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

Purpose: To inform recommendations for 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 health and care settings.

Target audience: All staff involved in the prevention and control of infection in NHS Scotland.

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 2029.

Cross reference: National Infection Prevention and Control Manual:

- Literature Review on Transmission Based Precaution Definitions
- Literature Review on the use of Respiratory Protective Equipment (RPE)
- Literature Review on the use of Eye/Face Protection
- Literature Reviews on Hand Hygiene

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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
2.0	03 August 2026	Scheduled update (includes evidence published from 2019-2024). The SICP- and TBP-focused surgical face mask research questions were combined into one main question set. Addition of research question 2 ‘what is a surgical face mask’.
1.1	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.
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.

Approvals

Version	Date Approved	Name
1.0	02 November 2020	Steering (Expert Advisory) Group for SICPs and TBPs
1.1	23 December 2021	ARHAI Scotland
2.0	April 2026	National Policies Evidence and Guidance (NPGE) Working Group, Care Home Infection Prevention and Control Group (CHIPC), Extraordinary Transmission-based Precautions (TBP) Definitions Working Group (research question 5 only).

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1. Objectives

The aim is to review the extant scientific literature regarding the use of surgical face masks in health and care settings to inform evidence-based recommendations for practice. The specific research questions are provided below:

- What legislative requirements or standards must surgical face masks adhere to for infection control purposes?
- What is a surgical face mask?
- What type of surgical face masks are recommended for health and care settings?
- What design features are desirable for surgical face masks?
- When should health and care workers wear a surgical face mask?
- When should patients/service users of health and care facilities wear a surgical face mask?
- When should visitors of health and care facilities wear a surgical face mask?
- When is eye/face protection required in addition to a surgical face mask?
- When should surgical face masks be removed/changed?
- Where and how should surgical face masks be donned/put on?
- Where and how should surgical face masks be doffed/taken off?
- How should surgical face masks be disposed of?
- How should surgical face masks be stored?

2. Methodology

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

A search was conducted in July 2022 to identify evidence published between October 2019 and June 2022. An additional top up search was conducted to identify evidence from 2022 to September 2024. This review therefore captures relevant evidence published between October 2019 and September 2024. A supplementary search was conducted in Medline and Embase for evidence which specifically compared mask types (that is respirators to surgical face masks) to ensure this research was also identified. The search strategies are detailed in Appendix 5. The search results are detailed in a PRISMA diagram in Appendix 1, adapted from Moher et al (2009).[1]

Definitions for grades of evidence are provided in Appendix 2.

Additional exclusion criteria were applied for this review, in addition to those listed within the NIPCM Development Process.

Studies were excluded if they:

- made no attempt to link infection cases (for example clear epidemiological link and molecular typing)
- focused on modelling
- focused on validating a novel method or assessed the efficacy of a novel mask (for example snorkel mask)
- reported the overall risk of infection only (for example reproduction number or were questionnaire-based)
- did not confirm positive cases (for example based on clinical symptoms only)
- did not attempt to monitor or observe or record mask use

- focused on occupational health impacts of surgical face mask use, including, acne or other impacts of mask use

Consultation of research question 5 and its associated draft recommendations and good practice points was undertaken via the Extraordinary transmission-based precautions (TBP) definitions Working Group during development of the TBP Definitions literature review. All other research questions underwent consultation via the National Policies Guidance and Evidence (NPGE) Working Group and the Care Home Infection Prevention and Control Group (CHIPC).

3. Discussion

3.1 Implications for practice

3.1.1 What legislative requirements or standards must surgical face masks adhere to for infection control purposes?

Nine documents were included to answer this question; four documents graded SIGN 50 level 4 expert opinion[2-5] and five legislation/regulations graded as mandatory.[6-10] Five sources were carried over from the previous version of this review,[5-8] including one that has been updated.[2] Four documents were included as part of this update.[4, 9-11]

There are no specific legislative requirements regarding the use of surgical face masks as personal protective equipment (PPE) for infection control purposes. The general use and provision of PPE in the health and care setting is covered by the UK Health and Safety at Work etc. Act (1974),[6] the Control of Substances Hazardous to Health 2002 Regulations (as amended) (COSHH),[7] the Personal Protective Equipment at Work (Amendment) Regulations 2022 (PPER),[8] and the EU Directive 2016/425 for PPE at work 2018.[9]

In the UK, the Health and Safety at Work Act 1974 is the generic health and safety legislation relating to occupational health at work.[6] This legislation is not healthcare specific and does not explicitly discuss the use of PPE but is relevant to the provision of PPE within health and care settings. More specific regulations are provided by COSHH, which describes the requirements to protect employees from substances hazardous to health within the workplace, including the use of PPE;[7] it can be applied in conjunction with the Health and Safety at Work Act 1974.[6] This legislation is not specific to but applicable to the health and care setting.[6, 7] The PPER 2022 provides regulations that outline employers' and employees' duties regarding PPE.[8]

Under COSHH Regulations (as amended), 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".[7] This includes, in

order of priority, a) appropriate design, processes, systems and engineering controls, b) control of substance at source ("including adequate ventilation systems and appropriate organisational measures") and finally c) personal protective equipment.[7] The COSHH regulations define PPE as "all equipment (including clothing) which is intended to be worn or held by a person at work and which protects that person against one or more risks to their health, and any addition or accessory designed to meet that objective" (Regulation 2).[7] This would appear to cover surgical face masks when worn to protect from hazards to health such as exposure to infectious materials, including from the splash and spray of blood and body fluids. Similarly, within the 2022 update of the UK PPER an interpretation of the definition of PPE is provided as follows: "personal protective equipment, unless the context requires otherwise, means all equipment (including clothing affording protection against the weather) which is intended to be worn or held by a person at work and which protects the person against one or more risks to that person's health and safety, and any addition or accessory designed to meet that objective".[8] This definition would align to the intended purpose of surgical face masks when worn as a device protecting the wearer from external hazards such as infectious agents and the splashing or spraying of blood or body fluids. The amended regulations highlight that employers must provide suitable PPE to their employees, if there are risks that cannot be eliminated as part of their work.[8]

There is some uncertainty in extant guidance regarding the status of surgical face masks as PPE, therefore bringing into question the applicability of the Health and Safety at Work Act, some aspects of the COSHH Regulations, and PPER.[6-8] The UK PPER and the accompanying approved code of practice (ACOP) guidance by the UK Health and Safety Executive (HSE) do not explicitly state whether a surgical face mask is considered as PPE.[4, 8] The updated EU Directive 2016/425 for PPE at work 2018 does not list surgical face masks or similar within their list of PPE to which to the regulation does not apply (Article 2, Scope).[9] Within this directive PPE is defined as "equipment designed and manufactured to be worn or held by a person for protection against one or more risks to that person's health or safety" (Article 3, Definitions).[9] This definition would appear to apply to surgical masks when worn for personal protection.

The UK Health Security Agency (UKHSA), in 2023 guidance, outlines the regulatory status of face masks in which they describe surgical face masks as a medical device when worn for protection of patients by health or care workers.[3] When worn for wearer protection, a surgical face mask is described as follows: “regulated as personal protective equipment and need to meet the regulations that cover PPE products (EU Directive, MHRA, 2023). They will need an EU Notified Body/UK Approved Body to verify the relevant requirements are met”.[3] Therefore according to UKHSA, surgical face masks can be defined as PPE when worn as protection for the wearer, for example for protection from splash and spray of blood and body fluids.

Surgical face masks are described as a medical device, including when worn as source control.[3, 10] They are considered by UKHSA as ‘Class 1 Medical Devices’ meaning they should meet associated standards or regulations.[3, 10] British Standards (BS) refer to surgical face masks as assisting the reduction of spread of infection when worn by a patient or other persons, as source control.[2] Similarly, the United States (US) Occupational Health and Safety Administration (OSHA) outlines that masks provide protection to others as they may “trap large particles of body fluids that may contain bacteria or viruses expelled by the wearer”.[5]

As stated, the broad definitions provided by the UK PPER and UK HSE do appear to cover surgical face masks when used in an infection prevention and control (IPC) capacity as they may afford protection to both staff and patients.[4, 8] Clarity on the definition of surgical face masks and PPE from legislative bodies may support in understanding the applicability of the legislation pertaining to surgical face masks when being used in health and care facilities as personal protection.

The British Standards Institute (BSI) BS EN 14683:2025 medical mask standards detail the requirements and test methods that surgical face masks must adhere to in order to be suitable for use within UK settings.[2] One of several requirements for surgical face masks is appropriate bacterial filtration efficiency (BFE). The test procedure, which is outlined in Annex B of the standard, provides the *in vitro* test requirements to measure surgical face mask BFE. It specifies that *Staphylococcus aureus* should be used to measure BFE, whereby ‘aerosolised’ (“0,65 µm” to “7,00µm” and maintained at “3,0 µm ± 0,3 µm”) particles should be passed through a mask and collected, through a vacuum, within an impactor to calculate a percentage

of colony forming units. While the standard appears to consider source control (particles passing from inside of the mask to the outside, emulating a mask worn by a person emitting infectious particles) as the norm, the standard does state that manufacturers should provide details of which side of the mask was facing the challenge bacteria. However, there is no guidance provided as to how the results should be interpreted should manufacturers differ in the mask side they expose to bacterial particles. As such, the afforded protection, source control or both, of masks meeting this standard is unclear and could differ. No evidence base was provided for these test methods or the other requirements detailed in this standard. The membership of the British Standards for surgical face masks committee and methods used to design these standards is not well described within this publication.[2] Therefore, it is not clear how the requirements were developed, and it has been graded SIGN 50 level 4 expert opinion evidence.

Summary

In summary, surgical face masks appear compatible with the definition of PPE provided within the UK PPER 2022, the COSHH Regulations and EU Directive. Consequently, the use of surgical face masks, when used as protection, should adhere to UK PPER, COSHH and the Health and Safety at Work etc. Act 1974 regulations. British Standards that are relevant for surgical face masks are intended for use in Scottish health and care settings. See appendix 3 for more details about standards for surgical face masks.

3.1.2 What is a surgical face mask?

Five expert opinion evidence sources (all graded SIGN 50 level 4),[2, 3, 5, 12, 13] and one guideline document graded as AGREE II 'recommend with provisos' were included.[14] This question was added as an update to this review therefore there was no evidence included from previous versions of this review for this question.

The literature refers interchangeably to medical, surgical and procedure face masks when discussing 'surgical' face masks. The difference, if any, between these is not consistently described. However, there is some consistency across the literature that a surgical face mask is a single use[12] device consisting of multiple layers of fabric,[2] fitted closely to the face,[2] with a flat or pleated design with straps (elastic loops or

ties) which are secured via the head, ears or both[2, 13] to cover the nose and mouth.[2, 12, 14]

A surgical face mask is described as both a medical device[2, 3, 5, 14] and/or as protection for the wearer [3, 5, 14] providing a physical barrier covering the nose and mouth which is closely fitted to the face.

