NHS National Services Scotland

Standard Infection Control Precautions (SICPs) and Transmission Based Precautions (TBPs) literature review

Surgical Face Masks

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ARHAI Scotland
Antimicrobial Resistance and Healthcare Associated Infection

Key Information

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Description: This literature review examines the available professional literature on Surgical Face Masks in the healthcare setting.

Purpose: To inform the Standard Infection Control Precaution (SICP) and Transmission Based Precaution section on PPE (Surgical Face Masks) in the National Infection Prevention and Control Manual in order to facilitate the prevention and control of healthcare associated infections in NHS Scotland healthcare settings.

Target Audience: All NHS staff involved in the prevention and control of infection in NHSScotland.

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 2023

Cross reference: National Infection Prevention and Control Manual

Literature review on the use of eye/face protection for SICPs and TBPs

Literature review on the use of RPE

Literature review on the use of RPE for High Consequence Infectious Diseases

Update level: **Practice** – Transparent masks may be used to aid communication with patients in some situations, if conditions are met.

Research – No significant changes

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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
1.0	October 2020	Updated using 2 person systematic methodology with surgical masks SICP (V3.1 Feb 2020) and TBP (V2.0 Oct 2017) reviews and invasive spinal procedures SBAR (V1.0 Sept 2013) combined into one review.
2.0	January 2022	This review has been updated to include recommendations for the use of transparent surgical face masks in health and care settings. This change has followed an approval by the Commodities and Advisory Panel for NHS Scotland and confirmation that an available transparent mask meets the current UK standard, published by the Department of Health and Social Care.

Approvals

Version	Date Approved	Name	Job Title	Division
1.0	02 November 2020	Steering (Expert Advisory) Group for SICPs and TBPs		
2.0	23 December 2021	Susie Dodd	Nurse Consultant	Infection Control

Contents

1. Objectives

The aim is to review the extant scientific literature regarding surgical face mask use in health and care settings to inform evidence based recommendations for practice. The specific objectives of the review are to determine:

- Are there any legislative requirements for the use of surgical face masks as PPE for infection control purposes?
- What type of surgical mask is recommended for use for SICPs in health and care settings?
- What standards (BS/EN) must surgical face masks adhere to and what design features are desirable?
- When should health care workers wear a surgical mask for SICPs?
- When should patients wear a surgical mask for SICPs?
- When should surgical masks be removed/changed?
- How should surgical masks be donned?
- How should surgical masks be removed?
- How should surgical masks be disposed of?
- How should surgical masks be stored?
- Should eye/face protection be worn when wearing a surgical mask for SICPs?

The specific objective of the review, in terms of TBPs, are to determine:

- What type of surgical mask is recommended for use for TBPs in health and care settings?
- When should healthcare workers wear a surgical mask for TBPs?
- When should visitors wear a surgical mask for TBPs?
- When should patients wear a surgical mask for TBPs?

- Should eye/face protection be worn when wearing a surgical mask for TBPs?

NB:

- **Literature review on the use of eye/face protection for SICPs and TBPs**
- **Literature review on the use of RPE**
- **Literature review on the use of RPE for High Consequence Infectious Diseases**

2. Methodology

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

3. Discussion

3.1 Implications for practice: SICPs

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

There are no specific legislative requirements regarding the use of surgical masks as PPE or medical devices for infection control purposes, that is, to prevent the spread of healthcare associated infection. However, UK legislation does require employers to provide PPE that affords adequate protection against the risks associated with tasks being undertaken.[1] Employers have a responsibility to provide clear instruction and information on how to use provided PPE and healthcare workers (HCWs) have a responsibility to ensure that suitable PPE is worn correctly for the task being undertaken.[1] The wearing of PPE is covered by the Health and Safety at Work Act (1974)[2], Control of Substances Hazardous to Health 2002 (as amended) regulations[1], and the Personal Protective Equipment at Work Regulations 1992 (as amended)[3].

The Health and Safety at Work etc. Act 1974 is the generic health and safety legislation for the UK and broadly covers the use of PPE and risk, but is not health and care setting specific.[2] 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 infectious agents in the hospital environment and the use of appropriate PPE – for example the use of gloves to protect against blood borne viruses during venepuncture.[1] 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 health and care environment this could be the use of gloves to protect against glass fragments when cleaning up broken glass;[3] however, if the glass contained a laboratory sample then the activity would be covered by the Control of Substances Hazardous to Health.[1]

Under COSHH Regulations, where it is not reasonably practicable to prevent exposure to a substance hazardous to health via elimination or substitution then the hazard must be adequately controlled by “applying protection measures appropriate to the activity and consistent with the risk assessment”.[1]

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".[1]

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 NHS Scotland employees and patients.

