Public Services Delivery
Scotland

NHS
SCOTLAND

Surgical Face Masks Literature Review

Evidence Tables:

Version 2.0

3 August 2026

Antimicrobial Resistance & Healthcare Associated Infection (ARHAI) Scotland
An NHS Scotland Assure Service, part of Public Services Delivery Scotland

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	3 August 2026	Addition of evidence identified from 2029-2024 during the scheduled update of the surgical face masks literature review (version 2.0).
1.0	2020	First version of evidence tables (unpublished).

Contents

Introduction

All studies which are critically appraised as part of the literature review are assigned a grade of evidence based on the SIGN 50 methodology grading system (SIGN, 2019), which allows scientific studies to be assessed for quality using a number of reviewing forms (available from the SIGN website). Guidelines are appraised and graded using the AGREE II grading system (details available from the AGREE website).

Main conclusions from evidence sources (studies and guidance) are summarised along with a brief description of the methods and limitations within evidence table entries. Evidence sources with sufficient quality, which specifically answer a defined research question, are grouped together to enable the formation of an overall assessment regarding the evidence base.

Evidence grading

The following grades were given to the papers included in this evidence table:

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

Grade	Description
3	Non-analytic studies, for example case reports, case series
4	Expert opinion

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 modifications'	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 modifications are made, the guideline could still be considered for use in 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.

Research questions for evidence tables

Question 1: What legislative requirements or standards must surgical face masks adhere to for infection control purposes?

Evidence added to version 2.0 update:

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The European Parliament and the Council of the European Union. 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. 2016.	Legislation/ Regulations for EU	Mandatory	N/A	N/A	N/A

Assessment of evidence
This EU regulation “was adopted in the context of establishing the internal market, in order to harmonise health and safety requirements for personal protective equipment (PPE) in all Member States and to remove obstacles to trade in PPE between Member States”. The following section(s) are relevant for this research question on what type of surgical face masks are recommended for health and care settings. On PPE for face, eyes and respiratory system, the document states “Any restriction of the user's face, eyes, field of vision or respiratory system by the PPE shall be minimised. The screens for those types of PPE must have a degree of optical neutrality that is compatible with the degree of precision and the duration of the activities of the user. If necessary, such PPE must be treated or provided with means to prevent misting-up. Models of PPE intended for users requiring sight correction must be compatible with the wearing of spectacles or contact lenses.” “The CE marking shall be affixed visibly, legibly and indelibly to the PPE. Where that is not possible or not warranted on account of the nature of the PPE, it shall be affixed to the packaging and to the documents accompanying the PPE” With the UK decision to leave the EU the evidence level of this guideline would be considered as expert opinion unless otherwise stated in updated British standards, regulatory or legislative documents.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Health and Security Agency (UKHSA). Medicines and Healthcare Products Regulatory Agency (MHRA). Regulatory status of equipment being used to help prevent coronavirus (COVID-19).	Guidance/Expert Opinion	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Published 26 March 2020 and last updated 01 July 2023. Last accessed 21 October 2024.					

Assessment of evidence

This British document describes regulatory and mandatory considerations for goods used in UK settings. The regulations must be adhered to, but this document lists those requirements and is considered as guidance only. The guidance is also specific to COVID-19. The following section(s) are relevant for this research question on the legislative requirements or standards (BS/EN) must surgical face masks adhere to for infection control purposes.

Surgical face masks are reported to be “mainly intended for health and care staff to wear to protect patients during surgical procedures or other medical settings”.

“If you make a surgical mask, intended to protect the patient, they are Class I medical devices. They must meet the design and safety requirements of the UK Medical Device Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) and be CE, CE UKNI or UKCA marked before you can sell them in the UK. If they are not CE/CE UKNI/UKCA marked you must apply for exemption from the regulations. We may authorise you to supply a non-CE/CE UKNI/UKCA marked device in the interest of protecting health. If the surgical masks you want to supply are sterile, then you also need a CE, CE UKNI or UKCA certificate from an EU Notified Body or UK Approved Body (please read as UK Notified Body in this document for the purposes of Northern Ireland) for the sterility aspects. We regulate these types of masks and the Guidance on Class 1 Medical Devices gives further information.”

On transparent masks, the document states as follows; “If you make a clear surgical/medical face mask intended to protect patients, they are Class I medical devices and must meet the design and safety requirements as above. Transparent masks may only state that they are Type IIR when they have met the requirements of the EN 14683:2019 standard in full.”. – please note that the transparent mask specification previously published by UKHSA and linked out to in this section was withdrawn 3 March, 2023 due to being “out of date”. Surgical masks must meet required regulations etc regardless of mask type.

Assessment of evidence
A guidance document published by the UK Health and Security Agency (UKHSA) which details the regulatory considerations for both medical device and personal protective equipment. Both terms are used to describe medical masks for use by a health care worker to protect a patient and use by a health care worker as a protective device, respectively.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and safety executive (HSE). ACOP. The Personal Protective Equipment at Work Regulations 1992 (as amended) Guidance on Regulations. (version 4). ISBN 9780717667468. 2022 (Fourth Edition) Accessed 17 October 2024	Guidance	**Level 4**	N/A	N/A	N/A

Assessment of evidence
HSE approved code of conduct (ACOP) guidance to inform the British 2022 PPE at work regulations. “Application to non-employees 23 Although these Regulations do not apply to people who are not workers as defined in regulation 2(1)(c) (for example, volunteers, children while in school, students at university, and visitors to worksites), there is provision within section 3 of the HSW Act that requires every employer to ensure, so far as is reasonably practicable, that people not in their employment but who may be affected by the work are not exposed to risks to their health and safety. If employers are required to provide PPE to comply with a section 3 duty, they are likely to do so by following the requirements of these Regulations; for example, by having a stock of hard hats, hi-vis jackets or disposable overalls for the use of visitors. The Regulations do apply to trainees and students on work experience programmes.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Statutory Instrument. The Medical devices regulations 2022. UK statutory instruments 2002 No. 618 Last Accessed: 15 January 2023 Available from: The Medical Devices Regulations 2002 (legislation.gov.uk)	Regulation/ legislation	**Mandatory**	N/A	N/A	N/A

Assessment of evidence

British legislation regarding the requirements for medical device. Below is a small section of the 'interpretation' section of the regulation pertaining to the current review.

""medical device" means an instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any software necessary for its proper application, which—

(a) is intended by the manufacturer to be used for human beings for the purpose of-

(i) diagnosis, prevention, monitoring, treatment or alleviation of disease,

(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,

(iii) investigation, replacement or modification of the anatomy or of a physiological process, or

(iv) control of conception; and

Assessment of evidence
(b) does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means”

Evidence from previous update(s):

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Statutory Instrument. Health and Safety at work Act 1974.	Regulation/ legislation	**Mandatory**	N/A	N/A	N/A

Assessment of evidence
“The Health and Safety at Work etc Act 1974 is the primary piece of legislation covering occupational health and safety in Great Britain. It's sometimes referred to as HSWA, the HSW Act, the 1974 Act or HASAWA”
“(1) The provisions of this Part shall have effect with a view to— (a) securing the health, safety and welfare of persons at work; (b) protecting persons other than persons at work against risks to health or safety arising out of or in connection with the activities of persons at work; (c) controlling the keeping and use of explosive or highly flammable or otherwise dangerous substances, and generally preventing the unlawful acquisition, possession and use of such substances; [F1[F2and]] [F1[F2(d) controlling the emission into the atmosphere of noxious or offensive substances from premises of any class prescribed for the purposes of this paragraph.]]”
“F9(2A) A description of undertaking included in regulations under subsection (2) may be framed by reference to— (a) the type of activities carried out by the undertaking, where those activities are carried out or any other feature of the undertaking; (b) whether persons who may be affected by the conduct of the undertaking, other than the self-employed person (or his employees), may thereby be exposed to risks to their health or safety.] (3) In such cases as may be prescribed, it shall be the duty of every employer and every self-employed person, in the prescribed circumstances and in the prescribed manner, to give to persons (not being his employees) who may be affected by the way in which he conducts his undertaking the prescribed information about such aspects of”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Statutory Instrument. Control of Substances Hazardous to Health L5 6th Edition. 2002.	Regulation/ legislation	**Mandatory**	N/A	N/A	N/A

Assessment of evidence

This document contains the Control of Substances Hazardous to Health Regulations 2002 (as amended) (COSHH) regulations.

Regulation 7 (3)

“Regulation 7 Prevention or control of exposure to substances hazardous to health

(3) Where it is not reasonably practicable to prevent exposure to a substance hazardous to health, the employer shall comply with his duty of control under paragraph (1) by applying protection measures appropriate to the activity and consistent with the risk assessment, including, in order of priority –

(a) the design and use of appropriate work processes, systems and engineering controls and the provision and use of suitable work equipment and materials;

(b) the control of exposure at source, including adequate ventilation systems and appropriate organisational measures; and

(c) where adequate control of exposure cannot be achieved by other means, the provision of suitable personal protective equipment in addition to the measures required by sub-paragraphs (a) and (b).”

Regulation 7 (9)

“Regulation 7 Prevention or control of exposure to substances hazardous to health

(9) Personal protective equipment provided by an employer in accordance with this regulation shall be suitable for the purpose and shall –

(a) comply with any provision in the Personal Protective Equipment Regulations 2002 which is applicable to that item of personal protective equipment; or

Assessment of evidence

(b) in the case of respiratory protective equipment, where no provision referred to in sub-paragraph (a) applies, be of a type approved or shall conform to a standard approved, in either case, by the Executive."

Regulation 8 (1)

"Regulation 8 Use of control measures etc

(1) Every employer who provides any control measure, other thing or facility in accordance with these Regulations shall take all reasonable steps to ensure that it is properly used or applied as the case may be.

Regulation 9 (5), (6), and (7)

"Regulation 9 Maintenance, examination and testing of control measures

(5) Every employer shall ensure that personal protective equipment, including protective clothing, is:

(a) properly stored in a well-defined place;

(b) checked at suitable intervals; and

(c) when discovered to be defective, repaired or replaced before further use.

(6) 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) The employer shall ensure that the equipment referred to in paragraph (6) is subsequently decontaminated and cleaned or, if necessary, destroyed"

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Statutory Instrument. The Personal Protective Equipment at Work (Amendment) Regulations 2022. 06 April 2022. ISBN 9780717667468. 2022.	Regulation/ legislation	**Mandatory**	N/A	N/A	N/A

Assessment of evidence

These British regulations were made on 5th January 2022, laid before parliament on 10th January and came into force on 6th April 2022. It amends the "Personal Protective Equipment at Work Regulations 1992 ("PPER 1992") to extend the duties contained in regulations 4 to 11 of the PPER 1992 from employees to workers, and to update cross-references to other legislation". The following section(s) are relevant for this research question on the legislative requirements or standards (BS/EN) must surgical face masks adhere to for infection control purposes.

Relevant amendments are listed below, please note extension or clarification to working for "employer" and "workers" as well as extension to include limb (b) workers and updates to other references such as the updated COSHH regulations. These are not described in detail below but are highlighted as amended and required. Employers and employees must adhere to all aspects of PPE at work regulations, where appropriate.

- Amendment to regulation 2 (interpretation) "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".

On 6th April 2022 the personal protective equipment use at work (amendment) regulations 2022 came into force. The amended version is unchanged from previous but extends employer and employee duties for PPE. Clarification was also provided to Regulation 2 regarding

Assessment of evidence
the interpretation of “personal protective equipment” which is defined as “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”. Please also note requirement to meet CE mark within 1992 regulations: “2. Before placing PPE on the market, importers shall ensure that the appropriate conformity assessment procedure referred to in Article 19 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the PPE bears the CE marking and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in Article 8(5) and (6).” Still applies but see UKHSA level 4 guidance regarding move to UKCA marking.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Occupational Safety and Health Administration (OSHA). OSHA Fact Sheet: Respiratory Infection Control: Respirators versus Surgical masks. May 2009.	Guidance/Expert Opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence
This is considered as expert opinion as it is presented in a fact sheet designed to provide users with more information about respirators and surgical masks. The following section(s) are relevant for this research question on what a surgical mask is:

Assessment of evidence
Occupational Safety and Health Administration (OSHA) defines facemasks as: • "Surgical masks are used as a physical barrier to protect the user from hazards, such as splashes of large droplets of blood or body fluids." • "Surgical masks also protect other people against infection from the person wearing the surgical mask. Such masks trap large particles of body fluids that may contain bacteria or viruses expelled by the wearer." More information contained within the Guidance on Preparing Workplaces for an Influenza Pandemic (osha.gov). Surgical masks are used as a physical barrier to protect employees from hazards such as splashes of large droplets of blood or body fluids. Surgical masks also prevent contamination by trapping large particles of body fluids that may contain bacteria or viruses when they are expelled by the wearer, thus protecting other people against infection from the person wearing the surgical mask.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution Medical face masks – Requirements and test methods. BS EN 14683:2025. 2025.	British/European Standards	**Level 4**	N/A	N/A	N/A
Assessment of evidence					
"This British Standard is the UK implementation of EN 14683:2025. It supersedes BS EN 14683:2019, which is withdrawn". ." This document specifies 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. A medical face mask with an appropriate microbial barrier can also be effective in reducing the emission of infective agents from the nose and mouth of an asymptomatic carrier or a patient with clinical symptoms. This document is not applicable to face masks intended exclusively for the personal protection of staff. Compliance with the requirements of the relevant PPE regulations".					

Assessment of evidence

“Medical face masks can be used as part of an infection control chain. The main intended use of medical face masks is to protect patients by attenuating the spread of larger particles from the wearer’s mouth and, additionally, in certain circumstances to protect the wearer against splashes of potentially contaminated liquids. Medical face masks may also be intended to be worn by patients and other persons to reduce the risk of spread of infections, particularly in epidemic or pandemic situations”.

The following section(s) are relevant for this research question on the legislative requirements or standards (BS/EN) must surgical face masks adhere to for infection control purposes.

Classification as Type I or II is based on bacterial filtration efficiency (BFE). For Type II there are non-splash resistant and splash resistant (Type IIR) options. It should be noted that Annex E proposes that future revisions of the standard should not include TYPE I medical masks “unless there is a convincing reason to allow it to remain”. The rationale for removal related to “confusion about appropriate use of Type I masks” which may lead to “potential misuse of Type I medical face masks”. Also noted is the fact that Type I masks are sometimes described by manufactures as “identical to their type II masks apart from the fact that they don’t have them tested for splash resistance. If correct, this would mean that there would not be significant impact on Type I medical face mask manufacturers. The PG also believes that the market for Type I medical face masks in Europe is very small”. The group outline that they appreciate that “certain guidance documents which were relied on during the Covid 19 pandemic recommends the use of Type I masks” to allow the WHO and others to update their guidance it was recommend this change happen in the next revision of the standard.

Bacterial filtration efficiency standards (%):

- “When tested in accordance with Annex B, the BFE of the medical face mask shall conform to the minimum value given for the relevant type in Table 1. For thick and rigid masks such as rigid duckbill or cup masks the test method might not be suitable as an effective seal cannot be maintained in the cascade impactor. In these cases, another valid equivalent method shall be used to determine the BFE. When a medical face mask consists of two or more areas with different characteristics or different layer-composition, each panel or area shall be tested individually. The lowest performing panel or area shall determine the BFE value of the complete mask.”
- Table 1 outlines the following minimum requirements: Type I ≥ 95, Type II ≥ 98 and Type IIR ≥ 98.

Related to bacterial filtration efficiency the following was obtained from Annex B which included methods of in vitro experimentation of medical mask bacterial filtration efficiency.

- Staphylococcus aureus (5×10^5 CFU/ml with bacterial challenge maintained at $1,2\times 10^3$ to $3,5 \times 10^3$ CFU per test) (definition noted as P1 = 7,00 µm P2 = 4,70 µm P3 = 3,30 µm P4 = 2,10 µm P5 = 1,10 µm P6 = 0,65 µm).

Assessment of evidence

- Experimental chamber introduced pathogen which is ‘drawn through’ the mask (cut sections or full mask – must include all layers and have a minimum area 100mm x 100mm). N=5 specimens must be tested.
- The percentage of colony forming units ‘passing through’ the mask based on the equation provided is considered as the filtration efficacy of the mask.
- “Unless otherwise specified, the testing shall be performed with the inside of the medical face mask in contact with the bacterial challenge” – suggesting the norm or unless stated, the focus is on source control rather than protection of the wearer. Within the information the manufacturer should/must provide in their test report it is stated that they should provide “which side of the test specimen was facing towards the challenge aerosol;” suggesting they can test either side but must state this.
- Control requirements are also outlined “perform a positive control run without a test specimen”.

Breathability/differential pressure (PaType I ≤200, type II ≤200 and Type IIR ≤300.

Splash resistance standards: “When tested in accordance with ISO 22609:2004 the resistance of the medical face mask to penetration of splashes of liquid shall conform to the minimum value given for Type IIR in Table 1.” “all tests shall be undertaken with the targeting plate”.

- Splash resistance pressure (kPa): Type I – ”not required”, Type II – ”not required”, Type IIR – ≥16,0

Microbial cleanliness (bioburden): “When tested according to EN ISO 11737-1:2018 the bioburden of the medical mask shall be ≤ 30 CFU/g tested” (page 9). A minimum of 5 masks from the same batch or lot must be tested and any other conditions in the EN ISO 1137-1:2018 must be adhered to. It is also noted that the total bioburden should be considered per individual mask based on the weight for the total bioburden per gram.

Biocompatibility: “The medical face mask shall be evaluated according to EN ISO 10993-1:2020”. .”

It is also reported that “Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I medical face masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.”

The following was obtained from annex A which provides ‘information for users’

- “Medical face masks, commonly referred to as surgical masks, are designed to attenuate the emission of larger droplets from the wearer. However, they are less effective at attenuating the emission of smaller aerosols, due to the fit and facial seal. In a workplace setting, where a risk assessment identifies a risk of respiratory exposure due to an airborne hazard, personal protective

Assessment of evidence
equipment [CE marked to Regulation (EU) 2016/425] such as a respirator may be required. A medical face mask is not a respirator. This document does not specify leakage performance requirements on the inward direction. Total inward leakage is often larger than total outward leakage for two reasons: the high velocity jet of the outward breath, leading to more impaction of particles than for the diffuse inward breath, and the rapid evaporation of particles after exhalation, making them smaller and harder to filter. This document describes two types of medical face masks with associated performance levels. Type I is the most basic performance level. Type II and type IIR medical face masks are principally intended for use by healthcare professionals in an operating room or other medical settings with similar requirements, and Type IIR medical face masks are also intended to protect the wearer against splashes of potentially contaminated fluids". Summary: The British Standards Institution standard publication for medical mask requirements and testing published in March 2019. The requirements for bacterial filtration, breathability are detailed and depend on the mask classification with Type IIR with greater requirements. The requirements for splash resistance, microbial cleanliness, biocompatibility remain as per previously published mask standards (ISO 22609:2004, EN ISO 11737-1:2018, EN ISO 10993-1:2009). The process and evidence-base for the development of these standards is not clear.

Question 2: What is a Surgical Face Mask?

Evidence added to version 2.0 update:

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution Standards Publication. BS EN 14683:2025+AC:2019, ICS 11.140. Medical face masks - Requirements and test methods. March 2025.	British Standards	**Level 4**	N/A	N/A	N/A
Assessment of evidence					
This document outlines the British Standards for medical masks (requirements and testing). It is not specific to mask use as PPE and other standards should be consulted. It supersedes EN 14683:2025. The following section(s) are relevant for this research question on what a surgical mask is: “The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of material. The medical face mask shall not disintegrate, split or tear during intended use. In the selection of the filter and layer materials, attention shall be paid to cleanliness and safety with regards to the release of potentially hazardous substances or particulates” “The medical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer when in use and which ensures that the medical face mask fits closely at the sides.” Splash resistance – For a Type IIR mask “when tested in accordance with ISO 22609:2004 the resistance of the medical face mask to penetration of splashes of liquid” should be greater than or equal to 16,0kPa.					

Assessment of evidence
When tested in accordance with BS EN 14683:2025, Type IIR masks used (for healthcare) should have a bacterial filtration efficiency (BFE) of no lower than ≥98% (a type II or Type IIR mask) and a differential pressure (breathability) value of ≤300 Pa. “When tested according to EN ISO 11737-1:2018 the bioburden of the medical mask shall be ≤ 30 CFU/g tested” Splash resistance – “ability of a medical face mask to withstand penetration of synthetic blood projected at a given pressure” TBPS - “Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I medical face masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.” Annex E of the 2025 revision to this standard proposes that future revisions of the standard should not include TYPE I medical masks “unless there is a convincing reason to allow it to remain”. The rationale for removal related to “confusion about appropriate use of Type I masks” which may lead to “potential misuse of Type I medical face masks”. Also noted is the fact that Type I masks are sometimes described by manufactures as “identical to their type II masks apart from the fact that they don’t have them tested for splash resistance. If correct, this would mean that there would not be significant impact on Type I medical face mask manufacturers. The PG also believes that the market for Type I medical face masks in Europe is very small”. The group outline that they appreciate that “certain guidance documents which were relied on during the Covid 19 pandemic recommends the use of Type I masks” to allow the WHO and others to update their guidance it was recommend this change happen in the next revision of the standard. The British Standards update for medical mask requirements and testing define medical masks as a medical device which will generally consist of a filter layer placed within layers of fabric. The 2025 revision of the medical mask standards include a section on transparent medical face masks (Annex F). This section outlines that “transparent medical face masks (TMFM) can support communication by ensuring the mouth and facial expressions can be seen”. It is also stated that the minimum requirements of TMFM are still evolving”. “It is envisaged that a transparent medical face mask can provide similar performance to that required by this document with minor modifications to the test methods and requirements. In addition, there are several suggested design features described”. There are details about breathability, differential pressure measurements, particle attenuation, filtration measurements, fit, function, condensation, acoustics, durability, visibility.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Occupational Safety and Health Administration (OSHA). OSHA Fact Sheet: Respiratory Infection Control: Respirators versus Surgical masks May 2009	Guidance/Expert Opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence

This is considered as expert opinion as it is presented in a fact sheet designed to provide users with more information about respirators and surgical masks. The following section(s) are relevant for this research question on what a surgical mask is:

Occupational Safety and Health Administration (OSHA) defines facemasks as:

- "Surgical masks are used as a physical barrier to protect the user from hazards, such as splashes of large droplets of blood or body fluids."
- "Surgical masks also protect other people against infection from the person wearing the surgical mask. Such masks trap large particles of body fluids that may contain bacteria or viruses expelled by the wearer."

More information contained within the Guidance on Preparing Workplaces for an Influenza Pandemic (osha.gov).

Surgical masks are used as a physical barrier to protect employees from hazards such as splashes of large droplets of blood or body fluids. Surgical masks also prevent contamination by trapping large particles of body fluids that may contain bacteria or viruses when they are expelled by the wearer, thus protecting other people against infection from the person wearing the surgical mask.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
National Health and Medical Research Council (NHMRC) Australian Guidelines for the Prevention and Control of Infection in Healthcare, 2019 2019 (revised 2024, v11.24) Accessed 11 October 2024	Guidance/Expert Opinion	**Level 4**	N/A	N/A	N/A
Assessment of evidence					
Aim: IPC guidance for Australian health and care settings. Target audience: Acute settings but the authors highlight transferability across settings. Methods: Methodologies for reviews are not provided and, except where references are given, guidelines seem to be formed from expert opinion. Recommendations are accompanied by a strength of evidence assessment, based on systematic review. • The authors state that “Loose-fitting, single-use items that cover the nose and mouth. These include products labelled as dental, medical procedure, isolation and laser masks.”					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Health and Security Agency (UKHSA). Medicines and Healthcare Products Regulatory Agency. Regulatory status of equipment being used to help prevent coronavirus (COVID-19) Published 26 March 2020 Last updated 01 July 2023 Last accessed 21 October 2024	Guidance/ Expert Opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence

While this document describes regulatory and mandatory considerations for goods used in UK settings it in itself is not regulatory and is therefore considered as expert opinion. The following section(s) are relevant for this research question on what a surgical mask is:

““CE-marked medical devices continue to be accepted on the Great Britain market with the deadline for acceptance depending on the type of device and the legislation it complies with. The latest of these deadlines is 30 June 2030. Separate rules exist for Great Britain and Northern Ireland. For further information on the regulatory requirements for medical devices, please refer to our guidance.”

“The government has extended acceptance of CE marked medical devices in Great Britain. For more detail on this see the implementation update on work towards a strengthened future medical devices regime.”

- Medical Device

Assessment of evidence
“These are mainly intended for health care staff to wear to protect patients during surgical procedures and other medical settings. If you make a surgical mask, intended to protect the patient, they are Class I medical devices. They must meet the design and safety requirements of the UK Medical Device Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) and be CE, CE UKNI or UKCA marked before you can sell them in the UK. If they are not CE/CE UKNI/UKCA marked you must apply for exemption from the regulations. We may authorise you to supply a non-CE/CE UKNI/UKCA marked device in the interest of protecting health. If the surgical masks you want to supply are sterile, then you also need a CE, CE UKNI or UKCA certificate from an EU Notified Body or UK Approved Body (please read as UK Notified Body in this document for the purposes of Northern Ireland) for the sterility aspects. We regulate these types of masks and the Guidance on Class 1 Medical Devices gives further information” • Personal protective equipment (PPE) On face masks intended to protect the wearer, the document states “If your masks are intended to protect the wearer, they are regulated as personal protective equipment and need to meet the regulations covering PPE products. They will need an EU Notified Body/UK Approved Body to verify the relevant requirements are met. They are not medical devices. If you need advice on these regulations, see the OPSS coronavirus guidance for business and local authorities.” Transparent masks are also considered in this document, but it links out to the technical specification considered above (within this evidence table). A guidance published by the UK Health and Security Agency (UKHSA) document which details the regulatory considerations for both medical device and personal protective equipment. Both terms are used to describe medical masks for use by a health care worker to protect a patient and use by a health care worker as a protective device, respectively. The type of face mask that should be worn should conform to the listed regulations.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
World Health Organization (WHO). Infection prevention and control in the context of coronavirus disease (COVID-19): A living guideline. Last updated 21 December 2023 Last accessed 15 October 2024	Living Guidance	**Level 4**	N/A	N/A	N/A
Assessment of evidence					
This international guidance considered COVID-19 research and IPC. It is intended for public health professionals, infection prevention and control professionals. The following section(s) are relevant for this research question on what a surgical mask is: Medical or procedure mask “flat or pleated and are affixed to the heat with straps around the ears, the head or both” (page 7) “Performance standards are tested according to a set of standardised test methods (American Society for Testing Materials (ASTM) ASTM F2100, EN 14683, or equivalent) that aim to balance high filtration, adequate breathability and, optionally, fluid penetration resistance” (page 7) references the WHO technical specifications of PPE for COVID-19.					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Loveday HP, et al., Epic3: National evidence-based guidelines for preventing healthcare-associated infections in NHS hospitals in England. J Hosp Infect. 2014 Jan;86 Suppl 1:S1-70.	Guidance	**AGREE: Recommend with provisos**	N/A	N/A	N/A

Assessment of evidence

This British guidance provides IPC guidance with a focus on preventing HAI in hospital and acute settings. The following section(s) are relevant for this research question on what a surgical mask is:

The document defines surgical masks as “A mask that covers the mouth and nose to prevent droplets from the wearer being expelled into the environment. As they are also fluid repellent, they provide some protection for the wearer against exposure of mucous membranes to splashes of blood/body fluid”.

The authors state that “Healthcare workers (and sometimes patients) may use standard, fluid-repellent surgical face masks to prevent respiratory droplets from the mouth and nose being expelled into the environment” but only include the following as part of their formal recommendations: Fluid repellent surgical masks should be worn when there is a risk of blood or bodily fluid splashes into the face and eyes.

Limitations: No updates since 2014. Limited literature review details and limited methods for formulating recommendations.

Question 3: What type of surgical face masks are recommended for health and care setting?

Evidence added to version 2.0 update:

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution Standards Publication. BS EN 14683:2025+AC:2019, ICS 11.140. Medical face masks - Requirements and test methods. March 2025.	British Standards	**Level 4**	N/A	N/A	N/A

Assessment of evidence

This document outlines the British Standards for medical masks (requirements and testing). It is not specific to mask use for source control (prevention of transmission from staff to patients during surgical procedures, and transmission from an asymptomatic carrier or patient with clinical symptoms). It is not applicable to face masks intended exclusively for the personal protection of staff.

The following section(s) are relevant for this research question on what a surgical mask is:

Splash resistance – For a Type IIR mask “when tested in accordance with ISO 22609:2004 the resistance of the medical face mask to penetration of splashes of liquid” should be greater than or equal to 16,0kPa.

When tested in accordance with BS EN 14683:2025, Type IIR masks used (for healthcare) should have a bacterial filtration efficiency (BFE) of no lower than ≥98% (a type II or Type IIR mask) and a differential pressure (breathability) value of ≤300 Pa.