Summary

There is consistency across the literature that within health and care settings surgical face masks are a close-fitting, disposable/single-use, multi-layered fabric device, with ear loops or ties. They are described as providing a physical barrier to cover the nose and mouth.

3.1.3 What type of surgical face masks are recommended for health and care settings?

Fourteen evidence sources are included for this research question. Eight of these[2, 14-20] were included in version 1.0 of this review and six [4, 8, 13, 21-23] were identified as part of this update. Two guideline documents were graded AGREE II 'recommend with provisos',[14, 16] one UK regulation (PPER) was graded 'mandatory'.[8] One British Standard was graded SIGN 50 level 4 expert opinion.[2] The remaining literature (n= 10) is guidance generated by expert opinion and was graded SIGN 50 level 4.[2, 4, 13, 15, 17-23] No primary research was included for this topic.

Seven of the guidance documents were published for UK health and care settings.[4, 8, 14, 15, 19-21] Level 4 evidence is potentially subject to bias as there is often a lack of supporting evidence and an unclear methodology for formulating the guidance. The British Standards and UK PPER are applicable to Scottish health and care settings. However, the membership of the British Standards for surgical face masks committee and method used to design these standards is not well described within this publication.[2]

There is variation in the design of surgical face masks used and recommended for health and care settings. Two main features are bacterial filtration efficiency (BFE) and fluid resistance.

Bacterial filtration

British Standard BS EN 14683:2025 provides details about surgical face masks worn as protection or as a medical device.[2] According to these standards there are three types of surgical face mask that may be appropriate for Scottish health and care settings; Type I, Type II and fluid resistant surgical face masks.[2] Type I and Type II surgical face masks are so named based on their bacterial filtration efficiency (BFE), with Type II providing increased filtration efficiency compared to Type I (98% versus 95% BFE, retrospectively). However, it is stated in Annex E that future revisions of this standard do not intend to refer to Type I surgical face masks.

Fluid resistance

According to the British standards, in addition to bacterial filtration efficiency, surgical face masks are also identifiable by the level of fluid resistance.[2] An 'R' added to the name, for instance 'Type IIR', signifies the masks' capability to resist penetration by fluids in accordance with splash resistance testing, for example a minimum resistance of 16.0 pascals (Pa) is required by the standards.[2] 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 be used to describe a mask that does not meet the BS EN 14683:2025 splash resistance standard and which is not suitable for protection against splash or spray. The British Standards Institute (BSI) indicate that a Type I surgical face mask should only be used for patients and other persons as source control particularly in epidemic or pandemic situations, and not during surgical procedures for source control (and presumably for protection against splash and spray although this is not explicitly stated).[2]

As discussed below, there is inconsistency in extant guidance regarding the requirement for masks worn by health and care workers (HCWs) to be fluid resistant, and this is in part due to the indications for use.

For source control, the 2014 UK Epic 3 National Evidence-based Guidelines (graded AGREE II 'recommend with provisos') 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 within the formal

recommendations and is therefore considered as expert opinion.[14] The guideline recommends fluid repellent surgical masks when splashing or spraying of body fluids is anticipated.[14] This is echoed by the UK guidance for adult social care IPC which specify Type IIR (fluid resistant) surgical masks be used where worn for protection against splash and spray of blood or body fluids.[21]

The Association of Anaesthetists of Great Britain and Ireland (AAGBI) outline that a fluid resistant surgical face mask should be used for all patients as part of standard precautions.[19]

New Zealand guidance on mask use, published 2021, advises fluid resistance for surgical face masks worn when caring for patients with an acute respiratory tract infection and 'droplet precautions', as well as for all surgical procedures where there is a risk of blood and body fluid splash.[23] Masks without fluid resistance are stated as suitable for source control. Both types (fluid resistant and non-fluid resistant) are stated as appropriate for preventing passage of microbes from the nose/mouth of a HCW into the sterile field during procedures. This document states that the New Zealand Standard for masks complies with the British and European Standard 14683:2019 (Type I, II and IIR).[23]

The WHO AGREE II 'recommend with provisos' IPC guideline for pandemic prone ARI refers to 'medical masks' which are categorised as either 'surgical' or 'procedural' masks; although different standards are provided as examples, clear minimum standards are not provided.[16] However, within the 2023 WHO COVID-19 mask guidance, it is advised that 'medical' masks be fluid resistant and meet EN 14683 as Type II or Type IIR or equivalent technical standards.[13]

Four guidance do not state a specific level of protection or fluid resistance.[15, 17, 18, 20] This includes guidance published in 2007, and updated in 2024, by HICPAC and CDC that highlights that two mask types are available for use in healthcare settings, surgical masks that are cleared by the U.S. Food and Drug Administration (FDA) and are required to have fluid-resistant properties, and masks referred to as 'procedure' or 'isolation' masks (unregulated by FDA).[17] In their formal recommendations, HICPAC 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. The differences in protection provided by fluid resistant masks and unregulated isolation/procedure masks are not addressed.

Legislation

The mandatory UK PPER 2002 states that “suitable” PPE providing adequate protection must be provided.[8] Further, that the employer should “ensure that an assessment is made to determine whether the personal protective equipment they intend will be provided is suitable”.[4] The UK HSE approved code of practice (SIGN 50 level 4), regarding the PPER, states “to choose PPE which gives maximum protection while ensuring minimum discomfort”.[4] This suggests that where a surgical face mask is used, it should have the highest protection factor available, while considering the discomfort to the wearer, which would be a Type II or IIR surgical face mask as per British Standard BS EN 14683:2025.

Transparent masks

A Canadian technical specification recommends that transparent surgical face masks may be worn in health and care settings where they may benefit communication or facial recognition.[22] In 2023 the UK withdrew their 2021 transparent mask specification suggesting that surgical masks of all types must meet the required regulations, legislation and standards as expected for non-transparent masks.[24]

The BSI medical mask standards refer to transparent masks within Annex F of the 2025 revision.[2] The document states that transparent masks support communication and that minimum requirements of these masks are still evolving; they are envisaged to provide similar performance as outlined in the standard but some minor modifications to test methods may be considered. This suggests that transparent face masks should meet the specification outlined within the BS EN 14683:2025.

Please note that face masks with integrated eye protection will be covered within the next update to the ARHAI Scotland Eye/Face Protection literature review, where appropriate.

Summary

There were no high-quality primary research studies identified to allow comparison of different mask types based on fluid resistance, transparency or bacterial filtration efficiency. The literature reviewed is primarily based on expert opinion and does not provide high-quality evidence regarding what constitutes a 'best' mask for all specific care activities or settings. The UK HSE guidance recommends that the highest level of protection should be afforded and is therefore indicative that a Type IIR surgical face mask be the preferred choice. However, the legislation states the protection level should be 'suitable', suggesting there may be instances where a Type II mask may be considered, if deemed as suitable.

3.1.4 What design features are desirable for surgical face masks?

Four documents were included for this research question.[2, 22, 25, 26] Three of these are graded SIGN 50 level 4: one British standard,[2] and two guidance documents published by the WHO (2020)[25] and the Government of Canada (2021).[22]
A controlled exhalation study (graded SIGN 50 level 3) was also included. [26] Three evidence sources were identified in the current update, [22, 25, 26] and one was included in version 1.0 of this review.

The BSI suggest that anti-fog functions may be relevant for some settings.[2] The BSI also highlight that a surgical face mask should be close fitting to the face and that this fit may be enhanced with an integrated nose clip/wire which contours the mask around the nose.[2] One observational study which included 54 healthy volunteers highlighted that surgical face masks with a nose clip/wire provided significantly better protection (inward leakage rate) compared to when a nose clip/wire was not used.[26] However, as a fixed experimental study the findings may have limited applicability, and based on a small sample the study may also have limited generalisability. It is also unclear if the mask described was fluid resistant.

In addition to features such as good breathability, particle filtration and fluid resistance the WHO recommend that masks be clearly labelled as to which are the inner and outer surfaces.[25]

Transparent face masks are described as having a transparent area (usually plastic) as well as other design features such as a foam strip or other material to facilitate close fitting to the wearers face.[22]

The use of loops or ties as a preferred method to secure a surgical face mask and in relation to IPC is not well addressed within the literature. The UK HSE published a safety notice regarding the use of respiratory protective equipment (RPE, respirators) which have ear loops as they were not considered to "provide protection as tightly fitting RPE".[27] This safety notice is not applicable to surgical face masks which do not require to form a tight seal or have formal fit checks and assessments. However, it may indicate possible differences in the type of ties used and the associated close fit of a surgical face mask. This may be a useful area for undertaking future research.

Summary

There is limited evidence available for assessment. Several design features are described within the literature, including nose clips/wire, anti-fog capabilities, foam strips, transparency, loops and ties. One primary study considered the efficacy of surgical face masks with or without nose clips, but no conclusions can be drawn based on this study alone. The remaining evidence graded as SIGN 50 level 4 did not assess the effectiveness of any design features.

3.1.5 When should health and care workers (HCW) wear a surgical face mask?

Forty-one evidence sources were included to address this question.[12-19, 21, 23, 28-58] This includes 13 from the previous iteration (version 1.0),[14-20, 40-43, 45, 46] and 28 new evidence sources included in this update.[12, 13, 21, 23, 28-39, 47-58]

The countries/ continents where the studies were conducted, or in which the guidance applies, include Australia (n=3),[12, 33, 52] Canada (n=1),[32] New Zealand (n=3),[23, 31, 47]Europe (n=2),[29, 30] international (WHO) (n=4),[13, 16, 41, 49] Japan (n=2),[51, 54] UK (n=11),[14, 15, 19-21, 35, 37, 42, 43, 45, 48]and the US (n=15).[17, 18, 28, 34, 36, 38-40, 46, 50, 53, 55-58]

Nine experimental or observational studies were graded SIGN 50 level 3.[50-58] Four guidelines were graded AGREE II 'recommend with provisos'.[14, 16, 48, 49] Twenty-eight documents were graded as SIGN 50 level 4 expert opinion.[12, 13, 15, 17-19, 21, 23, 28-47]

Furthermore, 14 studies were excluded due to their methodological limitations. This includes four randomised controlled trials (RCTs)[59-62] and ten systematic reviews with meta-analysis.[63-72] As per the NIPCM Development Process, studies graded SIGN 50 level 1- or 2- are excluded.

The following sections consider 'when' a surgical face mask should be considered for use by health and care workers.