There is slight contradiction in Health and Safety Executive literature on whether surgical masks are considered PPE, therefore bringing into question the applicability of the Health and Safety at Work Act (1974)[2], Control of Substances Hazardous to Health 2002 regulations[1], and the Personal Protective Equipment at Work Regulations 1992[3] in regards to surgical masks. One HSE site outlines that "whilst they will provide a physical barrier to large projected droplets, they do not provide full respiratory protection against smaller suspended droplets and aerosols [and as such] are not regarded as personal protective equipment (PPE) under the European Directive 89/686/EEC (PPE Regulation 2002 SI 2002 No. 1144)" [4] whilst another HSE source outlines that surgical masks "are not considered to be PPE when worn outside of healthcare activities".[5]

What type of surgical mask is recommended for use for SICPs in health and care settings?

In health and care settings, surgical masks may be worn for protection of the patient, for example, when worn by the operator to maintain surgical field sterility. A surgical mask used to protect the patient would be classed as a medical device. When worn as protection for the wearer, surgical masks are classed as personal protective equipment (PPE) and must be fluid resistant.

No standard definition of a surgical face mask was identified in the literature. A surgical mask is an item of PPE or medical device (depending on purpose of wear), worn over the nose and mouth as a physical barrier.[6-11]

Surgical masks must be 'CE' marked and compliant with Medical Device Directive (MDD/93/42/EEC) and the Personal Protective Equipment Regulations 2002.[1, 6-8, 12, 13]There appears to be a wide variation in the design of masks in use. It is recommended that surgical masks should be well fitting and fit for purpose,[1] covering the mouth and nose in order to prevent venting (exhaled air 'escaping' at the sides of the mask).[6-10]

Surgical masks which are worn as PPE or a medical device in health and care settings must be tested against the safety standard BS EN 14683:2019 this series of tests measures the performance of a surgical mask in bacterial filtration efficiency (BFE), breathing resistance and splash resistance. Type II and Type IIR surgical masks are both tested against this standard with them needing to meet a minimum BFE of 98%; however only Type IIR masks must pass the splash resistance test (synthetic blood projected at a given pressure) with a resistance of at least 16.0kPa. 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 14683:2019 splash resistance standard and which is not suitable for protection against splash or spray. A type I mask has a lower minimum BFE ($\geq$95%) than a type II mask and is not fluid resistant. The British Standards Institute indicate that, in the context of patient use during an epidemic or pandemic, a type I surgical mask may be of value in reducing the spread of infection, but indicate that a type I surgical mask is not recommended for HCW use, specifically in regards to maintenance of surgical field sterility.[14]

Further details on the standards relating to quality and performance of surgical masks are provided in Appendix 1.

Transparent face masks have been recommended by the Royal College of Speech and Language Therapy to aid communication with patients.[15] The Department of Health and Social Care recently developed a specification detailing the standards to which all transparent surgical face masks must adhere to be considered for use in UK health and care settings.[16] This specification permits transparent surgical face masks to be used in limited clinical settings. [16] There are currently few transparent face masks that meet the developed UK specification and only one that is approved by the Commodities and Advisory Panel for NHS Scotland. It is recommended that transparent surgical face masks may be used to aid communication with patients in some settings. Transparent face masks must; meet the specification standards of the Transparent Face Mask Specification (Department of Health and Social Care - July 2021) and have been approved (following submission for assessment against the standard) by the UK

Transparent Mask Review Group for use within health and social care settings.[16] Transparent face masks must only be worn in areas where Fluid Resistant Type IIR surgical face masks are used as personal protective equipment.

Fluid resistance

Multiple guidance documents outline that surgical masks should be worn when there is risk of blood or body fluid splashes to the face, but only one piece of UK guidance specifies that the mask, used for this purpose, must be fluid resistant.[10] Siegel et al state that a face visor which fully covers the face and its sides can be worn in place of a surgical mask and goggles when used for protection against splash and spray, however no evidence is cited for this recommendation.[17]

In eye protection standards BS EN 166 and BS EN 168 it is outlined that face visors can be tested to meet splash but not droplet, protection requirements.[18, 19] However, these standards are not specific to infection control within the health and care setting and are more suited to use within industrial work place environments. From interpretation of standards, face visors used in isolation may be appropriate for routine splash and spray, however, they are likely unsuitable for AGPs. Limited anecdotal evidence has shown contamination beneath face visors following aerosol generating dental procedures with addition of a fluorescent dye marker.[20]

It is logical to deduce that surgical masks, worn to protect the mouth and nose against blood and body fluid splashes, should be fluid resistant, however, it is unclear from the literature as to whether this feature is required of masks worn under different clinical circumstances, for example, a surgeon wearing a face mask to maintain surgical field sterility. Many guidance documents refer to face, surgical or medical masks worn as part of SICPs but do not stipulate specific filtration or fluid resistance criteria.[9, 11, 21-23]