“When tested according to EN ISO 11737-1:2018 the bioburden of the medical mask shall be ≤ 30 CFU/g tested”

Splash resistance – “ability of a medical face mask to withstand penetration of synthetic blood projected at a given pressure”

Assessment of evidence
“Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I medical face masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.” Annex E of the 2025 revision to this standard proposes that future revisions of the standard should not include TYPE I medical masks “unless there is a convincing reason to allow it to remain”. The rationale for removal related to “confusion about appropriate use of Type I masks” which may lead to “potential misuse of Type I medical face masks”. Also noted is the fact that Type I masks are sometimes described by manufactures as “identical to their type II masks apart from the fact that they don’t have them tested for splash resistance. If correct, this would mean that there would not be significant impact on Type I medical face mask manufacturers. The PG also believes that the market for Type I medical face masks in Europe is very small”. The group outline that they appreciate that “certain guidance documents which were relied on during the Covid 19 pandemic recommends the use of Type I masks” to allow the WHO and others to update their guidance it was recommend this change happen in the next revision of the standard. The 2025 revision of the medical mask standards include a section on transparent medical face masks (Annex F). This section outlines that “transparent medical face masks (TMFM) can support communication by ensuring the mouth and facial expressions can be seen”. It is also stated that the minimum requirements of TMFM are still evolving”. “It is envisaged that a transparent medical face mask can provide similar performance to that required by this document with minor modifications to the test methods and requirements. In addition, there are several suggested design features described”. There are details about breathability, differential pressure measurements, particle attenuation, filtration measurements, fit, function, condensation, acoustics, durability, visibility.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Government of Canada. Guidance for transparent medical mask technical specifications: Overview. 2021	Guidance/ Expert Opinion	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Date modified 30 July 2021					
Assessment of evidence					
This guidance document provides an overview and specifications required in a Canadian setting for the use of single use transparent masks. It was last modified on 30/06/2021 (the 'other requirement' section was last modified on 12/11/2021). The following section(s) are relevant for this research question on what type of surgical face masks are recommended for health and care settings. "Transparent medical masks will generally include a transparent area (made of plastic). The wearer's mouth and parts of the face are visible to people who communicate by reading lips or have other speech and/or hearing-impairments. This transparent area may be attached to or surrounded by a filter area or a flexible element, such as a foam strip. This helps the mask fit the face." Transparent masks must meet EN14683 Type IIR or ASTM F2100 or comparable standards for medical mask materials and "other test requirements" to be considered transparent medical masks. "Transparent medical masks make it easier for the wearer to communicate. Visual cues are important to people with hearing impairments and special learning needs. A transparent medical mask allows the mouth of the wearer to be seen" Summary: An overview of transparent surgical face mask use and specifications within a Canadian setting. Transparent surgical face masks are recommended for use in Canadian health and care settings in place of surgical face masks where they assist communication for example to allow for lip reading by allowing the wearers mouth to be seen.					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
New Zealand Ministry of Health. Guide to Mask Use in Health Care Settings August 2021	Guidance/ Expert Opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence
This New Zealand guidance was published to “provide information about mask types and appropriate mask use.” The following section(s) are relevant for this research question on what type of surgical face masks are recommend for healthcare settings. The document provides the following purposes and examples for the following mask types for healthcare workers: Fluid resistant surgical mask: “Fluid resistant medical mask - Purpose: protect wearer e.g. when providing care for patients with acute respiratory infection where droplet precautions required. Fluid resistance medical mask with “moderate to high” fluid resistance level 3, type IIR- Purpose: protect the wearer (level 2, 3, or type IIR) e.g. surgical or trauma procedures where risk of exposure to blood or body fluids is high - standard precautions. Fluid resistant medical mask with “moderate” fluid resistance level 2 - Purpose: protects the wearer (level 1) e.g. procedures with low risk of blood and body fluid splash - standard precautions.” Non-fluid resistant surgical masks: Non-fluid resistant medical mask - Purpose: protects the patient e.g. during medical procedure “the mask prevents the passage of microbes from the nose and mouth of the health care worker into the sterile field” States that the New Zealand Standard for masks complies with the British and European Standard 14683:2019 (Type I, II and IIR). And that medical masks used in New Zealand are required to meet the New Zealand Standard (British Standard (BS) and European Standard (EN) 14683:2019 (Type I, II and IIR) or an equivalent Standard such as the American Society of Testing and Materials (ASTM) Standard F2100-11 (2011) (Level 1, 2 and 3). Limitation: Expert opinion guidance – methods for forming the guidance are unclear.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Statutory instruments. Personal Protective equipment (PPE) at work regulations from 06 April 2022.	Mandatory	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
ISBN 9780717667468. 2022.					
Assessment of evidence					
PPE at work regulations, PPER 1992) to PPE at work regulations -cite as PPER 2022. Relevant amendments are listed below, please note extension or clarification to working for “employer” and “workers” as well as extension to include limb (b) workers and updates to other references such as the updated COSHH regulations. These are not described in detail below but are highlighted as amended and required. Employers and employees must adhere to all aspects of PPE at work regulations, where appropriate. • “Subject to paragraph (1A) every employer shall ensure that suitable personal protective equipment is provided to their workers who may be exposed to a risk to their health or safety while at work except where and to the extent that such risk has been adequately controlled by other means which are equally or more effective.” • (1) Before choosing any personal protective equipment which by virtue of regulation 4 they are required to ensure is provided, an employer or relevant self-employed person shall ensure that an assessment is made to determine whether the personal protective equipment they intend will be provided is suitable.					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE) ACOP. Personal protective equipment at work. The Personal Protective Equipment at Work Regulations 1992 (as amended) Guidance on Regulations.	Guidance/Expert Opinion	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
(version 4). ISBN 9780717667468. 2022 (Fourth Edition) Accessed 17 October 2024					
Assessment of evidence					
“39 The aim should be to choose PPE which gives maximum protection while ensuring minimum discomfort to the wearer, as uncomfortable equipment is unlikely to be worn properly.” Guidance which accompanies the UK legislation for PPE at work which was amended 2022.					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Department of Health and Social Care. Infection prevention and control: resource for adult social care Published 31 March 2022 Updated 01 March 2024 Accessed: 11 October 2024	Guidance/Expert Opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence
This English guidance provides “general infection prevention and control (IPC) principles to be used in combination with advice and guidance on managing specific infections. The following section(s) are relevant for this research question on what type of surgical face masks are recommended for health and care settings. Face masks were considered within a PPE section alongside other type of PPE including gloves/goggles. On Face masks, the document states “Type IIR fluid-repellent surgical masks protect the wearer by providing a fluid repellent barrier between the wearer and the environment. They provide additional protection from respiratory droplets. Consider wearing fluid-repellent type IIR masks where there is a risk of splashing of blood or body fluids into the worker’s nose or mouth. These should be well-fitting and cover the nose, mouth and chin and should not be touched when worn. Type IIR masks should be worn when carrying out aerosol-generating procedures (AGPs). Fluid-resistant type IIR masks should not be worn for longer than 4 hours. They must be disposed of after the episode of care is completed, when damaged or when the mask becomes moist. Care workers should move to a safe area to remove the mask.” Summary: This level 4 expert guidance document from DHSC is intended for the adult and social care setting only (England) and covers general infection prevention and control (IPC) principles. It states that fluid-repellent type IIR must protect the wearer by providing a fluid repellent barrier between the wearer and the environment and additional protection from respiratory droplets. It must be well-fitting and cover the nose, mouth and chin and should not be touched when worn.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
World Health Organization (WHO). Infection prevention and control in the context of coronavirus disease (COVID-19): A living guideline.	Guidance/Expert opinion	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Last updated 21 December 2023 Last accessed 15 October 2024					

Assessment of evidence

This international guidance candies COVID-19 IPC research. It is intended for public health professionals, infection prevention and control professionals at both the national and facility levels, health care facility administrators, managers, and health workers. There was not a systematic review for the recommendations specific for surgical face masks. The following section(s) are relevant for this research question on what type of surgical face masks are recommended for health and care settings.

On medical masks, the document states “Their performance standards are tested according to a set of standardised test methods (American Society for Testing Materials (ASTM) ASTM F2100, EN 14683, or equivalent) that aim to balance high filtration, adequate breathability and, optionally, fluid penetration resistance” (page 7) – references the WHO technical specifications of PPE for COVID-19

The document also provides the following performance standards and characteristics

- Medical masks for healthcare worker
  - Performance standards - EN 14683 (type II or type IIR); ASTM F2100 (level 1, 2, or 3); or YY 0469 or YY/T 0969 (at least 98% bacterial filtration efficiency).
  - Characteristics - Medical mask, good breathability, internal and external faces should be clearly identified, 98% droplet filtration, preferably fluid resistance.
- Medical mask for patient
  - Performance standards - When bacterial droplet filtration is less than 98%, EN 14683 Type I YY 0469 or YY/T 0969 Or alternative equivalent.
  - Characteristics - Medical mask, good breathability, internal and external faces should be clearly identified.

Assessment of evidence
Funding/conflicts of interest: Conflict of interests are decided by a technical officer who collects declarations of interests from the Guideline Development Group members, removing those with conflicts from voting/discussion for recommendations according to where the conflict of interest lies. Limitations: There are no details on how literature was searched, what terms were used etc so this guidance has been graded expert opinion as it did not meet the standards of AGREE recommend. Summary: A living guidance document published by WHO and funded by CDC. It did not provide sufficient detail to be considered AGREE recommend but was included as level 4 expert opinion level evidence. While it is reported that multidisciplinary experts were involved in the development of these guidelines it is not clear how evidence was identified or selected and therefore it is subject to bias.

Evidence from previous update(s):

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Coia JE, Ritchie L, Adisesh A, et al. Guidance on the use of respiratory and facial protection equipment. Journal of hospital Infection. 2013 Nov 1;85(3):170-82.	Expert opinion	**Level 4**	N/A	N/A	N/A
Assessment of evidence					
This British paper was published to provide guidance to support the prevention of HCW infections in health care settings. The following section(s) are relevant for this research question on what type of surgical face masks are recommended for health and care settings.					

Assessment of evidence
“Surgical face masks provide a barrier to splashes and droplets impacting on the wearer's nose, mouth and respiratory tract. They do not provide protection against airborne (aerosol) particles and are not classed as RPE. Whilst some surgical masks claim to have particulate filtration properties, they do not have the filtering efficiencies required for adequate respiratory protection.” “Although not classified as RPE, surgical face masks used for protection against infection must be fluid repellent, compliant with the Medical Devices Directive (MDD 93/42/EEC),10 and be ‘CE’ marked.” ‘Surgical masks used for protection against infection must be fluid repellent’. (no reference given) • They should be compliant with MDD 93/42/EEC. • They should be CE marked • Masks should fully cover the nose and the mouth of the wearer. Methods: Coia et al., (2014) is a summary of Coia et al (2013) and Bunyan et al (2013) was the review that informed ref Coia et al (2013). Reference of interest is Coia 2013. Full references of supporting documents: Coia, et al. Use of respiratory and facial protection. 2014. Nursing Times. Vol 110 (4) p18-20. Coia, JE, et al, The Healthcare Infection Society Working Group on Respiratory and Facial Protection. Guidance on the use of respiratory and facial protection. Journal of hospital infection 85(2013) 165-169. Bunyan D et al, Respiratory and facial protection: a critical review of recent literature. 2013. Journal of Hospital Infection. Vol 85 p165-169. Limitation: Caution is advised as this guidance was published in 2014 and some aspects may be out of date. Summary: This expert consensus provides guidance on surgical masks and respirators. It advises on the standards that both these types of masks should meet in the UK, when they should be worn, how they should be fit checked/tested if necessary and how they should be removed and disposed of. It refers to relevant health and safety/governmental legislation.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Loveday HP, Wilson JA, Pratt RJ et al. epic3: National evidence-based guidelines for preventing healthcare-associated infections in NHS hospitals in England. J Hosp Infect. 2014 Jan;86 Suppl 1:S1-70.	Guidance/ expert opinion	**AGREE: recommend with provisos**	N/A	N/A	N/A

Assessment of evidence

This British guidance provide IPC recommendations to prevent HAI in hospital and acute settings. The following section(s) are relevant for this research question on what type of surgical face masks are recommended for health and care settings.

“Surgical masks: A mask that covers the mouth and nose to prevent droplets from the wearer being expelled into the environment.”

The authors state that “Healthcare workers (and sometimes patients) may use standard, fluid-repellent surgical face masks to prevent respiratory droplets from the mouth and nose being expelled into the environment” but only include the following as part of their formal recommendations: “Fluid repellent surgical masks should be worn when there is a risk of blood or bodily fluid splashes into the face and eyes.”

“In other circumstances, such as where the agent is transmitted via droplet rather than aerosol or where the level of aerosol exposure is low, the risk assessment may conclude that other forms of RPE (e.g. APF10/ FFP2) or a physical barrier (e.g. surgical face mask) may be appropriate, such as when caring for patients with influenza.”

“Healthcare workers (and sometimes patients) may use standard, fluid-repellent surgical face masks to prevent respiratory droplets from the mouth and nose being expelled into the environment.”

Assessment of evidence
Limitations: No updates since 2014. Limited literature review details and limited methods for formulating recommendations. Not graded recommendations.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
World Health Organization (WHO). Infection prevention and control of epidemic and pandemic prone acute respiratory infections in health care. 2014.	Guidance	**AGREE: 'recommend with provisos'**	N/A	N/A	N/A
Assessment of evidence					
This international guidance document "provide recommendations, best practices and principles for non-pharmacological aspects of infection prevention and control (IPC) for acute respiratory infections (ARI) in health care, with special emphasis on ARI that can present as epidemics or pandemics. The guidelines are intended to help policy-makers, administrators and health-care workers to prioritize effective IPC measures". The following section(s) are relevant for this research question on what type of surgical face masks are recommended for health and care settings. On medical masks standards, the document states that "there are no minimum standards or standardized testing methods for mask filter efficiency, and available masks vary widely in the efficiency of their filters." The Authors go on to outline FDA standards for masks which includes fluid resistance but consistent mask terminology throughout the document does not indicate the type of mask recommended.					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Siegel JD, Rhinehart E, Jackson M et al. Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Health Care Settings. 2007 (updated 2024).	Guidance/Expert Opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence

This American CDC guideline provides “infection control recommendations for all components of the healthcare delivery system, including hospitals, long-term care facilities, ambulatory care, home care and hospice”. The following section(s) are relevant for this research question on what type of surgical face masks are recommended for health and care settings.

“Two mask types are available for use in health care settings: surgical masks that are cleared by the FDA and required to have fluid-resistant properties, and procedure or isolation masks. No studies have been published that compare mask types to determine whether one mask type provides better protection than another. Since procedure/isolation masks are not regulated by the FDA, there may be more variability in quality and performance than with surgical masks. Masks come in various shapes (e.g., molded and non-molded), sizes, filtration efficiency, and method of attachment (e.g., ties, elastic, ear loops). Healthcare facilities may find that different types of masks are needed to meet individual healthcare personnel needs.

“Masks may be used in combination with goggles to protect the mouth, nose, and eyes, or, alternatively, a face shield may be used instead of a mask and goggles to provide more complete protection for the face...”

“Procedures that generate splashes or sprays of blood, body fluids, secretions, or excretions (e.g., endotracheal suctioning, bronchoscopy, invasive vascular procedures) require either a face shield (disposable or reusable) or a mask and goggles.”

Assessment of evidence
Limitation: Caution is advised as this guidance was based on expert opinion and was published in 2007 and some aspects may be out of date.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Occupational Safety and Health Administration (OSHA). Guidance on Preparing Workplaces for an Influenza Pandemic. 2009.	Guidance/Expert Opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence
This American guidance document provides a general overview of the steps and considerations required to prepare workplaces for an influenza pandemic. The following section(s) are relevant for this research question on what type of surgical face masks are recommended for health and care settings. “Surgical Masks - Surgical masks are used as a physical barrier to protect employees from hazards such as splashes of large droplets of blood or body fluids. Surgical masks also prevent contamination by trapping large particles of body fluids that may contain bacteria or viruses when they are expelled by the wearer, thus protecting other people against infection from the person wearing the surgical mask.” “Only surgical masks that are cleared by the U.S. Food and Drug Administration and legally marketed in the United States have been tested for their ability to resist blood and body fluids.” Limitation: Caution is advised as this guidance was published in 2009 and some aspects may be out of date.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The Association of Anaesthetists of Great Britain and Ireland. AAGBI safety guideline: Infection Control in Anaesthesia. 2020 Last accessed: 16 October 2024	Guidance/Expert Opinion	**Level 4**	N/A	N/A	N/A
Assessment of evidence					
This consensus document was produced by expert members of Working Party established by the Association of Anaesthetists of Great Britain and Ireland (AAGBI). The following section(s) are relevant for this research question on what type of surgical face masks are recommended for health and care settings: “The AAGBI recommends the use of Standard Precautions, which incorporate additional safeguards for specific procedures and patients, including single-use gloves, fluid resistant masks with a transparent face shield and gowns”					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Department of Health, England Health Protection Agency. Pandemic (H1N1) 2009 influenza	Guidance/Expert Opinion	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Summary infection control guidance for ambulance services during an influenza pandemic. 2009					
Assessment of evidence					
This British publication provides guidance for pandemic infection control for the ambulance services. • “A fluid repellent surgical mask will provide a physical barrier and minimise contamination of the nose and mouth by respiratory droplets and must be worn when working in close contact (within about one metre) with a patient suspected of having influenza.”					

Question 4: What design features are desirable for surgical face masks?

Evidence added to version 2.0 update:

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Onishi, K. and Nojima, M. Comparison of the inward leakage rate between N95 filtering facepiece respirators and modified surgical masks during the COVID-19 pandemic. Environmental Health and Preventative Medicine. 2024; 29(8), doi: 10.1265/ehpm.23-00303.	Observational	Level 3	The study assessed the inward leakage of an unadjusted surgical mask, and a surgical mask adjusted to improve fit. NaCl particles (particle size: 0.075 ± 0.02 uM) at 85 L/min flow rate were used to assess filtration-collection efficiency.	Inward leakage rate according to mask/respirator type	Inward leakage rate (median) according to mask type. Based on fit factor (number of particles outside mask / number of particles inside of mask converted to inward leakage rate based on fine particulate matter number).
Assessment of evidence					
Setting: University hospital, Tokyo, Japan Methodology: Volunteers from the general population as well as healthcare workers ((HCWs)) including nursing students). N = 54 participants in total (20 men, 34 women; 31 from general population; 23 HCWs). Leakage rates of included masks were assessed using various measurements: • Measurement 1 - Mask B (surgical mask) worn with pleats spread out and the nose wire pressed down onto the nose					

Assessment of evidence

- Measurement 2 – Mask B (surgical mask) worn with nose wire adjusted to a 'W' shape prior to donning, according to the shape of the participants' noses. To standardise this approach, the researcher's bent the wire to the appropriate shape according to the participant's nose.
- Measure 5 – Mask D (N95) were put on by participants after the researchers taught them how to achieve a tight fit. A fit test was performed on some participants (n = 39) to validate fit.

The fit check was performed using an optical particle counter (MT-05U; SIBATA, Tokyo, Japan). Ambient particles (>0.3 uM in diameter) inside and outside of masks were counted. To validate these results, a CNC counter was used to count particles 0.15 – 1 uM in size (AccuFIT 9000 PRO 3000-J1. Kanomax Japan Ink, Osaka, Japan). Exercises were taken from the OSHA CNC QNFT protocol were used (29 CFR 1910.134, OSHA), namely: 1) normal breathing, 2) bending over, 3) moving head up and down, 4) turning head side to side, 5) talking (counting down from 100), 6) normal breathing. NaCl particles (particle size: 0.075 ± 0.02 uM) at 85 L/min flow rate were used to assess filtration-collection efficiency and inhalation resistance. Fit factor (FF; number of particles outside mask / number of particles inside of mask) was calculated using mean of FF for each exercise, then converted to inward leakage rate (ILR) based on the fine particular matter number in order to compare results.

Main findings: Median ILR (IQR) of surgical mask with W-shaped nose wire: 50.82 (35.36 – 76.82) versus surgical mask with nose-wire pressed down: 96.44 (72 – 100), p-value <0.001, p-value using Bonferroni's correction <0.001.

Limitations:

- Small sample size
- Large proportion of participants were from the general population, thus lack relevant experience of wearing SFM and RPE in clinical settings.
- Single study site
- Only one respirator type included, where it is unclear if multiple brands of this type have been used. This limitation also applies to surgical masks.
- N95 duckbill type not typically used in NHSScotland, limiting generalisability of findings.
- Fit test only performed on 39 participants.
- Unclear if surgical mask if fluid resistant. One type of mask considered.

Assessment of evidence
• Optical particle counter measured ambient particles >0.3 uM in diameter. Particles smaller than this were not counted, which may impact the findings. It is unclear in which direction this would bias the findings. • Unclear no mask control results. • Fixed experimental conditions with a lack of applicability. This study contributes to the evidence base that in a controlled, experimental setting, surgical face masks with a nose wire provide significantly better protection (inward leakage rate) than when the nose wire is not used. Unclear how this compares to no mask and the clinical significance of these results is unclear as transmission risk is unknown.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Government of Canada. Guidance for transparent medical mask technical specifications: Overview. Last modified 30 June 2021. Other requirements. Last modified 12 Nov 2021. Technical specifications. Last modified 30 June 2021. Definitions. Last modified 30 June 2021.	Guidance/Expert Opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence

This guidance document provides an overview and specifications required in a Canadian setting for the use of single use transparent masks. It was last modified on 30/06/2021 (the 'other requirement' section was last modified on 12/11/2021). The following section(s) are relevant for this research question on desirable design features for surgical face masks.

"Transparent medical masks will generally include a transparent area (made of plastic). The wearer's mouth and parts of the face are visible to people who communicate by reading lips or have other speech and/or hearing-impairments. This transparent area may be attached to or surrounded by a filter area or a flexible element, such as a foam strip. This helps the mask fit the face."

"The medical masks must:

- not restrict breathing
- not disintegrate, split or tear during use
- be made of non-toxic materials so it's safe to inhale and the skin won't be irritated
- fit closely over the nose, mouth, chin and sides of the face or provide enough coverage in a manner, which ensures adequate source control and wearer protection

Transparent medical masks intended for specific uses (such as speech and language assessments) should:

- give an adequate view of the face to accommodate facial movement without slipping or displacing the mask
- ensure that the volume of the voice is not distorted or reduced significantly when the mask is in place

Transparent medical masks may have different shapes and constructions. They may also have additional features such as a:

- face shield, to protect the wearer's face against splashes and droplets
- nose bridge, to enhance fit by conforming to the contours of the nose

The filter area and seating element (a flexible element like a foam strip, which seats the mask to the face) must enable the wearer to breathe and wear the mask comfortably. Like all masks and respirators, transparent masks should not contain any valves or air holes, which may release contaminated air. These are not recommended for use during the pandemic.

There may be other design requirements important to specific wearers, which are not dealt with in this specification."

An overview of transparent surgical face mask use and specifications within a Canadian setting. Transparent face masks should allow the wearer's mouth and part of the face to be visible. It should cover the wearer's mouth and nose, a filter area or flexible element such as a

Assessment of evidence
foam strip may be used to improve fit. It is stated that transparent surgical face masks may differ in shape and construction but that they should not restrict breathing, not split or disintegrated during use, should be conducted with non-toxic materials and should fit closely.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
World Health Organization (WHO) Technical specifications of personal protective equipment for COVID-19. 2020.	Guidance/ Expert Opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence
This interim international guidance “defines the basic technical characteristics of PPE. The decision as to the appropriate clinical use of each of these devices is reserved to medical staff and according to IPC guidance”. The following section(s) are relevant for this research question on desirable design features for surgical face masks. The document provides the following characteristics for the following kinds of medical masks. • “Mask, medical for health care worker: Medical mask, good breathability, internal and external faces should be clearly identified, 98% droplet filtration, preferably fluid resistance” • “Mask, medical for patient: Medical mask, good breathability, internal and external faces should be clearly identified”. This COVID-19 specific interim guidance document from WHO contains specifications for medical masks for healthcare workers and patients which were reviewed by members of the Technical Advisory Group of experts on Personal Protective Equipment (TAG PPE), who also provided technical input; and by WHO staff and consultants from WHO. No methodology has been described hence it can only be graded as Level 4. With regards to design features, it looks at breathability, particle filtration, labelling each side and fluid resistance.

Evidence from previous update(s):

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Publication. Medical face masks – Requirements and test methods. BS EN 14683:2019. 2019.	British/European Standards	**Level 4**	N/A	N/A	N/A

Assessment of evidence

"This British Standard is the UK implementation of EN 14683:2019, incorporating corrigendum August 2019. It supersedes BS EN 14683:2014, which is withdrawn." It "specifies 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." It is not specific to mask use as PPE and other standards should be consulted. It supersedes EN 14683:2014. The following section(s) are relevant for this research question on desirable design features for surgical face masks.

- "The medical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides" (Page 8)
- "Medical face masks may have different shapes and constructions as well as additional features such as a face shield (to protect the wearer against splashes and droplets) with or without anti-fog function, or a nose bridge (to enhance fit by conforming to the nose contours)" (Page 8)
- Type I or II based on bacterial filtration efficiency (BFE) with the 'R' added for splash resistance "ability of a medical face mask to withstand penetration of synthetic blood projected at a given pressure"
- "shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides."
- "shall not disintegrate, split or tear during intended use"

Assessment of evidence
• Splash resistance – For a Type IIR mask “when tested in accordance with ISO 22609:2004 the resistance of the medical face mask to penetration of splashes of liquid” should be greater than or equal to 16kPa. • When tested in accordance with BS EN 14683:2019 the mask used should have a BFE of no lower than 98% (a type IIR mask) • When tested in accordance with BS EN 14683:2019 the mask used should have a differential pressure (breathability) value of <60 Pa/cm² • “When tested according to EN ISO 11737-1:2018 the bioburden of the medical mask shall be ≤ 30 CFU/g” Summary: The British Standards update for medical mask requirements and testing published March 2019 suggest that a medical masks may differ in some design features but that generally they should be “closely” fitted at the sides as well as over a wearers nose, mouth and chin. Nose clip, anti-fog and a shield are optional design features that may enhance protection.

Question 5: When should healthcare workers wear a surgical face mask?

Evidence added to version 2.0 update:

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Buetti N, Marschall J, Drees M, et al. Strategies to prevent central line-associated bloodstream infections in acute-care hospitals: 2022 Update. Infection Control & Hospital Epidemiology. 2022 May;43(5):553-69.	Guidance/ expert opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence

Guidelines noted as collaboratively produced by SHEA (society for healthcare epidemiology of America), IDSA (infectious diseases society of America), APIC (Association for professionals in infection control and epidemiology), AHA (American hospital association) for central line-associated bloodstream infections in acute-care hospital settings.

“Use maximum sterile barrier precautions during CVC insertion (Quality of Evidence: MODERATE) a. Use maximum sterile barrier precautions: i. A mask, cap, sterile gown, and sterile gloves are to be worn by all HCP involved in the catheter insertion procedure.”

Limitations:

- There is not sufficient detail within the methodology to appraise fully. The recommendations are considered as the expert opinion of the aforementioned organisations based on a literature review and expertise of the “expert panel”.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
World health Organisation (WHO). Guidelines for the prevention of bloodstream infections and other infections associated with the use of intravascular catheters. Part 1 peripheral catheters. 2024	Guidance	**AGREE: 'Recommend with provisos'**	N/A	N/A	N/A

Assessment of evidence

WHO guidelines to reduce BSI and IPC for peripheral catheter insertion/use.

"WHO recommends using a sterile technique for the insertion of PICCs and PACs in adults, adolescents-children and neonates. (Good practice statement) Remarks • GDG members considered that a sterile technique should be used for the insertion of longer term catheters, such as PICCs, as the tip of the catheter is located in a major central vein. Hence, any infection would likely be associated with bacteraemia. A similar consideration was made for PACs as these catheters are used almost solely in intensive care unit settings where patients are severely ill and the potential risk of health care-associated catheter-related infection is high. • A sterile technique consists of sterile barrier precautions. The GDG decided that for the insertion of PICCs and PACs, the sterile technique should include the use of a medical mask, sterile gown, sterile gloves and a sterile drape that adequately covers the area around the insertion site to prevent contamination of the catheter. The GDG noted that this is different from maximal sterile barrier precautions (22) in which a cap is included and the drape is a full body sterile drape (similar to the sterile drapes used in the operating room)"

Limitations:

- The search strategies are not included in the publication.
- No pilot and limited patient/service user involvement.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
European Centre for Disease Prevention and Control (ECDC). Infection prevention and control and preparedness for COVID-19 in healthcare settings – Sixth update. 9 February 2021	Guidance/ Expert Opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence

This EU, level 4 document provides guidance for health and care facilities and providers regarding IPC in light of the SARS-CoV-2 pandemic. This version is the 6th update of this guidance and replaces the previous version (published 6 October 2020). The following section(s) are relevant for this research question on when healthcare workers should wear a surgical face mask.

- The following was reported as guidance for acute health care settings: "The use of medical face masks by healthcare workers for personal protection and source control should be strongly considered during all routine activities and in communal areas as a measure for reducing transmission within healthcare settings in areas with community transmission".
    - "Staff, visitors and patients should wear a face mask when physical distancing is not possible. Visitors may use non-medical face masks, if in line with local recommendation."
    - "In areas with any kind of community transmission, all staff who provide care for patients or have contact with patients should consider wearing a medical face mask, in addition to practising meticulous hand hygiene"
    - "Healthcare workers in contact with a possible or confirmed COVID-19 case should wear a well-fitted respirator and eye protection (i.e. visor or goggles) [40]. In case of shortage of respirators, the use of medical face masks and options for prolonged use of respirators, decontamination and reuse of respirators can be considered in agreement with the health and safety committee or OSH experts at facility level."

Assessment of evidence
• Within the cleaning, ventilation and waste management section: “Staff engaged in environmental cleaning and waste management should wear a medical face mask, eye protection (visor or goggles), gloves and a gown [43]” • Within the long-term care facility section: “in areas with community transmission of COVID-19, all LTCF workers, including LTCF staff, agency staff, volunteers and/or other informal carers, who provide care for residents or have contact with residents or communal areas of the LTCF, should consider wearing a medical face mask, in addition to practising meticulous hand hygiene;” • Additional precautions: “Face masks should be worn both by staff administering vaccines and by the individuals being vaccinated” Note: There have been several iterations of this guidance and other pandemic specific guidance’s published by ECDC. The PPE needs in healthcare settings for the care of patients with suspected or confirmed novel coronavirus February 2020 stated that the PPE requirements for confirmed or suspected COVID-19 cases was FFP2 or FFP3. It is not clear what evidence was used to create this earlier recommendation or the updated surgical mask recommendations. Pandemic specific guidance produced by the European Centre for Disease Prevention (ECDC). There is a ‘background’ section with citations however, the methodology used to identify this evidence is not clear and therefore it is considered as level 4. The primary mask citations were limited literature reviews. Within acute care settings ECDC recommend the use of medical masks for staff as a method of both source control and for personal protective equipment (PPE) in all care and non-care settings where there is community transmission of SARS-CoV-2. All staff within acute care settings are also recommended to wear a medical face mask where physical distancing is not possible.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
European Centre for Disease Prevention and Control. (ECDC). Considerations for infection prevention and control practices in relation to	Guidance/ Expert Opinion	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
respiratory viral infections in healthcare settings 06 February 2023. Accessed 16 March 2023					

Assessment of evidence

The target user for this level 4 guidance "National public health agencies, healthcare facility administrators, IPC and other professionals developing relevant IPC guidance and healthcare workers in EU/EEA countries."

General guidance for healthcare workers:

- "During periods of high community transmission … all staff who provide care for patients or have contact with patients should wear a medical face mask as part of universal or targeted clinical masking policies" (references WHO living guidance, 13 January 2023)
- "For RSV infections, particularly in infants, young children and immunocompromised adults, the use of gloves, gowns and face mask or eye protection (e.g. goggles) is recommended" (references Red Book 2018: Report of the Committee on Infectious Diseases, Kimberlin et al. and CDC Transmission-based precautions guidance, 2016)
- "A risk assessment should be conducted to support appropriate selection of PPE. It is recommended that healthcare workers interacting with patients who have viral respiratory infections, without close proximity or long exposure to the patient, should wear a medical face mask, as a minimum. For prolonged contact in close proximity to the patient, including the performance of high-risk procedures, a well-fitted respirator (see 'Definitions') and eye protection are recommended. Gloves and a long-sleeve gown are recommended when there is a risk of exposure to body fluids and in settings where there is a high risk of exposure to respiratory viruses, such as when performing procedures with a high risk of transmission (also referred to as 'aerosol-generating procedures' - AGPs). If gloves and gowns are used, these should always be changed after contact with each individual patient."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health New Zealand. Infection prevention and control Last updated 26 November 2024	Guidance/ Expert Opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence

This Guidance published by Health New Zealand includes standard and transmission-based precautions and it includes COVID-19/ mpox guidance (TBPs). The following section(s) are relevant for this research question on when healthcare workers should wear a surgical face mask.