Protection against splash and spray

Two guidelines, graded as AGREE II 'recommend with provisos', outline that surgical face masks should be used where there is a risk of splash or spray of blood and body fluids.[14, 16] One of these documents is specific to 'pandemic-prone' or epidemic acute respiratory infections (WHO, 2014) while the other is specific to hospital settings (Loveday et al., 2014).[14] While these documents include some details of a literature review, they generally included low quality research studies involving bundled approaches, studies with a high risk of bias and/or those focused on community settings. There is consistency across seven SIGN 50 level 4 guidance that, if there is anticipated splashing or spraying of blood or body fluids during the provision of care, a surgical face mask should be worn as a barrier for the protection of the wearer.[12, 15, 17, 18, 21, 34, 73]

Use to maintain a sterile field

There is uncertainty in the literature regarding the effectiveness of surgical face masks when worn by surgical teams to maintain a sterile field during surgical procedures. The mask is being worn to prevent exhaled breath and other debris shed from the face (hair, skin cells) from entering the surgical field/ wound. It is expected that surgical site infection (SSI) rates may be reduced if a mask is worn. However, there is a paucity of evidence to confirm this. Use of surgical masks during surgery is a long-established practice; conducting a study whereby masks are removed might be met with resistance among clinicians and patient groups and may explain the lack of research in this area. It may also have ethical considerations.

A Cochrane systematic review on the use of face masks by surgical teams during clean surgery was unable to draw substantive conclusions on whether use of face masks had an impact on rates of SSI, due to limited evidence.[74] The most recent update of the review included only three studies, all with a high risk of bias (which met the exclusion criteria for this review).

Despite this limited evidence base, extant guidance published by the WHO, the CDC, and the Association of Anaesthetics of Great Britain and Ireland (AAGBI) recommends that scrubbed surgical team members should wear a surgical mask to protect the surgical field.[17, 18, 48] Coia et al. suggested that a risk assessment may be appropriate in identifying possible requirements or appropriateness for surgical face mask use, for example within surgical settings or during surgical procedures.[15] This literature was published nearly 10 years ago and may not fully reflect current health and care expert opinion or practice. The Healthcare Infection Society (HIS) and the European Society of Clinical Microbiology and Infectious Disease (ESCMID) rituals and behaviours in the operating theatre guidance for the UK was updated in 2023 and recommends that surgical masks should be worn by all staff in the operating room, in accordance with local polices.[48] This suggests that this may differ dependant on local requirements. This was based primarily on expert opinion and the opinion of public/ patient representatives who indicated a preference for masks in this setting. The recommendations related to masks being worn in operating theatres are therefore considered as expert opinion despite the document being graded as AGREE II 'recommend with provisos' overall.

Guidance from the AAGBI does not clearly differentiate between scrubbed or non-scrubbed staff.[19] However, the HIS/ESCMID theatre guidance states that all staff working in the operating room should wear a surgical face mask in accordance with local policy.[48] Therefore, it is assumed this would apply to non-scrubbed staff, unless advised by local policy. While this guidance was graded as AGREE II 'recommend with provisos', this recommendation was based primarily on expert opinion.[48] This guideline suggests that, where it aligns with local policy, both scrubbed and non-scrubbed staff should wear a surgical mask. Overall, the evidence is limited.

Several studies with a high risk of bias (that were of low quality and met the exclusion criteria for this review and were therefore excluded) present findings which

associate contamination of 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 wear a face mask.[75-80] In addition to the intra spinal injection cases described above, a case of intra-articular septic arthritis had been reported with the hypothesized cause being identified as related to the practitioner having not worn a face mask.[81]

The use of a surgical face mask during invasive procedures is advised across three guidelines graded as AGREE II 'recommend with provisos'[14, 48, 49] and five grey literature sources.[19, 28, 40, 42, 73] This appears to apply both to maintaining a sterile field and to protecting the wearer from splash and spray of blood or body fluids. 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.[40] Both the CDC and UK Faculty of Pain Medicine advise that a 'facemask' or 'mask' be worn during procedures such as injecting into the epidural or subdural space and epidural catheter insertion.[42, 73] Mask use is also recommended as part of an appropriate PPE ensemble while conducting sterile procedures, including central venous catheters, by WHO, epic3 (AGREE II 'recommend with provisos')[14, 49] and SHEA/APIC.[28] The Association of Anaesthetists of Great Britain and Ireland (AAGBI) also recommend mask use during maximal sterile barrier precautions for the performance of all invasive procedures on immunocompromised patients.[19] Three guidance documents advise surgical face mask use for invasive spinal procedures such as myelography, lumbar puncture and spinal anaesthesia to minimise the risk of infection to patients.[19, 40, 73]

In summary, there is consistency within three SIGN 50 level 4 graded literature, and one AGREE II 'recommend with provisos' guideline, that a surgical face mask should be worn by scrubbed surgical team members. The use of surgical face masks by non-scrubbed team members is less certain. However, one SIGN 50 level 4 graded guidance document and one AGREE II 'recommend with provisos' grade guidelines did not clearly differentiate between scrubbed and non-scrubbed team members suggesting that they too should wear a mask where it aligns with local policy. Extant guidance primarily based on expert opinion recommends that surgical face masks

should be worn for preparation and performing invasive procedures including intra-articular (joint) injections, peripheral and central venous access, invasive spinal procedures such as myelography, lumbar puncture and spinal anaesthesia.

Use as source control for respiratory infections

Surgical face masks are also presented as a method to protect others from the wearer (when the wearer is a possible source of respiratory infection), to provide source control within eight experimental research studies, graded as SIGN 50 level 3,[50-53, 55-58] and in six SIGN 50 level 4 guidance documents.[15, 18, 29, 32, 37, 39]

Eight experimental research studies (SIGN 50 level 3), assessed the effectiveness of surgical face masks as a form of source control.[82-88] This evidence is also relevant to settings where a patient or visitor may be required to wear a surgical face mask for source control purposes. These studies assess the ability of surgical face masks to reduce particle emission during real or simulated respiratory activities. Three of the eight studies included human participants[50, 85, 88] and five conducted experiments with manikins.[51, 53, 55, 56, 86] Of the experimental studies, two included healthy volunteers who undertook respiratory activities while wearing a mask, for example, breathing, talking and coughing.[85, 88] As expected, face masks reduced particle emission rates during these activities. Of note, sample sizes were small and statistical power unclear. Factors such as the number of people in the room, impact of room ventilation, humidity and temperature are unclear. These factors may impact the applicability of the results of these studies which are specific to the fixed setting of the experiments. One controlled study included individuals who had confirmed SARS-CoV-2 infection.[50] Within the fixed experimental conditions of this study, a surgical face mask provided statistically significant reductions in the measured emitted particles (74% [95%CI: 65-81%] reduction in viral load) during respiratory activities (breathing, speaking) compared to no mask. However, only 44 participants were included in this analysis (with variable age, gender, vaccination status and variant of SARS-CoV-2) reducing generalisability and reliability of the results.
A manikin-based study tested surgical face masks as a form of source control in a simulated negative pressure room (12 air changes per hour) during simulated tidal breathing and coughing.[53] The receiver manikin exposure was significantly reduced when the source manikin wore a surgical face mask at a 3-foot (91.44cm) distance.

These findings are limited by simulated airflow patterns (from a source to a receiver only), and varied humidity (33-58%). In a second manikin study, when compared to a no mask control, a surgical face mask worn by a source manikin was associated with a significant reduction in detectable RNA and viral titres (VeroE6/TMPRSS2 (JCRB1819) SARS-Cov-2 viral cells) at a no masked 'receiver' manikin head, 50cm away.[51] Two further manikin studies utilised a similar experiment design and demonstrated that in a simulated environment with 6 air changes per hour and manikin spaced approximately 3-foot apart (91.44cm), a surgical face mask worn by the source significantly reduced exposure at the receiver.[55, 86] However, the specific *p* values, indicating significance, were not provided. It is also unclear whether results were due to a reduction in particles, a disruption to air flow or another factor and this requires further investigation. In the fifth experimental manikin study, a surgical face mask worn by a manikin as source control blocked 58.5% of the simulated cough aerosols produced; this was a significant reduction ($P < 0.001$) compared to no mask.[56] Together these studies provide evidence of the mechanistic efficacy of surgical face masks in reducing respiratory expulsions from the source.

In summary, the eight controlled experimental studies show that, when compared to no mask, a surgical face mask worn by a source is associated with an observed reduction in the measured exposure at the receiver or emitted particles during respiratory activities. The results are interpreted with caution due to the limitations of these studies and the paucity of evidence from real-life settings regarding any potential impact on transmission rates. Extant expert opinion guidance supports the use of surgical masks as a source control measure in health and care settings.

Protection against respiratory infection

Surgical face masks have historically been worn by healthcare workers for protection against respiratory infection when providing direct patient care. Four experimental studies (SIGN 50 level 3) were included that assessed the effectiveness of face masks for this purpose (versus no mask).[51, 54, 55, 58] Nine guidance documents (SIGN 50 level 4) and one guideline (AGREE II 'recommend with provisos') discuss their use for this purpose.[12, 16, 17, 20, 31, 33, 34, 43, 45, 46] Four excluded RCTs and ten excluded systematic reviews are discussed for information.

Experimental Studies

Four experimental manikin or simulation studies (SIGN 50 level 3) modelled an interaction between a source (emitting nebulised particles) not wearing a mask and receiver (inhaling particles) wearing a mask.[51, 54, 55, 58] In the first study, when compared to a no mask control, a surgical face mask was associated with a significant reduction in detectable nebulised viral particles (in this case VeroE6/ TMPRSS2 (JCRB1819) SARS-Cov-2 viral cells) penetrating the mask when secured (reportedly according to manufacturer instructions) to a 'receiver' manikin head at 50cm distance but not in viral titer.[51] When both the receiver and source wore a mask both detectable RNA and viral titres were reported as being significantly reduced compared to no mask. This study had several limitations including that it was unclear if the surgical mask used was equivalent to a Type IIR fluid resistant surgical face mask, the confidence intervals were not provided, and only 3 repetitions were undertaken. The setting is specific to a relative humidity of 60-65% with 23-25°C temperature. In the second study, a significant reduction in RNA copies was reported when using a surgical face mask (with BFE $\geq$98%) within a novel vacuum pump system during the use of electric ultrasonic scalpels on pellets infected with HeLa-ACE2-TMPRSS2 and HCoV-229E cells.[54] During this study, the surgical face mask was attached to the vacuum system and therefore may not reflect the natural fit when worn by a person. The room/ setting was not clearly described and the ventilation, temperature and humidity (which may impact particle behaviour) were unclear. Within these two *in vitro* study settings surgical face masks were effective when compared to no mask. However, the results are limited to the fixed conditions of the experiment, and the wider limitations of these studies should also be considered.

In contrast, two experimental manikin studies with a similar methodology demonstrated no significant reduction in artificially generated particle exposure when a surgical face mask (meeting Type II standards) was used by the receiver.[55, 58] However, a significant reduction was observed when the mask was worn by both the source and the receiver. It should be noted that in both studies, there was a lack of certainty regarding statistical power, the number of sample repetitions, variable humidity and temperature as well as uncertain applicability given the simulated

airflow and particle generation which may not reflect natural human breathing. The differences in experimental setup, including size and type of nebulised particles expelled, flow rate, temperature, humidity and distance from source are likely to impact the results of such experimental studies. Briefly, in the above two studies, surgical masks and unsealed N95 respirators had comparable results when compared to a no mask control. Only a mask sealed to the manikin with Vaseline performed better than a surgical mask alone suggesting the influence of an artificial seal rather than the mask type used.