A minor exception to this, however, is found within the 2014 UK Epic 3 National Evidence based Guidelines, where authors state that HCWs may use *"*standard fluid repellent masks to prevent respiratory droplets from the mouth or nose being expelled into the environment*"*, although this is not included in the formal recommendations.[10] It is instead emphasised that these fluid repellent surgical masks should be worn when splashing or spraying of body fluids is anticipated.[10] Other UK experts more broadly advise that fluid repellent surgical masks must be "used for protection against infection" which suggests a requirement for these types of masks in all infection prevention and control scenarios.[6, 7] The Association of Anaesthetists of Great Britain and Ireland (AAGBI) outline that generally SICPs involve use of a fluid resistant surgical

mask, however, in providing recommendations for maximal barrier precautions (e.g. for central venous catheter placement) they simply use the term 'mask'.[23] In summary, no literature or guidance clearly states or provides adequate evidence that fluid resistant surgical masks are needed for all surgical mask infection prevention and control purposes.

What standards (BS/EN) must surgical face masks adhere to and what design features are desirable?

Specific standards relating to surgical face masks are outlined in **Appendix 1** of this document.

When should healthcare workers wear a surgical mask for SICPs?

The rationale for the use of surgical mask as part of SICPs in health and care settings is twofold; to protect the wearer from sources of infection via splashing or spraying of body fluids (if fluid resistant), and to protect others from the wearer as a source of infection.[7-11, 17, 21-23]

As anticipated splashing and spraying of body fluids is implicit in the performance of aerosol generating procedures (AGPs), it is recommended that either of the following should be used for protection of the wearer; 1) a type IIR fluid resistant surgical mask with an integrated upper visor; **OR** 2) a type IIR fluid resistant surgical mask with goggles; **OR** 3) a full face visor with a type IIR fluid resistant surgical mask.[18-20] In guidance, this is considered a SICP for patients who **are not** suspected of being infected with an agent, for which respiratory protection is otherwise recommended.[7, 10, 17]

There is ongoing debate in the literature regarding the use of face masks by surgical teams to protect patients during surgical procedures.[24-27] However, these discursive papers do not consistently refer to a certain mask type. Only one paper specifically refers to a type IIR fluid resistant surgical mask.[24] 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.[28, 29]. Three studies were included in the Cochrane review, two of which did not outline mask type [30, 31] (with one stating that masks were not standardised for the study) and one of which cited use of three mask types via denotation of brand type.[32] Through online research it is evidence that two of

these masks were likely to be equivalent to a type IIR fluid resistant mask, but the paper is dated and manufacturing standards for these products may have changed.[32]

Despite the lack of evidence, there is a consensus of opinion in the literature that scrubbed members of the surgical team should routinely wear surgical masks during all surgical procedures for the protection of patients [9, 28, 33, 34] and that masks with fluid resistance are required for procedures where splash or spray of body fluids is anticipated.[10]

Opinion is divided on the use of surgical masks by non-scrubbed members of the surgical team for the protection of patients. Whilst some literature advocates the use of surgical masks by all members of the surgical team, whether scrubbed or non-scrubbed,[9, 33] conversely, there is support for the view that it is not necessary for non-scrubbed staff to wear masks[27] but this literature does not stipulate a specific mask type. A 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, however, reflecting other evidence, no mask type was given.[30] Although this trial lends support to the view that surgical masks are not necessary for non-scrubbed staff, the evidence overall is limited and there is no consensus on the issue.

Fluid resistant surgical 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.[6-8, 10]

Many case studies present findings which associate droplet contamination with microorganisms from the operator's nasopharynx/oropharynx with cases of meningitis following invasive spinal procedures such as myelography, lumbar puncture and spinal anaesthesia where operators did not use a face mask.[35-40]

In addition to the intra spinal injection cases described above, a case of intra-articular septic arthritis has been reported where the probable cause was identified as being non-mask use by the practitioner during injection administration.[41]

The US Association for Professionals in Infection Control and Epidemiology (APIC) advise that a 'mask' is used to contain respiratory droplets when preparing and injecting solution into an intracapsular space (joint), the spine and during lumbar puncture[42] whilst the Healthcare Infection Control Practices Advisory Committee (HICPAC) in association with the Centers for Disease Control and Prevention (CDC) advise that a 'facemask' be worn when placing a

catheter or injecting material into the epidural or subdural space.[43] Similarly, the Faculty of Pain Medicine of the Royal College of Anaesthetists outline that epidural catheter insertion must be performed with use of a 'mask'.[44]

It has been recommended that maximal sterile barrier precautions be employed when performing central venous access and guidance by Loveday et al. outlines that this includes the use of a 'mask'.[10]

The Association of Anaesthetists of Great Britain and Ireland (AAGBI) recommend maximal sterile barrier precautions for the performance of all invasive procedures on immunocompromised patients which they outline, includes use of a 'mask'.[23]

Although the infectious complication risk is believed to be low, the consequences are serious. It is therefore recommended that operators wear a type II or type IIR surgical mask when performing intra-articular (joint) injections[42], central venous access[10] and invasive spinal procedures such as myelography, lumbar puncture and spinal anaesthesia[23, 42-44] to minimise the risk of infection to patients.