Standard precautions:

- "Select PPE before any health care activity based on an assessment of the likely risk of exposure to body substances or contaminated surfaces. For example, wear gloves if your hands may be in contact with body fluids, wear an apron or gown to prevent soiling of clothing, and wear a face shield/mask/goggle if droplets or splashes are likely to be generated near your face (e.g., when taking a nasopharyngeal swab)".

Droplet precautions (interacting with people with suspected or known infection or disease spread by droplet):

- "Wear a medical mask upon room entry or when interactions mean that physical distancing of 1 metre cannot be maintained"

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health New Zealand.	Guidance/ Expert Opinion	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Mask use and visitor guidance for hospitals and other health and disability care settings December 2023					
Assessment of evidence					
Advises mask use at all times in the following situations: • in admitting units (ED, medical assessment units, surgical assessment units) when assessing patients with 'undifferentiated illness'. • In higher risk units depending on local situation – units providing care to vulnerable patients (cancer/ transplants, dialysis), and units known to have suboptimal physical environment (including ventilation). Advises mask use as 'surge response' based on local risk assessment for example in 'higher prevalence periods (winter months, outbreaks/community surges) for all HCWs providing direct patient care in all environments. In community-based acute health care (e.g. GP, urgent care, oral care, ambulance staff), advises mask use during higher prevalence periods (e.g. winter months, outbreaks/ community surges) for all clinical and non-clinical staff when having patient contact (waiting room, clinical assessment, treatment, patient transport). Advises HCWs can choose to wear a mask based 'on their own health needs and risks for more severe respiratory infection'.					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
New Zealand Ministry of Health.	Guidance/ Expert Opinion	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Guide to Mask Use in Health Care Settings August 2021					
Assessment of evidence					
This New Zealand guidance was published to “provide information about mask types and appropriate mask use.” The following section(s) are relevant for this research question on when healthcare workers should wear a surgical face mask. The document provides the following purposes and examples for the following mask types for healthcare workers: Fluid resistant surgical mask: “Fluid resistant medical mask - Purpose: protect wearer e.g. when providing care for patients with acute respiratory infection where droplet precautions required. Fluid resistance medical mask with “moderate to high” fluid resistance level 3, type IIR- Purpose: protect the wearer (level 2, 3, or type IIR) e.g. surgical or trauma procedures where risk of exposure to blood or body fluids is high - standard precautions. Fluid resistant medical mask with “moderate” fluid resistance level 2 - Purpose: protects the wearer (level 1) e.g. procedures with low risk of blood and body fluid splash - standard precautions.” Non-fluid resistant surgical masks: Non-fluid resistant medical mask - Purpose: protects the patient e.g. during medical procedure “the mask prevents the passage of microbes from the nose and mouth of the health care worker into the sterile field” Limitation: Expert opinion guidance – methods for forming the guidance are unclear.					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Government of Canada. Updated guidance for Infection	Guidance/ Expert opinion	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
prevention and control in the health care setting when COVID-19 is suspected or confirmed – April 2024. Updated 12 April 2024 (published 23 December 2021) Accessed 21 October 2024.					

Assessment of evidence

This Canadian guidance updates previous guidance produced to consider IPC requirements across health and care settings COVID-19. These recommendations extend across health and care settings, and are informed by expert opinion from the National Advisory Committee on Infection Prevention and Control (NAC-IPC), review of scientific literature and "an environmental scan of international, provincial and territorial guidance". The use of "patient" refers to any person receiving health care, including patients, residents, clients.

Recommended PPE for all patient encounters should be based on a point of care risk assessment (PCRA), including:

- "Patients not yet clinically evaluated (e.g., emergency areas)
- Likelihood of exposure to SARS-CoV-2 and other pathogens based on:
    - specific interaction (e.g., requirement of extensive or prolonged close proximity)
    - specific task (e.g., performance of higher risk examinations, such as those of the mouth, nose, and throat)
    - specific patient factors (e.g., patient's ability to tolerate a mask), patient signs, symptoms, and behaviours (such as shouting, coughing, or heavy breathing)
    - specific environment

Assessment of evidence

- A PCRA may include: community epidemiology of SARS-CoV-2 ventilation”

It is reported that a fit-tested, seal-checked N95 respirator be worn for ‘direct’ care of covid-19 (confirmed or suspected) patients. It is unclear if the decision to wear these is based on the above or for all COVID-19 patients. However, this appears to apply to COVID-19 only and not to other respiratory infections.

- “Source control is recommended for individuals in health care settings who have suspected or confirmed COVID-19, or with symptoms and signs of a respiratory infection”.
- “HCWs with suspected or confirmed COVID-19, or with symptoms and signs of a respiratory infection, should wear a well-fitting medical mask and refer to their facility's OHS policies”
- “Based on the epidemiological and clinical context, facilities should consider implementing broad masking for source control for all HCWs, visitors, and patients in clinical areas and spaces where HCWs, other staff, and visitors may come into contact with patients (e.g., patient rooms, clinical units, hallways, elevators, waiting rooms).
- The decision to implement broader masking for source control should be made in consideration of the following epidemiological and clinical factors:
    - Epidemiological context, including:
        - Increasing community transmission
        - Facility/unit outbreaks of COVID-19 or other respiratory infections
        - Increasing hospitalizations and ICU admissions
        - Increasing staff COVID-19 cases
    - Clinical context, including working:
        - With immunocompromised persons or those at greater risk of acquiring an infection
        - In clinical areas/units at higher risk of SARS-CoV-2 transmission (e.g., COVID-19 designated units, emergency departments, open space critical care areas, oncological units, haemodialysis units, etc.)

If implementing broad masking for source control, consider the impact on persons with cognitive impairment or where masks could impede communication or otherwise hinder the ability to provide equitable care.

Assessment of evidence

Implementation of broad source masking may vary based on jurisdictional and facility-specific context, including organizational risk assessment."

On masking for the full-shift for staff and duration of visits, the document states "Given ongoing community spread of COVID-19 within Canada and evidence that transmission occurs from those who have few or no symptoms, masking for the full duration of shifts or visits has become normal practice during the COVID-19 pandemic. The rationale for full-shift or visit masking of all staff and visitors is to reduce the risk of transmitting COVID-19 from staff or visitors to others, at a time when no symptoms of illness are recognized, but the virus can be transmitted. The mask also protects the wearer. Depending on community transmission rates, the mask chosen can be a medical mask or a respirator. There is increasing evidence that the fit of the mask is the most important feature. Visitors should wear well-fitting medical masks or KN95 respirators (recognizing that there are many counterfeit KN95 respirators that may be difficult to verify at point of entry)."

This pandemic specific guidance published by the Canadian Government a key finding was the recommendation that a risk assessment be conducted to determine the requirements for PPE. With indication that it is personal choice if a medical mask or RPE is worn during periods of high community transmission.

It is stated that all other COVID-19 infection prevention and control guidance is outlined by healthcare sector and applies to long term care facilities, acute settings, home care and ambulatory/outpatient care)

Limitations:

- This document supersedes the previous setting-specific COVID-19 guidance produced by the Canadian Government. As such, for some recommendations it was not clear which had been updated and which remained in place.
- These recommendations are described as being updated based on emerging evidence meaning they may quickly become out of date or replaced
- It is not clear when a PCRA risk assessment should inform mask use over universal masking.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Australian Government National COVID-19 Clinical Evidence Taskforce	Guidance/Expert opinion	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Australian guidelines for SARS-CoV-2 infection prevention and control of COVID-19 in healthcare workers. 2021 Last accessed 01 December 2022					

Assessment of evidence

The aim of this document was to provide guidance intended to assist with decision making to prevent SARS-CoV-2 infection in healthcare workers.

Methods: Living evidence document, incorporating new evidence weekly and as it becomes available to ensure guidelines remain up to date. Evidence is graded based on quality (GRADE) which influences the certainty of evidence.. The methods, processes and definitions section provides a link to a technical report and search methods document, from which rigour of the process beyond search strategy is unclear. This guidance was appraised as level 4 and is considered expert opinion.

Recommendation: “All healthcare workers should follow standard and transmission-based precautions as described in the Australian Guidelines for the Prevention and Control of Infection in Healthcare (2019)”

The Australian Guidelines for the Prevention and Control of Infection in Healthcare (2019) included two specific recommendations for surgical masks and P2/N95 respirators:

- “24. It is suggested that a surgical mask should be worn when entering a patient-care environment to prevent droplet transmission.”
- “27. It is suggested that a correctly fitted P2/N95 respirator is worn when entering the patient-care area when an airborne-transmissible infectious agent is known or suspected to be present.”
- “The panel considers that for clinical examination or procedures involving close or extended face-to-face patient/client/resident exposure, surgical masks and eye protection are required in accord with standard precautions, for those patients/clients/residents

Assessment of evidence

assumed to have a respiratory infection, or who have not engaged in public health strategies such as social distancing, vaccination programs and therefore pose a potential increased risk to the HCW."

Recommendation: "… in situations where fit testing has not yet been carried out, and a P2/N95 respirator is recommended for use, a fit-checked P2/N95 respirator is preferred over a surgical face mask." (page 15)

- Evidence does not suggest superior effect of P2/N95 respirator over a surgical mask.
- Based on 16 observational studies ((retrospective cohort, cross-sectional, case-control) and 1 randomised controlled trial)
- Based on 11 observational studies comparing SARS-CoV-2 in healthcare workers wearing surgical masks or N95 respirators, there was no significant difference between the rate of infection between mask/respirator groups (OR=1.23 [95% CI:0.99, 1.53])*
- However, there was a significant difference when studies including other coronaviruses were considered, favouring N95 respirators over surgical masks (OR=1.34 [95% CIs: 1.06-1.70])

Recommendation: "For healthcare workers providing direct patient care or working within the patient/client/resident zone for individuals with suspected or confirmed COVID-19, the choice between P2/N95 respirator or surgical mask should be based on an assessment of risk of transmission."

"Assessment of risk of transmission to healthcare workers should include consideration of:

the individual patient/client/resident's pre-existing likelihood of COVID-19

current prevalence and transmission of COVID-19 in the population

setting-specific factors such as the likelihood of increased generation and dispersion of airborne particles and enclosed areas with low levels of ventilation

closeness and duration of contact"

Recommendation: "Likely high-risk of SARS-CoV-2 transmission…Healthcare workers providing direct care or working within the patient/client/resident zone for individuals where assessment suggests a high-risk of transmission, should use P2/N95 respirators rather than surgical masks, along with the other PPE required." (page 17)

Assessment of evidence
The authors provide an example of this as direct care for a confirmed case during their infectious period, a suspected case with epidemiological risk factors and symptoms, or someone who is asymptomatic but have epidemiological risk factors. The authors also advise that healthcare workers should wear surgical masks in addition to standard precautions to prevent droplet transmission, and that surgical masks and eye protection should be worn for extended patient contact for patients with respiratory infection or who have not been vaccinated or followed guidance like social distancing. Whether a healthcare worker chooses to wear a respirator or a surgical mask for patients with suspected/confirmed COVID-19 should be based on risk assessment for transmission. Although evidence in the literature assessed for this guidance does not indicate a clear advantage of respirators over surgical masks, respirators are preferred over surgical masks in situations where risk of transmission is high.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
National Health and Medical Research Council (NHMRC) Australian Guidelines for the Prevention and Control of Infection in Healthcare, 2019 2019 (revised 2024, v11.24) Accessed 11 October 2024	Guidance/ Expert opinion	**Level 4**	N/A	N/A	N/A
Assessment of evidence					
Aim: IPC guidance for Australian health and care settings. Target audience: Acute settings but the authors highlight transferability across settings. Recommendation 30: “It is suggested that face and eye protection should be worn during procedures that generate splashes or sprays of blood and body substances into the face and eyes.” This recommendation is evidence-based, theoretical-based, and conditional, meaning					

Assessment of evidence

that desirable effects of adherence likely outweigh undesirable effects. Although the practical information for this recommendation does come with some references, there are no clear methodologies for review so would not be AGREE recommend, but is presented as expert opinion. Some of these references were from before 2000.

In the section of the guidance which discusses involving patients in care, under the use of PPE section, the authors state: “Healthcare workers wear an appropriate mask if there is risk of them inhaling an infectious agent.” And “Appropriate masks, eye protection or face-shields are worn by a healthcare worker in situations where the patient’s body substances may splash onto his or her face.”

Transmission-based precautions are defined as those for patients with a suspected or confirmed infected agent transmitted by contact/droplet/airborne routes. In the transmission-based precautions section of the guidance, authors advise to “Make sure you know which type of mask is needed in different situations and how to check that they are properly fitted.”

- Contact transmission is defined as when one’s clothes or hands, patient-care devices or care environment become contaminated, or infectious patients are in contact with other patients.
- Droplet transmission is defined as transfer of hands contaminated with respiratory droplets to susceptible mucosal surfaces or when infectious respiratory droplets come into direct contact with mucosa.
- Meanwhile, airborne transmission is defined as when small particles containing infectious agents are inhaled.

Under recommendation 21, a conditional recommendation suggesting hand hygiene and personal protective equipment worn to prevent contact transmission, in the practical information the authors reiterate that “A surgical mask and protective eyewear or face shield must be worn if there is the potential for generation of splashes or sprays of blood and body substances into the face and eyes.”

Recommendation 24: “It is suggested that a surgical mask should be worn when entering a patient-care environment to prevent droplet transmission.” This recommendation is evidence-based, theoretical-based, and conditional, meaning that desirable effects of adherence likely outweigh undesirable effects. In the practical information for recommendation 24, the authors advise that “Although surgical masks do not protect the wearer from infectious agents that are transmitted via the airborne route, surgical masks that [meet Australian Standards] are fluid impervious and protect the wearer from droplet contamination of the nasal or oral mucosa. The surgical mask is generally put on upon room entry, with hand hygiene practised before putting on the mask and after taking off the mask.” And reference recommendation 30 above for further information

Alongside the rationale for recommendation 26 which recommends airborne precautions in combination with standard precautions when an airborne transmissible infectious agent is known/suspected, authors suggest that “Healthcare workers should prioritise the use of P2 / N95 respirators and other respiratory protection, where available.” Under the practical information for recommendation 27 which states

Assessment of evidence
that a correctly fitted P2 respirator should be worn when entering a patient-care area where an airborne infectious agent is known/suspected, the authors state that “In the majority of situations where standard respiratory protection is needed, a single use surgical mask (minimum level 2 barrier) is appropriate.” In Table 32, the authors state that if a member of staff has herpes simplex (cold sores) they “may provide direct patient care to other patients and do not need to wear a mask. However, sores should be covered with a dressing where possible, and hygiene practices to minimise the risk of transmission need to be maintained.” The authors reference the Communicable Diseases Network Australia guidelines for specific diseases (CDNA Series of National Guidelines (SoNGs) | Australian Government Department of Health and Aged Care), but this page does not mention herpes. Where there are specific guidelines for certain pathogens, in relation to face masks the authors advise (from page 230): Bronchiolitis – standard, contact and droplet precautions; use mask according to standard precautions Norovirus – standard, contact and sometimes droplet precautions; should wear a surgical mask while patient is vomiting, and people cleaning heavily contaminated areas (faeces or vomitus) should consider wearing a mask RSV – standard, contact and droplet precautions; use mask according to standard precautions SARS – standard, contact, droplet and airborne precautions; surgical mask if P2/N95 unavailable and eye protection Marburg – standard, contract, droplet and airborne precautions; face/eye protection with masks

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
World Health Organization (WHO). Infection prevention and control in the context of coronavirus disease	Guidance/ Expert opinion	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
(COVID-19): A living guideline. Last updated 21 December 2023 Last accessed 15 October 2024					

Assessment of evidence

A living guidance document which includes recommendations for mask use in health and care settings in light of the SARS-CoV-2 pandemic. It is considered as expert opinion as it did not meet the standards of AGREE recommend.

Methodology: Consensus approach described with GRADE approach and evidence searched. However, there are no details on how literature was searched, what terms were used etc so this guidance has been graded expert opinion.

Target audience: National and facility level decision-makers, policy makers, public health and infection prevention and control professionals; healthcare facility administrators, managers and other healthcare workers

“WHO recommends universal masking in health-care facilities when there is a significant impact of COVID-19 on the health system.”

- Situational Level 3 is a situation with significant impact on the health system and a risk of health services becoming overwhelmed, or resulting in unacceptably high morbidity and mortality, even in cases where the health system capacity is sufficient. In these situations, a larger combination of PHSMs may need to be put in place to limit transmission, manage morbidity and avoid overwhelming the health system.
- Situational Level 4 corresponds to an uncontrolled epidemic with very high morbidity/mortality and limited or no additional health system response capacity available, thus requiring extensive PHSMs to avoid overwhelming health services and to limit substantial excess morbidity and mortality.
- “Universal masking is the practice of all health and care workers and other staff, caregivers, visitors, outpatients and service providers wearing a well-fitting medical mask (unless otherwise specified, e.g., when performing AGPs) at all times within the health facility and in any common area (e.g. cafeteria, staff rooms).”

Assessment of evidence

"Strong recommendation for, very low certainty evidence" - This is labelled as a strong recommendation based on very low certainty evidence which appeared to show it is associated with reduced transmission of SARS-CoV-2. The benefits of wearing a medical mask were considered to be based on low quality evidence but the group "judged that the benefits of implementing universal mask use in healthcare facilities outweigh potential harms in settings experiencing a significant impact of COVID-19".

The authors discuss benefits and harms to universal mask use in hospitals for protection against SARS-CoV-2 but recognise limitations of before-after study design and limited control over confounding variables. They highlight that there is limited evidence for harms of universal mask use beyond "bothersome" and "non-serious harms", so the benefits were determined by the group to outweigh the harms.

The evidence is regarded low quality due to number of studies available and study design.

"In the context of universal masking, some health workers may prefer to wear respirators instead of a medical mask, based on their perception of what offers the better protection against COVID-19 – indicating allowance for personal preference.

Impact on resources is determined as low to moderate.

The reference list for this section was checked which revealed that some of the studies contributing to this evidence did not meet criteria for ARHAI review or were examining SARS-CoV-2 rates within a healthcare setting following universal masking out-with the healthcare setting.

Universal mask use is expected to be deemed acceptable as a protective factor for healthcare workers, visitors and patients, and feasible.

> "WHO suggests targeted continuous medical masking in health-care facilities when there is minimum to moderate impact of COVID-19 [in situational level 0, 1, 2] on the health system."
>
> - "Targeted continuous masking is the practice of wearing a medical mask by all health and care workers and caregivers in clinical areas during all routine activities throughout the entire shift [unless otherwise specified (e.g. when performing AGP)].
> - In non-patient areas, staff who have no patient contact are not required to wear a medical mask during routine activities.
> - If caring for a suspected or confirmed COVID-19 patient, please see the recommendation on mask type for health and care workers."
>
> Strong recommendation, low certainty of evidence: "a medical mask should be worn along with other PPE – a gown, gloves and eye protection – by health and care workers providing care to a patient with suspected or confirmed COVID-19."

Assessment of evidence
"Conditional recommend for, very low certainty evidence" - The authors highlight that protective effects of masks outweigh potential harms, referencing studies associating (universal) mask use with decreased risk of SARS-CoV-2 in healthcare settings experiencing a significant impact of COVID-19, while mild- to moderate- impacted settings suggested targeted continuous masking. Studies referenced in this section were excluded for this or a previous SFM review. Impact on resources is determined as low to moderate. The authors expect continuous mask use to be deemed 'acceptable'. ○ The authors expect continuous mask use to be deemed 'acceptable' with 'general feasibility' given that target continuous mask use is less burdensome and many health-care facilities have transitioned to (from universal masking), though "clear policies and training may be required". A living guidance document published by WHO and funded by CDC. It did not provide sufficient detail to be considered AGREE recommend but was included as level 4 expert opinion level evidence. While it is reported that a multidisciplinary experts were involved in the development of these guidelines it is not clear how evidence was identified or selected and therefore it is subject to bias. Generally, universal masking is recommended with health and care staff strongly recommended to wear a medical mask throughout the entirety of their shift (except for exemptions and where masks are removed/changed as appropriate). Where transmission is sporadic medical mask use is still recommended for areas treating COVID-19 patients as well as in areas not treating COVID-19 patients throughout the shift. But that health and care workers not working in patients areas do not need to wear a medical mask if they have no patient contact.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Association of perioperative Registered Nurses (AORN) 2019 Guideline Quick View: Transmission-	Guidance/ Expert opinion	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Based Precautions. 2019 Last accessed 21 November 2022					

Assessment of evidence

References are not provided for the formation of each section. The guidance is reported to be developed for nursing staff who work in USA. Refers to 'masks' with a picture of a surgical mask. Information gathered from 'mask' section (covers multiple masks) as well as precaution level sections (provides type of mask per 'level of protection').

- Droplet precautions are described as used in addition to standard precautions to be implemented when a patient has a "known or suspected infection transmitted by respiratory droplets (e.g., adenovirus, group A Streptococcus, influenza, Neisseria meningitides, Bordetella pertussis, rhinovirus)" which are considered as "i.e. greater than 5µm".

General guidance (general across mask types):

"Wear a mask when splashes, spray, splatter, or droplets of blood, other body fluids, or other potentially infectious materials may be generated, and nose or mouth contamination can be reasonably anticipated"

"Select the type of mask needed by the task, degree of exposure anticipated, and according to the barrier level as stated on the product label"

"Ensure the mask completely covers the mouth, nose, and chin and fits snugly, preventing gaps at the sides of the mask."

Contact precautions:

No mention of mask

Droplet precautions (i.e. particles >5µm, specific to surgical masks):

"don upon entering room or cubicle of a patients with suspected or proven infection transmitted by respiratory droplets (i.e., large particle droplets that are > 5 µm) that are generated by a patient who is coughing, sneezing, or talking"

N95 for AGP.

During patient (who is undergoing droplet precautions) transport – "do not wear a mask during transport".

Assessment of evidence
Airborne precautions (i.e., particles or droplet nuclei < 5 µm): N95 recommended no mention of surgical mask for HCW. An expert opinion (level 4) guidance designed for use by nursing staff in US settings. The guidance states, surgical masks should be worn by health care workers whenever there is a risk of spray, splatter, droplet of blood or contamination with infectious materials is "reasonably" anticipated to contaminate the nose or mouth. Surgical face masks are recommended specifically, when entering the room or cubicle of a patient who is suspected to confirmed as having an infection transmitted by respiratory particles (>5µm). It is not clear how this guidance was formed, or which references were used to form the guidance.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Scientific advisory Group for Emergencies (SAGE) NIHR: The effectiveness of PPE in reducing the transmission of COVID-19 in health and social care settings: December 2021 update summary, 12 December 2021 23 December 2021	Expert Opinion	**Level 4**	N/A	N/A	N/A
Assessment of evidence					
An expert opinion guidance document detailing preventative measures to consider in relation to transmission of COVID-19. A methodology for the selection of references/research for this guidance is not provided.					

Assessment of evidence
It is not clear what evidence was used to form the conclusions within this document. It was created in response the COVID-19 pandemic. It was designed to provide clarity regarding PPE use in health and care settings. • "medical masks offer 30-50% against particles meeting aerosol definition (penetration 44%)." • "N95 (FFP2) masks are associated with decreased risk compared with surgical masks (ORs in the region of 0.75 in most cases)" • "As most environments and contacts are in conditions of low viral abundance, surgical masks are effective, but virus rich environments require masks with greater filtering/barrier properties such as N95/FFP2. HSE guidelines require use of FFP3 respirators during AGPs (alongside other PPE)." "Consistent use of masks provide better protection than inconsistent use, (e.g. this includes use in staff break rooms as well as when with residents)."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Lai J, Coleman KK, Tai SH, et al. Relative efficacy of masks and respirators as source control for viral aerosol shedding from people infected with SARS-CoV-2: a controlled human exhaled breath aerosol experimental study. EBioMedicine. 2024 May 28.	Observational	**Level 3**	No mask, N95, KN95, surgical mask, cloth mask use for source control.	Exhaled breath aerosol per mask type and across particle sizes (fine and course).	Viral load, defined as a fraction of unmasked aerosol detected in masked samples. Source-control factor (similar to established definition for fit factor), defined as the percentage reduction in viral load realised in the environment (%)

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
					Relative efficacy of mask/respirator (%), calculated using ration of outward leakage. Exhaled breath aerosols were considered in total (combined) and for coarse (>5 uM) and fine (≤5 uM) aerosol particles.

Assessment of evidence

Setting: The study took place un a US-based university between 2020 and 2022.

Methods: This controlled human experimental study involved paired samples (exhalations with and without a mask) from 44/106 human participants who had one or more samples positive for SARS-CoV-2 (variant type was considered). The aim of this study was to analyse the efficacy of various face masks (surgical, cloth, KN95, N95) as source control (through a measure of reduction in total exhaled particles (combined fine and coarse), fine particles and coarse particles for SARS-CoV-2 positive persons.

There were some variations in the methods used depending on the type of mask, activities (saying the alphabet, shouting and saying happy birthday song loudly or breathing) based on symptoms, time the person took part. Generally, participants were asked to undertake speaking or shouting activities with and without a mask for up to 30 minutes. A particle counter (Gesundheit-II (G-II) human exhaled bioaerosol collector) was utilized to measure 'exhaled' particles. Outcomes were measured for total exhaled particles as well as fine (≤5 µm) or coarse (>5 µm) particles. Mask use compared to no mask use and efficacy between types of masks were considered within the analyses. The statistical analysis was based on a sample of 44 and it is not indicated by the authors if this met any conducted power calculation.

Results: The relevant results indicate that when compared with no masks, wearing a surgical face mask reduced the detected viral load significantly (P <0.05) across fine and coarse particle sizes. After coughing was controlled, it was reported that when compared to no

Assessment of evidence
masks, wearing a surgical mask resulted in a 74% (95%CI 65-81%) reduction in total exhaled viral load. It appears that there was a statistically significant greater reduction in exhaled viral particles when N95 respirators were worn compared to other mask types, including surgical face mask. P values for this aspect of the analysis are not clear across the tables and figures. It was also reported that cloth masks resulted in a significantly higher reduction in total exhaled particles compared to surgical and KN95 masks. Though it was reported that this significance was not maintained when only coarse or fine particles were considered. The reduction in total exhaled viral load for surgical masks was not statistically significantly different to KN95 masks. These results suggest that within the context of the fixed experimental conditions, surgical masks reduced exhaled viral load (source control) when compared to no mask. It also suggests that there may be greater reduction in exhaled particles (source control) provided from the N95 mask tested in this study compared to the surgical face mask. Alternatively, KN95 and surgical masks appeared to perform similarly. It is not clear how these reductions may impact onward transmission of infection. It is also not clear how far away the particle counter was from the participant and it difficult to state with any certainty how these results would compare to a clinical interaction or how they inform infection transmission and prevention. Strength: • Participants were eligible if samples (at least one) was positive) – may have higher applicability to SARs-CoV-2 transmission than a proxy particle or substance. However, period of sampling per mask type differed. **Limitations:** • Recruitment was from community testing facilities, it is unclear if there were other people (not within the 106) who were also tested but who chose not to participate. Differences between those eligible/ineligible, are not provided. – lack of generalizability. • Lack of replicability – unclear how far away the particle collector was from the participant and if this was standardized for all experiments. It was stated that participants had no prior training of wearing RPE. It is not clear if fit checking/testing was conducted. • Participants were asked to wear their own or a supplied mask the brand/type of supplied mask is provided. It is not clear how many masks were brought by patients, it is stated “mostly cloth” indicating some SFM or RPE may have been supplied by the participants and it is not clear if these met minimum standards. The indication for use was reported as the researchers decided they were “well-fitted”. • Small sample (44 in total but under 27 per group of masks), unclear power. – lack of reliability.

Assessment of evidence
• Variations in sampling time, activities undertaken (happy birthday, shouting), differences in level of illness (as demonstrated by some people being reported as too unwell to undertake the speaking activities). Impact (if any) of these baseline differences are unclear. • Variations in the type of mask (provided SFM are described but unclear how many if any were brought by the participant). • Lack of replicability and applicability - room humidity, temperature, distance of counter from participant, ventilation in place and other persons in the room are unclear. • It is unclear how this experimental setup may compare to real clinical interactions within health and care settings. • The true risk of transmission is unclear. This controlled exhalation study contributes to the evidence base as it suggests that in this controlled, fixed experimental condition surgical face masks provide statistically significant reductions in emitted particles compared to no masking, across the measured particle sizes (fine and coarse). It also highlights that the tested N95 respirators may provide statistically significant reductions in emitted particles compared to the tested surgical face masks but that this superiority may not be consistently reported with other respirator types (KN95). The clinical significance of these differences is unclear, and the transmission risk is also not clear.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Lynch JB, et al,. Infectious Diseases Society of America Guidelines on Infection Prevention in Patients with Suspected or Known COVID-19. Infectious Diseases Society of	Guidance/Expert Opinion	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
America 2021; Version 2.0.0 Last accessed: 22 November 2022					
Assessment of evidence					
Guidance provided by the Infectious disease society of America, produced to support HCW in making IPC related decisions during COVID-19 pandemic. Target Audience: health care workers who care for suspected or confirmed COVID-19 patients. Relevant recommendations: “Recommendation 1: The IDSA guideline panel recommends that healthcare personnel caring for patients with suspected or known COVID-19 use either a medical/surgical mask or N95 (or N99 or PAPR) respirator compared with no mask as part of appropriate PPE*. (Strong recommendation, moderate certainty of evidence)” “Recommendation 5: The IDSA guideline panel recommends that healthcare personnel involved with aerosol-generating procedures on suspected or known COVID-19 patients use an N95 (or N99 or PAPR) respirator instead of a medical/surgical mask, as part of appropriate PPE*. (Strong recommendation, very low certainty of evidence)” **Limitations:** • Selection process unclear for studies details provided about study type. Unclear involvement of studies labelled as high risk of bias. • Included studies are considered as out-with the scope and/or subject to bias and therefore excluded from current or previous (2019) surgical face mask review updates. • Unclear involvement of patients/public • No pilot and applicability limited.					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
SAGE - Hospital Onset COVID-19 Working Group (HOCI) and Environmental Modelling Group (EMG) HOCI and EMG: Masks for healthcare workers to mitigate airborne transmission of SARS-CoV-2, 25 March 2021 Published 23 April 2021	Guidance/ Expert Opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence

This report was produced by members of the Hospital Onset COVID-19 Working Group and Environmental Modelling Group (EMG). It has not been updated since 21 March 2021 and may not reflect recent publications nor more recent UKHSA publications. It was produced in response to and in the context of the COVID-19 pandemic. The document is not peer reviewed, it was considered by SAGE 84 on 25 March, 2021. The selection process for the included evidence is not clear and therefore this is considered subject to bias.