The manikin studies also compared surgical face masks to RPE, the results of these comparisons are discussed within the NIPCM RPE Literature Review. It is difficult to ascertain any conclusions from these four experimental studies which differ in their experimental setup and had mixed results. More high-quality research is required to better understand the effectiveness of surgical face masks across health and care settings.

Extant guidance

Extant guidance (eight SIGN 50 level 4 guidance, one AGREE II 'recommend with provisos' guideline)[16] is consistent in advising that HCWs should wear a 'mask' or 'surgical mask' when caring for a patient known, or suspected, to be infected with a microorganism historically classified as spread by the 'droplet' route,[12, 16, 17, 20, 31, 33, 34, 43, 46] or specifically for respiratory infections such as influenza.[45] The CDC guidance and the WHO guideline include an evidence base which consists of a limited evidence review with some systematic methods described.[16, 17] The remaining guidance documents did not provide sufficient detail about how the evidence referenced within their guidance was identified and appraised for the development of mask recommendations. The US AORN 2019 guidance did not provide a clear methodology.[34]

At the time of writing, it is an established practice that surgical face masks are worn by HCWs where "droplet" precautions are required. The droplet/airborne dichotomy is considered within the updated version of the NIPCM Transmission Based Precautions Definitions Literature Review. Briefly, the definition of 'droplet' differs

across the literature and similar terms can be used with lack of a clear definition, including large droplet,[18, 89] respiratory droplet, and respiratory aerosol.[16, 17, 46]

The UK Scientific Advisory Group for Emergencies (SAGE) published an evidence summary regarding the effectiveness of PPE for reducing SARS-CoV-2 transmission in health and social care settings.[35] In this they suggested 'medical masks' offer 30-50% protection from particles which meet their definition of an aerosol. The references included in the document were unclear and not systematically identified. Generally, the reference to 'droplets' and definitions provided across literature were not based on evidence or not based on high-quality evidence.[16-18, 89] The WHO provide a small number of references in their 2014 guidance when discussing 'droplets' including a limited experimental study, another WHO (2009) guidance on TB, and a textbook written by Wenzel et al (2003).[16] For their surgical mask recommendations, the 2014 WHO guidance references a range of evidence, however, clear search strategies were not detailed nor were specific results for any systematic review of surgical face mask literature. The extent to which a previous iteration of the Cochrane review published by Jefferson et al was used (in addition to or instead of other evidence) to inform recommendations is also unclear in that document.

Overall, the percentage level of protection across the identified grey literature was not well-supported by high quality evidence, with variable definitions of 'droplets' and the risk they pose, and an unclear risk level to indicate when a mask should be worn.

Excluded studies

There were 14 studies that had some relevance for this research question but were excluded due to risk of bias. This includes four RCTs,[59-62] and 10 systematic reviews with meta-analysis.[63-72] As per the NIPCM Development Process, studies graded as SIGN 50 level 1- or 2- are excluded. These studies have been included within this discussion section for transparency but will not be used to inform recommendations or good practice points.

For laboratory-confirmed influenza as an outcome measure, none of the excluded RCTs reported a statistically significant difference when an N95 respirator (near-equivalence to FFP2 respirators) was compared to a surgical face mask,[59, 61, 62] or

only found a difference under specific circumstances, including the evaluation of the continuous use of the respirator.[60] The RCTs reviewed were all assessed as having a high risk of bias and ill-defined control arms, specifically regarding influenza. Of further note (excluding Radonovich et al' study which utilised type IIR masks)[60] the types of masks could either not be established (for instance type I, II or IIR) and were being compared to N95 respirators, which are not currently recommended for use in UK health and care settings (see Literature review on the use of RPE).

A recently updated Cochrane systematic review with meta-analysis considered surgical face masks and N95 respirators.[63] While Cochrane reviews are considered the gold standard in terms of methodological rigour, the review was downgraded to SIGN 50 level 1- based on the limitations of the included studies. The above four excluded RCTs were included in pooled analysis in the meta-analysis as well as studies by Ide et al, Jacobs et al, and MacIntyre et al; all of which were considered eligible for exclusion from this review. The results provide wide estimates which Cochrane concluded provides 'low certainty' of a non-significant difference in the efficacy in preventing HCW acquiring an influenza-like illness between the mask-wearing and non-mask wearing group. A further pooled analysis for the four aforementioned excluded RCTs demonstrated non-significant differences for clinically diagnosed influenza, influenza-like-illness or laboratory confirmed influenza ($p > 0.05$) between the surgical mask and respirator wearers.[59-62] There were an additional seven systematic reviews with meta-analysis that were excluded, these also considered the same four excluded RCTs in pooled analyses with or without other studies. These reviews reported that the considered surgical masks were associated with comparable risk of HCWs acquiring laboratory-confirmed influenzas or laboratory-confirmed viral respiratory infections when compared to an N95 respirator.[64, 65, 67, 69-72] It would appear from these studies that in real-world settings, where confounders cannot be controlled, the masks (RPE or medical mask) did not perform significantly differently in terms of reducing infection rates. These studies demonstrate the high risk of bias that is prevalent in this research field. The challenges of conducting an RCT, with a low risk of bias, on this topic considering the ethics and uncontrollable confounders, should be acknowledged. For example, it would be unethical to have a no mask control group if standard practice would currently recommend mask use within the trial settings. It is also difficult to establish

with any accuracy the exact transmission route which led to infection in a healthcare worker (acknowledging that acquisition may have occurred outside of the workplace or not whilst providing patient care).

Summary

Surgical face masks have historically been used as part of the traditionally termed 'droplet' precautions. The few experimental studies included indicate that the tested masks provide a varied protective effect. However, these results are specific to the fixed experimental conditions and may not be extrapolatable to real-world Scottish health and care settings. The studies are unable to demonstrate the true protective effect of a surgical mask to prevent onward transmission of respiratory infections. Therefore, conclusions cannot be made based on these limited experimental studies. Despite a general lack of high-quality evidence, extant guidance on mask use is consistent in advising that surgical face masks are worn by health and care staff where there is a risk of respiratory infection exposure or transmission.

Extended use

The UK Department of Health provide recommendations on the use of a fluid repellent surgical mask during an influenza pandemic, advising that all general ward staff, community, ambulance and social care staff should wear fluid resistant surgical face masks when within 3 feet (1 metre) from a source with symptoms.[20, 45] It is also advised that surgical masks should be used at all times in cohort areas for practical purposes (inclusive of non-clinical staff).[45] There is no clarity about the evidence (if any) used to formulate these recommendations. The membership of the guidance development groups is unclear and there is limited detail about consultation with experts or external stakeholders.

The SARS-CoV-2 pandemic raised the profile of the arguments both for and against the use of surgical face masks by health and care staff as a preventative measure against respiratory infection. At times during the COVID-19 pandemic, surgical mask use was recommended for HCWs providing direct care and other clinical and non-clinical staff across care pathways, including in non-patient care areas - with a few exceptions or when wearing RPE.[29] Scottish Government guidance recommended that health and care workers wear a Type IIR surgical face mask for the duration of

their shift as part of the SARS-CoV-2 pandemic 'extended mask use' recommendations for health and care settings. This was consistent with the directorate letter (DL) published by the Chief Nursing Officer in August 2022. The guidance was withdrawn on 16 May 2023 following a DL published by the Chief Nursing Officer on 9 May 2023. This DL aligned with guidance from UKHSA, DHSC, NHS Wales, and Public Health Agency Northern Ireland. Pandemic SARS-CoV-2 guidance was often rapidly produced with unclear processes for developing recommendations and unsystematic methods or no provision of methods to identify the included evidence.

Guidance by international organisations regarding SARS-CoV-2,[13, 32, 39] or more generally for respiratory infections, including SARS-CoV-2,[30, 47] published more recently (2023 onwards) continues to recommend extended mask use for source control and/or during a cluster/outbreak or high local prevalence, following a risk assessment, and/ or based on HCW or facility preferences. Guidance from Canada, New Zealand and the CDC advises consideration of epidemiological factors (increasing community transmission/ higher prevalence periods, facility outbreaks, increasing hospitalisations/ICU admissions, increasing staff cases) and clinical factors (presence of high-risk/immunocompromised persons (cancer/transplant/ dialysis patients), working in high transmission risk units for example emergency departments, open space critical care areas, oncology units, outbreak wards, medical/ surgical assessment units) when risk assessing the need for extended mask use.[32, 39, 47] Health New Zealand advises mask use at all times in units known to have a suboptimal physical environment (including ventilation), when caring for patients requiring respiratory TBPs.[47] COVID-19 guidance from the WHO advises "targeted continuous medical masking" for HCWs in health-care facilities when there is "minimum to moderate" impact of COVID-19 on the health system. This covers situations where there have been no known transmission in the preceding 28 days (minimum), and also situations where there is moderative impact on the health system and additional measures may be required to reduce transmission.[13] This recommendation was graded 'strong' but with very low certainty supporting evidence.

In summary, universal, extended or prolonged use of surgical face masks was consistently recommended in international and national expert opinion guidance during the SARS-CoV-2 pandemic. More recent extant guidance continues to recommend extended or prolonged use of surgical face masks to some extent based on an assessment of the risk, for example based on an increase of cases of infection in a facility or increasing levels being indicated within the wider community. The intention of this enhanced IPC measure has been in reducing the risk of respiratory infection exposure and transmission. The evidence underpinning this approach is limited.

