There is no direct legislative requirement for healthcare workers to wear a FRSM when delivering care, however, UK legislation does require employers to provide PPE that affords adequate protection against the risks associated with the task being undertaken. Healthcare workers have a responsibility to ensure that suitable PPE is worn correctly for the task being undertaken.

### **(Mandatory)**

#### **When should healthcare workers wear a FRSM?**

As part of Standard Infection Control Precautions, healthcare workers should wear a FRSM during any activities/procedures where there is a risk of blood, body fluids, secretions or excretions splashing or spraying onto their nose or mouth. It has been recommended that healthcare workers should wear a FRSM when caring for a patient known, or suspected, to be infected with a microorganism spread by the droplet route.<sup>1;13</sup> Masks should be donned by healthcare workers upon entry into the patient room/area.<sup>1;13</sup>

### **(AGREE rating: Recommend)**

A FRSM should be donned by healthcare workers before entry into the patient room/area.

### **(AGREE rating: Recommend)**

NHSScotland have adopted the [Department of Health](#) formal recommendations on the use of RPE during an influenza pandemic; advising that all general ward staff, community, ambulance and social care staff should wear FRSMs for close patient contact (at least 3 feet (1 metre)).<sup>14</sup>

For additional information on respiratory protection equipment (RPE) see:

<http://www.nipcm.hps.scot.nhs.uk/documents/tbp-respiratory-protective-equipment-rpe/>

### **(Good Practice Point (GPP))**

**When should patients wear a FRSM?**

If it can be tolerated, a FRSM may be worn by a patient known or suspected to be infected with a microorganism spread by the droplet route during patient transportation from one clinical area to another.<sup>13</sup> Guidance published by WHO in 2008 expanded on this to include other patient settings/procedures (physical exam/triage; during general nursing care; and blood specimen collection) whilst noting that this recommendation depended on the patient's ability to tolerate wearing a mask.<sup>6</sup>

**(AGREE rating: Recommend)**

**When should a visitor wear a FRSM?**

There is very little scientific evidence on the use of PPE, including FRSMs, by visitors. It is therefore not possible to make evidence-based recommendations on this issue.

The use of a FRSM may be offered to those visiting patients known or suspected to be infected with a microorganism spread by the droplet route this should be based on a risk assessment by the clinical staff managing the patient

**(Good Practice Point (GPP))**

**When should a FRSM masks be removed/changed?**

It has been recommended that masks, when used, are changed after every patient contact or operation.<sup>3;4;8;15</sup> FRSMs should be changed if they become damaged, damp or contaminated.<sup>3-5;8;11;16</sup>

**(Good Practice Point (GPP))**

### 3.2 Implications for research

Further research to establish the effectiveness of FRSMs in protecting healthcare workers from infection would strengthen evidence-based recommendations on their use. The use of multiple infection control measures in addition to FRSM use makes it difficult to draw conclusions when examining research into the effectiveness of their use.<sup>17</sup>

Further research may be required to establish recommendations on the use of FRSMs by visitors and patients.<sup>17</sup>

Further research is required to confirm the role of continuous FRSM use in reducing nosocomial transmission of influenza.<sup>18</sup>

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## Appendix 1

<b><u>Standards pertaining to surgical face mask as PPE</u></b>			
<b>Standard</b>	<b>Title</b>	<b>Description</b>	<b>Publication date</b>
<b>BS EN 14683:2005</b>	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.
<b>ISO22609 : 2004 EDTN1 (R08)</b>	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.
<b>BS EN 13921:2007</b>	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.
<b>Statutory Instrument 2002 No. 1144</b>	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 <b>all</b> PPE is <b>CE marked</b> . 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](http://www.bsigroup.co.uk))

EN = European Standards (European Norm) produced by the European Committee for Standardisation ([www.cen.eu](http://www.cen.eu))

ISO = International Standards produced by the International Standards Organization ([www.iso.org](http://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.