- "There is variation in nosocomial COVID-19 rates across NHS trusts and there are multiple factors that may explain this variation. It is not currently possible to identify whether any of this variation is related to RPE use (high confidence)."
- "Improved understanding of aerosol risks supports the need for a greater consideration of this route of transmission within risk assessment and IPC strategies, including ensuring compliance with wearing of FRSM as source control by staff and patients (as far

Assessment of evidence

as possible) and paying specific attention to the effectiveness of ventilation in both clinical and non-clinical areas (medium confidence)."

- Recommended for clinical and non-clinical areas - "Ensuring FRSM are routinely worn by all staff and patients as far as possible to provide source control"
- "In terms of PPE and RPE, the risk assessment should also reflect on: whether there is good adherence to appropriate fitting and use of FRSM and/or FFP3 masks, as inappropriate use can increase the risk of hand contamination and onward infection transmission (see later); whether staff are routinely wearing eye protection (important to reduce risk to eyes including inadvertently touching them); and whether patients are routinely being asked to wear masks whenever this is possible"
- Please note that this guidance recommends that "Where an unacceptable risk of transmission remains after rigorous application of the risk assessment process" FFP3 respirators should be considered. And a risk assessment should be used to determine this. Things to consider as reported as over-crowding/ poor ventilation with consideration for hierarchy of controls.

An expert opinion, level 4 guidance and evidence review published by UKHSA organisations in 2021 in response to the SARS-CoV-2 pandemic. The guidance highlights a paucity of evidence confirming the risk to persons in health and care settings from particles emitted by infectious persons. It recommends that the hierarchy of controls be in place with fluid resident surgical face masks recommended as 'PPE'. FFP3 respirators were recommended in place of FRSM where there was an "unacceptable risk" despite control as per hierarchy of control, with risk assessment recommended. The methods used to identify and appraise the evidence included in their document is not clear and therefore, the results may be subject to bias.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Department of Health and Social Care. Infection prevention and control: resource for adult social care	Guidance/ Expert Opinion	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Published 31 March 2022 Updated 01 March 2024 Accessed: 11 October 2024					

Assessment of evidence

- "Type IIR fluid-repellent surgical masks protect the wearer by providing a fluid repellent barrier between the wearer and the environment. They provide additional protection from respiratory droplets."
- "Consider wearing fluid-repellent type IIR masks where there is a risk of splashing of blood or body fluids into the worker's nose or mouth. These should be well-fitting and cover the nose, mouth and chin and should not be touched when worn. Type IIR masks should be worn when carrying out aerosol-generating procedures (AGPs)."

"Care or domestic task involving likely contact with blood or body fluids (giving personal care, handling soiled laundry, emptying a catheter or commode): Risk assess if splashing likely (Type IIR if splashing likely)

General cleaning with hazardous products (disinfectants or detergents): Risk assess if splashing likely (Type IIR if splashing likely)

Undertaking an AGP on a person who is not suspected or confirmed to have an infection spread by the airborne or droplet route: Yes – type IIR to be used for single task only"

This level 4 expert guidance document from UKHSA is intended for the adult social care setting only (England) and covers general infection prevention and control (IPC) principles. It states that fluid-repellent type IIR masks should be worn where there is a risk of splashing of blood or body fluids into the worker's nose or mouth and following risk assessment (e.g. giving personal care, handling soiled laundry, emptying a catheter or commode, general cleaning with hazardous products such as disinfectants or detergents). In addition, Type IIR masks should be worn when carrying out aerosol-generating procedures (AGPs) on a person who is not suspected or confirmed to have an infection spread by the airborne or droplet route. It also states the duration, which should not be longer than 4 hours.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
CDC and HICPAC. CDC's Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings, 2017. Last reviewed 29 November 2022 Last accessed 01 December 2022	Guidance/Expert Opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence

An update to the core IPC practices provided by the CDC and HICPAC. It applies across health and care settings as well as across health care workers, patients and visitors, where appropriate. This is considered as expert opinion. The authors describe a process of consulting other CDC materials as well as input from HICPAC in drafted recommendations produced 2014 which were reviewed in October 2022 by "experts within the Division of Healthcare Quality Promotion at CDC" as well as reviewed by HICPAC.

- Within the standard precautions (basic practices applied in all settings for all patients) sections it states: "Risk assessment with use of appropriate personal protective equipment (e.g., gloves, gowns, face masks) based on activities being performed".
- Within the 'infection and medication safety' section it states: "Wear a facemask when placing a catheter or injecting material into the epidural or subdural space (e.g., during myelogram, epidural or spinal anesthesia)"
- Within the 'risk assessment with appropriate use of PPE' section it states: "Use protective eyewear and a mask, or a face shield, to protect the mucous membranes of the eyes, nose and mouth during procedures and activities that could generate splashes or sprays of blood, body fluids, secretions and excretions. Select masks, goggles, face shields, and combinations of each according to the need anticipated by the task performed."

Assessment of evidence
• Within the ‘minimising potential exposures it states: “Prompt patients and visitors with symptoms of respiratory infection to contain their respiratory secretions and perform hand hygiene after contact with respiratory secretions by providing tissues, masks, hand hygiene supplies and instructional signage or handouts at points of entry and throughout the facility“

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centers for Disease Control and Prevention (CDC) Infection Control Guidance: SARS-Cov-2 Last updated 24 June 2024 Last accessed: 15 October 2024	Guidance/Expert Opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence
Noted that recommendations in this guidance, including recommended PPE, are being reviewed as part of updates to the 2007 Guideline for Isolation Precautions. This interim guidance has been updated based on available information relating to COVID-19 and the current situation in the United States. Updates were incorporated to reflect high levels of immunity (via vaccination and infection) and availability of treatments and prevention. This guidance provides a framework for healthcare facilities to implement IPC practices based on individual circumstances (e.g., levels of community respiratory virus transmission). It is applicable to all US settings that delivers healthcare, inclusive of nursing homes. A rapidly produced guidance document for health care personnel during the SARS-CoV-2 pandemic. It is therefore specific to this context and given a lack of rigorous and clear methodology it is considered as level 4 expert opinion evidence. Recommended routine infection prevention and control (IPC) practices during the COVID-19 pandemic

Assessment of evidence

Source control options for HCW:

- “A NIOSH-approved particulate respirator with N95 filters or higher;
- A respirator approved under standards used in other countries that are similar to NIOSH-approved N95 filtering
- Facepiece respirators (Note: These should not be used instead of a NIOSH-approved respirator when respiratory protection is indicated);
- A barrier face covering that meets ASTM F3502-21 requirements including Workplace Performance and Workplace
- Performance Plus masks; OR
- A well-fitting facemask”.

“Even when a facility does not require masking for source control, it should allow individuals to use a mask or respirator based on personal preference, 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.”

“Source control is recommended for individuals in healthcare settings who:

- Have suspected or confirmed SARS-CoV-2 infection or other respiratory infection (e.g., those with runny nose, cough, sneeze); or
- Had close contact (patients and visitors) or a higher-risk exposure (healthcare personnel) with someone with SARS-CoV-2 infection for 10 days after their exposure.”

Source control is recommended more broadly [as per CDC’s Core IPC Practices] in the following circumstances:

- By those residing or working on a unit or area of the facility experiencing a SARS-CoV-2 or other outbreak of respiratory infection; universal use of source control could be discontinued as a mitigation measure once the outbreak is over (e.g., no new cases of SARS-CoV-2 infection have been identified for 14 days); or
- Facility-wide or, based on a facility risk assessment, targeted toward higher risk areas (e.g., emergency departments, urgent care) or patient populations (e.g., when caring for patients with moderate to severe immunocompromise) during periods of higher levels of community SARS-CoV-2 or other respiratory virus transmission (See Appendix)

Assessment of evidence
• Have otherwise had source control recommended by public health authorities (e.g., in guidance for the community when COVID-19 hospital admission levels are high” Implement Universal Use of PPE for HCP: • “If SARS-CoV-2 infection is not suspected in a patient presenting for care (based on symptom and exposure history), HCP should follow Standard Precautions (and Transmission-Based Precautions if required based on the suspected diagnosis)” This is an expert level guidance document from the CDC which is specific to the SARS-CoV-2 pandemic. This document highlights a focus on personal preference in mask use or type of mask, where appropriate.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Ueki H, et al., Effectiveness of face masks in preventing airborne transmission of SARS-CoV-2. MSphere. 2020 Oct 28;5(5):e00637-20. (Japan-based study)	Experimental Study (simulation)	**Level 3**	Protective effect of surgical or N95 masks against SARS-CoV-2 aerosolized particles when worn for protection and/or as a form of source control. Surgical mask (double tie straps).	Surgical mask (double tie straps) compared to no mask or N95 respirator mask (sealed). Conditions: Spreader: no mask, receiver: no mask Spreader: no mask, receiver mask Spreader: mask, receiver: no mask Spreader: mask, receiver: mask	Viral loads and infective virus that passed through the masks were measured by use of a plaque assay and quantitative real-time reverse transcription PCR (qRT-PCR), respectively. Viral titre (Log10PFU), PFU = plaque forming units. Viral RNA (Log10 copies)

Assessment of evidence
A level 3 experimental study, involving two manikin heads at 50cm distance with nebulized (manikin 1) or ventilated (manikin 2) air to simulate exhalation and inhalation. Penetration through the mask of the receiver was assessed using qRT-PCR. Methods: Nebuliser manikin = 6ml of virus suspension in culture medium or diluted in phosphate saline. 5x 105 plaque forming units or 1x108 PFU, 1 × 105 PFU, 1 × 104 PFU. It ran continuously for coughs (2m/s for 20 minutes). Particle sizes = 5.5 ± 0.2 µm in mass median diameter (particle size percentages were as follows: <3 µm, 20%; 3 to 5 µm, 40%; >5 to 8 µm, 40%). The ventilation manikin = attached to an artificial ventilator (5.5 liter of tidal volume, a respiratory rate of 18 breaths/min, and a 50% gas exchange rate). Cells – VeroE6/TMPRSS2 (JCRB1819) cells maintained in Dulbecca modified Eagles medium containing 10% foetal calf serum and antibiotics 37°C with 5% CO_2. Virus - UT-NCGM02/Human/2020/Tokyo SARS-CoV-2 virus propagated in VeroE6/TMPRSS. Room – 60-65% RH and 23-25 degrees Celsius. Distance of manikin 25, 50 and 100cm. Results: Where the source wore a surgical mask and the receiver did not, both viral titers and RNA copy numbers were significantly reduced compared to no mask use for surgical masks and N95 respirator use. A similar result was obtained where the source wore a surgical mask and the receiver wore a surgical mask, cloth mask, or N95 (various configurations). When the receiver wore a surgical mask but the source did not, there was a significant reduction viral RNA copies but not in viral titers. • receiver wearing a surgical mask, source not wearing a surgical mask - Surgical masks: viral titre = 53% (non-significant), RNA copy number 50% ($p < 0.05$). • source wearing a surgical mask, receiver not wearing a surgical mask -Surgical masks: viral titre = 24% ($p < 0.05$), RNA copy number 42% ($p < 0.05$). • both the source and receiver wearing a surgical mask – $p < .05$ for surgical mask compared to no mask control. Limitations: Lack of generalisability and applicability with fixed experimental conditions, use of N95 not FFP and unclear BFE of surgical mask, particle size not clear, one strain SARS; prolonged use not considered, also a short report with limited details and lack of reliability with only 3 repetitions. A level 3 experimental study where two manikins placed 50 cm apart within a test chamber simulated an infectious source and health receiver. The results indicate that a surgical mask worn by a source was generally effective in reducing viral titers and RNA copies inhaled by a receiver. A reduction was also reported where both a source and receiver wore a surgical mask ($P< .05$). It is therefore not possible to compare the effectiveness of either intervention. The results suggest that a surgical mask provides some protection for a receiver against particle penetration when a receiver and but not a source (reduction in RNA copy but not viral titers). Surgical masks were also

Assessment of evidence
source wear a surgical face mask (P<.05). This suggests that within the fixed conditions of this study there may be benefits in both the source and receiver wearing a surgical mask in this experiment.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Wilson NM, et al., The effect of respiratory activity, non-invasive respiratory support and facemasks on aerosol generation and its relevance to COVID-19. Anaesthesia. 2021 Nov;76(11):1465-74. (Australia-based study)	Experimental study (observational)	**Level 3**	Surgical face mask (Bacterial filtration efficiency ≥98%.) compared to no mask while completing respiratory activities.	Mask versus no mask on the expired particles (source control)	Differences between mean particles exhaled during of activities or therapies with 95%CI. Particle volumes in each size category were transformed to estimate particle volumes. Mixed effects linear regression to compare sampling per particle size category.

Assessment of evidence
A level 3, experimental study comparing mean expelled particles when 10 participants undertook respiratory activities (quiet breathing, talking, shouting, exercise, forced expirations and coughing) while wearing a surgical face mask compared to not wearing a face mask. • 10 healthy participants (4 females, 6 male, mean age 29). Use of custom chamber with cone connected to a particle counter with categories (bins) at 0.5–0.7; 0.7–1; 1–3; 3–5; 5–10; and 10–25µm. • The results showed that wearing a surgical face mask during talking, shouting, forced respirations and coughing showed a significant reduction in mean expired particles (0.2-0.4-fold reduction, P< 0.05).

Assessment of evidence
Limitations: There were several limitations of this study including the lack of generalisability and applicability to real world settings, differences in room temperature and humidity, forced respirations, long range particle expulsions unclear, power calculations were unclear, lack of reliability (3 repetitions) This level 3 experimental study comparing mean expelled particles when 10 healthy participants undertook respiratory activities (quiet breathing, talking, shouting, exercise, forced expirations and coughing) while wearing a surgical face mask compared to not wearing a face mask. The results suggested that talking, shouting, forced respirations and coughing showed a significant reduction in mean expired particles (0.2-0.4-fold reduction, P< 0.05). This suggests that within the fixed conditions of this experiment wearing a surgical face mask reduced the expulsion of particles (from 0.5-25 µm). It is not clear to what extent this may impact possible onward transmission of particles.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Patel RB, et al., Respiratory source control using a surgical mask: an in vitro study. Journal of occupational and environmental hygiene. 2016. Jul 2;13(7):569-76. (US-based study)	Experimental Study (simulation)	**Level 3**	Ear loop surgical mask (appears to meet ASTM level 3)	The use of a surgical face mask (reported as meeting Level 3 ASTM) or respirator (N95 with and without a Vaseline seal). Control – no mask with particles measured near source.	Maximum Exposure - the percent of nebulized particles captured (i.e. inhaled) by the filter within the receiver when no masks are worn by the source or receiver. Receiver protection was calculated as ratio of maximum exposure to actual exposure.

Assessment of evidence

Methods: Two manikin heads placed just over 3ft apart within a chamber where air changes per hours were set at 0, 6 or 12. Both manikins were set to replicate tidal breathing (tidal volume 500ml, RR 15 breaths/min). The source manikin could also replicate coughing through a series of 1.5L breaths generating a peak flow of 5.2L/sec. Collection periods were set to 8 minutes. Manikins expelled radiolabelled wet aerosol particles. Combinations of source/receiver/control were trialled using two types of surgical mask (appears to meet ASTM level 3), an N95 respirator and a Vaseline sealed respirator. Wash out of air between experiments. Air flow 1) no ambient air flow, 0 changes per hour; 2) all air movement secondary to coughing/breathing from source/receiver manikin; or 3) 6 (171 CFM) air changes per hour to model hospital setting or 4) 12 (343 CFM) air changes per hour modelled on negative pressure isolation room (smoke testing to check direction of air flow) in hospital setting. Relative humidity = 33–58% and temperature = 21.0–22.8°C.

Results:

Protection

- **"Surgical masks: viral titre = 53% (non-significant), RNA copy number 50% ($p < 0.05$)".**
- "With cough, source control (mask or respirator on Source) was statistically superior to mask or unsealed respirator protection on the Receiver (Receiver protection) in all environments"

Please note that for the following results figure 4 & 5 were used to determine significance - *p* values were not provided.

- Tidal breathing - Significant reduction in receiver exposure reported when receiver wore a surgical face mask in none of the rooms. Suggesting limited protection reported in this in vitro manikin study.
- Coughing – significant reduction in receiver exposure for sealed N95 in no airflow and hospital but not negative pressure but not for other respirator or surgical mask experiments.

Source Control

- "In the Negative pressure room applying either surgical mask or respirator to the Source resulted in statistically significant reductions in exposure"

Please note that for the following results figure 4 was used to determine significance - *p* values were not provided.

- Tidal breathing – significant reduction in receiver exposure shown for surgical face masks when worn by the receiver no air flow, and negative pressure room simulations.

Assessment of evidence
• Coughing – significant reduction in receiver exposure shown for surgical face masks in all rooms when worn by the source. Filtration at the source – natural fit surgical mask (~ 5–20%), secure fit surgical mask filter (~50%), N95 (~80-90%) and sealed N95 (~100%). It was reported that increased fit led to 100% capture efficiency, unclear how this was assessed. Limitations: This study had several limitations including a lack of generalisability and applicability based on the fixed experimental conditions, fixed distance of manikin (3 foot), airflow not reflective of real-world settings, unclear particle size, p-values are not provided though significance is stated, wet particles may be impacted by humidity/temperature. Although limited by its in vitro nature, fixed 'higher' distance from source to receiver and airflow being optimized for HCW protection (from receiver to source) which may enhance the reported effect of source control. Overall, this study suggests that in this fixed experimental setting surgical masks (appears to meet ASTM level 3) may be useful as source control but do not provide clear evidence that surgical masks or N95 (without Vaseline) would be effective form of protection. However, the results may be subject to bias based on the limitations and therefore the results of this study should not be used in isolation to make recommendations.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Yokoe, T., et al., Detection of human coronavirus RNA in surgical smoke generated by surgical devices. 2021 The Journal of hospital infection, 117, 89–95 (Japan-based study)	Experimental Study (simulation)	**Level 3**	To evaluate if wearing of surgical masks can prevent transmission of infective coronaviruses that exist in surgical smoke. Use of a surgical face mask (BFE ≥98%)	Comparison made with and without mask. 2 instruments were compared: Surgical smoke generated by: -electronic scalpel -ultrasonic scalpel	Filtration of surgical smoke and reduction in the amount of viral RNA through a surgical mask.

Assessment of evidence

Methods:

- Cells and virus strain: HeLa-ACE2-TMPRSS2 cells and Human coronavirus 229E. RNA isolation and RT-qPCR was done according to manufacturer's instructions. Viral RNA in 1 mL of Eagles minimum essential medium (absorbed surgical smoke) 6.3x107 and 1.3x108 copies.
- Surgical smoke was generated (via surgical device = electronic scalpel or ultrasonic) and "collected with a vacuum pump at a flow rate of 18 L/min." Smoke was analysed for presence of viral RNA.
- "The instruments were operated for 3 min at intervals of 10 s of work and 10 s of pause."
- PPE: a surgical mask with reported bacterial filtration efficiency of ≥98% was cut and put into a filter holder within the vacuum line between material and collection tube.

Results:

Efficacy of surgical mask for filtering surgical smoke (i.e. reduction in viral RNA):

- Electric scalpel: From 6.3x107 to 6.3x104 copies (99.90% reduction) (P<.05)
- Ultrasonic scalpel: from 1.3x108 to 2.5x105 copies (99.80% reduction) (p<.05)

Infectivity (viral RNA in surgical smoke#0:

- "inoculation of EMEM containing surgical smoke with 1.3x108 copies/mL of viral RNA did not induce a visible cyto-pathic effect in cells".

After 4 days of incubation:

- "of the HeLa-ACE2-TMPRSS2 with 50 mL EMEM containing surgical smoke generated by the electric scalpel, the viral RNA in the medium was reduced by more than 97.50% from 3.2x106 to 7.9x102 copies".
- "viral RNA in the culture supernatant with surgical smoke generated from the ultrasonic scalpel increased from 6.5x106 to 1.3x109 copies. it was unable to induce visible plaques".

Limitations: This study was limited by its fixed experimental conditions which are unlikely to apply or generalise across real-world health and care settings, limited details about the room conditions (temperature/humidity/ventilations).

Assessment of evidence
This level 3 experimental study demonstrated that surgical smoke generated by incision of cells with electric or ultrasonic scalpels may contain human coronavirus RNA. However, infectivity was reduced. The surgical mask used in this study was reported to have a BFE of ≥99.80%. Based on the findings of this study, a surgical mask used during the fixed conditions of this experimental study showed filtration capabilities significantly higher than no mask conditions (*P*< .05). This study had several limitations and it should not be used in isolation to form recommendations.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Diaz KT, Smaldone GC. Quantifying exposure risk: surgical masks and respirators. American journal of infection control. 2010 Sep 1;38(7):501-8. (US-based study)	Experimental Study (simulation)	**Level 3**	NIOSH approved N95 respirator worn by either source or receiver; Earloop surgical mask (appears to meet ASTM level 3) worn by either the receiver or source manikin.	Exposure and filtration was compared in different masking setups: Control – no masks worn by any manikin. Risk factor: mask use (surgical face mask or N95) compared with no mask use	Maximum exposure – total particles inhaled by the receiver based on no mask on receiver or source. This represents the exhaled particles which mix with ambient air. Used to calculate protection factor (unclear calculation). Radioactivity captured by each mask quantified the effectiveness of filtration and deflection on exposure.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
					Filtration – particles captured by the mask. With pure filtration measured by sealing mask and ambient air flow 0. Deflection – particles not captured by filtration but deflected away from the receiver. Also measured with head turned (90 degrees) to the left.

Assessment of evidence

Methods: Two manikins set up with radio-labelled wet particles produced within chamber from one manikin head (source) towards another manikin head (receiver) approx. 3ft apart. Radioactivity captured by each mask quantified the effectiveness of filtration and deflection on exposure. Tidal volumes of 500 mL and respiratory rates of 15 breaths/min. Surgical mask type, brand provided no details of certification but from wider search may adhere to type 11R status. Temperature 20-22ºC and relative humidity 21-26%.

Results: Please note that significance is not well described.

- The receiver wearing a surgical mask did not result in a significant reduction in exposure (captured within receiver manikin).
- The use of a surgical mask at the source resulted in ‘significant’ reductions in exposure (protection factor of 172 - 317). This indicates that in this experimental setup a surgical face mask may assist with disruption to the flow or behaviour of particles flowing towards a receiver which increased protection to the receiver despite less effective filtration. The results of this study also suggest

Assessment of evidence
that there was no observed reduction in exposure to the receiver when only the receiver wore either an N95 or surgical face mask (protection factor 1.37-2.21). Limitations: This study had a number of limitations including a lack of generalisability and applicability based on the fixed experimental conditions, fixed distance of manikin (3 foot),limited details of p values, constant flow rate, wet particles may be affected by humidity etc, fit may not apply. The findings from this level 3 experimental study highlight that surgical face masks provided some effectiveness when worn by a source when both exposure and filtration were considered. The overall protectiveness when a surgical mask was worn by only the receiver (which could include a HCW, visitor or other patients in health and care settings) was limited. The limitations of this study should be considered and the artificial airflow towards the receiver may have skewed the results towards source control effectivity. With a high risk of bias this study should not be used in isolation to make recommendations.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Lindsley, W. G. et al. Efficacy of face masks, neck gaiters and face shields for reducing the expulsion of simulated cough-generated aerosols. 2021	Experimental (simulation)	**Level 3**	Procedure mask (reported as ASTM Level 3). Procedure mask is described as fluid resistant.	Efficacy of procedure mask and respirators as a form of source control (reducing particles emitted into the environment from a ‘source’ manikin) Comparators: N95 respirator	Collection efficiency: percentage of aerosol particles blocked by the PPE under investigation (%) when compared to experiments without the use of PPE. Air particle mass in collection chamber

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Aerosol Science and Technology, 55 (4), pp. 449-457. (US)					(ug) as a proxy measure for how effectively the PPE under study reduced the mass of air particles emitted into the environment.

Assessment of evidence

Experimental setup: 14% KCl and 0.4% sodium fluorescein solution was nebulised using a single jet Collison nebuliser. Nebulised solution passed through a diffusion drier and then mixed with 10L/min of dry filtered air. Masks (surgical or N95) on manikin head for 2 consecutive tests. A cough (4.2L/sec and peak flow 11L/second). Cough sampled from bellows before coughing to normalise particle mass.

Sampling: Portacount used to assess fit factor of masks (e.g. ratio particles outside compared to inside mask). Anderson impactor (28.3L/min) run for 20 minutes after each cough. Capable of measuring/separating particles per following sizes: <0.6 uM, 0.6 – 1.1 uM, 1.1 – 2.1 uM, 2.1 – 3.3 uM, 3.3 – 4.7 uM, 4.7 – 7.0 uM, >7uM. Note, particle >7 μm were not analysed due to small concentration of this size. Fluorescence measured via fluorometer.

Results: N95 (98.6% filtration efficacy), Surgical mask (58.5% filtration efficacy). For comparison of air particle mass (μg) into chamber = N95 vs no device: -504 (-567, -422) p<0.0001, N95 vs procedure mask: -205 (-277, -133), p<0.0001, Procedure mask vs no device: -299 (-361, -237), p<0.0001.

In this study, the N95 and fluid resistant surgical face mask was more effective than no mask or PPE, at reducing mean air particle mass (uG) in the enclosed chamber when placed over the mouth of the manikin in an enclosed chamber where one cough was simulated, producing particles <0.6 uM – 7 uM in size. However, the N95 respirator was more effective than both the procedure mask and the use of no PPE.

Limitations: There were several limitations of this study including the lack of generalisability and applicability to real world settings, may lack reliability (2 repetitions), breathing and speaking not assessed, one cough simulated.

This level 3 simulation study considered the ability of surgical masks in preventing dispersal of nebulized sodium fluorescein solution. It provides evidence to suggest that in this specific experimental setting a procedure masks was more effective than no mask as a form of

Assessment of evidence
source control. However, the N95 respirator may be more effective than a fluid resistant surgical mask. However, the study may have limited generalisability and the evidence should not be considered in isolation to make recommendations.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Asadi, S. et al. Efficacy of masks and face coverings in controlling outward aerosol particle emission from expiratory activities, 2020. Nature Scientific Reports, 2020 Sep 24;10(1):1-3. doi: 10.1038/s41598-020-72798-7 (appears to be US-based)	Experimental Study (observational)	**Level 3**	Surgical mask (unclear fluid resistance), tested by 10 participants. Non-vented KN95 respirator, tested by 10 participants A vented N95 respirator, tested by 2 participants	The efficacy of surgical face masks and respirators in reducing particle emission rates when volunteers undertook breathing, speaking and coughing. Jaw movement (mimicking chewing gum) also assessed but considered out-with scope of the review. No mask (control)	Particle emission rate (particle/second) Observed particle size distribution (particle fraction, %)

Assessment of evidence
Methods: This level 3 experimental study compared particle emission when wearing a mask (respirator or surgical face mask) or no mask while competing respiratory activities including gentle breathing, talking (reading a passage) and forced coughing. Healthy volunteers undertook these activities while sitting with their mouth in front of a funnel attached to an aerosol particle sizer (measuring 0.3-20µm). Results: particle emission reduced for breathing (from 0.31 particles to 0.06 SFM and 0.07 KN95), talking (SFM0.18 and KN950.36 particles) and coughing (from 10.1 to SFM 2.44 particles).

Assessment of evidence
The results indicated that wearing a surgical mask resulted in a significant reduction in particle emission rate compared to wearing no mask. Surgical mask and respirators were comparable with the exception of coughing where only a surgical mask showed a reduction with statistical significance. Limitations: Lack of generalisability and applicability with fixed experimental conditions, small sample, forced coughs, specific particle sizes, plume travel distance, time suspended unclear. The results of this level 3 experimental study suggest that surgical masks used as source control during talking, coughing and gentle breathing may significantly reduce particle emission compared to not using a mask. In this small cohort surgical mask and KN95 respirators performed comparably showing reduced particle emission except for coughing where only surgical masks showed statistical significance. However, the study may be limited based on its small sample and simulation of respiratory activities which may limit its generalizability. The results should not be used in isolation to form recommendations.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Mansour MM and Smaldone GC Respiratory Source Control Versus Receiver Protection: Impact of Facemask Fit J Aerosol Med Plum. 2013;26(3);pp:131.137 Doi:10.1089/jamp.2012.0998	Experimental Study (simulation)	**Level 3**	This study compared mask types (N95 or surgical mask) using two manikin (a source and a receiver) with simulated tidal breathing at 3ft apart to determine the degree of protection for source N95 and surgical mask combinations as well as receiver N95 and	no mask on either head defined as maximum exposure, a surgical mask tightly fit on the source, a surgical mask looped ‘‘naturally’’ around the ears of the source, an N95 on the source,	Particle distributions and mass median aerodynamic diameters (MMAD) Exposure data, expressed as % of nebulised activity (Nebulized activity represented the difference between initial nebulizer charge and that

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
			surgical mask combinations.	an N95 on the source sealed to the face with Vaseline, a surgical mask tightly fit on the receiver, a surgical mask looped around the ears of the receiver, an N95 on the receiver, an N95 on the receiver sealed to the face with Vaseline	remaining after nebulization) Exposure data, defined as simulated workplace protection factor (sWPF) (ratio of max exposure to actual exposure). "The protective effect of each intervention in reducing exposure is best illustrated by the magnitude of the sWPF." Mask filtration – radioactivity captured by each mask, reported as a % of activity exhaled at source Separation of 95% CIs indicated statistical significance.
Assessment of evidence					
This level 3 in-vitro, experimental study involved two manikin heads which represented 3-foot distancing between a source and receiver. The study suggests that there was a significant reduction in exposure to particles when a source wore a tightly fitted or loosely fitted					

Assessment of evidence
surgical face mask compared to no mask. There were non-significant reductions in exposure when only a receiver wore a surgical mask (tightly or loosely fitted) or when they wore an unfitted N95 respirator. 6 air changes per hour in room. Results: SFM/N95 worn by source: • SFM naturally fitted: Exposure decreased to 0.000637% (95% 95% CI: 0.00163–0.01110%), SWPF = 214 • SFM tightly fitted: Exposure decreased to 0.00019% (0.00023% (95% CI: 0.00009–0.00038%), sWPF = 5,850 • N95 (no Vaseline): 0.00019% (95% CI: 0.00012– 0.00027%), sWPF = 7,174 Compared to the control, these were deemed statistically significant reduction in aerosol exposure. SFM/N95 worn by receiver: • SFM naturally fitted: 1.38% (95% CI: 0.992–1.77%), sWPF =0.99 • SFM tightly fitted: 0.669% (CI: 0.0641–1.27%), sWPF = 2.04 • N95 (no Vaseline): 0.181% (95% CI: 0.106–0.256), sWPF of 7.53 Compared to the control, these results were not statistically significantly lower than the control. Limitations: This study had a number of limitations including a lack of generalisability and applicability based on the fixed experimental conditions, Vaseline seal is not reflective of real life mask use, unclear number of repetitions, unclear if the source manikin wore a mask/respirator when the experiments involving source masking occurred. This level 3 experimental study, although limited by its in-vitro nature and set parameters of air flow, air changes and 3-foot distancing between source and receiver, suggests that surgical face masks when worn by a source only significantly reduced exposure when compared to no mask use. A significant reduction was not reported when only a receiver wore a mask. This study suggests a surgical face mask worn by a source ‘naturally’ or ‘tightly’ with loops around the ears provided protection to a receiver. However, the study is limited by its in-vitro nature, and potential lack of generalizability to real-life scenarios due to set parameters of air flow, air changes and distancing between source and receiver.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Humphreys H, Bak A, Ridgway EJ, et al. Rituals and behaviours in the operating theatre – joint guidelines of The Healthcare Infection Society and The European Society of Clinical Microbiology and Infectious Diseases. Journal of Hospital Infection. 2023;140:165.e1-165.e28.	Guidelines/Expert consensus	**AGREE: recommend with provisos**	N/A	N/A	N/A

Assessment of evidence

This guideline was conducted using the NICE methodology. The primary evidence which was included for the good practice points (GPP) related to the use of surgical face masks was described as low quality and generally working party and lay person views were considered. These GPP were considered as primarily based on expert opinion.