Personal preference

Extant guidance from Health New Zealand advises that HCWs can choose to wear a surgical face mask based 'on their own health needs and risks for more severe respiratory infection'.[47]

CDC SARS-CoV-2 guidance (2024) also states HCW preference for use of a surgical face mask "informed by their perceived level of risk for infection based on their recent activities (e.g. attending crowded indoor gatherings with poor ventilation) and their potential for developing severe disease if they are exposed".[39]

3.1.6 When should patients/service users of health and care facilities wear a surgical face mask?

Twenty-four pieces of evidence were included for this research question; six were included in the previous iteration (version 1.0),[16-18, 20, 45, 90] of this review and 18 were added as part of this update. [2, 12, 13, 29, 31, 32, 34, CDC, 2022, 37, 39, 50-53, 55-58, 73] Eight were experimental studies which considered simulated mask use with non-mask use, all graded as level 3 according to SIGN 50 methodology.[50-53, 55-58] Two guidelines were graded AGREE II 'recommend with provisos'.[16, 90] Twelve guidance documents and one British standard[2] were graded SIGN 50 level 4 expert opinion.[12, 13, 17, 18, 20, 29, 31, 32, 34, 37, 39, 45, 73] The evidence included for this research question was produced for the following countries: Australia;[12, 52] New Zealand,[31] Canada;[32] International/Europe;[13, 16, 29] Japan;[51] UK,[2, 20, 37, 45, 90] and America. [17, 18, 34, 39, 50, 53, 55-58, 73]

Use as source control

The use of surgical face masks by patients to prevent onward transmission of infections via expelled infectious particles, for example during coughing or sneezing, has been a focus of eight experimental simulation studies (SIGN 50 level 3). Refer to, 'When should HCW wear a surgical face mask?' for more details on these studies. While these studies may lack applicability and generalisability to real life health and care settings, they indicate that there may be some benefit of mask wearing as a form of source control when compared to no mask in fixed experimental conditions. [50-53, 55, 56, 58]

Briefly, one of these studies showed a significant reduction ($P < 0.05$) in viral RNA (42%) and viral titre (24%) following nebulised SARS-CoV-2 virus propagated in VeroE6 cells (5.5 ± 0.2 µm in mass median diameter) through a manikin wearing a surgical face mask (fluid resistance unknown), 50cm from a receiver manikin.[51] Three studies highlighted that there was a significant reduction in maximum exposure when a manikin was at 3-foot (91.44cm) distance from a source.[53, 55, 58] Similarly, Lindsley et al (2021) demonstrated that air particle mass was significantly lower (-299 [-361, -237], $p < .001$**)** for simulated coughs when a source manikin wore a fluid resistant surgical face mask compared to no mask.[56] Across the experimental studies, the sampling time ranged from 8 to 20-minutes which may not be reflective of the actual wear times experienced in health and care settings. When healthy human participants completed respiratory activities with or without a surgical face mask (reported as ≥98% BFE, equivalent to Type II) such as breathing,[57] talking,[52, 57] shouting,[52] forced respiration,[52] and coughing,[52, 57] surgical mask use was associated with a significant reduction in mean amount,[52]or rate,[57] of exhaled particles ($P < 0.05$). These experimental studies are limited as they include small samples of healthy persons or manikin simulations, and which are specific to the fixed experimental settings in which they are conducted (humidity, air changes etc). However, together they provide evidence of the mechanistic efficacy of surgical face masks in reducing respiratory expulsions at the source. The conclusions of these studies should be interpreted with caution and awareness that differing infectious/non-infectious agents, air flow patterns, air change rates, symptoms of participants, humidity conditions and room temperatures could produce different results. There remains a lack of high-quality evidence in the form of clinical trials that

assess the effectiveness of surgical face masks however, it must be acknowledged that designing such studies is highly challenging.

British Standard BS EN 14683:2025 states that Type I surgical face masks should only be used for patients (and other persons) to reduce the risk of transmission of infections 'particularly in epidemic or pandemic situations'.[2] Extant guidance is consistent in advising that a surgical face mask may be worn by a patient, where tolerated, to prevent the onward spread of infections including from patients with a known or suspected respiratory infection,[31, 32, 34, 39, 90] and/or where the patient is exhibiting symptoms suggestive of a respiratory infection (such as sneezing or coughing).[16, 17, 20, 29, 31, 34, 39, 45, 73] 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.[90] However, this guideline (graded AGREE II 'recommend with provisos') is specific to TB and may not apply otherwise. Guidance from the CDC advises that symptomatic patients be encouraged to wear a 'surgical mask', if tolerable, from the beginning of the health and care setting encounter.[17] Generally, the guidance that supports patient use of surgical masks as source control was based on expert consensus, [12, 17, 73] and/ or contained primary evidence but provided limited or no details of the methods used to identify and/or appraise this evidence. Seven of these guidance documents were specific to epidemic/pandemic scenarios.[13, 20, 29, 32, 37, 39, 45] One guideline, graded AGREE II 'Recommend with provisos', had limited evidence related to mask efficacy and was reliant on expert opinion; the WHO (2014) guidelines recommend that as part of cough etiquette, persons with symptoms of a respiratory infection should cover their nose/ mouth with a medical mask (or a cloth mask, hand, elbow) and this is labelled as a strong recommendation based on "very low quality of evidence".[16] The references included alongside this recommendation were limited. Two were community-based studies (France et al, 2010; Lau et al., 2010); another was the aforementioned Cochrane review by Jefferson[91] (2011 iteration, SIGN 50 level 1-); one was an experimental study published in 1966 (Couch et al, 1966); one was a limited experimental study (Johnson et al, 2009) and the remaining study appears to be a meeting abstract (Dharmadhikari et al., 2011).

Extant guidance graded as SIGN 50 level 4 highlights that patients should be encouraged to wear a surgical face mask during movement outside of their room,[31] or during transfers/ transport where they are suspected or confirmed to have a respiratory infection,[12, 13, 16, 17, 34, 39, 45] including during ambulatory care.[20] The 2014 WHO guidance (AGREE II recommend with provisos) for 'pandemic-prone' illnesses also supports encouraging patients to wear face masks during transfers/ transport.[16]

In conclusion, extant guidance advises that individuals who have a known or suspected respiratory infection should wear a surgical face mask, if it can be tolerated, and if it does not compromise their clinical care. This may include during transfers between or through departments. As the evidence was largely based on limited quality, fixed-condition, experimental studies, the true level of protection afforded to others when infectious individuals wear a surgical face mask in the health and care environment remains uncertain.

Extended/prolonged use

Extended or prolonged use of a surgical face mask is advised within four SIGN 50 level 4 guidance and one AGREE II 'recommend with provisos' guideline.[13, 16, 29, 32, 39]

A universal or extended masking approach (mask wearing for all patients during health care encounters) was recommended by many international health organisations including ECDC,[29] during the SARS-CoV-2 pandemic. Three organisations more recent publications continue to recommend this for periods of high community transmission of SARS-CoV-2 and other respiratory infections or after risk assessment.[13, 32, 39] The evidence which underpins universal mask use is unclear within most of these documents and is based largely on expert opinion. In current WHO SARS-CoV-2 guidance, the recommendation for universal masking in stations where there is significant impact on the health system is noted as being 'strong' but based on very low certainty evidence.[13]

A guideline for epidemic or 'pandemic-prone' acute respiratory infections published by WHO in 2014 states that mask use by patients (if tolerated) should include scenarios where provision of care is undertaken outside of their isolation room or cohort area.[16]

3.1.7 When should visitors of health and care facilities wear a surgical face mask?

In total, 21 documents were included which considered the use of surgical face masks by visitors. Five were included within the previous iteration (version 1.0) of this review,[17, 43, 45, 73, 92] and sixteen were included as part of the update. [13, 29, 32, 34, 39, 47, 48, 50-53, 55-58, 73] Twelve documents were graded SIGN 50 level 4 expert opinion.[13, 17, 29, 32, 34, 37, 39, 43, 45, 47, 73, 92] One guideline was graded AGREE II 'recommend with provisos'.[48] Eight experimental studies, graded as SIGN 50 level 3, were included which considered mask efficacy as a form of personal protection, source control or both. Two of these studies included healthy volunteers,[52, 57] one included SARS-CoV-2 positive persons [50] and five included manikins. [51, 53, 55, 56, 58] None of the configurations featured in the studies were specific to visitor use of masks. Across the studies it was evident that surgical face masks may provide some efficacy as source control compared to no masks. However, due to the fixed and specific experimental conditions (room size, ventilation, humidity, temperature, particle type/size) of each of these studies they may lack applicability and generalisability to health and care settings. The impact of these conditions on the behaviour of particles and therefore the performance of the mask is unclear, and this may limit the extent to which these studies can assist in understanding visitor surgical mask use. Some general limitations across the studies included small sample size, or use of manikins with controlled or one-way air flow which does not represent human interactions where both persons are inhaling/ exhaling.

Personal protection

Eight experimental studies (SIGN 50 level 3) were consistent in demonstrating the effectiveness of a face mask as a form of source control compared to no mask, within varied fixed experimental conditions.[50-53, 55-58] However, this was not specific to visitors and was set to the fixed experimental condition of the individual studies which included either healthy volunteers,[52, 57] volunteers with a positive SARS-CoV-2 sample[50] or manikins.[51, 53, 55, 56, 58]

Four expert opinion guidance (SIGN 50 level 4) documents advise the use of surgical face masks for visitors for personal protection against respiratory infection or droplet spread respiratory infection.[34, 43, 45, 92] This guidance generally refers to

respiratory infections spread by the 'droplet' route, the definition of droplet was based on expert opinion at the time, was unclear or referred to transmission of infection by particle sizes >5µm. The UK Department of Health pandemic influenza guidance recommend visitors wear a surgical mask when in cohort areas.[45]

Specifically, the AORN suggest that where droplet precautions (defined as where a patient has a known or suspected infection spread by respiratory droplets, >5µm) are required, visitors may be encouraged to wear a face mask while in the patient's room. [34] Steer et al and SHEA note that there may be occasions for mask use by visitors where patients are being cared for in acute settings with 'droplet' precautions, in situ, but without clarification for the definition of droplet.[43, 92] Whereas HICPAC/CDC highlight that mask use may be appropriate where visitors and patients/service users have symptoms of respiratory infection.[73] However, in the CDC's guidance for isolation precautions it is stated that there is limited evidence for mask use by visitors and no recommendation is made.[17]

Source control

Evidence on effectiveness of mask use for source control is inconsistent: two experimental studies suggest that masks may significantly reduce exposure for a mask wearer.[51, 54] However, in two studies there was minimal reduction in exposure at the receiver manikin except for N95 respirators sealed with Vaseline.[55, 58] These studies have several limitations and are unable to provide evidence regarding the absolute transmission risk with or without surgical masks. Furthermore, none are specific to visitors or mask use by visitors.

Mask use by visitors for source control, for the prevention of respiratory transmission, and to protect surgical patients, is advised by the CDC[73] and HIS guidance for operating theatres respectively.[48] The latter guideline is graded AGREE II 'recommend with modifications' however the good practice point was created by the HIS expert working group as a precautionary measure in the absence of evidence, noting that PPE may not be necessary from an IPC perspective.

Extended use

Expert-opinion including guidance from public health organisations ECDC, WHO, and CDC highlight that during periods of high SARS-CoV-2 transmission,[13, 29, 32, 37, 39] or high transmission of other respiratory viruses,[47] visitors in health and care facilities should be encouraged to wear a surgical face mask. Three guidance documents suggest that visitors to health and care facilities wear a mask for the duration of their stay.[29, 37, 47] This is considered as an enhanced IPC measure.

The sixth update of the ECDC COVID-19 IPC preparedness guidance, published in 2021, clearly indicates that for acute settings visitors should wear a 'medical face mask' (non-medical masks were considered as appropriate if in line with local recommendations) where physical distancing is not possible.[29] Within inpatient areas it is further recommended that medical masks be worn by visitors for the duration of their stay.[29] The CDC, WHO, Canada (SARS-CoV-2 guidance) and Health New Zealand (respiratory virus guidance) recommend that where community or cluster transmission is high, or where there is significant impact on the health system, universal use of surgical face masks by visitors should be considered.[13, 32, 39, 47] Health New Zealand extends this to winter months where prevalence may be higher, recommending mask use at this time when visiting settings with vulnerable patients or residents (immunocompromised individuals, for example those in cancer and transplant units, dialysis units, especially if "units [are] known to have suboptimal physical environment (including ventilation)".[47] Whereas UK SAGE (2021) indicated in a 2021 SARS-CoV-2 report that if clinically appropriate "face masks/coverings" should be worn by visitors "at all times".[37]

The Scottish Government (2022) no longer has specific policy regarding extended face mask use: associated SARS-CoV-2 guidance was withdrawn in May 2023. This previously recommended that visitors who are not medically exempt wear a fluid resistant surgical face mask if it can be tolerated and a face covering, if not, for the duration they are in the facility.