Before and after studies identified a statistically significant drop in respiratory viral infection incidence amongst immunocompromised (oncology, bone marrow transplant and neonatal) patients following the introduction of a HCW and visitor surgical mask wearing policy, however it is unclear as to the types of mask that were used.[45, 46] Overall, limited evidence was identified to support the use of surgical masks by HCWs and visitors for the protection of immunocompromised patients.

It is recommended that transparent surgical face masks may be used in Scottish health and care settings to aid communication with patients in some settings. Transparent masks must; meet the specification standards of the Transparent Face Mask Specification (Department of Health and Social Care - July 2021) and have been approved by the UK Transparent Mask Review Group for use within health and social care settings.[16] Transparent face masks must only be worn in areas where Fluid Resistant Type IIR surgical face masks are used as personal protective equipment.

When should patients wear a surgical mask for SICPs?

One observational, before and after study showed a significant decrease in invasive pulmonary aspergillosis in both leukaemia and bone marrow transplant patients following introduction of 'surgical mask' wearing by patients upon being transported out with their rooms during periods of hospital construction.[47] Health Protection Scotland *Aspergillus spp.* guidance advises that during periods of construction/renovation, severely immunocompromised patients should wear surgical masks when outside of their rooms in order to reduce potential exposure to spores.[48] As a low cost intervention, type II or type IIR surgical masks may be considered a possible infection prevention and control measure on the rare occasion that immunocompromised patients such as leukaemia and bone marrow transplant patients need to be relocated within the hospital grounds during surrounding estates work.

Low level evidence was identified to support the use of surgical masks by patients being treated for epistaxis. Patients wearing surgical masks of unknown fluid resistance level appeared to reduce the number of blood splashes which projected onto the healthcare workers' face.[49]

When should surgical masks be removed/changed?

It has been recommended that surgical masks should be treated as a single use item and therefore changed after every patient contact or operation.[9, 27, 50-54] Surgical masks should be changed if they become damaged, damp or contaminated.[6, 7, 9, 22, 23, 27, 53-55]

How should surgical masks be donned?

Experts advise that the following steps be followed when donning a surgical mask;

1) hand hygiene should be performed before donning a mask;[56, 57]
2) examine the mask for holes and/or tears;[54, 57]
3) bring the top ties to the crown of the head and secure with a bow;[53, 54, 58, 59]
4) tie bottom ties at the nape of the neck and secure with a bow;[53, 54, 58, 59]

5) ensure the coloured side is facing outwards;[57]

6) mould the flexible nose piece/metal strip over the bridge of the nose;[53, 57, 58]

7) once covering the nose, extend to cover the mouth and chin making sure there are no gaps between the face and the mask;[53, 57-59]

8) do not touch the front of the mask once donned,[57] if this occurs, perform hand hygiene;[56]

9) do not wear the mask hanging around the neck.[9]

How should surgical masks be removed?

The front of surgical masks are considered to be contaminated after use.[10, 52] As such, it has been recommended that surgical masks are removed by handling only the side ties or elastic.[6, 7, 9, 23, 53, 54, 58] It has also been recommended that the bottom ties are broken/untied first, followed by the top ties.[6, 7, 53, 54, 58] For ear loop style surgical masks, the mask should be removed from the side with the head tilted forward.[54] It is frequently advised that surgical masks should be removed last in the doffing sequence.[10, 22, 53, 58, 60]

How should surgical masks be disposed of?

Surgical masks should be disposed of immediately after use as healthcare (including clinical) waste in accordance with local policy (See National Infection Prevention and Control Manual **'Safe Management of Waste'**).[6, 7, 53]

It is recommended that surgical masks are handled only by the ties/elastics when disposing.[9, 22, 23, 54]

Hand hygiene should be performed immediately after surgical mask disposal.[6, 7, 10, 58]

How should surgical masks be stored?

This review identified insufficient evidence on the correct storage of surgical masks to enable a graded recommendation to be made. However, it is recommended that surgical 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. Masks should ideally be stored out with patient rooms/zones.

Should eye/face protection be worn when wearing a surgical mask for SICPs?

When a type IIR fluid resistant surgical mask is required for protection against splashes or spraying of blood and body fluids, it is consistently recommended that eye/face protection is also required.[6-10, 17, 21, 22, 27]

If an employer provides eye/face protection to be worn with a fluid resistant surgical mask they must be compatible with one another and continue to be effective against the risk posed to the HCW.[3] Manufacturers' instructions will sometimes indicate which types of equipment are compatible with their product.[3]

For more information see the **eye/face protection literature review**.