Relevant GPP are as follows: “8.11. (a) Should staff cover their hair? (b) Should staff use face masks?” “Good practice points GPP 11.1: Ensure that all staff working in the operating room wear a head covering and a face mask in accordance with local policies”.

Limitations:

- Majority of primary evidence were of low quality. Al of those related to surgical masks were eligible for exclusion from this review. References related to surgical masks are noted above.
- The recommendations/GPP provided for surgical masks use were formulated primarily by expert opinion.

Assessment of evidence
• Lack of details to ascertain the extent of consultation with the target population (patients, public). It is not clear if those involved in creation of these guidelines reflect the complete spectrum of relevant patient groups. • Lack of specific implementation tools and resources. • The weight of evidence and how it was specially used to form recommendation is not clear. Though expert opinion is provided for the GPP related to surgical masks which support understanding in how these were formed. • The methodology to update this guideline is not clear though it is stated that it is subject to possible future updates. • The GPP related to surgical masks use are somewhat vague ('face masks' rather than TYPE II or TYPE IIR and timeline for changing a mask is not specified) making it difficult to audit, follow and etc. • It appears that a meta analysis was conducted as part of the evidence review of surgical masks. The results of this are not well described. The appropriateness of conducting this type of analysis with different study designs and unclear differences in comparator or quality is unclear.

Evidence from previous update(s):

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Loveday HP, et al., Epic3: National evidence-based guidelines for preventing healthcare-associated infections in NHS hospitals in England.	Guidance/ Expert opinion	**AGREE: 'Recommend with provisos'**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
J Hosp Infect. 2014 Jan;86 Suppl 1:S1-70.					

Assessment of evidence

A UK guidance document published 2014 detailing core IPC principles. The document includes some evidence.

- "Fluid repellent surgical masks should be worn when there is a risk of blood or bodily fluid splashes into the face and eyes." – RECOMMENDATION
- Use maximal sterile barrier precautions (which includes use of a facemask) for the insertion of central venous access devices. – RECOMMENDATION

"may use standard, fluid-repellent surgical face masks to prevent respiratory droplets from the mouth and nose being expelled

into the environment".

It is reported that where droplet (rather than aerosol) transmission is expected or where the level of aerosol exposure is low:

"(e.g. APF10/ FFP2) or a physical barrier (e.g. surgical face mask) may be appropriate, such as when caring for patients with influenza."

Droplet nucelli are defined as follows: "Particles 1–10 μm in diameter comprising the dried residue formed by evaporation of droplets coughed or sneezed from the respiratory tract"

Limitations:

- No updates since 2014. Limited literature review details and limited methods for formulating recommendations.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Coia JE, Ritchie L, Adisesh A, et al. Guidance on the use of respiratory and	Guidance/Expert Opinion	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
facial protection equipment. Journal of hospital Infection. 2013 Nov 1;85(3):170-82.					

Assessment of evidence

Methods: Coia et al., (2014) is a summary of Coia et al (2013) and Bunyan et al (2013) was the review that informed ref Coia et al (2013). Reference of interest is Coia 2013. Full references of supporting documents: Coia, et al. Use of respiratory and facial protection. 2014. Nursing Times. Vol 110 (4) p18-20. Coia, JE, et al, The Healthcare Infection Society Working Group on Respiratory and Facial Protection. Guidance on the use of respiratory and facial protection. Journal of hospital infection 85 (2013) 165-169. Bunyan D et al, Respiratory and facial protection: a critical review of recent literature. 2013. Journal of Hospital Infection. Vol 85 p165-169.

This expert consensus guidance provides guidance on surgical masks and respirators. It advises on the standards that both these types of masks should meet in the UK, when they should be worn, how they should be fit checked/tested if necessary and how they should be removed and disposed of. It refers to relevant health and safety/governmental legislation. This document specifies from the outset that the information provided is purely advisory guidance and is not a standard or a regulation. This differs from the legal obligations of employers and employees that are found within other OSHA documents such as the OSHA standards or the Occupational Safety and Health Act (OSH Act).

- Surgical face masks are recommended to protect the wearer from sources of infection e.g. splashing or spraying of blood and to protect others from the wearer as a source of infection. This would include health and care workers.
- Surgical masks were recommended during AGP's in patients who are not known or suspected of being infected with a respiratory infection. This would include health and care workers.
- this document contains a table of 'commonly encountered infections' and the PPE that should be worn (FFP3 for AGP). This included: Bordetella pertussis (until 5 days of antibiotics), Chlamydia pneumoniae (duration of acute symptoms and not infectious), Haemophilus influenzae (until 24 hours of antibiotics), Influenza virus (for duration of symptoms), mumps virus (until patient not infectious), Mycoplasma pneumoniae (for duration of symptoms), Neisseria meningitidis (until 24 hours of antibiotics), norovirus (only if risk of splash), rubella virus (until not infectious), streptococcus pneumoniae (where ongoing transmission in facility until 24

Assessment of evidence

hours antibiotics), other respiratory viruses including adenovirus, rhinovirus, non-SARS coronavirus, parainfluenza, respiratory syncytial virus (for duration of symptoms).

- Masks are necessary "when procedures may generate staphylococcal aerosols, e.g. during sputum suction or chest physiotherapy."; "Action to be taken on identification of a case of VISA/glycopeptide-intermediate S. aureus (GISA) or VRSA" and "Disposable masks and eye protection should be worn by carers for procedures likely to generate aerosols/splashing."
- The use of surgical masks or respirators is one component of infection control practices that may reduce transmission between infected and non-infected persons."
- "The effectiveness of surgical masks and respirators has been inferred on the basis of the mode of influenza transmission, particle size, and professional judgment."
- "During an influenza pandemic, surgical masks and respirators should be used in conjunction with interventions that are known to prevent the spread of infection, such as respiratory etiquette, hand hygiene, and avoidance of large gatherings."
- "Surgical masks also prevent contamination by trapping large particles of body fluids that may contain bacteria or viruses when they are expelled by the wearer, thus protecting other people against infection from the person wearing the surgical mask."
- It is also stated that surgical face masks may not be designed or certified for use for protection from "small airborne contaminants".
- When selecting the correct PPE the authors recommend a "risk assessment based approach" considering "the task or procedure to be undertaken; the suspected or known infectious status of the patient; and the presenting symptoms of the patient." As well as other IPC measures that may be in place.
- "in summary, it should be emphasized from the foregoing that in the majority of situations where respiratory and facial protection is required, a surgical mask will be adequate. For a very small number of pathogens truly transmissible via the airborne route, or where AGPs involving infectious body fluids are being undertaken, a respirator will be required. The requirement for eye protection will largely be determined by the risk of splashing/spraying of blood and/or body fluids to the eyes/face."
- "Selected based upon the hazard to the employee;

  _ Properly fitted and some must be periodically refitted (e.g., respirators);

  _ Conscientiously and properly worn;

Assessment of evidence
_ Regularly maintained and replaced, as necessary; _ Properly removed and disposed of to avoid contamination of self, others or the environment.” Caution is advised as this guidance was published in 2013 and some aspects may be out of date.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Dolan et al., Association for Professionals in Infection control and Epidemiology (APIC). APIC Position Paper: Safe Injection, Infusion, and Medication Vial Practices in Health Care. 2016. AM Journal of Infection Control 2016 Jul 1;44(7):750-7. Doi: 10.1016/j.ajic.2016.02.033	Guidance/ Expert Opinion	**Level 4**	N/A	N/A	N/A
Assessment of evidence					
• Under the heading of aseptic technique the authors recommended the following: “Use a mask to contain respiratory droplets when preparing and injecting solution into an intracapsular space (joint), the spine and during lumbar puncture”.					

Assessment of evidence
As a position paper this evidence is graded as level 4, expert opinion. The method for identifying the evidence included in this document are not clear.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Occupational Safety and Health Administration (OSHA) Occupational Safety and Health Act (OSHA). Guidance on Preparing Workplaces for an Influenza Pandemic. 2009. OSHA 3327-06R 2009	Guidelines/ Expert Opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence
This document specifies from the outset that the information provided is advisory guidance and is not a standard or a regulation. This differs from the US legal obligations of employers and employees that are found within other OSHA documents such as the OSHA standards or the Occupational Safety and Health Act (OSHA). “Surgical masks are used as a physical barrier to protect employees from hazards such as splashes of large droplets of blood or body fluids. Surgical masks also prevent contamination by trapping large particles of body fluids that may contain bacteria or viruses when they are expelled by the wearer, thus protecting other people against infection from the person wearing the surgical mask” (p21) “surgical/procedure masks are used for several different purposes, including the following […] worn by healthcare providers to prevent accidental contamination of patients’ wounds by the organisms normally present in mucus and saliva, worn by employees to protect

Assessment of evidence
themselves from splashes or sprays of blood or body fluids: they may also have the effect of keeping contaminated fingers/hands away from the mouth and nose” Caution is given regarding the appropriate use of both surgical masks and respirators: “Surgical masks are not designed or certified to prevent the inhalation of small airborne contaminants. These small airborne contaminants are too little to see with the naked eye but may still be capable of causing infection. Surgical/procedure masks are not designed to seal tightly against the user’s face. During inhalation, much of the potentially contaminated air passes through gaps between the face and the surgical mask, thus avoiding being pulled through the material of the mask and losing any filtration that it may provide. Their ability to filter small particles varies significantly based upon the type of material used to make the surgical mask, and so they cannot be relied upon to protect employees against airborne infectious agents.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
World Health Organization (WHO) Infection prevention and control of epidemic-and pandemic-prone acute respiratory infections in health care. 2014. ISBN 978 92 4 150713 4	Guidance/ Expert Opinion	**AGREE: ‘Recommend with provisos’.**	N/A	N/A	N/A
Assessment of evidence					
Like the majority of the other guidance on this topic, it is clear that the medical mask is not recommended in isolation but as part of a PPE ensemble and a group of IPC recommendations. Furthermore, the use of medical masks by healthcare workers should be done on a risk assessment basis.					

Assessment of evidence

Within this document a medical mask is defined as: “Medical mask - Also known as a surgical or procedure mask. As personal protective equipment, a facial mask is intended to serve as part of facial protection for patient-care activities that are likely to generate splashes or sprays of blood, body fluids, secretions or excretions (Annex A provides details of usage and standards for medical masks). In this document, the term refers to disposable masks only.”

“A.2.3 Medical mask standards - Medical masks protect the wearer's nose and mouth from inadvertent exposures (e.g. through splashes) to blood and other body fluids. However, there are no minimum standards or standardized testing methods for mask filter efficiency, and available masks vary widely in the efficiency of their filters. As an example of standards, the Association of Perioperative Registered Nurses recommends that surgical masks filter particles of at least 0.3 μm for regular use and 0.1 μm for laser use (i.e. to protect the wearer against laser smoke), or have 90–95% bacterial filtration efficiency. Furthermore, surgical masks are classified as medical devices in Europe and the US and are regulated appropriately. For example, the US Food and Drug Administration (FDA) standards for surgical masks are as follows: 1

• Fluid resistance:

– American Society for Testing and Materials (ASTM) F 1862–00a: standard test method for resistance of surgical mask to penetration by synthetic blood.

• Filtration efficiency:

– particulate filtration efficiency (PFE) – 0.1 μ polystyrene latex sphere;

– bacterial filtration efficiency (BFE) – ASTM F 2101–01: standard test method for evaluating the BFE of surgical masks using a biological aerosol of Staphylococcus aureus.

• Air exchange (differential pressure, delta-P):

– measure of breathability and comfort of surgical masks.

• Flammability:

– Class 1 and Class 2 flammability rating material for use in the operating room (OR);

– Class 4 flammability rating is not appropriate for use in the OR (would be labelled as “not for OR use”).

• Biocompatibility.”

Assessment of evidence

Table 2.1 recommends the use of medical masks by healthcare workers in the following instances:

when patient presents with ILI but is not yet diagnosed with or considered a risk for ARI virus or TB.

When a patient is diagnosed with Influenza virus known to have sustained human-to-human transmission.

New influenza virus known to have sustained human-to-human transmission.

SARS

RISK ASSESSED as suitable when patient has tested positive for bacterial ARI

RISK ASSESSED as suitable when patient has tested positive for any other ARI viruses.

"Droplet Precautions include (95):

• PPE – Use a medical mask if working within 1 m of the patient (154, 242-244). For practical purposes, it is advisable to use a medical mask when entering the patient's room."

Influenzas, new influenza, SARS and other ARI viruses are noted as requiring droplet precautions (+ contact precautions for ARI, new influenzas and SARS).

- droplet: "The spread of an infectious agent caused by the dissemination of droplets. Droplets are primarily generated from an infected (source) person during coughing, sneezing and talking. Transmission occurs when these droplets that contain microorganisms are propelled (usually < 1 m) through the air and deposited on the conjunctivae, mouth, nasal, throat or pharynx mucosa of another person. Most of the volume (> 99%) comprises large droplets that travel short distances (< 1 m) and do not remain suspended in the air. Thus, special air handling and ventilation are not required to prevent droplet transmission"
- "droplets – respiratory aerosols > 5 μm in diameter"

Please note, that this guidance included systematic reviews and an appropriate consultation process. However, specific details regarding the quality appraisal results were not clear. The studies which were reported as considered for mask related recommendations were limited. The search included studies pre-2000, studies with a bundled approach and studies focused on a community setting. It was also

Assessment of evidence
published 2014 and does not consider more recent research or evidence. The included studies related to surgical mask use were of low-quality/high risk of bias. As such the conclusions made may not apply to health and care settings in Scotland today.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Siegel JD, Rhinehart E, Jackson M et al. Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Health Care Settings. 2007 Last updated September 2024	Guidance	**Level 4**	N/A	N/A	N/A

Assessment of evidence
US – focused expert opinion guidance. • The use of masks that cover the mouth and nose are standard for surgical teams. In order to minimize the contamination in the operating room the operating team should wear masks during the operation. Healthcare workers are recommended to wear a surgical mask when: “(1) placed on HCWs to protect them from contact with infectious material from patients (e.g., respiratory secretions and sprays of blood or body fluids), consistent with Standard Precautions and Droplet Precautions”

Assessment of evidence
Recommendations: “Use Droplet Precautions as recommended in Appendix A for patients known or suspected to be infected with pathogens transmitted by respiratory droplets (i.e., large-particle droplets >5μ in size) that are generated by a patient who is coughing, sneezing or talking14, 23, Steinberg, 1969 #1708, 41, 95, 103, 111, 112, 755, 756, 989, 1017. Category IB” “Implement Droplet and Contact Precautions as recommended for diseases listed in Appendix A. Transmission-Based precautions for viral infections may need to be prolonged because of the patient’s immunocompromised state and prolonged shedding of viruses930, 1010, 928, 932, 1011. Category IB” • Droplet precautions: “a distance of 3 feet around the patient is best considered an example of what is meant by ‘‘a short distance from a patient’’ and should not be used as the sole criterion for determining when a mask should be donned to protect from droplet exposure. Based on these considerations, it may be prudent to don a mask when within 6 to 10 feet of the patient or on entry into the patient’s room, especially when exposure to emerging or highly virulent pathogens is likely” (pp S79) • Droplet precautions*:* “Droplet size is another variable under discussion. Droplets traditionally have been defined as being >5 μm in size. Droplet nuclei*,* particles arising from desiccation of suspended droplets, have been associated with airborne transmission and defined as ≤5 μm in size, a reflection of the pathogenesis of pulmonary tuberculosis which is not generalizeable to other organisms.” • “Masks may be used in combination with goggles to protect the mouth, nose, and eyes, or, alternatively, a face shield may be used instead of a mask and goggles to provide more complete protection for the face, as discussed below.” • “Procedures that generate splashes or sprays of blood, body fluids, secretions, or excretions (e.g., endotracheal suctioning, bronchoscopy, invasive vascular procedures) require either a face shield (disposable or reusable) or a mask and goggles.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
World Health Organization WHO guidelines for safe surgery: 2009:	Guidance/ Expert opinion	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
safe surgery saves lives ISBN 978 92 4 159855 2					
Assessment of evidence					
This guidance document was created to provide guidance to promote “safe surgery”. It was not clear if systematic reviews were conducted to unpin the recommendations as review results are not provided. Some evidence is discussed, and the methods highlight that expert opinion was utilised where appropriate to form recommendations. The working group used to form these guidelines include multiple professional from multiple disciplines. The use of masks that cover the mouth and nose are standard for surgical teams. In order to, minimize the contamination in the operating room the operating team should wear masks during the operation. This is classified as “Recommended”. • “The purpose is to prevent contamination of the patient’s tissues with microorganisms from the upper respiratory tract of the surgical team and also to prevent exposure of the mouth and nose of operating room staff from splashes of blood or other fluids from patients during a procedure. Use of masks significantly reduces contamination of the surgical site, but the association between mask use and surgical infections is less clear” • “There is evidence that the use of masks protects from splashes of blood or other fluids from patients during surgery, but its role in preventing the transmission of microorganisms is not clear.”					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Faculty of Pain Medicine. The Royal College of Anaesthetists. Best practice in the management of	Guidance/ Expert Opinion	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
epidural analgesia in the hospital setting. 2010					
Assessment of evidence					
This document is specifically focused on a procedure (epidural Anaesthesia) for which masks are recommended as part of an aseptic technique. This document was due for review in 2015 but an update has not been found vis online searches. It is therefore considered as subject to bias on the basis. It was updated and re-published 01 September 2020. "5 Catheter insertion. 5.1 Epidural catheter insertion must be performed using an aseptic technique. This should include hand washing, sterile gloves, sterile gown, hat, mask, appropriate skin preparation and sterile drapes around the injection site." – this quotation has not changed in the 2020 update of this document. The type of mask is not provided. Influenced by data collected during: The 3rd national audit project of the Royal College of Anaesthetists. Major complications of central neuroaxial block in the United Kingdom. RCoA, London 2009 (www.rcoa.ac.uk/index.asp?PageID=717).					
Study	**Study Type**	**Evidence Level**	**Intervention**	**Comparison**	**Outcome measure**
The Association of Anaesthetists of Great Britain and Ireland. AAGBI safety guideline: Infection Control in Anaesthesia. 2020	Guidance/Expert Opinion	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Last accessed: 16 October 2024					

Assessment of evidence

It updates and replaces previous guidance published in 2008, to reflect “changes and advances in IPC”, including greater use of single-use equipment and a reduced threat of variant Creutzfeldt-Jakob disease. “The advice has been updated and consensus guidance included on single-use equipment”.

Relevant statements included in this guidance:

- “Facemasks. The use of facemasks to decrease the incidence of postoperative wound infection has been questioned”.
- “Masks should also be worn by anaesthetists when carrying out a sterile procedure under full aseptic conditions. When worn, masks should not be taken down to speak and should be changed if they become damp or contaminated. Masks should only be handled by the ties and should be replaced between patients...”
- “The AAGBI recommends the use of Standard Precautions, which incorporate additional safeguards for specific procedures and patients, including single-use gloves, fluid resistant masks with a transparent face shield and gowns. Precautions are recommended for all patients, regardless of their diagnosis or presumed infectious status, and should be implemented whenever there is a possibility of contact with blood, other bodily fluids, non-intact skin and mucous membranes.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Steer JA, et al., Guidelines for prevention and control of group A streptococcal infection in acute healthcare and	Guidelines/ Expert opinion	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
maternity settings in the UK. 2012. Journal of Infection. Vol 64 p1-18.					
Assessment of evidence					
“Fluid repellent surgical masks with visors must be used at operative debridement/change of dressings of necrotising fasciitis and for procedures where droplet spread is possible.” Recommendation classed as SIGN good practice point which is why it is considered expert opinion (level 4 evidence). **Limitation:** • Methods used to formulate the recommendations are unclear. • Methods for selecting evidence were not clearly described. • The methods section is short and does not provide a detailed account of the search and review methodologies.					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Department of Health and Health Protection Agency. Pandemic influenza: Summary infection control guidance for ambulance services during an influenza pandemic. 2009	Guidance	**Level 4**	N/A	N/A	N/A

Assessment of evidence
A fluid repellent surgical mask should be worn by staff when caring for a patient (within 1 metre) known to be infected with influenza. • "A fluid repellent surgical mask will provide a physical barrier and minimise contamination of the nose and mouth by respiratory droplets and must be worn when working in close contact (within about one metre) with a patient suspected of having influenza". • "Putting a mask on only when within one metre of the patient is not workable, therefore, for practical reasons, ambulance staff should wear a surgical mask at all times when transporting patients with symptoms of influenza. The mask should be kept on for the duration of the transportation/activity or until the surgical mask requires replacement, e.g it is wet or damaged." This is listed under "droplet precautions" section of the report.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Department of Health and Health Protection Agency PANDEMIC (H1N1) 2009 INFLUENZA A summary of guidance for infection control in healthcare settings. Published 08 January 2010	Guidance	**Level 4**	N/A	N/A	N/A

Assessment of evidence

Report providing information on IPC recommendations for influenza. Published 2010.

- "Fluid repellent surgical masks must be worn when working in close contact (within approximately one metre) of a patient with symptoms".
- "In an area where influenza patients have been cohorted together, it may be more practical for staff to wear a surgical mask at all times, rather than only when in close proximity to or close contact with a patient".
- "Surgical masks should be fluid repellent and should be worn by healthcare workers for any close contact with patients with influenza symptoms (i.e. within approximately one metre)."
- "in outpatient settings – general practice, dental surgeries, accident and emergency (A&E) or similar – it may be more practical for staff working in the segregated area for influenza patients to put on a surgical mask on entry to the area and to keep it on for the duration of the activity or until the surgical mask requires replacement."
- Surgical face mask is recommended on entry to a cohort area even if no patient contract (i.e. extended use), when in close contact with a patient (within 1 meter).

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Association of periOperative Registered Nurses (AORN). Recommended Practices for Prevention of Transmissible Infections in the Perioperative Practice Setting. AORN, 85(2); 383-396, 2007.	Guidance/ Expert Opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence

Within the glossary masks are referred to as personal protective equipment (PPE).

- Wear a mask when aerosolized exposure to infectious microorganisms is expected.
- Wear a mask when within 3ft of an infectious patient where droplet precautions are advised (i.e. when suspected or confirmed to have an infection spread by a drop let route defined by the authors as “i.e., larger than 5 microns in size) and generally travel short distances of three feet or less (e.g., diphtheria, pertussis, influenza, mumps, pneumonic plague.”
- Wear a mask for AGP.
- Also recommended as part of ‘droplet recommendations’ are use of surgical mask on symptomatic patients during transport.

Unclear evidence used to form these guidelines, if any.

Interchangeable use of the work ‘mask’ or ‘surgical mask’ but this is assumed.

Question 6: When should patients/service users of health and care facilities wear a surgical face mask?

Evidence added to version 2.0 update:

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution Standards Publication. Medical face masks – Requirements and test methods. BS EN 14683:2025. 2025.	British Standards	**Level 4**	N/A	N/A	N/A
Assessment of evidence					
This document outlines the British standards for medical masks (requirements and testing). It is not specific to mask use as PPE and other standards should be consulted. It supersedes EN 14683:2014. “Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.” (Page 9) The British Standards Institution for medical mask requirements and testing published March 2019 highlights that Type I medical masks may be used by patients or other persons to reduce the risk of infection and provide the examples of endemic or pandemic situations. This may apply to seasonal mask use to reduce the spread of seasonal respiratory infections, but this is not explicit.					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health New Zealand. Infection prevention and control Last updated 26 November 2024	Guidance/ Expert Opinion	**Level 4**	N/A	N/A	N/A
Assessment of evidence					
This Guidance published by Health New Zealand includes standard and transmission-based precautions. The following section(s) are relevant for this research question on when patients/ service users should wear a surgical face mask. Standard precautions: • "Place people with acute respiratory symptoms at least 1 metre away from others in common waiting areas or in a single room (if available). Ask the person to wear a mask until they can be moved to a single room" Droplet precautions (interacting with people with suspected or known infection or disease spread by droplet): • "Where possible, the patient should wear a medical mask whilst awaiting assessment, or for any movement outside of the single room, along with strict adherence to respiratory hygiene and cough etiquette".					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
European Centre for Disease Prevention and Control (ECDC). Infection prevention and control and preparedness for COVID-19 in	Guidance/ Expert Opinion	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
healthcare settings – Sixth update. 9 February 2021.					
Assessment of evidence					
An EU document produced by ECDC providing COVID-19 specific guidance document recommending optimum IPC measures in healthcare settings during the pandemic. This is the 6th update of this guidance and supersedes earlier versions. The following was reported as guidance for acute health care settings: “The use of medical face masks by healthcare workers for personal protection and source control should be strongly considered during all routine activities and in communal areas as a measure for reducing transmission within healthcare settings in areas with community transmission” (page 4) and “Staff, visitors and patients should wear a face mask when physical distancing is not possible. Visitors may use non-medical face masks, if in line with local recommendation” (page 4). “They should wear a medical face mask if available, or at least cover their mouth with a tissue when coughing, and practise appropriate hand hygiene” (page 6) Pandemic specific guidance produced by the European Centre for Disease Prevention (ECDC). As this guidance was rapidly provides and the methodology is not clear it is considered as level 4 expert opinion level evidence. Within acute care settings ECDC recommend that patients wear a medical face mask when physical distancing is not possible. The document later states that for patient management those with possible COVID-19 should wear a medical mask if available.					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centers for Disease Control and Prevention (CDC) Infection Control Guidance: SARS-Cov-2	Guidance/expert opinion	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Last updated 24 June 2024 Last accessed: 15 October 2024					

Assessment of evidence

Expert opinion, no systematic review or other methods described.

“Source control is recommended for individuals in healthcare settings who:

- Have suspected or confirmed SARS-CoV-2 infection or other respiratory infection (e.g., those with runny nose, cough, sneeze); or
- Had close contact (patients and visitors) or a higher-risk exposure (healthcare personnel) with someone with SARS-CoV-2 infection for 10 days after their exposure.”

Source control is recommended more broadly [as per CDC’s Core IPC Practices] in the following circumstances:

- By those residing or working on a unit or area of the facility experiencing a SARS-CoV-2 or other outbreak of respiratory infection; universal use of source control could be discontinued as a mitigation measure once the outbreak is over (e.g., no new cases of SARS-CoV-2 infection have been identified for 14 days); or
- Facility-wide or, based on a facility risk assessment, targeted toward higher risk areas (e.g., emergency departments, urgent care) or patient populations (e.g., when caring for patients with moderate to severe immunocompromise) during periods of higher levels of community SARS-CoV-2 or other respiratory virus transmission (See Appendix)
- Have otherwise had source control recommended by public health authorities (e.g., in guidance for the community when COVID-19 hospital admission levels are high”
- “Even when a facility does not require masking for source control, it should allow individuals to use a mask or respirator based on personal preference, 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.”
- “Other factors, such as end-stage renal disease, may pose a lower degree of immunocompromise. However, people in this category should still consider continuing to use of source control while in a healthcare facility.”

Assessment of evidence
Additional wording: • Frequently asked questions: “For transport, the patient should wear a well-fitting source control (if tolerated) to contain secretions…” • Duration of TBPs for Patients with SARS-CoV-2 infection: “In general, patients should continue to wear source control until symptoms resolve or, for those who never developed symptoms, until they meet the criteria to end isolation [outlined in document]. Then they should revert to usual facility source control policies for patients.” • Nursing Homes, Indoor visitation during an outbreak response: “ideally occur in the resident’s room. The resident and their visitors should wear well-fitting source control (if tolerated) and physically distance (if possible) during the visit).

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
CDC and HICPAC CDC’s Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings Last reviewed 29 November 2022 Last accessed 01 December 2022	Guidance/Expert Opinion	**Level 4**	N/A	N/A	N/A
Assessment of evidence					
An update to the core practices provided by the CDC. It applies across health and care settings as well as across health care workers, patients and visitors, where appropriate. This is considered as expert opinion as the authors describe a process of consulting other CDC					

Assessment of evidence
materials as well as input from HICPAC in drafted recommendations produced 2014 which were reviewed in October 2022 by “experts within the Division of Healthcare Quality Promotion at CDC” as well as reviewed by HICPAC. • Within the ‘minimising potential exposures it states: “Prompt patients and visitors with symptoms of respiratory infection to contain their respiratory secretions and perform hand hygiene after contact with respiratory secretions by providing tissues, masks, hand hygiene supplies and instructional signage or handouts at points of entry and throughout the facility“.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
World Health Organization (WHO). Infection prevention and control in the context of coronavirus disease (COVID-19): A living guideline, 13 January 2023 Last updated 21 December 2023 Last accessed 15 October 2024	Guidance/ Expert opinion	**Level 4**	N/A	N/A	N/A
Assessment of evidence					
A living guidance document which includes recommendations for mask use in health and care settings in light of the SARS-CoV-2 pandemic. It is considered as expert opinion as it did not meet the standards of AGREE recommend. Methodology: Consensus approach described with GRADE approach and evidence searched. However, there are no details on how literature was searched, what terms were used etc so this guidance has been graded expert opinion.					