Summary

In summary, there is a lack of high-quality research which focuses on surgical mask use by visitors attending health and care settings. While possible benefits of mask use for both protection and source control may apply to visitors it is not well evidenced in which circumstance masks would or would not be appropriate. Extant expert-opinion guidance advises that surgical face masks may be offered to visitors based on an assessment of transmission risk and when they are visiting patients with a suspected or known respiratory infection. For enhanced surgical face mask use by visitors it is not always clear in the aforementioned guidance if the purpose of this was source control, personal protection, or both. The guidance regarding the enhanced use of a surgical mask is primarily focused on SARS-CoV-2 pandemic scenarios and the methodology for forming this guidance was limited. Despite this limitation, there is some consistency across the included SIGN 50 level 4 guidance that visitor use of surgical face masks may be an appropriate enhanced IPC measure for times of high community or cluster transmission of SARS-CoV-2.

3.1.8 When is eye-face protection required in addition to a surgical face mask?

For information on the use of eye/face protection, see the NIPCM Eye/Face Protection Literature Review.

3.1.9 When should surgical face masks be removed/changed?

Eighteen evidence sources were included: two guidelines graded AGREE II 'recommend with provisos',[16, 48] fifteen guidance graded as SIGN 50 level 4 expert-opinion, [12, 13, 15, 19-21, 29, 34, 39, 45, 73, 93-96] and one British Standard also graded SIGN 50 level 4 expert opinion.[2] No primary research of sufficient quality was included. Five sources were included in the previous iteration of this review (version 1.0),[15, 16, 20, 45, 48] and the remaining twelve were added as part of the current update.[12, 13, 19, 21, 29, 34, 39, 73, 93-96] Of these, one was created for/by organisations within Australia;[12] three Canada;[94-96] four international/ European,[13, 16, 29, 93] seven UK,[2, 15, 19-21, 45, 48] and three US.[34, 39, 73] The guidance which was not produced for a UK or Scottish health and care setting may have reduced applicability where health systems differ

significantly. Furthermore, some of the included guidance was published 10-15 years ago which may limit applicability to health and care settings in Scotland today, for example based on the possible advancement in healthcare and the evidence-base, impact and learning during the SARS-CoV-2 pandemic.[15, 16, 20, 45]

Mask condition as an indication

There was consistency across the literature that a surgical face mask should be removed/ changed when it becomes contaminated, soiled, damaged or wet/damp.[12, 15, 19, 21, 34] This is also recommended in SARS-CoV-2 guidance and pandemic ARI/ influenza guidance where extended or prolonged face mask use is advised.[13, 16, 20, 29, 39, 45, 93-96]

Completion of a task as an indication

Two guidance documents advise that surgical face masks should be removed/ changed after completion of a patient care task[73] or an episode of care.[21] The British Standard 14683:2025 advises that surgical face masks be 'changed between procedures'.[2]

Between patients as an indication

Five guidance documents, three of which are an organisational 'bundle' of COVID-19 guidance, advise removal or replacement between patients.[12, 19, 94-96] Australian IPC guidance advises that to reduce the risk of disease transmission between patients, PPE (including surgical face masks) should be removed/replaced before attending to another patient.[12] UK IPC guidance for anaesthetists states that surgical face masks should be replaced between patients.[19] Canadian COVID-19 guidance (for long term care homes, acute care settings, and outpatient/ambulance) advises removal after seeing a resident/ patient with suspected/ confirmed infection.[94-96]

Change during extended or prolonged use

The term sessional or prolonged use refers to continuous use of a surgical face mask across a period where a healthcare worker may undertake a set of duties in a specific setting or exposure environment. This may include caring for patients within a single ward or cohort area or performing a surgery over many hours in an operating theatre. 'Sessional use' may be used interchangeably with 'extended use'

within the included guidance, though the latter is also used to refer to use of a mask by multiple persons for source control across care settings (for instance staff, patients and visitors from entry to a facility).

Extended use for source control

The CDC, in 2024 COVID-19 guidance, indicate that when a mask is being used for source control for extended periods it should be changed when soiled, damaged or hard to breathe through; if used during this time for personal protection (to care for a patient with COVID-19 infection) it should be changed as normal (after the patient care encounter).[39] This is mirrored in Canadian COVID-19 guidance, which advises that when surgical masks are worn for extended periods for source control they should be changed when damaged, wet, damp or soiled, and after treating a patient on 'droplet and contact precautions'.[94-96]

Sessional use for cohorted patients

The 2023 WHO 'living' SARS-CoV-2 guidance advises changing masks between cohorted patients only if the patient requires 'contact/ droplet precautions' for other infectious agents.[13] Interim guidance for rational use of PPE for COVID-19 (WHO, 2020) advises that sessional use of surgical masks for cohorted COVID-19 patients should only be implemented if the patients are not additionally suspected or confirmed of any other healthcare transmissible infections; this implies that masks should be changed between patients if this were the case.[93]

Frequency of change

The total time a mask may be worn is not clear within extant guidance. WHO interim pandemic guidance published in 2020 advised that a medical mask may be worn for "up to 6 hours, when caring for a cohort of patients with COVID-19".[97] This guidance is applicable to the SARS-CoV-2 pandemic and/ or times of high SARS-CoV-2 transmission. As the evidence base which underpins this guidance is considered unclear or limited, the recommendations may lack applicability to other settings or scenarios. IPC guidance published by the UK Department of Health and Social Care in 2022 states that a fluid resistant surgical face mask should not be worn for longer than a 4-hour period.[21]

A guideline for operating theatres (Humphreys et al 2023) indicates that in surgical settings surgical masks should be changed “periodically” however indication for what would conclude a ‘period’ is not provided.[48] Whilst this guideline is graded AGREE II ‘recommend with provisos’, the good practice point within the guideline has no supporting evidence and no rationale given by the guideline working group.

Summary

In summary, there is a lack of high-quality primary research regarding the indications for changing or removal of a surgical face mask. Across the extant guidance there is consistency that surgical face masks should be removed/ changed if they become damaged, damp/wet or soiled/contaminated. Extant guidance also advises that surgical face masks should be treated as a single use item and therefore removed/ changed after every care activity or procedure. There was inconsistency in the extant guidance regarding the duration of continuous use of a surgical face mask, however most guidance advises a change of mask between patients within a cohort to reduce the risk of cross-infection.

3.1.10 Where and how should a surgical face mask be donned/put on?

Sixteen pieces of literature were included for this question.[2, 12, 15, 20, 31, 34, 45, 94-96, 98-103] Of these, six were included as part of the previous iteration of this review (version 1.0),[15, 20, 45, 101-103] and nine were added as part of the current update. [2, 12, 31, 34, 94-96, 98-100] All were low quality, graded SIGN 50 level 4, expert opinion.

How to don/put on a surgical face mask

There was some consistency across nine documents (eight guidance documents, one British Standard), including the view that hand hygiene should be performed before donning a surgical face mask.[2, 12, 94-96, 98-100, 103]

If being donned as part of an ensemble of other protective equipment, three guidance advise that a surgical face mask be donned second in the sequence (for example after performing hand hygiene and donning of an apron or gown).[12, 98, 99] Differing donning sequencing may be associated with surgical settings.[12]

The WHO advise that manufacturers guidance should be followed for donning method. WHO also advise that donning should involve identifying the top side "where the metal piece or stiff edge is", facing the coloured side outward and placing the metal piece or stiff edge on to the nose.[100] Five guidance documents advise that for surgical face masks with tie straps the wearer should bring the top ties to the crown of the head and secure,[12, 20, 98, 101, 102] and then the bottom ties should be tied at the nape of the neck and secured. [12, 20, 98, 101, 102] The metal nose clip should be secured/ moulded around the bridge of the nose.[2, 20, 101] The mask should be extended to cover the nose, the mouth and the chin,[15, 20, 34, 45, 94-96, 98-101, 103] fit 'snugly',[20, 34, 94-96, 101] and adjustments made to reduce gaps at the side.[34, 100, 103]

The WHO and APIC recommend that the mask should be inspected for damage or defects before use.[100, 102] The UK Department of Health and Government of Canada state that the mask should not be allowed to hang around the neck.[45, 94-96]

Where to don/put on a surgical face mask

No high-quality primary research is available which compared the location of surgical face mask donning with regards to mask effectiveness or transmission risk. Extant guidance is consistent, advising to don before[45] or upon[31, 34, 94-96] entering a patient's care area or room; all guidance was specific to the use of surgical masks for protection against 'droplet' respiratory infection or respiratory infectious agents (pandemic influenza, SARS-CoV-2).

AORN advise donning upon entry specifically when entering the room or cubicle of a patient with 'suspected or proven infection transmitted by respiratory droplets'.[34] The NHMRC (Australian) IPC guidance provides a conditional recommendation that surgical masks should be worn 'when entering a patient-care environment to prevent droplet transmission'.[12]

Both 'before' and 'upon' suggest a need to don the mask before or at the point of entry to a care area.

Summary

In summary, extant guidance is consistent in advising donning upon entry to a care area; evidence to support this is unavailable. Extant guidance advises that the following be conducted when donning a surgical mask:

- perform hand hygiene prior to donning a mask
- examine the mask for holes and/ or tears
- ensure the fluid repellent coloured side is facing outwards
- for ear loops, secure the loops behind the ears or for ties, bring the top ties to the crown of the head and secure; then tie bottom ties at the nape of the neck and secure
- mould the flexible nose piece/ metal strip over the bridge of the nose
- once covering the nose, extend to cover the mouth and chin making sure there are no gaps between the face and the mask
- do not wear the mask hanging around the neck

3.1.11 Where and how should surgical face masks be doffed/taken off?

Sixteen records were included for this research question. Of these, the UK COSHH regulations are graded mandatory,[7] two guidelines are graded AGREE II 'recommend with provisos',[14, 16] and twelve guidance documents[12, 13, 15, 20, 34, 73, 98-102, 104] and one British Standard[2] are graded SIGN 50 level 4 expert opinion.