3.2 Implications for practice: TBPs

What type of surgical mask is recommended for use for TBPs in health and care settings?

Surgical masks do not provide protection against airborne (aerosol) particles and are not classified as respiratory protective devices.[6-8, 54] They are not regarded as respiratory protective equipment (RPE) under the European Directive 89/686/EEC (PPE Regulation 2002 SI 2002 No.1144).[61]

UK and American guidance outlines that a surgical mask can be worn as a physical barrier to prevent exposure to infectious agents transmissible by the droplet route[10, 54, 62] whilst specific UK pandemic guidance stipulates that this mask should be fluid repellent.[53] TBP-specific WHO

and HICPAC guidance is unclear as to the type of mask required for use in health and care settings. The WHO refers to 'medical masks' which are categorised as either 'surgical' or 'procedural' masks[22] whilst Siegel et al use the term 'mask', 'surgical mask' and 'face mask' somewhat interchangeably. They highlight that two mask types are available for use in health and care settings: surgical masks that are cleared by the FDA and required to have fluid-resistant properties, and those referred to as 'procedure' or 'isolation' masks.[17] It is also emphasised that at the time of publication, no studies had been published comparing mask types to determine whether one mask type provided better protection than another.[17] As procedure or isolation masks are not regulated by the FDA, these masks may be more variable in terms of quality and performance.[17] In their formal recommendations, Siegel et al use the term 'mask' to describe facial protection worn as part of droplet precautions by HCWs and patients but 'surgical mask' when advising on the type of mask to be used by patients infected with airborne spread infections.[17]

Within the 2014 UK Epic 3 national evidence based guidelines, authors state that HCWs may use "standard fluid repellent masks to prevent respiratory droplets from the mouth or nose being expelled into the environment", although this is not included in the formal recommendations.[10] This may suggest that masks worn by symptomatic patients to prevent dissemination of infectious particles should be fluid resistant but this is based on interpretation and is not specifically outlined in any sources.

As previously outlined, surgical masks are designed and tested to provide a reduction in respiratory particles being expelled into the environment from the wearer, however, guidance consistently indicates that fluid resistant surgical masks also provide protection against droplets, splashes and/or sprays contacting the mucosa. The barrier limitations of fluid resistant surgical masks , in relation to droplet size, are not clearly outlined in the literature, however, the majority of low-quality trials, where surgical masks are compared to FFP2 respirators in the close proximity treatment of influenza patients, do not indicate inferiority.[63-66]

When should healthcare workers wear a surgical mask for TBPs?

If deemed to be required, surgical masks should be donned by HCWs before entry into the patient room/area.[17, 22]

Questions have been raised as to the effectiveness of surgical masks in preventing HCW infection during direct contact/treatment of a patient with droplet transmitted respiratory infection. *In vitro* studies demonstrate the superiority of FFP2 and FFP3 respirators compared to surgical masks in filtering aerosol particles,[63, 66, 67] however, in relation to the care of patients infected with droplet transmitted infectious agents (where the contribution of close range aerosol transmission remains unknown) superiority has not been reflected by the *in vivo* evidence base, where rates of HCW respiratory infection do not appear to be significantly different, dependent on mask type used.

A number of randomised clinical trials have been conducted to compare rates of respiratory infection among HCWs when treating patients infected with infectious agents spread via the droplet route; for example, influenza cases following the use of either a surgical mask or N95 respirator. Whilst some reported a statistically significant difference in efficacy of the N95 respirators versus surgical masks, [68] most did not, [63-65] or only found a difference under specific circumstances such as evaluation of an alternative outcome (droplet transmitted infection versus laboratory confirmed influenza) or continuous use of the respirator.[69, 70] The RCTs reviewed were all assessed as having a high risk of bias, ill-defined control arms, specificity regarding influenza and lack of applicability to UK health and care settings, especially as (excluding Radonovich et al' study which utilised type IIR masks[64]) types of masks could either not be established (e.g. type I, II or IIR) and were compared to N95 respirators (equivalent to FFP2 respirators) which are not recommended for use in UK health and care settings. Systematic reviews found no evidence to suggest that N95 respirators were superior to surgical masks when treating patients with droplet spread infections.[63, 66, 71] Systematic reviews assessed a range of studies with differing mask types, often considering them under the single banner of 'surgical' or 'medical' mask.[63, 66, 71, 72]

Studies often provide limited details on the types of masks used, making critical assessment challenging. There is currently insufficient *in vivo* evidence to establish whether FFP2 or 3 respirators are more effective than surgical masks in preventing (predominantly droplet transmitted) respiratory infection to HCWs in health and care settings. Guidance, however, consistently recommends that HCWs should wear a 'mask' or 'surgical mask' when caring for a patient known, or suspected, to be infected with a microorganism spread by the droplet route[10, 11, 17, 22, 54, 62] with one UK guidance document specifically outlining that this mask should be fluid resistant.[53]

The Department of Health provide formal recommendations on the use of facial and respiratory PPE during an influenza pandemic; advising that all general ward staff, community, ambulance and social care staff should wear type IIR fluid resistant surgical masks for close patient contact (at least 3 feet (1 metre)).[53] The Department of Health advise, however, that surgical masks are also recommended for use at all times in cohort areas for practical purposes.[73]

When should visitors wear a surgical mask for TBPs?