Assessment of evidence

Target audience: National and facility level decision-makers, policy makers, public health and infection prevention and control professionals; healthcare facility administrators, managers and other healthcare workers

Results:

- For health-care facilities with minimum to moderate impact of COVID-19: “WHO suggests targeted continuous medical mask use in health-care facilities in situations with minimum to moderate impact of COVID-19 on the health system: In non-patient areas, staff who do not have patient contact are not required to wear a medical mask during routine activities.”.- Labelled as a conditional recommendation based on very low certainty evidence.
- “WHO recommends universal masking in health-care facilities when there is a significant impact of COVID-19 on the health system: “: Inpatients are not required to wear a medical mask unless physical distancing of at least 1 metre cannot be maintained (e.g., during examinations or bedside visits) or when outside of their care area (e.g., when being transported), provided the patient is able to tolerate the mask and there are no contraindications” - “Strong recommendation for, very low certainty evidence” This is labelled as a strong recommendation based on very low certainty evidence which appeared to show it is associated with reduced transmission of SARS-CoV-2. The authors discuss there is limited evidence for harms of universal mask use beyond “bothersome” and “non-serious harms”, so the benefits were determined by the group to outweigh the harms. The evidence is regarded low quality due to number of studies available and study design.
- Universal mask use is expected to be deemed acceptable as a protective factor for healthcare workers, visitors and patients, and feasible.

PPE section and use: Conditional recommendation, low certainty of evidence for particulate respirators versus medical masks:

- “Suggested factors for informing the choice of the type of mask include a risk assessment and health and care workers’ values and preferences. WHO suggests respirators be used in care settings where ventilation is known to be poor2 or cannot be assessed, or where the ventilation system is not properly maintained.
    - The risk assessment should consider: the activity (procedure), the setting (patient care environment) and the patient. This recommendation applies to any setting where regular care is provided to patients with suspected or confirmed COVID-19, including home care, long-term care facilities and community care settings.”

      The authors highlight that there is limited evidence for the effectiveness of respirators over medical masks for SARS-CoV-2 is inconsistent. The evidence is regarded low quality due to number of studies available and their methodological limitations.

Assessment of evidence
Impact on resources is determined as low to moderate. This recommendation is considered likely acceptable for health and care workers, policymakers and hospital administrators. A living guidance document published by WHO and funded by CDC. It did not provide sufficient detail to be considered AGREE recommend but was included as level 4 expert opinion level evidence. While it is reported that multidisciplinary experts were involved in the development of these guidelines it is not clear how evidence was identified or selected and therefore it is subject to bias. Generally, and during period of significant impact of COVID-19 universal masking is recommended. However, in patients are not recommended to wear a medical face mask unless 1m psychical distancing cannot be maintained or when outside of their care area. However, this should only be conducted where the patient can tolerate the mask and there are no contraindications to mask use. Masks should not be used in children 5 years of age or younger.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Association of periOperative Registered Nurses (AORN) 2019 Guideline Quick View: Transmission-Based Precautions. 2019 Last accessed 21 November 2022	Guidance/ Expert Opinion	**Level 4**	N/A	N/A	N/A
Assessment of evidence					
An expert opinion guidance. References are not provided for the formation of each section. The guidance is reported to be developed for nursing staff who work in USA. Refers to ‘masks’ with a picture of a surgical mask. Information gathered from precaution level sections (provides type of mask per ‘level of protection’).					

Assessment of evidence
Droplet precautions described as used in addition to standard precautions to be implemented when a patient has a “known or suspected infection transmitted by respiratory droplets (e.g., adenovirus, group A Streptococcus, influenza, Neisseria meningitides, Bordetella pertussis, rhinovirus)” which are considered as “i.e. greater than 5µm”. Contact precautions: • No mention of mask Droplet precautions (i.e. particles >5µm): • Masks advised as protection for staff and to prevent transmission. • Patient wearing - “if possible, place a mask on the patient and instruct the patient to follow respiratory and cough etiquette during transport” Airborne precautions (i.e., particles or droplet nuclei < 5 µm): • Patient wearing – “if possible, place a mask on the patient and have the patient follow respiratory hygiene and cough etiquette during transport” – may refer to surgical mask and not N95, but this is not clear. An expert opinion (level 4) guidance design for use by nurses in the US. This document states ‘masks’ should be worn by patient during transport as an aspect of respiratory hygiene where a patient is suspected or confirmed as having an infection with particles of > 5µm. For particles < 5µm a mask is also recommended to be worn by patients during transport. The authors refer to ‘masks’ rather than specifically surgical masks for this recommendation. It is not clear how this guidance was formed, or which references were used to form the guidance.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
National Health and Medical Research Council (NHMRC) Australian Guidelines for the Prevention and Control of Infection in Healthcare, 2019 2019 (revised 2024, v11.24) Accessed 11 October 2024	Guidance/ Expert opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence

Aim: IPC guidance for Australian health and care settings.

Target audience: Acute settings but the authors highlight transferability across settings

Methods: The recommendations were made based on a range of methods. While some systematic reviews were included but there was limited details about the methods to extract data regarding surgical face masks.

In the section of the guidance which discusses involving patients in care, under the management of outbreak situations section, the authors state:

“Outbreak situations may require patients to be aware of changes to infection prevention and control activities within the healthcare facility…. If infected patients are transferred, they may be asked to wear a mask.”

- Transmission-based precautions are defined as those for patients with a suspected or confirmed infected agent transmitted by contact/droplet/airborne routes. In the transmission-based precautions section of the guidance, authors reiterate to “Ask patients on droplet or airborne precautions to wear a surgical mask if they are being moved from one patient-care area to another.”

Assessment of evidence
• Here, droplet transmission is defined as transfer of hands contaminated with respiratory droplets to susceptible mucosal surfaces or when infectious respiratory droplets come into direct contact with mucosa. Meanwhile, airborne transmission is defined as when small particles containing infectious agents are inhaled. • Under the practical information for recommendation 25, which is a good practice statement on single-patient room isolation for patients on droplet precautions, the authors suggest “asking the patient to wear a fluid resistant surgical mask while they are being transferred and to follow respiratory hygiene and cough etiquette. Children should wear a correctly fitting mask when they are outside an isolation room.” (page 100) • Under the practical information for recommendation 26, which recommends standard precautions in combination with airborne precautions when a patient is infected with a known/suspected agent transmitted by the airborne route, the authors state “In situations when personal protective equipment may be limited and a patient is exhibiting the signs of a respiratory disease, consider placing a mask or tissue over the patient's mouth as tolerated.” • Under the practical information for recommendation 28, which is a good practice statement on placing airborne precaution patients in a negative pressure room, the authors suggest that during patient transfer patients should “wear a correctly fitted surgical mask while they are being transferred and to follow respiratory hygiene and cough etiquette” and that “Children should wear a correctly fitting mask when they are outside an isolation room.” • Under the practical information for recommendation 30, which is a conditional recommendation suggesting face and eye protection are worn during procedures which generate splash/spray of body and body fluids into the face and eyes, the authors state that “Surgical masks can be placed on coughing patients to limit potential dissemination of infectious respiratory secretions from the patient to others” and that “Children should wear a specifically designed child mask and their oxygen saturation should be monitored.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Scientific Advisory Group for Emergencies (SAGE) Hospital Onset COVID-19 Working Group (HOCI) and Environmental Modelling Group (EMG) HOCI and EMG: Masks for healthcare workers to mitigate airborne transmission of SARS-CoV-2, 25 March 2021. Published 23 April 2021	Guidance/ Expert Opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence

This report was produced by members of the Hospital Onset COVID-19 Working Group and Environmental Modelling Group (EMG). It has not been updated since 21 March 2021 and may not reflect recent publications nor more recent UKHSA publications. It was produced in response to and in the context of the COVID-19 pandemic. The document is not peer reviewed, it was considered by SAGE 84 on 25 March, 2021. The selection process for the included evidence is not clear and therefore this is considered subject to bias.

- ‘patients and visitors should wear facemasks/coverings at all times, unless it is clinically impossible to do so’

Assessment of evidence
• 'wearing of facemasks by all inpatients, at all times, across all care pathways, providing this is tolerated by the patient and not detrimental to medical/care needs. • within Appendix 1 of this document an SBAR is presented as per the UK Cell position statement in IPC guidance which includes: An expert opinion, level 4 guidance and evidence review published by UKHSA in 2021 in response to the COVID-19 pandemic. The guidance highlights a paucity of evidence confirming the risk to persons in health and care settings from particles emitted by infectious persons. It recommends that inpatients should wear facemasks/coverings at all times, across all care pathways. If it is tolerated and not detrimental to medical/care needs. But this is not specific to surgical masks. The methods used to identify and appraise the evidence included in their document is not clear and therefore, the results may be subject to bias.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Government of Canada. Updated guidance for infection prevention and control in the health care setting when COVID-19 is suspected or confirmed – April 2024. Updated 12 April 2024 (published 23 December 2021) Accessed 21 October 2024.	Guidance/ Expert opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence

These Canadian recommendations extend across health and care settings.

The authors outline further COVID-19 IPC guidance for employers:

- "Source control is recommended for individuals in health care settings who have suspected or confirmed COVID-19, or with symptoms and signs of a respiratory infection".
- "Patients with suspected or confirmed COVID-19 or respiratory infection should wear a well-fitting medical mask when outside of their room or bedspace (in multi-bedded rooms)"
- " and spaces where HCWs, other staff, and visitors may come into contact with patients (e.g., patient rooms, clinical units, hallways, elevators, waiting rooms)".
- "The decision to implement broader masking for source control should be made in consideration of the following epidemiological and clinical factors:
    - Epidemiological context, including:
        - Increasing community transmission
        - Facility/unit outbreaks of COVID-19 or other respiratory infections
        - Increasing hospitalizations and ICU admissions
        - Increasing staff COVID-19 cases
    - Clinical context, including working:
        - With immunocompromised persons or those at greater risk of acquiring an infection
        - In clinical areas/units at higher risk of SARS-CoV-2 transmission (e.g., COVID-19 designated units, emergency departments, open space critical care areas, oncological units, haemodialysis units, etc.)"
- "If implementing broad masking for source control, consider the impact on persons with cognitive impairment or where masks could impede communication or otherwise hinder the ability to provide equitable care".
- "Implementation of broad source masking may vary based on jurisdictional and facility-specific context, including organizational risk assessment".

Assessment of evidence
• "Patients who are unable or unwilling to mask should not be denied care. Protocols should be in place to allow for the safe assessment and treatment of symptomatic, unmasked patients. Patient masking is not recommended for paediatric patients two years of age or younger or for any patient unable to tolerate masking for medical or developmental reasons". **Limitations:** • This guidance supersedes the setting-specific guidance produced by the Canadian Government, but it is not made clear which recommendations are current. • It is not clear when a PCRA should be conducted in place of universal masking

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Ueki H, et al., Effectiveness of face masks in preventing airborne transmission of SARS-CoV-2. MSphere. 2020 Oct 28;5(5):e00637-20. (Japan-based study)	Experimental Study (simulation)	**Level 3**	Protective effect of surgical or N95 masks against SARS-CoV-2 aerosolized particles when worn for protection and/or as a form of source control. Surgical mask (double tie straps).	Surgical mask (double tie straps) compared to no mask or N95 respirator mask. Conditions: Source: no mask, receiver: no mask Source: no mask, receiver mask Source: mask, receiver: no mask Source: mask, receiver: mask	Viral loads and infective virus that passed through the masks were measured by use of a plaque assay and quantitative real-time reverse transcription PCR (qRT-PCR), respectively. Viral titer (Log10PFU), PFU = plaque forming units. Viral RNA (Log10 copies)

Assessment of evidence

A level 3 experimental study, involving two manikin heads at 50cm distance with nebulized (manikin 1) or ventilated (manikin 2) air to simulate exhalation and inhalation. Penetration through the mask of the receiver was assessed using qRT-PCR.

Methods: No mask (control), surgical mask, N95 and N95 (sealed to face with tape) were worn by either the receiver or source or both in the experiments.

Nebuliser manikin = 6ml of viral suspension (Cells – VeroE6/TMPRSS2 (JCRB1819) cells maintained in Dulbecca modified Eagles medium containing 10% foetal calf serum and antibiotics 37°C with 5% CO2. Virus - UT-NCGM02/Human/2020/Tokyo SARS-CoV-2 virus propagated in VeroE6/TMPRSS. in culture medium or diluted in phosphate saline. 5x 105 plaque forming units or 1x108 PFU, 1 × 105 PFU, 1 × 104 PFU. It ran continuously for coughs (2m/s for 20 minutes). Particle sizes = 5.5 ± 0.2 μm in mass median diameter (particle size percentages were as follows: <3 μm, 20%; 3 to 5 μm, 40%; >5 to 8 μm, 40%). The ventilation manikin = attached to an artificial ventilator (5.5 liter of tidal volume, a respiratory rate of 18 breaths/min, and a 50% gas exchange rate).

Results:

- receiver wearing a surgical mask, source not wearing a surgical mask - Surgical masks: viral titer = 53% (non-significant), RNA copy number 50% ($p < 0.05$).
- source wearing a surgical mask, receiver not wearing a surgical mask -Surgical masks: viral titer = 24% ($p < 0.05$), RNA copy number 42% ($p < 0.05$).
- both the source and receiver wearing a surgical mask – $p < .05$ for surgical mask compared to no mask control.

The results were presented in figures and more information could have been provided. However, based on the results a source wearing no mask and receiver wearing a surgical face mask resulted in a reduction in viral RNA but not in viral titer compared to the no masked control. N95 respirators without tape showed a similar result. Where the source wore a surgical mask and the receiver did not both viral titers and RNA copy numbers were significantly reduced compared to no mask use for surgical masks and N95 respirator use. A similar result was obtained where the source wore a surgical mask and the receiver wore a surgical mask, cloth mask, or N95 (various configurations).

Limitations: Lack of generalisability and applicability with fixed experimental conditions, use of N95 not FFP and unclear BFE of surgical mask, particle size not clear, one strain SARS; prolonged use not considered, also a short report with limited details and lack of reliability with only 3 repetitions. Particle size not clear in terms of release and collection. Though the nebulizers capabilities are noted. Short distance within the exposure box and small space to consider which may not represent clinical interactions.

Assessment of evidence
A level 3 experimental study where two manikins placed 50cm apart within a test chamber simulated an infectious source and ventilating receiver manikin. The results indicate that a surgical mask or N95 worn by a source (could simulate an infectious patients) were generally effective in reducing viral titers and RNA copies inhaled by a receiver. A reduction was also reported where both a source and receiver wore a surgical mask. The results suggest that a surgical mask provides some protection for a receiver against particle penetration when a receiver and source wear a surgical face mask.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Wilson NM, et al., The effect of respiratory activity, non-invasive respiratory support and facemasks on aerosol generation and its relevance to COVID-19. Anaesthesia. 2021 Nov;76(11):1465-74. (Australia-based study)	Experimental study (observational)	**Level 3**	Surgical face mask (Bacterial filtration efficiency ≥98%.) compared to no mask while completing respiratory activities.	Mask versus no mask on the expired particles (source control).	Differences between mean particles exhaled during of activities or therapies with 95%CI. Particle volumes in each size category were transformed to estimate particle volumes. Mixed effects linear regression to compare sampling per particle size category.
Assessment of evidence					
An experimental study comparing mean expelled particles when 10 participants undertook respiratory activities (quiet breathing, talking, shouting, exercise, forced expirations and coughing) (FEV and coughing every 7-8 second for 45 seconds) while wearing a surgical face mask (≥98% BFE) compared to not wearing a face mask. This study may be considered as assessing the efficacy of a mask as source					

Assessment of evidence
control as it assessed leakage from the source (i.e. healthy person exhaling or completing respiratory activities). Differing order of activities for accuracy. • The results showed that wearing a surgical face mask during talking, shouting, forced respirations and coughing showed a significant reduction in mean expired particles (0.2-0.4 fold reduction, P< .05). • Study characteristics: 10 healthy participants (4 females, 6 male, mean age 29). Use of custom chamber with cone connected to a particle counter with categories (bins) at 0.5–0.7; 0.7–1; 1–3; 3–5; 5–10; and 10–25μm. Limitations: There were several limitations of this study including the lack of generalisability and applicability to real world settings, differences in room temperature and humidity, forced respirations, long range particle expulsions unclear, power calculations were unclear, lack of reliability (3 repetitions). This level 3 experimental study comparing mean expelled particles when 10 healthy participants undertook respiratory activities (quiet breathing, talking, shouting, exercise, forced expirations and coughing) while wearing a surgical face mask (BFE >98%) compared to not wearing a face mask. The results suggested that talking, shouting, forced respirations and coughing showed a significant reduction in mean expired particles (0.2-0.4 fold reduction, P< .05). This suggests that wearing a surgical face mask may reduce the expulsion of particles (from 0.5-25 μm). It is not clear to what extent this may impact possible onward transmission of particles. The results may indicate that surgical masks may provide some protection by reducing the mean expulsion of particles by a wearer.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Patel RB, et al., Respiratory source control using a surgical mask: an in vitro study. Journal of occupational and	Experimental Study (simulation)	**Level 3**	Earloop surgical mask (appears to meet ASTM level 3)	The use of a surgical face mask (reported as meeting Level 3 ASTM) or respirator (N95 with and without a Vaseline seal).	Maximum Exposure - the percent of nebulized particles captured (i.e. inhaled) by the filter within the receiver when no masks are

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
environmental hygiene. 2016 Jul 2;13(7):569-76. (US-based study)				Control – no mask with particles measured near source.	worn by the source or receiver. Receiver protection was calculated as ratio of maximum exposure to actual exposure.

Assessment of evidence

Methods: Two manikin heads placed just over 3ft apart within a chamber where ACHs were set at 0, 6 or 12. Both manikins were set to replicate tidal breathing (tidal volume 500ml, RR 15 breaths/min). The source manikin could also replicate coughing through a series of 1.5L breaths generating a peak flow of 5.2L/sec. Collection periods were set to 8 minutes. Manikins expelled radiolabelled wet aerosol particles. Combinations of source/receiver control were trialled using two types of surgical mask and an N95 respirator. Wash out of air between experiments. Air flow 1) no ambient air flow, 0 changes per hour; 2) all air movement secondary to coughing/breathing from source/receiver manikin; or 3) 6 (171 CFM) air changes per hour to model hospital setting or 4) 12 (343 CFM) air changes per hour modelled on negative pressure isolation room (smoke testing to check direction of air flow) in hospital setting. Relative humidity = 33–58% and temperature = 21.0–22.8°C.

Results:

Source Control

- “In the Negative pressure room applying either surgical mask or respirator to the Source resulted in statistically significant reductions in exposure”

Please note that for the following results figure 4 was used to determine significance - *p* values were not provided.

- Tidal breathing – significant reduction in receiver exposure shown for surgical face masks when worn by the receiver no air flow, and negative pressure room simulations.
- Coughing – significant reduction in receiver exposure shown for surgical face masks in all rooms when worn by the source.

Assessment of evidence
Filtration at the source – natural fit surgical mask (~ 5–20%), secure fit surgical mask filter (~50%), N95 (~80-90%) and sealed N95 (~100%). It was reported that increased fit led to 100% capture efficiency, unclear how this was assessed. Limitations: This study had several limitations including a lack of generalisability and applicability based on the fixed experimental conditions, fixed distance of manikin (3 foot), airflow not reflective of real-world settings, unclear particle size, p-values are not provided though significance is stated, wet particles may be impacted by humidity/temperature (33–58%). Although limited by its in vitro nature, fixed 'higher' distance from source to receiver and airflow being optimized for HCW protection (from receiver to source) which may enhance the reported effect of source control. Overall, this study suggests that in this experimental setting surgical masks showed reduced exposure suggesting a surgical mask may have some efficacy as a form of source control. The results suggest that surgical masks may be effective as source control within experimental conditions. This suggests that there may be some benefit in patients exhaling infectious particles wearing a surgical mask where appropriate.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Diaz KT, Smaldone GC Quantifying exposure risk: surgical masks and respirators. American journal of infection control. 2010 Sep 1;38(7):501-8. (US-based study)	Experimental Study (simulation)	**Level 3**	NIOSH approved N95 respirator worn by either source or receiver; Earloop surgical mask (appears to meet ASTM level 3) worn by either the receiver or source manikin.	Exposure and filtration was compared in difference masking setups: Control – no masks worn by any manikin. Risk factor: mask use (surgical face mask or N95) compared with no mask use	Maximum exposure – total particles inhaled by the receiver based on no mask on receiver or source. This represents the exhaled particles which mix with ambient air. Used to calculate protection factor (unclear calculation). Radioactivity captured by each

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
					mask quantified the effectiveness of filtration and deflection on exposure. Filtration – particles captured by the mask. With pure filtration measured by sealing mask and ambient air flow 0. Deflection – particles not captured by filtration but deflected away from the receiver. Also measured with head turned (90 degrees) to the left.

Assessment of evidence

Methods: two manikins set up with radio-labelled wet particles produced within chamber from one manikin head (source) towards another manikin head (receiver) approx. 3ft apart. Radioactivity captured by each mask quantified the effectiveness of filtration and deflection on exposure. Tidal volumes of 500 mL and respiratory rates of 15 breaths/min. Surgical mask type, brand provided no details of certification but from wider search may adhere to type 11R status. Temperature 20-22ºC and relative humidity 21-26%. 50 cm distance

- Greater filtration was reported not to result in a reduction in exposure (captured within receiver manikin) compared with the surgical mask (0.003-0.006% of Max exposure) suggesting a disruption in airflow may be a continuing factor to receiver exposure.

Assessment of evidence
• The use of a surgical mask or N95 respirator at the source resulted in reductions in exposure (protection factor of 172 - 317). This indicates that a surgical face mask may assist with disruption to the flow or behaviour of particles flowing towards a receiver which increased protection to the receiver despite less effective filtration. The results of this study also suggest that there was no observed reduction in exposure to the receiver when only the receiver wore either an N95 or surgical face mask (protection factor 1.37-2.21). Limitations: This study had a number of limitations including a lack of generalisability and applicability based on the fixed experimental conditions, fixed distance of manikin (3 foot), limited details of p values, constant flow rate, wet particles may be affected by humidity etc, fit may not apply. The findings from this level 3 study highlight that N95 respirators and surgical face masks were comparable in their protectiveness when worn by a source. This suggests that a surgical face mask may be beneficial if worn as source control by patients or persons in health and care who may be emitting infectious particles. However, the limitations of this study should be taken into account as it has a moderate to high risk of bias and it should not be used in isolation to make recommendations.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Lindsley, W. G. et al. (2021) Efficacy of face masks, neck gaiters and face shields for reducing the expulsion of simulated cough-generated aerosols. Aerosol Science and Technology, 55 (4), pp. 449-457.	Experimental (simulation)	**Level 3**	Procedure mask (reported as ASTM Level 3). Procedure mask is described as fluid resistant.	Efficacy of procedure mask and respirators as a form of source control (reducing particles emitted into the environment from a 'source' manikin) Comparators: N95 respirator	Collection efficiency: percentage of aerosol particles blocked by the PPE under investigation (%) when compared to experiments without the use of PPE. Air particle mass in collection chamber (ug) as a proxy measure for how

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
(US)					effectively the PPE under study reduced the mass of air particles emitted into the environment.

Assessment of evidence

Experimental setup: 14% KCl and 0.4% sodium fluorescein solution was nebulised using a single jet Collison nebuliser. Nebulised solution passed through a diffusion drier and then mixed with 10L/min of dry filtered air. Masks (surgical or N95) on manikin head for 2 consecutive tests. A cough (4.2L/sec and peak flow 11L/second). Cough sampled from bellows before coughing to normalise particle mass.

Sampling: Portacount used to assess fit factor of masks (e.g. ratio particles outside compared to inside mask). Anderson impactor (28.3L/min) run for 20 minutes after each cough. Capable of measuring/separating particles per following sizes: <0.6 uM, 0.6 – 1.1 uM, 1.1 – 2.1 uM, 2.1 – 3.3 uM, 3.3 – 4.7 uM, 4.7 – 7.0 uM, >7uM. Note, particle >7 μm were not analysed due to small concentration of this size. Fluorescence measured via fluorometer.

Results: N95 (98.6% filtration efficacy), Surgical mask (58.5% filtration efficacy). For comparison of air particle mass (μg) into chamber = N95 vs no device: -504 (-567, -422) p<0.0001, N95 vs procedure mask: -205 (-277, -133), p<0.0001, Procedure mask vs no device: -299 (-361, -237), p<0.0001.

In this study, the N95 and fluid resistant surgical face mask was more effective than no mask or PPE, at reducing mean air particle mass (uG) in the enclosed chamber when placed over the mouth of the manikin in an enclosed chamber where one cough was simulated, producing particles <0.6 uM – 7 uM in size. However, the N95 respirator was more effective than both the procedure mask and the use of no PPE.

Limitations: There were several limitations of this study including the lack of generalisability and applicability to real world settings, may lack reliability (2 repetitions), breathing and speaking not assessed, one cough simulated. Unclear on the flow rate chosen for the simulated cough. The flow rate chosen was based on one study on influenza patients. It is also unclear if the investigators used the peak flow rate from this investigation, or mean flow rate. Only peak flow rate is mentioned in their results section.

This level 3 simulation study considered the ability of surgical masks in preventing dispersal of nebulized sodium fluorescein solution. It provides evidence to suggest that in this specific experimental setting a ‘procedure’ masks was more effective than no mask as a form of

Assessment of evidence
source control. However, the study may have limited generalisability and the evidence should not be considered in isolation to make recommendations.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Asadi, S. et al. Efficacy of masks and face coverings in controlling outward aerosol particle emission from expiratory activities. 2020 Nature Scientific Reports, 10(15665), doi: 10.1038/s41598-020-72798-7 (appears to be US-based)	Experimental Study (observational)	**Level 3**	Surgical mask (unclear fluid resistance), tested by 10 participants. Non-vented KN95 respirator, tested by 10 participants A vented N95 respirator, tested by 2 participants	The efficacy of surgical face masks and respirators in reducing particle emission rates when volunteers undertook breathing, speaking and coughing. Jaw movement (mimicking chewing gum) also assessed but considered out-with scope of the review. No mask (control)	Particle emission rate (particle/second) Observed particle size distribution (particle fraction, %)
Assessment of evidence					
Methods: This level 3 experimental study compared particle emission when wearing a mask (respirator or surgical face mask) or no mask while competing respiratory activities including gentle breathing, talking (reading a passage) and forced coughing. Healthy volunteers undertook these activities while sitting with their mouth in front of a funnel attached to an aerosol particle sizer (measuring 0.3-20µm). Results: breathing (from 0.31 particles to 0.06 SFM and 0.07 KN95), talking (SFM0.18 and KN950.36 particles) and coughing (from 10.1 to SFM 2.44 particles). KN95 used in coughing did not significantly reduce particle emission rate.					

Assessment of evidence
The results indicated that wearing a surgical mask resulted in a significant reduction in particle emission rate compared to wearing no mask. Surgical mask and respirators were comparable with the exception of coughing where only a surgical mask showed a reduction with statistical significance. Breathing 0.31 emission rate with no mask compared to 0.06 with a surgical mask. Limitations: Lack of generalisability and applicability with fixed experimental conditions, small sample, forced coughs, specific particle sizes, plume travel distance, time suspended unclear. Stats presented as part of figure are quite difficult to interpret without further clarification. P values not provided but significance is described as $p<0.05$. The results of this level 3 experimental study suggest that surgical masks used as source control during talking, coughing and gentle breathing may significantly reduce particle emission compared to not using a mask. In this cohort surgical mask and KN95 respirators performed comparably showing reduced particle emission except for coughing where only surgical masks showed statistical significance. This has relevance for question 5-7. However, the study may be limited based on its small sample and simulation of respiratory activities which may limit its generalizability. The results should not be used in isolation to form recommendations.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Mansour MM and Smaldone GC. Respiratory Source Control Versus Receiver Protection: Impact of Facemask Fit. J Aerosol Med Plum. 2020;26(3);pp:131.137 Doi:10.1089/jamp.2012.0998	Experimental Study (simulation)	**Level 3**	This study compared mask types (N95 or surgical mask) using two manikin (a source and a receiver) with simulated tidal breathing at 3ft apart to determine the degree of protection for source N95 and surgical mask combinations as well as receiver N95 and	no mask on either head defined as maximum exposure, a surgical mask tightly fit on the source, a surgical mask looped ‘‘naturally’’ around the ears of the source, an N95 on the source,	Particle distributions and mass median aerodynamic diameters (MMAD) Exposure data, expressed as % of nebulised activity (Nebulized activity represented the difference between initial nebulizer charge and that remaining after nebulization)

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
			surgical mask combinations.	an N95 on the source sealed to the face with Vaseline, a surgical mask tightly fit on the receiver, a surgical mask looped around the ears of the receiver, an N95 on the receiver, an N95 on the receiver sealed to the face with Vaseline	Exposure data, defined as simulated workplace protection factor (sWPF) (ratio of max exposure to actual exposure). "The protective effect of each intervention in reducing exposure is best illustrated by the magnitude of the sWPF." Mask filtration – radioactivity captured by each mask, reported as a % of activity exhaled at source Separation of 95% CIs indicated statistical significance.
Assessment of evidence					
This level 3 in-vitro, experimental study involved two manikin heads which represented 3-foot distancing between a source and receiver. The study suggests that there was a significant reduction in exposure to particles when a source wore a tightly fitted or loosely fitted surgical face mask compared to no mask. There were non-significant reductions in exposure when only a receiver wore a surgical mask (tightly or loosely fitted) or when they wore an unfitted N95 respirator. 6 air changes per hour in room.					

Assessment of evidence
Results: SFM/N95 worn by source: • SFM naturally fitted: Exposure decreased to 0.000637% (95% 95% CI: 0.00163–0.01110%), SWPF = 214 • SFM tightly fitted: Exposure decreased to 0.00019% (0.00023% (95% CI: 0.00009–0.00038%), sWPF = 5,850 • N95 (no Vaseline): 0.00019% (95% CI: 0.00012– 0.00027%), sWPF = 7,174 Compared to the control, these were deemed statistically significant reduction in aerosol exposure. Limitations: This study had a number of limitations including a lack of generalisability and applicability based on the fixed experimental conditions, Vaseline seal is not reflective of real-life mask use, unclear number of repetitions, unclear if the source manikin wore a mask/respirator when the experiments involved source control. Therefore, these comparisons are consisted as subject to bias. Set parameters of air flow, air changes and 3ft distancing between source and receiver. This level 3 experimental study, although limited by its in-vitro nature and set parameters of air flow, air changes and 3 foot distancing between source and receiver, suggests that surgical face masks when worn by a source only significantly reduced exposure when compared to no mask use.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Lai J, Coleman KK, Tai SH, et al. Relative efficacy of masks and respirators as source control for viral	Observational	**Level 3**	No mask, N95, KN95, surgical mask, cloth mask use for source control.	Exhaled breath aerosol per mask type and across particle sizes (fine and course).	Viral load, defined as a fraction of unmasked aerosol detected in masked samples.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
aerosol shedding from people infected with SARS-CoV-2: a controlled human exhaled breath aerosol experimental study. EBioMedicine. 2024 May 28.					Source-control factor (similar to established definition for fit factor), defined as the percentage reduction in viral load realised in the environment (%) Relative efficacy of mask/respirator (%), calculated using ration of outward leakage. Exhaled breath aerosols were considered in total (combined) and for coarse (>5 uM) and fine (≤5 uM) aerosol particles.