Nine of these documents were included in this update of the review,[2, 12, 13, 34, 73, 98-100, 104] and seven were included from the previous iteration (version 1.0).[7, 14-16, 20, 101, 102] Two of the documents are specific to SARS-CoV-2,[13, 104] one is pandemic influenza-specific,[20] and one is focused on pandemic/ epidemic prone respiratory infections.[16]

How to doff/remove a surgical face mask

The front of surgical face masks are considered to be contaminated after use.[12, 99] As such, nine of the guidance (eight SIGN 50 level 4[12, 13, 15, 20, 34, 99, 102, 104] and one AGREE II 'recommend with provisos' guideline)[16] were consistent in advising that

surgical face masks should be removed by handling the straps or ties only. Specifically, surgical face masks with loops should be taken off using the elastic ear loops[12] and masks with ties be removed by untying bottom ties first followed by top ties,[15, 20, 101, 102] with head tilted forwards.[102] Six guidance documents and a British Standard[2] were consistent in advising that the front of the mask should not be touched when removing a surgical face mask.[12, 13, 34, 99, 101, 104]

When worn as part of an ensemble, it is advised within seven guidance documents[12, 20, 34, 98, 99, 101, 104] and one guideline (AGREE II 'recommend with provisos')[14] that surgical face masks be the last item of protective equipment to be removed. There is consistency that the removal of a face mask should be followed by hand hygiene.[12, 14, 15, 98-102, 104] This literature considered multiple health and care settings however, the AORN guidance was specific to surgical settings.[34] Within the literature included, the sequence or order for removal is described as gloves, followed by hand hygiene,[12, 98, 104] apron/ gown, eye protection, surgical face mask and then hand hygiene,[2, 12, 14, 98, 104] with two documents suggesting hand hygiene between each PPE item removal, as required based on contamination.[12, 99]

Where to doff/ remove a surgical face mask

There were few recommendations in extant guidance specific to removal of a surgical face mask. Generally, there was inconsistency across SIGN 50 level 4 guidance, on the optimal location for mask removal. UK and US guidance advise that PPE, including masks, may be removed after leaving a "work area",[15] or when no longer in the "clinical space".[102] The US CDC advises removal before leaving the patients room or care area.[73] The definition of work area is unclear in this context and the specific location of removal after leaving these areas is also unclear. The UK COSHH regulation states that "Personal protective equipment which may be contaminated by a substance hazardous to health shall be removed on leaving the working area and kept apart from uncontaminated clothing and equipment."[7] For more information about legislation relevant to surgical face masks refer to, 'What legislative requirements or standards must surgical face masks adhere to for infection prevention and control purposes?'.

Summary

Overall, there was consistency across the SIGN 50 level 4 literature that surgical face masks should be removed by the straps/loops (for masks with straps: untie the bottom then the top strap with the head tilted forwards) taking care not to touch the surfaces of the mask; that hand hygiene should follow removal of a face mask. Extant guidance advises that surgical face masks worn as part of an ensemble for providing care should be doffed last in the sequence. There is ambiguity in extant guidance regarding the location for doffing, with advice to remove on or after leaving a patient area or room.

3.1.12 How should surgical face masks be disposed of?

Eleven documents, graded SIGN 50 level 4 expert-opinion, were included for this research question. This includes 10 guidance documents[12, 13, 15, 20, 34, 73, 94-96, 102] and one British Standard.[2] Three were included from previous updates of this review,[15, 20, 102] and eight new evidence sources were included for this update.[2, 12, 13, 34, 73, 94-96] Two of the included guidance documents were created with a UK context in mind.[15, 20]

Disposal of a surgical mask immediately after it has been removed is advised specifically by two published guidance documents.[13, 15] The transmission-based guidance published by AORN, 2019 highlights that a waste receptacle should be used to discard a face mask.[34] The use of an “appropriate” waste receptacle is advised by the UK Department of Health 2009 ambulance influenza guidance.[20] British Standard 14683:2025 advises disposal into a “suitable collection container”.[2] The SARS-CoV-2 infection prevention and control guidance published by the Canadian Government for long term care, acute and outpatient/ambulance care highlights that a non-touch waste receptacle should be used for disposal of a face mask.[94-96]

It is advised that that only the ties should be handled when disposing of a mask,[102] and hand hygiene should follow removal and disposal.[12, 15, 20, 102]

Refer to ‘Where and how should surgical face masks be doffed?’ for more details on doffing of surgical face masks.

Summary

In summary, across the included low-quality SIGN 50 level 4 expert opinion it is suggested that surgical masks be:

- disposed of immediately after removal
- handled by only the straps/ loops during disposal
- disposed of in an appropriate or non-touch waste receptacle
- disposed followed by hand hygiene.

3.1.13 How should a surgical face mask be stored?

This review included eight documents which considered the storage of face masks. Six guidance documents were graded SIGN 50 level 4 expert opinion,[12, 94-96, 105, 106] and two documents are legislative regulations, graded mandatory.[7, 8] Research question 1 of this review discusses the relevance of these regulations (Control of Substances Hazardous to Health 2002 Regulations (as amended) (COSHH),[7] and the Personal Protective Equipment at Work (Amendment) Regulations 2022 (PPER)),[8] to surgical face masks. Of the eight documents, two were included as part of the previous iteration of this review,[7, 106] and six were included as part of the current update.[8, 12, 94-96, 105]

An accessible (point of use) and dedicated room or space for mask storage is recommended by the Australian NHMRC and also within SARS-CoV-2 pandemic specific guidance produced by the Canadian Government.[12, 94-96] While the UK PPE at work (Amendment) 2022 regulations state that “appropriate accommodation” for PPE must be provided,[8] the HSE approved code of practice (ACOP) guidance provides the example of a clean, dry cupboard.[105] The UK COSHH legislation states that a “well-defined place” should be identified for PPE but specifics are not provided.[7] The HSE guidance for this regulation states that storage should be “adequate” to provide protection from “contamination, loss or damage”.[106] But specifics are not provided on the requirements of this storage space. While these references are not specific to health and care settings it applies to UK workplaces

where personal protective equipment is required to protect persons from hazards in the workplace.

There was limited evidence available for this topic and a lack of consistency and specificity.

3.2 Implications for research

As demonstrated by this review, the evidence base which assesses the efficacy or effectiveness of surgical face masks within health and care settings for personal protection or source control is generally limited and reliant on expert opinion or established rituals and behaviours which have unclear origin. There are several specific areas in which future research would be beneficial for improving the understanding of surgical face mask effectiveness for infection prevention and control within health and care settings.

Firstly, the use of a surgical face mask by HCWs in surgical settings can be considered as personal protection from anticipated splash and spray of blood/ body fluids, source control and to maintain sterile field to reduce the risk of surgical site infections (SSI). However, the efficacy of surgical face masks in reducing SSI remains under-researched. A systematic review recommended that well-conducted randomised controlled trials (RCTs) are required to determine the effectiveness of surgical face masks in surgical settings by scrubbed and non-scrubbed surgical team members.[74] The review also recommends that a focus for further research should be on the use of disposable surgical face masks by surgical teams with and without other forms of face protection such as visors and helmets for the protection of both patients and staff. Further research in this area would increase understanding about the effectiveness of surgical face masks in preventing SSI.

There were ten systematic reviews with meta-analysis,[63-72] and four RCTs that were excluded at the critical appraisal stage of the current review due to their poor quality (for example graded SIGN 50 1-).[59-62] Refer to 'When should HCWs wear a surgical face mask?' for a discussion on these studies, which were not used to formulate recommendations or good practice points. The primary focus of these studies was comparing respirators (usually N95) to surgical masks without a control or no mask

group comparator. Generally, these RCTs did not support a superior effectiveness of N95 respirators in comparison to surgical face masks, unless under specific conditions.[59-62] As stated above, these studies were methodologically limited. They were however included within the analyses of the 10 excluded systematic reviews with meta-analysis. The reliability of the results of those reviews is unclear given the limitations of the underlying included studies. While it can be argued that meta-analytic methods can be used to control or account for some limitations of included studies it is not possible to accurately identify the extent to which the results may be confounded or biased based on the original studies. A large proportion of guidance and literature concerning surgical face mask use to prevent transmission of respiratory infection is based on these four RCTs, and/ or some or multiple of the meta-analysis considering these four RCTs. When considering the limitations, these studies do not support the view that surgical masks are not effective, nor do they support that they are less effective than N95 respirators. Instead, they are simply unable to confirm the effectiveness of surgical face masks compared to N95 respirators in practice and they clearly highlight a lack of high-quality research considering the effectiveness of surgical face masks.

The current review also considered a small number of limited experimental studies simulating health care environments and human interactions. These studies can demonstrate the mechanistic performance of surgical face masks. In isolation they are unable to provide assurances regarding transmission risk in real life settings. The efficacy provided by surgical face masks to prevent or reduce the spread of exhaled particles which may emulate exhaled infectious agents is implied by the authors of these experimental studies but is not confirmed. These studies were part of a wider body of innovative experimental or observational research which was excluded from this review. This research focused on novel and evolving experimental methods with limited to no applicability to real-world settings and limited generalisability within health and care populations. Manikin or simulation experiments often involving lasers and light effects, descriptive studies with limited reliability as well as other limitations including a lack of power, small sample size, and specific room or environmental conditions were considered as non-applicable for health and care settings. Many of these studies also focused on the comparison between respirators (often N95) and surgical/ other mask types but lacked a valid control (negative or positive). It is

difficult to make conclusions from any unvalidated novel experimental studies which have multiple methodological limitations as they are specific to the fixed setup within which they were conducted. That is, the results cannot be used to determine the effectiveness of surgical face masks being used by HCWs, patients or visitors for IPC precautions within health and care settings. Experimental research can demonstrate efficacy under fixed conditions but should be supplemented by high-quality research in clinical settings to better understand the applicability of the results. 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 effectiveness of surgical masks across settings by HCWs, patients and visitors.

Further to these and a general limitation of surgical face mask, and wider IPC, research is the tendency to introduce IPC measures as part of a bundle. Generally, the use of a bundle or simultaneous infection control measures in addition to surgical mask use makes it difficult to draw conclusions regarding the effectiveness of surgical mask use alone. Bundled interventions are excluded from NIPCM literature reviews because they cannot differentiate between the included intervention measures to determine individual effectiveness (or lack thereof).
Most of the observational, case study, outbreak report and cohort studies, particularly those published during the COVID-19 pandemic, considered a bundle of measures (for example multiple PPE, distancing and/ or behavioural interventions), which included but was not limited to surgical face masks. Studies which focus specifically on surgical masks and not on ensembles or bundled IPC measures would assist in understanding the settings in which a surgical mask may be an effective measure of infection prevention and control. However, the feasibility of such studies is limited as real IPC in practice will often consist of bundled approaches.

The extant guidance covering surgical face mask use in health and care settings is limited as it tends to focus on expert opinion and/ or research which has several limitations, including the aforementioned RCTs and/ or meta-analyses. In addition, guidance produced during the SARS-CoV-2 pandemic was often produced rapidly, and reliant on expert opinion. It is not clear to what extent the SARS-CoV-2 specific guidance or research will apply to non-pandemic or even future pandemic settings. Where possible SARS-CoV-2 guidance is considered and incorporated into the

current review. Several of the SARS-CoV-2 guidance documents identified during grey literature searching were withdrawn from circulation during the development of this review. It is therefore unclear if/ how this literature may be used to establish lessons learned to guide future epidemic/ pandemic respiratory infections. While a small number of guidance documents remained live at the time of writing, including the updated WHO living guidance,[13] these may be updated or withdrawn following the publication of this review. This is acknowledged as a risk. The SARS-CoV-2 pandemic response led to increased scrutiny of surgical face mask research. Further high-quality research is needed to determine the effects of extended use or reuse of surgical masks, the effectiveness of different mask types and the value of mask wearing by those who are at increased risk of infection and/ or subsequent morbidity/ mortality.