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

The use of a type IIR 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.[8, 43, 74, 75]

When should patients wear a surgical mask for TBPs?

If it can be tolerated, guidance recommends and weak evidence suggests, that a surgical mask may be worn by a patient known or suspected to be infected with a microorganism spread by the airborne or droplet route during patient transportation from one clinical area to another to reduce rates of onward transmission.[11, 17, 43, 53, 76] Guidance published by WHO in 2014 expanded on this to include scenarios where care for the patient is necessary outside of the isolation room or cohort area whilst noting that this recommendation depended on the patient's ability to tolerate wearing a 'medical' mask.[22] Further guidance regarding surgical mask wearing, by patients in communal areas, is seen in the Tuberculosis guidance produced by the National Centre for Health and Care Excellence (NICE).[77] NICE highlights the need for patients with pulmonary Tuberculosis to wear a 'surgical mask' when leaving their room and continue this practice until they have received a minimum of two weeks of treatment.[77] Guidance from the US goes further by advising that symptomatic patients be encouraged to wear a 'surgical mask', if tolerable, from the beginning of the health and care setting encounter.[17]

A systematic review with moderate bias was identified which presented the findings of three studies. Two controlled trials found type IIR masks to be effective in reducing aerosol *Pseudomonas aeruginosa* load produced by cystic fibrosis (CF) patients during coughing,

however, an RCT found no difference in exam room contamination rate with use of 'surgical masks'.[78] These are both indirect measures of *P. aeruginosa* transmission amongst CF patients.

Should eye/face protection be worn when wearing a surgical mask for TBPs?

In accordance with SICPs, when a type IIR fluid resistant surgical mask is required for protection against splashes or spraying of body fluids, eye/face protection should also be worn.

During close contact/caring for a patient infected with an infectious agent spread by the droplet route, spraying of secretions during coughing and/or sneezing may be anticipated, in which case, eye/face protection should be worn,[6-8, 22, 62]

For more information see the **eye/face protection literature review**.

3.3 Implications for research

Further research to establish the effectiveness of surgical masks in protecting HCWs from infection, specifically in relation to the treatment of patients infected with respiratory infectious agents, would strengthen evidence-based recommendations. The use of multiple infection control measures in addition to surgical mask use makes it difficult to draw conclusions when examining research into the effectiveness of their use. Further research may be required to establish recommendations on the use of surgical mask use by visitors and patients.

In their systematic review, Vincent and Edwards recommended that further research on this topic should be in the form of well-conducted randomised trials that aim to compare the effect of surgical mask use by surgical teams with non-use of surgical masks in relation to rates of surgical wound infection in patients.[28] They also recommend that a focus for further research should be on the use of disposable surgical masks by surgical teams compared with other forms of face protection such as visors and helmets for the protection of both patients and staff.[28]

Given the frequency with which surgical masks are routinely used across the health and care environment, further research should also seek to examine the use and efficacy of surgical masks in non-surgical settings by both HCWs and patients. Furthermore, there may be a need to clarify or expand existing legislation relating to the use of appropriate PPE in the health and

care setting. At present much of the legislation relates to the handling and management of dangerous substances and/or chemicals with no specific regulation for infectious agents in a non-laboratory clinical environment.

Additional robust evidence is needed to further clarify the infection and prevention control value of the following; the use of surgical masks by patients being treated for epistaxis, cystic fibrosis patients wearing surgical masks when in health and care settings, continuous versus targeted surgical mask use by HCWs during influenza season[79] and wearing surgical masks in settings where immunocompromised persons such as transplant patients and neonates are treated.

In line with guidance which advises wearing a fluid resistant surgical mask when splashes of body fluids are anticipated, UK guidelines for the prevention and control of group A streptococcal infection in acute healthcare and maternity settings recommend that FRSMs be worn for the operative debridement and/or changing of dressings of necrotising fasciitis.[74] Nosocomial droplet based transmission of group A streptococcal infection, from patient to HCW, appears to be rare but has been reported in the absence of facial protection.[80]

The COVID-19 pandemic response and associated PPE shortages led to increased scrutiny of surgical mask research and highlighted additional scientific questions. It is clear that further research is needed to determine the effects of extended use or reuse of surgical masks, the effectiveness of different mask types, the value of mask wearing by those who are at increased risk of infection and/or morbidity/mortality wearing masks and the potential benefit of multiple mask layers.