Assessment of evidence

Setting: The study took place un a US-based university between 2020 and 2022.

Methodology: This controlled human experimental study involved paired samples (exhalations with and without a mask) from 44/106 human participants who had one or more samples positive for SARS-CoV-2 (variant type was considered). The aim of this study was to analyse the efficacy of various face masks (surgical, cloth, KN95, N95) as source control (through a measure of reduction in total exhaled particles (combined fine and coarse), fine particles and coarse particles for SARS-CoV-2 positive persons.

Assessment of evidence

There were some variations in the methods used depending on the type of mask, activities (saying the alphabet, shouting and saying happy birthday song loudly or breathing) based on symptoms, time the person took part. Generally, participants were asked to undertake speaking or shouting activities with and without a mask for up to 30 minutes. A particle counter (Gesundheit-II (G-II) human exhaled bioaerosol collector) was utilized to measure 'exhaled' particles. Outcomes were measured for total exhaled particles as well as fine (≤5 µm) or coarse (>5 µm) particles. Mask use compared to no mask use and efficacy between types of masks were considered within the analyses. The statistical analysis was based on a sample of 44 and it is not indicated by the authors if this met any conducted power calculation.

Main findings: The relevant results indicate that when compared with no masks, wearing a surgical face mask reduced the detected viral load significantly (P <0.05) across fine and coarse particle sizes. After coughing was controlled, it was reported that when compared to no masks, wearing a surgical mask resulted in a 74% (95%CI 65-81%) reduction in total exhaled viral load. It appears that there was a statistically significant greater reduction in exhaled viral particles when N95 respirators were worn compared to other mask types, including surgical face mask. P values for this aspect of the analysis are not clear across the tables and figures. It was also reported that cloth masks resulted in a significantly higher reduction in total exhaled particles compared to surgical and KN95 masks. Though it was reported that this significance was not maintained when only coarse or fine particles were considered. The reduction in total exhaled viral load for surgical masks was not statistically significantly different to KN95 masks.

These results suggest that within the context of the fixed experimental conditions, surgical masks reduced exhaled viral load (source control) when compared to no mask. It also suggests that there may be greater reduction in exhaled particles (source control) provided from the N95 mask tested in this study compared to the surgical face mask. Alternatively, KN95 and surgical masks appeared to perform similarly. It is not clear how these reductions may impact onward transmission of infection. It is also not clear how far away the particle counter was from the participant and it difficult to state with any certainty how these results would compare to a clinical interaction or how they inform infection transmission and prevention.

Strength:

- Participants were eligible if samples (at least one) was positive) – may have higher applicability to SARs-CoV-2 transmission than a proxy particle or substance. However, period of sampling per mask type differed.

Limitations:

Assessment of evidence

- Recruitment was from community testing facilities, it is unclear if there were other people (not within the 106) who were also tested but who chose not to participate. Differences between those eligible/ineligible, are not provided. – lack of generalizability.
- Lack of replicability – unclear how far away the particle collector was from the participant and if this was standardized for all experiments. It was stated that participants had no prior training of wearing RPE. It is not clear if fit checking/testing was conducted.
- Participants were asked to wear their own or a supplied mask the brand/type of supplied mask is provided. It is not clear how many masks were brought by patients, it is stated “mostly cloth” indicating some SFM or RPE may have been supplied by the participants and it is not clear if these met minimum standards. The indication for use was reported as the researchers decided they were “well-fitted”.
- Small sample (44 in total but under 27 per group of masks), unclear power. – lack of reliability.
- Variations in sampling time, activities undertaken (happy birthday, shouting), differences in level of illness (as demonstrated by some people being reported as too unwell to undertake the speaking activities). Impact (if any) of these baseline differences are unclear.
- Variations in the type of mask (provided SFM are described but unclear how many if any were brought by the participant).
- Lack of replicability and applicability - room humidity, temperature, distance of counter from participant, ventilation in place and other persons in the room are unclear.
- It is unclear how this experimental setup may compare to real clinical interactions within health and care settings.
- The true risk of transmission is unclear.

This controlled exhalation study contributes to the evidence base as it suggests that in this controlled, fixed experimental condition surgical face masks provide statistically significant reductions in emitted particles compared to no masking, across the measured particle sizes (fine and coarse). It also highlights that the tested N95 respirators may provide statistically significant reductions in emitted particles compared to the tested surgical face masks but that this superiority may not be consistently reported with other respirator types (KN95). The clinical significance of these differences is unclear, and the transmission risk is also not clear.

Evidence from previous update(s):

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Department of Health and Health Protection Agency. Pandemic influenza: Summary infection control guidance for ambulance services during an influenza pandemic. 2010	Guidance	**Level 4**	N/A	N/A	N/A
Assessment of evidence					
• "When transporting a patient with symptoms of influenza, the patient should be encouraged to wear a surgical mask to minimise droplet dispersal. The mask should be worn throughout the period of transport" • "If the patient cannot tolerate a mask, good respiratory hygiene should be encouraged and a tissue or similar can be offered to hold against their mouth and nose to 'catch' secretions from coughing, sneezing or blowing the nose" • "Patients suspected of having influenza should not be transported with other patients who do not have influenza"					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Department of Health and Health Protection Agency PANDEMIC (H1N1) 2009 INFLUENZA A summary of guidance for infection control in healthcare settings. 2009 Published 08 January 2010	Guidance/ Expert opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence

- "The provision of surgical masks to patients with suspected or confirmed pandemic influenza to be worn from the point of assessment or triage in any healthcare setting (except when in a dedicated influenza area) should be considered."
- "In common waiting areas or during transport, symptomatic patients may wear surgical masks to minimise the dispersal of respiratory secretions and reduce environmental contamination."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Occupational Safety and Health Act (OSHA). Guidance on Preparing Workplaces for an Influenza Pandemic. 2009 OSHA 3327-06R 2009	Guidelines/ Expert Opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence

This document specifies from the outset that the information provided is purely advisory guidance and is not a standard or a regulation. This differs from the US legal obligations of employers and employees that are found within other OSHA documents such as the OSHA standards or the Occupational Safety and Health Act (OSH Act).

Caution is given regarding the appropriate use of both surgical masks and respirators:

- "Surgical masks are not designed or certified to prevent the inhalation of small airborne contaminants. These small airborne contaminants are too little to see with the naked eye but may still be capable of causing infection. Surgical/procedure masks are not designed to seal tightly against the user's face. During inhalation, much of the potentially contaminated air passes through gaps between the face and the surgical mask, thus avoiding being pulled through the material of the mask and losing any filtration that it may provide. Their ability to filter small particles varies significantly"
- "based upon the type of material used to make the surgical mask, and so they cannot be relied upon to protect employees against airborne infectious agents."
- "Note: Additional respirator and surgical mask guidance for healthcare workers has been developed and is available at www.pandemicflu.gov/plan/healthcare/maskguidancehc.html. This document, "Interim Guidance on Planning for the Use of Surgical Masks and Respirators in Health Care Settings during an Influenza Pandemic," provides details on the differences between a

Assessment of evidence
surgical mask and a respirator, the state of science regarding influenza transmission, and the rationale for determining the appropriate protective device." • Within this document on p21 it states the following: "Placed on sick people to limit the spread of infectious respiratory secretions to others.".

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
World Health Organization (WHO) Infection prevention and control of epidemic-and pandemic-prone acute respiratory infections in health care. 2014 ISBN 978 92 4 150713 4	Guidance/ Expert Opinion	**AGREE: recommend with provisos**	N/A	N/A	N/A

Assessment of evidence
Within this document a medical mask is defined as: "Medical mask - Also known as a surgical or procedure mask. As personal protective equipment, a facial mask is intended to serve as part of facial protection for patient-care activities that are likely to generate splashes or sprays of blood, body fluids, secretions or excretions (Annex A provides details of usage and standards for medical masks). In this document, the term refers to disposable masks only." Medical masks should be part of a number of IPC supplies that are accessible within the healthcare environment. "In people with ARIs, encourage the use of respiratory hygiene (i.e. covering the mouth and nose during coughing or sneezing with a medical mask [surgical or procedure mask], cloth mask, tissue, sleeve or flexed elbow), followed by hand hygiene, to reduce the dispersal of respiratory secretions containing potentially infectious particles (Strong recommendation, very low quality of evidence)…"

Assessment of evidence
It is recommended that patients with Acute Respiratory Infection or TB should always don a medical mask when outside of isolation areas. “Encourage the use of medical masks by patients with ARI during transport or when care is necessary outside of the isolation room or area” Within this document a medical mask is defined as: *“*Medical mask**:** Also known as a surgical or procedure mask. As personal protective equipment, a facial mask is intended to protect caregivers and health-care workers against droplet-transmitted pathogens, or to serve as part of facial protection for patient-care activities that are likely to generate splashes or sprays of blood, body fluids, secretions or excretions (Annex A provides details of usage and standards for medical masks). In this document, the term refers to disposable masks only.” “A.2.3 Medical mask standards: Medical masks protect the wearer's nose and mouth from inadvertent exposures (e.g. through splashes) to blood and other body fluids. However, there are no minimum standards or standardized testing methods for mask filter efficiency, and available masks vary widely in the efficiency of their filters. As an example of standards, the Association of Perioperative Registered Nurses recommends that surgical masks filter particles of at least 0.3 μm for regular use and 0.1 μm for laser use (i.e. to protect the wearer against laser smoke), or have 90–95% bacterial filtration efficiency. Furthermore, surgical masks are classified as medical devices in Europe and the US and are regulated appropriately. For example, the US Food and Drug Administration (FDA) standards for surgical masks are as follows: 1

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Siegel JD, Rhinehart E, Jackson M et al. Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Health Care Settings. 2007 Updated September 2024	Guidance	**Level 4**	N/A	N/A	N/A

Assessment of evidence

This set of recommendations is supported by a review of scientific literature. It is split into multiple parts many of which contain relevant information to answer this RQ. It is intended for a US setting.

- "Respiratory hygiene/cough etiquette (source containment of infectious respiratory secretions in symptomatic patients, beginning at initial point of encounter, e.g., triage and reception areas in emergency departments and physician offices)"
- "Instruct symptomatic persons to cover mouth/nose when sneezing/ coughing; use tissues and dispose in no-touch receptacle; observe hand hygiene after soiling of hands with respiratory secretions; wear surgical mask if tolerated or maintain spatial separation, >3 feet if possible."
- Recommendation: surgical mask when: "placed on coughing patients to limit potential dissemination of infectious respiratory secretions from the patient to others (i.e., respiratory hygiene/cough etiquette)."

Assessment of evidence
• Transportation of patients: “When transport is necessary, applying appropriate barriers on the patient (e.g., mask, gown, wrapping in sheets or use of impervious dressings to cover the affected areas) when infectious skin lesions or drainage are present, consistent with the route and risk of transmission.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
National Institute for Health and Care Excellence (NICE). Internal Clinical Guidelines Team. Tuberculosis. Published 13 January 2016 Updated 16 February 2024.	Guideline	**AGREE: recommend with provisos**	N/A	N/A	N/A
Assessment of evidence					
“1.5.1.12 Explain to inpatients with suspected infectious or confirmed pulmonary or laryngeal TB that they will need to wear a surgical mask in the hospital whenever they leave their room. Ask them to continue wearing it until they have had at least 2 weeks of treatment. [2016]”					

Question 7: When should visitors of health and care facilities wear a surgical face mask?

Evidence added to version 2.0 update:

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
European Centre for Disease Prevention and Control (ECDC). Infection prevention and control and preparedness for COVID-19 in healthcare settings – Sixth update. 9 February 2021.	Guidance/ Expert Opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence

A COVID-19 specific guidance document recommending optimum IPC measures in healthcare settings during the pandemic. This is the 6th update of this guidance and supersedes earlier versions.

The following was reported as guidance for acute health care settings:

- "Staff, visitors and patients should wear a face mask when physical distancing is not possible. Visitors may use non-medical face masks, if in line with local recommendation"
- "Visitors may use non-medical face masks, if in line with local recommendations."
- Inpatient settings: "Visitors should wear a medical face mask and keep a distance of at least 1.5 metres from a patient for the duration of the visit"
- Long-term care facilities: "The use of medical face masks for visitors and visited residents should be strongly considered"

Assessment of evidence
Pandemic specific guidance produced by the European Centre for Disease Prevention (ECDC). The methodology is not clear. It is considered as level 4 expert opinion level evidence. Within acute care settings ECDC recommend that visitors wear a face mask when physical distancing is not possible, however it is not stated that it is required that they wear a medical mask. Later in the document (when discussing inpatient care of COVID-19 positive patients) medical mask use by visitors is recommended.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centers for Disease Control and Prevention (CDC) Infection Control Guidance: SARS-CoV-2 Last updated 24 June 2024 Last accessed: 15 October 2024	Guidance/Expert Opinion	**Level 4**	N/A	N/A	N/A
Assessment of evidence					
"Source control is recommended for individuals in healthcare settings who: • Have suspected or confirmed SARS-CoV-2 infection or other respiratory infection (e.g., those with runny nose, cough, sneeze); or • Had close contact (patients and visitors) or a higher-risk exposure (healthcare personnel) with someone with SARS-CoV-2 infection for 10 days after their exposure." Source control is recommended more broadly [as per CDC's Core IPC Practices] in the following circumstances:					

Assessment of evidence
• By those residing or working on a unit or area of the facility experiencing a SARS-CoV-2 or other outbreak of respiratory infection; universal use of source control could be discontinued as a mitigation measure once the outbreak is over (e.g., no new cases of SARS-CoV-2 infection have been identified for 14 days); or • Facility-wide or, based on a facility risk assessment, targeted toward higher risk areas (e.g., emergency departments, urgent care) or patient populations (e.g., when caring for patients with moderate to severe immunocompromise) during periods of higher levels of community SARS-CoV-2 or other respiratory virus transmission (See Appendix) • Have otherwise had source control recommended by public health authorities (e.g., in guidance for the community when COVID-19 hospital admission levels are high" • "Even when a facility does not require masking for source control, it should allow individuals to use a mask or respirator based on personal preference, 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." • "Other factors, such as end-stage renal disease, may pose a lower degree of immunocompromise. However, people in this category should still consider continuing to use of source control while in a healthcare facility." • Nursing Homes, Indoor visitation during an outbreak response: "ideally occur in the resident's room. The resident and their visitors should wear well-fitting source control [masks or respirator] (if tolerated) and physically distance (if possible) during the visit). • Frequently asked questions: "CDC recommends that people visiting healthcare facilities use the most protective form of source control (masks or respirators) that fits well and will be worn consistently. Healthcare facilities may choose to offer well-fitting facemasks as a source control option for visitors but should allow the use of a clean mask or respirator with higher level protection by people who chose that option based on their individual preference." • Care homes: "If indoor visitation is occurring in areas of the facility experiencing transmission, it should ideally occur in the resident's room. The resident and their visitors should wear well-fitting source control (if tolerated) and physically distance (if possible) during the visit." • General advice: "Healthcare facilities may choose to offer well-fitting facemasks as a source control option for visitors but should allow the use of a mask or respirator with higher-level protection that is not visibly soiled by people who chose that option based on their individual preference"

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Scientific Advisory Group for Emergencies (SAGE). Hospital Onset COVID-19 Working Group (HOCI) and Environmental Modelling Group (EMG) HOCI and EMG: Masks for healthcare workers to mitigate airborne transmission of SARS-CoV-2, 25 March 2021. Published 23 April 2021	Guidance/ Expert Opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence

This report was produced by members of the Hospital Onset COVID-19 Working Group and Environmental Modelling Group (EMG). It has not been updated since 21 March 2021 and may not reflect recent publications nor more recent UKSHA publications. It was produced in response to and in the context of the COVID-19 pandemic. The document is not peer reviewed, it was considered by SAGE 84 on 25 March, 2021. The selection process for the included evidence is not clear and therefore this is considered subject to bias.

- ‘patients and visitors should wear facemasks/coverings at all times, unless it is clinically impossible to do so’

Assessment of evidence
• 'wearing of facemasks by all inpatients, at all times, across all care pathways, providing this is tolerated by the patient and not detrimental to medical/care needs. An expert opinion, level 4 guidance and evidence review published by UKHSA in 2021 in response to the COVID-19 pandemic. The guidance highlights a paucity of evidence confirming the risk to persons in health and care settings from particles emitted by infectious persons. It recommends that visitors should wear facemasks/coverings at all times. But this is not specific to surgical masks. The methods used to identify and appraise the evidence included in their document is not clear and therefore, the results may be subject to bias.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Association of perioperative Registered Nurses (AORN) 2019 Guideline Quick View: Transmission-Based Precautions. 2019 Last accessed 21 November 2022	Guidance/ Expert opinion	**Level 4**	N/A	N/A	N/A
Assessment of evidence					
An expert opinion guidance. References are not provided for the formation of each section. The guidance is reported to be developed for nursing staff who work in USA. Refers to 'masks' with a picture of a surgical mask. Information gathered from precaution level sections (provides type of mask per 'level of protection'). • Droplet precautions described as used in addition to standard precautions to be implemented when a patient has a "known or suspected infection transmitted by respiratory droplets (e.g., adenovirus, group A Streptococcus, influenza, Neisseria meningitides, Bordetella pertussis, rhinovirus)" which are considered as "i.e. greater than 5µm".					

Assessment of evidence
General guidance (general across mask types): Contact precautions: • No mention of mask Droplet precautions (i.e. particles >5µm): • Visitor wearing – “Instruct the patient’s visitors to wear masks in the patient’s room and to perform hand hygiene upon entering and exiting the room.” Airborne precautions (i.e., particles or droplet nuclei < 5 µm): • Visitor wearing - “Instruct visitors to wear masks while in the patient’s room and to perform hand hygiene upon entering and exiting the room”. – may refer to surgical mask and not N95, but this is not clear. An expert opinion (level 4) guidance designed for use by US nurses. It states ‘masks’ should be worn by visitors when visiting patients who have a suspected or confirmed infection spread by respiratory particles (> and < 5µm). The mask type is not specified. It is not clear how this guidance was formed, or which references were used to form the guidance.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
World Health Organization (WHO) Infection prevention and control in the context of coronavirus disease (COVID-19): A living guideline, 13 January 2023.	Guidance/ Expert opinion	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Last updated 21 December 2023 Last accessed 15 October 2024					

Assessment of evidence

Evidence in the scientific literature is continually reviewed for the purpose of this living guidance.

A living guidance document which includes recommendations for mask use in health and care settings in light of the SARS-CoV-2 pandemic. It is considered as expert opinion as it did not meet the standards of AGREE recommend.

Methodology: Consensus approach described with GRADE approach and evidence searched. However, there are no details on how literature was searched, what terms were used etc so this guidance has been graded expert opinion.

Target audience: National and facility level decision-makers, policy makers, public health and infection prevention and control professionals; healthcare facility administrators, managers and other healthcare workers.

- "WHO recommends universal masking in health-care facilities when there is a significant impact of COVID-19 on the health system."
- The authors discuss benefits and harms to universal mask use in hospitals for protection against SARS-CoV-2, but recognise limitations of before-after study design and limited control over confounding variables. They highlight that there is limited evidence for harms of universal mask use beyond "bothersome" and "non-serious harms", so the benefits were determined by the group to outweigh the harms. The evidence is regarded low quality due to number of studies available and study design. Impact on resources is determined as low to moderate. Universal mask use is expected to be deemed acceptable as a protective factor for healthcare workers, visitors and patients, and feasible.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health New Zealand. Mask use and visitor guidance for hospitals and other health and disability care settings December 2023	Guidance/ Expert Opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence

- Advises visitor mask use during 'higher prevalence periods' (winter months, during outbreak/community surges).
- Advises visitor use during 'surge response'; "Visitors may be required to wear masks if the local IPC and public health teams have determined risk from infection warrants increased mask use during a surge within hospital setting".
- Optionally, healthcare facilities can request visitors to wear masks when visiting higher risk units (those providing care to vulnerable patients e.g. cancer/transplants, dialysis, especially if the units are known to have suboptimal physical environments (including ventilation)).

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Government of Canada. Updated guidance for infection prevention and control in the health care setting when COVID-19 is suspected or	Guidance/ Expert opinion	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
confirmed – April 2024. Updated 12 April 2024 (published 23 December 2021) Accessed 21 October 2024					

Assessment of evidence

These recommendations extend across health and care settings and apply to COVID-19.

- "Facilities should ensure availability of medical masks for all HCWs, patients, and visitors at facility entry points and throughout the facility for use as required
- "Information should be provided to staff, visitors, and patients who are asked to wear a respirator or medical mask about the importance of performing hand hygiene prior to putting on, and after removing or touching their mask, to reduce risk of self-contamination."
- "Visitors exhibiting signs or symptoms of an acute respiratory infection, including COVID-19, should not enter the facility. However, if visitation is required (e.g., end of life decisions), refer to institutional policies and procedures"
- "Masks used for the purpose of source control should be of medical grade and well-fitting."
- "Based on the epidemiological and clinical context, facilities should consider implementing broad masking for source control for all HCWs, visitors, and patients in clinical areas and spaces where HCWs, other staff, and visitors may come into contact with patients (e.g., patient rooms, clinical units, hallways, elevators, waiting rooms)".
- "the decision to implement broader masking for source control should be made in consideration of the following epidemiological and clinical factors:
    - Epidemiological context, including:
        - Increasing community transmission

Assessment of evidence
▪ Facility/unit outbreaks of COVID-19 or other respiratory infections ▪ Increasing hospitalizations and ICU admissions ▪ Increasing staff COVID-19 cases ○ Clinical context, including working: ▪ With immunocompromised persons or those at greater risk of acquiring an infection ▪ In clinical areas/units at higher risk of SARS-CoV-2 transmission (e.g., COVID-19 designated units, emergency departments, open space critical care areas, oncological units, haemodialysis units, etc.) If implementing broad masking for source control, consider the impact on persons with cognitive impairment or where masks could impede communication or otherwise hinder the ability to provide equitable care. Implementation of broad source masking may vary based on jurisdictional and facility-specific context, including organizational risk assessment". **Limitations:** • This guidance supersedes the setting-specific guidance produced by the Canadian Government, but it is not made clear which recommendations are current. • It is not clear when a PCRA should be conducted in place of universal masking.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Ueki H, et al., Effectiveness of face masks in preventing airborne transmission of SARS-CoV-2.	Experimental Study (simulation)	**Level 3**	Protective effect of surgical or N95 masks against SARS-CoV-2 aerosolized particles when worn for protection and/or as	Surgical mask (double tie straps) compared to no mask or N95 respirator mask. Conditions:	Viral loads and infective virus that passed through the masks were measured by use of a plaque assay and quantitative real-time

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
MSphere. 2020 Oct 28;5(5):e00637-20. (Japan-based study)			a form of source control. Surgical mask (double tie straps).	Spreader: no mask, receiver: no mask Spreader: no mask, receiver mask Spreader: mask, receiver: no mask Spreader: mask, receiver: mask	reverse transcription PCR (qRT-PCR), respectively. Viral titer (Log10PFU), PFU = plaque forming units. Viral RNA (Log10 copies)

Assessment of evidence

A level 3 experimental study, involving two manikin heads at 50cm distance with nebulized (manikin 1) or ventilated (manikin 2) air to simulate exhalation and inhalation. Penetration through the mask of the receiver was assessed using qRT-PCR.

Methods: No mask (control), surgical mask, N95 and N95 (sealed to face with tape) were worn by either the receiver or source or both in the experiments.

Nebuliser manikin = 6ml of virus suspension in culture medium or diluted in phosphate saline. 5x 105 plaque forming units or 1x108 PFU, 1 × 105 PFU, 1 × 104 PFU. It ran continuously for coughs (2m/s for 20 minutes). Particle sizes = 5.5 ± 0.2 µm in mass median diameter (particle size percentages were as follows: <3 µm, 20%; 3 to 5 µm, 40%; >5 to 8 µm, 40%). The ventilation manikin = attached to an artificial ventilator (5.5 liter of tidal volume, a respiratory rate of 18 breaths/min, and a 50% gas exchange rate). Cells – VeroE6/TMPRSS2 (JCRB1819) cells maintained in Dulbecca modified Eagles medium containing 10% foetal calf serum and antibiotics 37°C with 5% CO_2. Virus - UT-NCGM02/Human/2020/Tokyo SARS-CoV-2 virus propagated in VeroE6/TMPRSS. Room – 60-65% RH and 23-25 degrees Celsius. Distance of manikin 25, 50 and 100cm.

Results: Where the source wore a surgical mask and the receiver did not, both viral titers and RNA copy numbers were significantly reduced compared to no mask use for surgical masks and N95 respirator use. A similar result was obtained where the source wore a surgical mask and the receiver wore a surgical mask, cloth mask, or N95 (various configurations). When the receiver wore a surgical mask but the source did not there was a significant reduction viral RNA copies but not in viral titers.

- receiver wearing a surgical mask, source not wearing a surgical mask - **Surgical masks: viral titer = 53% (non-significant), RNA copy number 50% ($p < 0.05$).**

Assessment of evidence
• source wearing a surgical mask, receiver not wearing a surgical mask -**Surgical masks: viral titer = 24% (p < 0.05), RNA copy number 42% (p < 0.05).** • both the source and receiver wearing a surgical mask – p <.05 for surgical mask compared to no mask control. Limitations: Lack of generalisability and applicability with fixed experimental conditions, use of N95 not FFP and unclear BFE of surgical mask, particle size not clear, one strain SARS; prolonged use not considered, also a short report with limited details and lack of reliability with only 3 repetitions. Particle size not clear in terms of release and collection. Though the nebulizers capabilities are noted. Short distance within the exposure box and small space to consider which may not represent clinical interactions. A level 3 experimental study where two manikins placed 50 cm apart within a test chamber simulated an infectious source and health receiver. The results indicate that a surgical mask worn by a source were generally effective in reducing viral titers and RNA copies inhaled by a receiver. A reduction was also reported where both a source and receiver wore a surgical mask. It is therefore not possible to compare the effectiveness of either intervention. The results suggest that a surgical mask provides some protection for a receiver against particle penetration when a receiver and source wear a surgical face mask (significant reduction in viral RNA companies not viral titers). But that this may be greater when worn by a source. This suggests that there may be benefits in both the source and receiver wearing a surgical mask in this experiment.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Wilson NM, et al., The effect of respiratory activity, non-invasive respiratory support and facemasks on aerosol generation and its relevance to COVID-19.	Experimental study (observational)	**Level 3**	Surgical face mask (Bacterial filtration efficiency ≥98%.) compared to no mask while completing respiratory activities.	Mask versus no mask on the expired particles (source control).	Differences between mean particles exhaled during of activities or therapies with 95%CI. Particle volumes in each size category were transformed to estimate particle volumes.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Anaesthesia. 2021 Nov;76(11):1465-74. (Australia-based study)					Mixed effects linear regression to compare sampling per particle size category.

Assessment of evidence

A level 3, experimental study comparing mean expelled particles when 10 participants undertook respiratory activities (quiet breathing, talking, shouting, exercise, forced expirations and coughing) while wearing a surgical face mask compared to not wearing a face mask.

- 10 healthy participants (4 females, 6 male, mean age 29). Use of custom chamber with cone connected to a particle counter with categories (bins) at 0.5–0.7; 0.7–1; 1–3; 3–5; 5–10; and 10–25µm.
- The results showed that wearing a surgical face mask during talking, shouting, forced respirations and coughing showed a significant reduction in mean expired particles (0.2-0.4 fold reduction, P< .05).

Limitations: There were several limitations of this study including the lack of generalisability and applicability to real world settings, differences in room temperature and humidity, forced respirations, long range particle expulsions unclear, power calculations were unclear, lack of reliability (3 repetitions). It is not clear if the supplementary materials were subject to peer review process. A large proportion of information and results in these documents.

This level 3 experimental study comparing mean expelled particles when 10 healthy participants undertook respiratory activities (quiet breathing, talking, shouting, exercise, forced expirations and coughing) while wearing a surgical face mask (>98% BFE) compared to not wearing a face mask. The results suggested that talking, shouting, forced respirations and coughing showed a significant reduction in mean expired particles (0.2-0.4 fold reduction, P< .05). This highlights that wearing a surgical face mask may reduce the expulsion of particles (from 0.5-25 µm) in the context of this fixed experiment. It is not clear to what extent this may impact possible onward transmission of particles.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Patel RB, et al., Respiratory source control using a surgical mask: an in vitro study. Journal of occupational and environmental hygiene. 2016 Jul 2;13(7):569-76. (US-based study)	Experimental Study (simulation)	**Level 3**	Earloop surgical mask (appears to meet ASTM level 3)	The use of a surgical face mask (reported as meeting Level 3 ASTM) or respirator (N95 with and without a Vaseline seal). Control – no mask with particles measured near source.	Maximum Exposure - the percent of nebulized particles captured (i.e. inhaled) by the filter within the receiver when no masks are worn by the source or receiver. Receiver protection was calculated as ratio of maximum exposure to actual exposure.
Assessment of evidence					
Methods: Two manikin heads placed just over 3ft apart within a chamber where ACHs were set at 0, 6 or 12. Both manikins were set to replicate tidal breathing (tidal volume 500ml, RR 15 breaths/min). The source mannequin could also replicate coughing through a series of 1.5L breaths generating a peak flow of 5.2L/sec. Collection periods were set to 8 minutes. Manikins expelled radiolabelled wet aerosol particles. Combinations of source/receiver control were trialled using two types of surgical mask (appears to meet ASTM level 3), an N95 respirator and a Vaseline sealed respirator. Wash out of air between experiments. Air flow 1) no ambient air flow, 0 changes per hour; 2) all air movement secondary to coughing/breathing from source/receiver manikin; or 3) 6 (171 CFM) air changes per hour to model hospital setting or 4) 12 (343 CFM) air changes per hour modelled on negative pressure isolation room (smoke testing to check direction of air flow) in hospital setting. Relative humidity = 33–58% and temperature = 21.0–22.8°C.					

Assessment of evidence

Results:

Protection

- "With cough, source control (mask or respirator on Source) was statistically superior to mask or unsealed respirator protection on the Receiver (Receiver protection) in all environments"

Please note that for the following results figure 4 & 5 were used to determine significance - *p* values were not provided.

- Tidal breathing - Significant reduction in receiver exposure reported when receiver wore a surgical face mask in none of the rooms. Suggesting limited protection reported in this in vitro manikin study.
- Coughing – significant reduction in receiver exposure for sealed N95 in no airflow and hospital but not negative pressure but not for other respirator or surgical mask experiments.

Source Control

- "In the Negative pressure room applying either surgical mask or respirator to the Source resulted in statistically significant reductions in exposure"

Please note that for the following results figure 4 was used to determine significance - *p* values were not provided.

- Tidal breathing – significant reduction in receiver exposure shown for surgical face masks when worn by the receiver no air flow, and negative pressure room simulations.
- Coughing – significant reduction in receiver exposure shown for surgical face masks in all rooms when worn by the source.