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. Furthermore, some have called into question the appropriateness of labelling surgical face masks as PPE (refer to, 'What legislative requirements or standards must surgical face masks adhere to for infection control purposes'). While surgical face masks do appear to clearly fit the definition of PPE provided within the UK PPE at work (Amendment) 2022 legislation, the categorisation of surgical masks as PPE is challenging when worn primarily for the purpose of source control, that is to protect others. Complimentary research on the types of surgical masks which should be used for different health and care purposes is needed in relation to both filtration efficacy and fluid resistance.

Additional robust evidence would provide further clarity on the infection and prevention control value of the following:

- the use of surgical masks by specific HCW or patient or service user groups
- patients or service user and visitors wearing surgical masks when in health and care settings

- continuous versus targeted surgical mask use by HCWs during influenza/ winter season
- the use of surgical face masks in settings where immunocompromised persons such as transplant patients and neonates are being treated

In summary, there are numerous important areas in which future research should focus to improve the understanding of the effectiveness of surgical masks in preventing the spread of infection when worn by staff, patients, and visitors. There is an urgent need for high-quality research, particularly regarding the effectiveness of face masks as a form of personal protection when exposed to respiratory infection.

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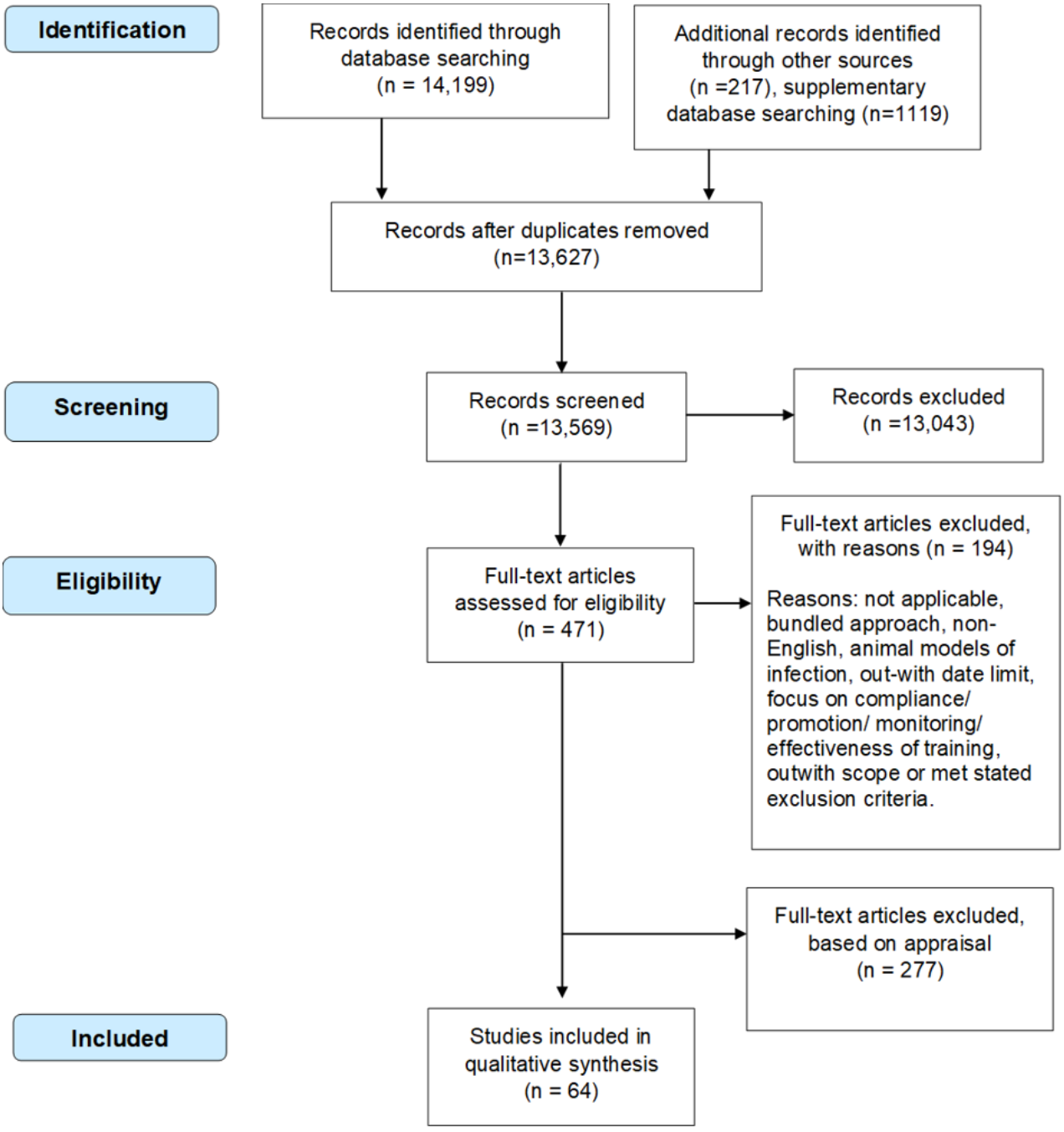
4. Appendices

Appendix 1: PRISMA Flow Diagram



Appendix 2: Evidence gradings

SIGN 50 Evidence grades

Grade	Description
1++	High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1+	Well conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
1-	Meta analyses, systematic reviews of RCTs, or RCTs with a high risk of bias
2++	High quality systematic reviews of case-control or cohort studies. High quality case-control or cohort studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is causal
2+	Well conducted case control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal
2-	Case control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal
3	Non-analytic studies, for example case reports, case series
4	Expert opinion

AGREE II Evidence grades

Grade	Description
AGREE II 'Recommend'	This indicates that the guideline is of high overall quality and can be considered for use in practice without modifications.
AGREE II 'Recommend with provisos'	This indicates that the guideline is of moderate overall quality. This could be due to insufficient or lacking information in the guideline for some items. If provisos or alterations are made, the guideline could still be considered for use in

Grade	Description
	practice when no other guidelines on the same topic are available.
AGREE II 'Do not Recommend'	This indicates that the guideline is of low overall quality and has serious shortcomings. Therefore, it should not be recommended for use in practice.

Appendix 3: Standards pertaining to surgical face masks

This appendix provides a non-exhaustive list of standards pertaining to surgical face masks. The versions listed were up to date at the point of writing. However, the listed standards are subject to amendments, and the most recent version of standards should be used.

Standard	Title	Description	Publication date
BS EN 14683:2025	Medical face masks – Requirements and test methods	This standard specifies the construction, design, performance requirements and test methods for medical face masks intended to limit the transmission of infective agents from staff to patients during surgical procedures and other medical settings with similar requirements.	January 2025
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.	This standard provides guidance on the generic ergonomic characteristics related to	September 2007.

Standard	Title	Description	Publication date
	Ergonomic principles.	personal protective equipment (PPE) – it does not however cover the requirements which relate to specific hazards that PPE may be designed.	
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 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.	May 2002.
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.	April 2018

Standard	Title	Description	Publication date
		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.	
UK Statutory Instrument 2022 No: 08	The Personal Protective Equipment (Amendment) Regulations 2022	This instrument provides amendments to the previously published 'Personal Protective Equipment (Enforcement) Regulations 1992' with updates, extension to the employer and employee duties in regard to the provision of PPE to persons and the inclusion of more casual employee/employer relationships. Clarity is also provided regarding the definition of PPE.	April 2022
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	June 1993

Standard	Title	Description	Publication date
		period where elements of both pieces of legislation apply up to May 2025.	
PD ISO/TS 20141:2022	Personal safety – Personal protective equipment – Guidelines on compatibility testing of PPE	Describes compatibility of PPE ensembles, i.e. wearing more than one piece of PPE at the same time. The principles of this document also apply to interactions between non-PPE items and PPE.	October 2022
EU directive	REGULATION (EU) 2016/425 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC	This document provides detail on the design and manufacturing requirements for PPE that is used or sold.	March 2016

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 (for example 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 4: Studies excluded following critical appraisal

The following primary studies were excluded during critical appraisal (SIGN 50) based on their limitations. This list covers those studies excluded in the current update, from evidence identified for the period 2020-2024.

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Appendix 5: Search Strategy

Please note that search limiters were applied as databases allowed, including for English language, date range and human studies.

Embase/Medline 2019-2022 (adapted as required per database)

1. exp Masks/
2. mask*.mp.
3. cloth.mp.
4. respirator*.mp.
5. not 3 and not 4
6. 1 or 2
7. 5 and 6
8. exp Infection Control/
9. exp Cross Infection/
10. exp Disease Transmission, Infectious/
11. transmission based precaution*.mp.
12. Universal Precautions/
13. ((enteric or isolat*) adj2 precaution*).mp.
14. ((contact or airborne or droplet) adj2 (infection* or precaution*)).mp.
15. exp Personal Protective Equipment/
16. 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15
17. 7 and 16

CINAHL 2019-2022

S13 S3 and S14

S12 S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11

S11 (MH "Personal Protective Equipment+")

S10 (contact or airborne or droplet) N2 (infection* or precaution*)

S9 (enteric or isolat*) N2 precaution*

S8 (MH "Universal Precautions")

S7 transmission based precaution*

S6 (MH "Disease Transmission+")

S5 (MH "Cross Infection+")

S4 (MH "Infection Control+")

S3 S1 OR S2 (NOT cloth AND NOT respirator*)

S2 mask*

S1 (MH "Masks")

Embase/Medline 2022-2024 (adapted as required per database)

1. exp Masks/
2. mask*.mp.
3. 1 or 2
4. 5 and 6
5. exp Infection Control/
6. exp Cross Infection/
7. exp Disease Transmission, Infectious/
8. transmission based precaution*.mp.
9. Universal Precautions/
10. ((enteric or isolat*) adj2 precaution*).mp.

11. ((contact or airborne or droplet) adj2 (infection* or precaution*)).mp.

12. exp Personal Protective Equipment/

13. 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15

14. 7 and 16

CINAHL 2022-2024

S13 S3 and S14

S12 S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11

S11 (MH "Personal Protective Equipment+")

S10 (contact or airborne or droplet) N2 (infection* or precaution*)

S9 (enteric or isolat*) N2 precaution*

S8 (MH "Universal Precautions")

S7 transmission based precaution*

S6 (MH "Disease Transmission+")

S5 (MH "Cross Infection+")

S4 (MH "Infection Control+")

S3 S1 OR S2

S2 mask*

S1 (MH "Masks")