For all of the above, complimentary research on the types of surgical mask which should be used for different health and care purposes is needed in relation to filtration efficacy and fluid resistance.

4. Recommendations

This review makes the following recommendations based on an assessment of the extant scientific literature on surgical masks for SICPs and TBPs in the health and care setting.

4.1 Recommendations for standard infection control precautions (SICPs)

Are there any legislative requirements for the use of surgical face masks 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), Control of Substances Hazardous to Health (2002 as amended) regulations and Personal Protective Equipment at Work Regulations 1992 (as amended) legislate that employers (i.e. NHSScotland) must provide PPE which affords adequate protection against the risks associated with the task being undertaken and have a responsibility to provide adequate instruction and information on how to use said PPE. 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)

What type of surgical mask is recommended for use for SICPs in health and care settings?

Surgical masks should be well fitting and fit for purpose

(Mandatory)

Surgical masks should cover the mouth and nose in order to prevent venting (exhaled air 'escaping' at the sides of the mask.)

(Category B recommendation)

Surgical masks must be 'CE' marked and compliant with Medical Device Directive (MDD/93/42/EEC) and the Personal Protective Equipment Regulations 2002.

(Mandatory)

Fluid resistant surgical face masks (Type IIR) (with eye protection) should be used when splashing or spraying of blood and/or body fluids is anticipated.

(Category B recommendation)

A face visor which fully covers the face and sides may be used in place of goggles and a surgical mask when worn for protection against blood and/or body fluid splash and spray, out with AGPs.

(Category C recommendation)

Surgical masks worn by healthcare workers for procedures where blood and/or body fluid splash and spray is not anticipated e.g. aseptic procedures, should meet type II or type IIR standards.

(Category C recommendation)

Transparent face masks may be used to aid communication with patients in some settings. Transparent face masks must; meet the specification standards of the Transparent face mask specification (Department of Health and Social Care - July 2021) and have been approved by the UK Transparent Mask review group for use within health and social care settings and only be worn in areas where Fluid Resistant Type IIR surgical face masks are used as personal protective equipment.

(Mandatory)

What standards (BS/EN) must surgical face masks adhere to and what design features are desirable?

Specific standards relating to the quality and performance of masks are outlined in **Appendix 1**

(Mandatory)

When should healthcare workers wear a surgical mask for SICPs?

A type IIR fluid resistant surgical mask should 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.

(Category B recommendation)

A face visor that fully covers the front and sides of the face may be worn as an alternative to a type IIR fluid resistant surgical mask for protection against blood and/or body fluid splash and spray, out with AGPs.

(Category C recommendation)

A type IIR fluid resistant surgical mask with eye/face protection (goggles or a full face visor that fully covers the front and sides of the face) 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.

(Category B recommendation)

A type IIR fluid resistant surgical mask with eye/face protection should be worn by scrubbed members of the theatre surgical team during all surgical procedures.

(Category B recommendation)

A type IIR fluid resistant surgical mask with eye/face protection 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.

(Category B recommendation)

A type II or IIR surgical mask should be worn when performing intra-articular (joint) injections **(Category C recommendation)** central venous access and invasive spinal procedures such as myelography, lumbar puncture and spinal anaesthesia.

(Category B recommendation)

Transparent face masks may be used to aid communication with patients in some settings. Transparent face masks must; meet the specification standards of the Transparent face mask specification (Department of Health and Social Care - July 2021) and have been approved by the UK Transparent Mask review group for use within health and social care settings and only be worn in areas where Fluid Resistant Type IIR surgical face masks are used as personal protective equipment.

(Mandatory)

When should patients wear a surgical mask for SICPs?

Immunocompromised patients should wear a type II or type IIR surgical mask, if it can be tolerated, when out with their room during periods of construction and/or renovation.

(Category B recommendation)

When should a surgical mask be removed/changed?

Surgical 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.

(Category C recommendation)

How should surgical masks be donned?

Experts advise that the following steps be followed when donning a surgical mask;

1) hand hygiene should be performed before donning a mask;

2) examine the mask for holes and/or tears;

3) bring the top ties to the crown of the head and secure with a bow;

4) tie bottom ties at the nape of the neck and secure with a bow;

5) ensure the coloured side is facing outwards;

6) mould the flexible nose piece/metal strip over the bridge of the nose;

7) once covering the nose, extend to cover the mouth and chin making sure there are no gaps between your face and the mask;

8) do not touch the front of the mask once donned, if this occurs, perform hand hygiene;

9) do not wear the mask hanging around the neck.

(Category C recommendation)

How should surgical masks be removed?

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

(Category B recommendation)

The bottom ties should be broken/untied first, followed by the top ties. For an ‘ear loop’ style surgical mask, the mask should be removed from the side with the head tilted forward.

(Category C recommendation)

How should surgical masks be disposed of?

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

(Category C recommendation)

Surgical masks should be handled by only the ties/elastics when disposing

(Category B recommendation)

Hand hygiene must be performed immediately after surgical mask disposal

(Category B recommendation)

How should surgical masks be stored?

Surgical 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 surgical masks from contamination. Masks should ideally be stored out with patient rooms/zones.

(Category C recommendation)

Should eye/face protection be worn when wearing a surgical mask for SICPs?

Eye/face protection must be worn to protect the wearer based on a risk assessment and/or when splashing/spraying of blood and/or body fluids is anticipated.

(Category B recommendation)

If an employer provides eye/face protection to be worn with a fluid resistant type IIR surgical mask it must be compatible with the mask and continue to be effective against the risk posed to the healthcare worker.

(Mandatory)

For more detailed recommendations on when eye/face protection should be worn in line with SICPs please refer to the **Eye/face protection literature review**.

4.2 Recommendations for transmission based precautions (TBPs)

What type of surgical mask is recommended for use for TBPs in health and care settings?

A type IIR fluid resistant surgical mask should be worn when caring for a patient known or suspected to be infected with a microorganism spread by the droplet route

(Category C recommendation)

Surgical masks worn by patients infected with droplet or airborne respiratory infectious agents should meet type II or IIR standards

(Category C recommendation)

When should healthcare workers wear a surgical mask for TBPs?

Healthcare workers should wear a (type IIR fluid resistant surgical mask)* when caring for a patient known or suspected to be infected with a microorganism spread by the droplet route.

(Category B recommendation)

(*Category C recommendation)

A fluid resistant type IIR, worn in line with TBPs, should be donned by healthcare workers before entry into the patient room/ area.

(Category B recommendation)

When should visitors wear a surgical mask for TBPs?

A type IIR fluid resistant surgical mask 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.

(Category C recommendation)

When should patients wear a surgical mask for TBPs?

If it can be tolerated, (a type II or type IIR surgical mask)* may be worn by a patient known or suspected to be infected with a microorganism spread by the airborne or droplet route when leaving their room and/or during patient transportation from one clinical area to another.

(Category B recommendation)

(*Category C recommendation)

Should eye/face protection be worn when wearing a surgical mask for TBPs?

Eye/face protection must be worn to protect the wearer based on a risk assessment, when splashing/spraying of blood and/or body fluids is anticipated which includes anticipated spraying produced by patients coughing or sneezing.

(Category B recommendation)

For more detailed recommendations on when eye/face protection should be worn in line with TBPs please refer to the **Eye/face protection literature review**.

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Appendix 1: Standards pertaining to surgical face masks

Standard	Title	Description	Publication date
BS EN 14683:2019	Medical face 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.	March 2019
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.
UK Statutory Instrument 2002 No. 1144	Health and Safety – Personal Protective Equipment Regulations 2002	This instrument sets out the standards for PPE manufacture and supply in the UK. It sets out the standards for conformity across the UK (and the EU) and requires	May 2002.

Standard	Title	Description	Publication date
		that **all** PPE is **CE marked** in accordance with EU directive 89/686/EEC. This directive applies to PPE placed on the market before 21st April 2019. 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.	
UK Statutory Instrument 2018 No: 390	The Personal Protective Equipment (Enforcement) Regulations 2018	This instrument sets out the standards for PPE manufacture and supply in the UK. It sets out the standards for conformity across the UK (and the EU) and requires that all PPE is CE marked in accordance with EU regulations 2016/425. These regulations apply to PPE placed the market on or after 21st April 2018. 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.	April 2018
Medical Devices Directive (MDD/93/42/EEC)	COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices	Outlines requirements that must be met before a medical device can be placed on the European market. This directive is due to be replaced by the Medical Device Regulation (MDR) which was published May 2017, with a transitional period where	June 1993

Standard	Title	Description	Publication date
		elements of both pieces of legislation apply up to May 2025.	

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.

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. exp Masks/
2. mask?.mp.
3. surgical mask?.mp.
4. 1 or 2 or 3
5. exp infection/
6. exp Infection Control/
7. exp Cross Infection/
8. exp Disease Transmission, Infectious/
9. transmission based precaution?.mp. (203)
10. exp infectious disease transmission, patient-to-professional/
11. ((contact or airborne or droplet) and infection$).mp.
12. ((contact or airborne or droplet) and precaution$).mp.
13. barrier precautions.mp.
14. exp Patient Isolation/
15. exp Universal Precautions/
16. enteric precautions.mp.
17. source isolation.mp.
18. isolation precautions.mp.
19. strict isolation.mp.
20. 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19
21. 4 and 20

Limit 21 to English language