Filtration at the source – natural fit surgical mask (~ 5–20%), secure fit surgical mask filter (~50%), N95 (~80-90%) and sealed N95 (~100%). It was reported that increased fit led to 100% capture efficiency, unclear how this was assessed.

Limitations: This study had several limitations including a lack of generalisability and applicability based on the fixed experimental conditions, fixed distance of manikin (3 foot), airflow not reflective of real-world settings, unclear particle size, p-values are not provided though significance is stated, wet particles may be impacted by humidity/temperature (33–58%).

Although limited by its in vitro nature, fixed 'higher' distance from source to receiver and airflow being optimized for HCW protection (from source to receiver) which may enhance the reported effect of source control. Overall, this study suggests that in this experimental setting surgical masks may provide some efficacy as source control. It also suggests that within these experimental settings the non-valved N95 (without Vaseline seal) and surgical face masks had limited effectiveness as protective devices during coughing. However, the results may

Assessment of evidence
be subject to bias based on the limitations and therefore the results of this study should not be used in isolation to make recommendations.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Diaz KT, Smaldone GC. Quantifying exposure risk: surgical masks and respirators. American journal of infection control. 2010 Sep 1;38(7):501-8. (US-based study)	Experimental Study (simulation)	**Level 3**	NIOSH approved N95 respirator worn by either source or receiver; Earloop surgical mask (appears to meet ASTM level 3) worn by either the receiver or source manikin.	Exposure and filtration was compared in difference masking setups: Control – no masks worn by any manikin. Risk factor: mask use (surgical face mask or N95) compared with no mask use	Maximum exposure – total particles inhaled by the receiver based on no mask on receiver or source. This represents the exhaled particles which mix with ambient air. Used to calculate protection factor (unclear calculation). Radioactivity captured by each mask quantified the effectiveness of filtration and deflection on exposure. Filtration – particles captured by the mask. With pure

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
					filtration measured by sealing mask and ambient air flow 0. Deflection – particles not captured by filtration but deflected away from the receiver. Also measured with head turned (90 degrees) to the left.

Assessment of evidence

Methods: two manikins set up with radio-labelled wet particles produced within chamber from one manikin head (source) towards another manikin head (receiver) approx. 3ft apart. Radioactivity captured by each mask quantified the effectiveness of filtration and deflection on exposure. Tidal volumes of 500 mL and respiratory rates of 15 breaths/min. Surgical mask type, brand provided no details of certification but from wider search may adhere to type 11R status. Temperature 20-22ºC and relative humidity 21-26%.

Results: Greater filtration did not result in a reduction in exposure (captured within receiver manikin) compared with the surgical mask (0.003-0.006% of Max exposure) suggesting a disruption in airflow may be a continuing factor to receiver exposure.

The use of a surgical mask or N95 respirator at the source resulted in reductions in exposure (protection factor of 172 - 317). This indicates that a surgical face mask may assist with disruption to the flow or behaviour of particles flowing towards a receiver which increased protection to the receiver despite less effective filtration. The results of this study also suggest that there was no observed reduction in exposure to the receiver when only the receiver wore either an N95 or surgical face mask (protection factor 1.37-2.21).

Limitations: This study had a number of limitations including a lack of generalisability and applicability based on the fixed experimental conditions, fixed distance of manikin (3 foot), limited details of p values, constant flow rate, wet particles may be affected by humidity etc, fit may not apply. No p-values provided and no definition of significance (other than CI values). Air flow towards receiver may not reflect real air flow (multiple persons in health settings, both inhalation and exhalation in progress during interactions). Flow towards receiver may overinflate source control results.

Assessment of evidence
The findings from this level 3 experimental study highlight that surgical face masks provided some effectiveness when worn by a source when both exposure and filtration were considered. The overall protectiveness when a surgical mask was worn by only the receiver (which could include a HCW, visitor or other patients in health and care settings) was limited. The limitations of this study should be considered and the artificial airflow towards the receiver may have skewed the results towards source control effectivity. With a high risk of bias this study should not be used in isolation to make recommendations.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Mansour MM and Smaldone GC. Respiratory Source Control Versus Receiver Protection: Impact of Facemask Fit. J Aerosol Med Plum. 2020;26(3);pp:131.137 Doi:10.1089/jamp.2012.0998	Experimental Study (simulation)	**Level 3**	This study compared mask types (N95 or surgical mask) using two manikin (a source and a receiver) with simulated tidal breathing at 3ft apart to determine the degree of protection for source N95 and surgical mask combinations as well as receiver N95 and surgical mask combinations.	no mask on either head defined as maximum exposure, a surgical mask tightly fit on the source, a surgical mask looped ‘‘naturally’’ around the ears of the source, an N95 on the source, an N95 on the source sealed to the face with Vaseline, a surgical mask tightly fit on the receiver,	Particle distributions and mass median aerodynamic diameters (MMAD) Exposure data, expressed as % of nebulised activity (Nebulized activity represented the difference between initial nebulizer charge and that remaining after nebulization) Exposure data, defined as simulated workplace protection factor (sWPF) (ratio of max exposure to actual exposure).

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
				a surgical mask looped around the ears of the receiver, an N95 on the receiver, an N95 on the receiver sealed to the face with Vaseline	"The protective effect of each intervention in reducing exposure is best illustrated by the magnitude of the sWPF." Mask filtration – radioactivity captured by each mask, reported as a % of activity exhaled at source Separation of 95% CIs indicated statistical significance.

Assessment of evidence

This level 3 in-vitro, experimental study involved two manikin heads which represented 3-foot distancing between a source and receiver. The study suggests that there was a significant reduction in exposure to particles when a source wore a tightly fitted or loosely fitted surgical face mask compared to no mask. There were non-significant reductions in exposure when only a receiver wore a surgical mask (tightly or loosely fitted) or when they wore an unfitted N95 respirator. 6 air changes per hour in room.

Results:

SFM/N95 worn by source:

- SFM naturally fitted: Exposure decreased to 0.000637% (95% 95% CI: 0.00163–0.01110%), SWPF = 214
- SFM tightly fitted: Exposure decreased to 0.00019% (0.00023% (95% CI: 0.00009–0.00038%), sWPF = 5,850

Assessment of evidence
• N95 (no Vaseline): 0.00019% (95% CI: 0.00012– 0.00027%), sWPF = 7,174 Compared to the control, these were deemed statistically significant reduction in aerosol exposure. SFM/N95 worn by receiver: • SFM naturally fitted: 1.38% (95% CI: 0.992–1.77%), sWPF =0.99 • SFM tightly fitted: 0.669% (CI: 0.0641–1.27%), sWPF = 2.04 • N95 (no Vaseline): 0.181% (95% CI: 0.106–0.256), sWPF of 7.53 Compared to the control, these results were not statistically significantly lower than the control. Limitations: This study had a number of limitations including a lack of generalisability and applicability based on the fixed experimental conditions, Vaseline seal is not reflective of real-life mask use, unclear number of repetitions, unclear if the source manikin wore a mask/respirator when the experiments involved source control. Therefore, these comparisons are consisted as subject to bias. No fit testing of respirators, only visual checking – confounding factor. This level 3 experimental study, although limited by its in-vitro nature and set parameters of air flow, air changes and 3-foot distancing between source and receiver, suggests that surgical face masks when worn by a source only significantly reduced exposure when compared to no mask use. A significant reduction was not reported when only a receiver wore a mask. This study suggests a surgical face mask worn by a source 'naturally' or 'tightly' with loops around the ears provided protection to a receiver. However, the study is limited by its in-vitro nature, and potential lack of generalizability to real-life scenarios due to set parameters of air flow, air changes and distancing between source and receiver.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Asadi, S. et al. Efficacy of masks and face coverings in	Experimental Study (observational)	**Level 3**	Surgical mask (unclear fluid	The efficacy of surgical face masks and respirators in	Particle emission rate (particle/second)

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
controlling outward aerosol particle emission from expiratory activities, 2020 Nature Scientific Reports, 10(15665), doi: 10.1038/s41598-020-72798-7 (appears to be US-based)			resistance), tested by 10 participants. Non-vented KN95 respirator, tested by 10 participants A vented N95 respirator, tested by 2 participants	reducing particle emission rates when volunteers undertook breathing, speaking and coughing. Jaw movement (mimicking chewing gum) also assessed but considered out-with scope of the review. No mask (control)	Observed particle size distribution (particle fraction, %)

Assessment of evidence

Methods: This level 3 experimental study compared particle emission when wearing a mask (respirator or surgical face mask) or no mask while competing respiratory activities including gentle breathing, talking (reading a passage) and forced coughing. Healthy volunteers undertook these activities while sitting with their mouth in front of a funnel attached to an aerosol particle sizer (measuring 0.3-20μm).

Results: breathing (from 0.31 particles to 0.06 SFM and 0.07 KN95), talking (SFM0.18 and KN950.36 particles) and coughing (from 10.1 to SFM 2.44 particles). KN95 used in coughing did not significantly reduce particle emission rate.

The results indicated that wearing a surgical mask resulted in a significant reduction in particle emission rate compared to wearing no mask. Surgical mask and respirators were comparable with the exception of coughing where only a surgical mask showed a reduction with statistical significance.

Limitations: Lack of generalisability and applicability with fixed experimental conditions, small sample, forced coughs, specific particle sizes, plume travel distance, time suspended unclear. Stats presented as part of figure are quite difficult to interpret without further clarification. P values not provided but significance is described as $p<0.05$. Simulation with forced coughing and activities may not reflect real life or particle emission. Statistics presented as part of figure are quite difficult to interpret without further clarification.

The results of this level 3 experimental study suggest that surgical masks used as source control during talking, coughing and gentle breathing may significantly reduce particle emission compared to not using a mask. In this cohort surgical mask and KN95 respirators

Assessment of evidence
performed comparably showing reduced particle emission except for coughing where only surgical masks showed statistical significance. However, the study may be limited based on its small sample and simulation of respiratory activities which may limit its generalizability. The results should not be used in isolation to form recommendations.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Lindsley, W. G. et al. (2021) Efficacy of face masks, neck gaiters and face shields for reducing the expulsion of simulated cough-generated aerosols, Aerosol Science and Technology, 55 (4), pp. 449-457. (US)	Experimental (simulation)	**Level 3**	Procedure mask (reported as ASTM Level 3). Procedure mask is described as fluid resistant.	Efficacy of procedure mask and respirators as a form of source control (reducing particles emitted into the environment from a 'source' manikin) Comparators: N95 respirator	Collection efficiency: percentage of aerosol particles blocked by the PPE under investigation (%) when compared to experiments without the use of PPE. Air particle mass in collection chamber (ug) as a proxy measure for how effectively the PPE under study reduced the mass of air particles emitted into the environment.

Assessment of evidence
Experimental setup: 14% KCl and 0.4% sodium fluorescein solution was nebulised using a single jet Collison nebuliser. Nebulised solution passed through a diffusion drier and then mixed with 10L/min of dry filtered air. Masks (surgical or N95) on manikin head for 2 consecutive tests. A cough (4.2L/sec and peak flow 11L/second). Cough sampled from bellows before coughing to normalise particle mass.

Assessment of evidence
Sampling: Portacount used to assess fit factor of masks (e.g. ratio particles outside compared to inside mask). Anderson impactor (28.3L/min) run for 20 minutes after each cough. Capable of measuring/separating particles per following sizes: <0.6 uM, 0.6 – 1.1 uM, 1.1 – 2.1 uM, 2.1 – 3.3 uM, 3.3 – 4.7 uM, 4.7 – 7.0 uM, >7uM. Note, particle >7 µm were not analysed due to small concentration of this size. Fluorescence measured via fluorometer. Results: N95 (98.6% filtration efficacy), Surgical mask (58.5% filtration efficacy). For comparison of air particle mass (µg) into chamber = N95 vs no device: -504 (-567, -422) p<0.0001, N95 vs procedure mask: -205 (-277, -133), p<0.0001, Procedure mask vs no device: -299 (-361, -237), p<0.0001. In this study, the N95 and fluid resistant surgical face mask was more effective than no mask or PPE, at reducing mean air particle mass (uG) in the enclosed chamber when placed over the mouth of the manikin in an enclosed chamber where one cough was simulated, producing particles <0.6 uM – 7 uM in size. However, the N95 respirator was more effective than both the procedure mask and the use of no PPE. Limitations: There were several limitations of this study including the lack of generalisability and applicability to real world settings, may lack reliability (2 repetitions), breathing and speaking not assessed, one cough simulated. Unclear on the flow rate chosen for the simulated cough. The flow rate based on one study on influenza patients. Only peak flow rate is mentioned in their results section. One type of procedure mask tested. This level 3 simulation study considered the ability of surgical masks in preventing dispersal of nebulized sodium fluorescein solution. It provides evidence to suggest that in this specific experimental setting a procedure masks was more effective than no mask as a form of source control. However, the N95 respirator may be more effective than a fluid resistant surgical mask. However, the study may have limited generalisability and the evidence should not be considered in isolation to make recommendations.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Lai J, Coleman KK, Tai SH, et al. Relative efficacy of masks and	Observational	**Level 3**	No mask, N95, KN95, surgical mask, cloth mask use for source control.	Exhaled breath aerosol per mask type and across	Viral load, defined as a fraction of unmasked aerosol

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
respirators as source control for viral aerosol shedding from people infected with SARS-CoV-2: a controlled human exhaled breath aerosol experimental study. EBioMedicine. 2024 May 28.				particle sizes (fine and course).	detected in masked samples. Source-control factor (similar to established definition for fit factor), defined as the percentage reduction in viral load realised in the environment (%) Relative efficacy of mask/respirator (%), calculated using ration of outward leakage. Exhaled breath aerosols were considered in total (combined) and for coarse (>5 uM) and fine (≤5 uM) aerosol particles.
Assessment of evidence					
Setting: The study took place un a US-based university between 2020 and 2022. Methodology: This controlled human experimental study involved paired samples (exhalations with and without a mask) from 44/106 human participants who had one or more samples positive for SARS-CoV-2 (variant type was considered). The aim of this study was to					

Assessment of evidence
analyse the efficacy of various face masks (surgical, cloth, KN95, N95) as source control (through a measure of reduction in total exhaled particles (combined fine and coarse), fine particles and coarse particles for SARS-CoV-2 positive persons. There were some variations in the methods used depending on the type of mask, activities (saying the alphabet, shouting and saying happy birthday song loudly or breathing) based on symptoms, time the person took part. Generally, participants were asked to undertake speaking or shouting activities with and without a mask for up to 30 minutes. A particle counter (Gesundheit-II (G-II) human exhaled bioaerosol collector) was utilized to measure 'exhaled' particles. Outcomes were measured for total exhaled particles as well as fine (≤5 µm) or coarse (>5 µm) particles. Mask use compared to no mask use and efficacy between types of masks were considered within the analyses. The statistical analysis was based on a sample of 44 and it is not indicated by the authors if this met any conducted power calculation. Main findings: The relevant results indicate that when compared with no masks, wearing a surgical face mask reduced the detected viral load significantly (P <0.05) across fine and coarse particle sizes. After coughing was controlled, it was reported that when compared to no masks, wearing a surgical mask resulted in a 74% (95%CI 65-81%) reduction in total exhaled viral load. It appears that there was a statistically significant greater reduction in exhaled viral particles when N95 respirators were worn compared to other mask types, including surgical face mask. P values for this aspect of the analysis are not clear across the tables and figures. It was also reported that cloth masks resulted in a significantly higher reduction in total exhaled particles compared to surgical and KN95 masks. Though it was reported that this significance was not maintained when only coarse or fine particles were considered. The reduction in total exhaled viral load for surgical masks was not statistically significantly different to KN95 masks. These results suggest that within the context of the fixed experimental conditions, surgical masks reduced exhaled viral load (source control) when compared to no mask. It also suggests that there may be greater reduction in exhaled particles (source control) provided from the N95 mask tested in this study compared to the surgical face mask. Alternatively, KN95 and surgical masks appeared to perform similarly. It is not clear how these reductions may impact onward transmission of infection. It is also not clear how far away the particle counter was from the participant and it difficult to state with any certainty how these results would compare to a clinical interaction or how they inform infection transmission and prevention. Strength: • Participants were eligible if samples (at least one) was positive) – may have higher applicability to SARs-CoV-2 transmission than a proxy particle or substance. However, period of sampling per mask type differed.

Assessment of evidence

Limitations:

- Recruitment was from community testing facilities. It is unclear if there were other people (not within the 106) who were also tested but who chose not to participate. Differences between those eligible/ineligible, are not provided. – lack of generalizability.
- Lack of replicability – unclear how far away the particle collector was from the participant and if this was standardized for all experiments. It was stated that participants had no prior training of wearing RPE. It is not clear if fit checking/testing was conducted.
- Participants were asked to wear their own or a supplied mask the brand/type of supplied mask is provided. It is not clear how many masks were brought by patients, it is stated “mostly cloth” indicating some SFM or RPE may have been supplied by the participants and it is not clear if these met minimum standards. The indication for use was reported as the researchers decided they were “well-fitted”.
- Small sample (44 in total but under 27 per group of masks), unclear power. – lack of reliability.
- Variations in sampling time, activities undertaken (happy birthday, shouting), differences in level of illness (as demonstrated by some people being reported as too unwell to undertake the speaking activities). Impact (if any) of these baseline differences are unclear.
- Variations in the type of mask (provided SFM are described but unclear how many if any were brought by the participant).
- Lack of replicability and applicability - room humidity, temperature, distance of counter from participant, ventilation in place and other persons in the room are unclear.
- It is unclear how this experimental setup may compare to real clinical interactions within health and care settings.
- The true risk of transmission is unclear.

This controlled exhalation study contributes to the evidence base as it suggests that in this controlled, fixed experimental condition surgical face masks provide statistically significant reductions in emitted particles compared to no masking, across the measured particle sizes (fine and coarse). It also highlights that the tested N95 respirators may provide statistically significant reductions in emitted particles compared to the tested surgical face masks but that this superiority may not be consistently reported with other respirator types (KN95). The clinical significance of these differences is unclear, and the transmission risk is also not clear.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Humphreys H, Bak A, Ridgway EJ, et al. Rituals and behaviours in the operating theatre – joint guidelines of The Healthcare Infection Society and The European Society of Clinical Microbiology and Infectious Diseases. Journal of Hospital Infection. 2023;140:165.e1-165.e28.	Guidance	**AGREE: Recommend with provisos.**	N/A	N/A	N/A

Assessment of evidence

This guideline was conducted using the NICE methodology. The primary evidence which was included for the good practice points (GPP) related to the use of surgical face masks was described as low quality and generally working party and lay person views were considered. These GPP were considered as primarily based on expert opinion.

Relevant GPP are as follows:

".15. (a) What should parents/carers wear when accompanying the patient to the operating theatre? (b) Do patients or other individuals dressed in ordinary (street) clothes in the operating room result in increased bacterial counts or increased infection post-operatively?"
"Good practice points GPP 15.1: Ask parents and carers to wear scrubs or equivalent (e.g. single-use coveralls), along with head

Assessment of evidence
coverings and face masks, on entering the operating room as per local policy. Changing shoes is not necessary" "GPP 15.2: Ensure that visitors (e.g. technicians or company representatives) comply with local departmental policy on theatre attire." The recommendations are concerned only with theatre staff in a theatre setting. **Limitations:** • Majority of primary evidence were of low quality. All of those related to masks were eligible for exclusion from this review. • The recommendations/GPP provided for mask use were formulated primarily by expert opinion. • Lack of details to ascertain the extent of consultation with the target population (patients, public). It is not clear if those involved in creation of these guidelines reflect the complete spectrum of relevant patient groups. • Lack of specific implementation tools and resources. • The weight of evidence and how it was specially used to form recommendation is not clear. Though expert opinion is provided for the GPP related to mask which support understanding in how these were formed. • The methodology to update this guideline is not clear though it is stated that it is subject to possible future updates. • The GPP related to mask use are somewhat vague ('face masks' rather than TYPE II or TYPE IIR and timeline for changing a mask is not specified) making it difficult to audit/follow. • It appears that a meta-analysis was conducted as part of the evidence review of mask. The results of this are not well described. The appropriateness of conducting this type of analysis with different study designs and unclear differences in comparator or quality is unclear.

Evidence from previous update(s):

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Steer JA, et al.,	Guidelines/ Expert opinion	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Guidelines for prevention and control of group A streptococcal infection in acute healthcare and maternity settings in the UK. 2012. Journal of Infection. Vol 64 p1-18.					

Assessment of evidence

"Visitors should be offered suitable information and relevant PPE following a risk assessment of the visitor's level of direct contact/involvement in the affected person's care."

Recommendation classed as SIGN good practice point which is why it is considered expert opinion (level 4 evidence)

Detail provided for this "Visitors must be given information about how to prevent the transmission of infection, and shown how to use appropriate PPE when visiting the affected individual. The PPE required by visitors will depend on risk assessment of the factors affecting transmission (e.g. if there is a high risk of droplet transmission) and also the visitor's level of direct contact and involvement in the affected person's care."

Limitation:

- Methods used to formulate the recommendations are unclear.
- Methods for selecting evidence were not clearly described.
- The methods section is short and does not provide a detailed account of the search and review methodologies.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
CDC and HICPAC. CDC's Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings Last reviewed 29 November 2022 Last accessed 01 December 2022	Guidance/Expert Opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence

2017 update - "Prompt patients and visitors with symptoms of respiratory infection to contain their respiratory secretions and perform hand hygiene after contact with respiratory secretions by providing tissues, masks, hand hygiene supplies and instructional signage or handouts at points of entry and throughout the facility"

An update to the core practices provided by the CDC. It applies across health and care settings as well as across health care workers, patients and visitors, where appropriate. This is considered as expert opinion. The authors describe a process of consulting other CDC materials as well as input from HICPAC in drafted recommendations produced 2014 which were reviewed in October 2022 by "experts within the Division of Healthcare Quality Promotion at CDC" as well as reviewed by HICPAC.

- Within the 'minimising potential exposures it states: "Prompt patients and visitors with symptoms of respiratory infection to contain their respiratory secretions and perform hand hygiene after contact with respiratory secretions by providing tissues, masks, hand hygiene supplies and instructional signage or handouts at points of entry and throughout the facility".

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Munoz-Price LS, et al., The Society for Healthcare Epidemiology of America (SHEA) Expert Guidance. Isolation precautions for visitors Infection control & hospital epidemiology. 2015 Jul;36(7):747-58	Guidance/ Expert opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence

This guidance used two methods; 1. Literature review; 2. Survey

The SHEA working group for isolation precautions for visitors in acute care hospitals recommend the following:

- "For visitors to rooms of patients on droplet precautions, we suggest the use of surgical masks. However, visitors with extensive documented exposure to the symptomatic patient prior to hospitalization such as parents/guardians/family members may be excluded from these precautions; they may either be immune to the infectious agent or already in the incubation period".
- "For visitors to patients on airborne precautions, we recommend the use of surgical masks. An alternative is an N95 respirator; however, this equipment is best used with training and fit testing".

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Department of Health and Health Protection Agency PANDEMIC (H1N1) 2009 INFLUENZA A summary of guidance for infection control in healthcare settings. Published 08 January 2010	Guidance	**Level 4**	N/A	N/A	N/A
Assessment of evidence					
• "All visitors entering a cohorted area must be instructed on hand hygiene practice and the use and removal of appropriate PPE, i.e. a surgical mask, when in a cohorted area, and a surgical mask, gloves and apron for close patient contact"					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Siegel JD, Rhinehart E, Jackson M et al. Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in	Guidance	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health Care Settings. 2007 Updated September 2024)					

Assessment of evidence

US – focused expert opinion guidance.

Has no specific recommendations regarding visitor masking.

Within 'adjunct measures' (measure that are not considered primary components of programs to prevent transmission of infectious agents, but improve the effectiveness of such programs), it is advised that visitors with pertussis o

- "Use of Standard and Transmission-Based Precautions in a Protective Environment: "VI.F.3 Barrier precautions (e.g., masks, gowns, gloves) are not required for healthcare personnel in the absence of suspected or confirmed infection unless indicated according to Standard Precautions or if recommended for source control (e.g., mask) for any individual entering the protective environment room[15]. *Category II*"

  References CDC Guidelines for preventing opportunistic infections among hematopoietic stem cell transplant recipients (2000) so may not be up to date evidence.

- "II.N.3.b. Use of barrier precautions by visitors. The use of gowns, gloves, or masks by visitors in healthcare settings has not been addressed specifically in the scientific literature."

Visitors are reported to have been identified as a source of infection with multiple references provided. The authors report that the literature was not clear on the use of masks and other PPE by visitors: "family members or visitors who are providing care to or otherwise are in very close contact with the patient (e.g., feeding, holding) may also have contact with other patients and could contribute to transmission in the absence of effective barrier precautions. Specific recommendations may vary by facility or by unit and should be determined by the specific level of interaction."

No specific recommendation.

Question 8: When is eye-face protection required in addition to a surgical face mask?

This section of the review links directly to the NIPCM eye and face protection literature review which should be consulted for more information on when eye and face protection should be worn in addition to a surgical face mask.

Question 9: When should surgical face masks be removed/changed?

Evidence added to version 2.0 update:

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution Standards Publication. BS EN 14683:2025+AC:2019, ICS 11.140. Medical face masks - Requirements and test methods. March 2025.	British Standards	**Level 4**	N/A	N/A	N/A

Assessment of evidence

This document outlines the British Standards for medical masks (requirements and testing). It is not specific to mask use as PPE and other standards should be consulted. It supersedes EN 14683:2019. The following section(s) are relevant for this research question on mask removal/change:

The 2025 revision of this document contains detail regarding changing/removal of medical face masks.

- “a used medical face mask should be disposed of or placed into suitable collection containers when no longer needed. Medical face masks should be changed between procedures”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
European Centre for Disease Prevention and Control (ECDC). Infection prevention and control and preparedness for COVID-19 in healthcare settings – Sixth update. 9 February 2021.	Guidance/ Expert Opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence

"While collecting the samples, healthcare workers can use the same respiratory protection equipment for several patients for a longer period of time without removing it, provided that it is not damaged or soiled, unless the manufacturer explicitly advises against this and in accordance with OSH regulations, codes of practice and in agreement with the occupational physician or health and safety committee"

Acute settings – "The use of medical face masks by healthcare workers for personal protection and source control should be strongly considered during all routine activities and in communal areas as a measure for reducing transmission within healthcare settings in areas with community transmission." – not clear if this includes sessional use or not.

"IPC measures for healthcare workers, such as universal masking for all routine clinical activities and appropriate PPE for care of COVID-19 patients, remain unchanged in the current epidemiological context throughout the EU/EEA." It is assumed therefore that the universal masking recommended in the 5th update of this document remains in place despite vaccination etc.

This expert opinion guidance was produced for a pandemic setting to guide IPC in health and care settings. Some evidence is cited and discussed though the process for identifying this evidence is not described. The reuse of PPE is described as extraordinary and not standard.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centers for Disease Control and Prevention (CDC) Infection Control Guidance: SARS-CoV-2 Last updated 24 June 2024 Last accessed: 15 October 2024	Guidance/Expert Opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence

Pandemic specific IPC guidance for health care personnel. It was updated to include guidance in the wake of the discovery and spread of the Omicron variant. A rapidly produced guidance document for health care personnel during the SARS-CoV-2 pandemic. It is therefore specific to this context and given a lack of rigorous and clear methodology it is considered as level 4 expert opinion evidence.

Source control:

A “well-fitting face mask” used as source control by HCW can be used for the whole working shift unless the mask is soiled, damaged or hard to breathe through. (sessional use) It is reported that source control and distancing are recommended for all persons in health care where possible.

Personal Protection:

For face masks that are being used as PPE during direct care should be removed or discarded after each patient encounter. A new mask should then be donned.

Does not provide advice regarding mask changing when worn within a cohort of covid patients.

COVID-19 pandemic specific CDC IPC guidance for health care personnel. It is recommended that during the pandemic PPE worn by HCW during patient care should be removed after each patient encounter to be discarded and replaced as appropriate.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Association of perioperative Registered Nurses (AORN) 2019 Guideline Quick View: Transmission-Based Precautions. 2019 Last accessed 21 November 2022	Guidance/ Expert opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence

An expert opinion guidance. References are not provided for the formation of each section. The guidance is reported to be developed for nursing staff who work in USA. Refers to 'masks' with a picture of a surgical mask. Information gathered from 'mask' section (covers multiple masks).

Droplet precautions described as used in addition to standard precautions to be implemented when a patient has a "known or suspected infection transmitted by respiratory droplets (e.g., adenovirus, group A Streptococcus, influenza, Neisseria meningitides, Bordetella pertussis, rhinovirus)" which are considered as "i.e. greater than 5µm".

General guidance (general across mask types):

- "Replace and discard the mask whenever it becomes wet or soiled"

An expert opinion (level 4) guidance designed for nursing staff in US settings. It states 'masks' should be replaced when the mask is soiled or wet. It is not clear how this guidance was formed, or which references were used to form the guidance.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
National Health and Medical Research Council (NHMRC) Australian Guidelines for the Prevention and Control of Infection in Healthcare, 2019 2019 (revised 2024, v11.24) Accessed 11 October 2024	Guidance/ Expert opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence

Aim: IPC guidance for Australian health and care settings.

Target audience: Acute settings but the authors highlight transferability across settings.

Methods: Methodologies for reviews are not provided and, except where references are given, guidelines seem to be formed from expert opinion. Recommendations are accompanied by a strength of evidence assessment, based on systematic review.

- In the surgical masks section of the guidelines, “masks should be changed between patients and when they become soiled or wet” and “masks should never be reapplied after they have been removed”.
- “When providing patient care in a room where patients are cohorted together, PPE should be changed when moving between patients in these rooms. The extended use of PPE items can increase the risk of cross infection for patients and healthcare workers and the risk of environmental contamination.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Department of Health and Social Care. Infection prevention and control: resource for adult social care Published 31 March 2022 Updated 01 March 2024 Accessed: 11 October 2024	Guidance/ Expert Opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence

This level 4 expert guidance document from UKHSA is intended for the adult social care setting only (England) and covers general infection prevention and control (IPC) principles.

- "Fluid-resistant type IIR masks should not be worn for longer than 4 hours. They must be disposed of after the episode of care is completed, when damaged or when the mask becomes moist. Care workers should move to a safe area to remove the mask."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
World Health Organization (WHO)	Guidance/ Expert opinion	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Infection prevention and control in the context of coronavirus disease (COVID-19): A living guideline 13 January 2023. Last updated 21 December 2023 Last accessed 15 October 2024					

Assessment of evidence

A living guidance document which includes recommendations for mask use in health and care settings in light of the SARS-CoV-2 pandemic. It is considered as expert opinion as it did not meet the standards of AGREE recommend.

Methodology: Consensus approach described with GRADE approach and evidence searched. However, there are no details on how literature was searched, what terms were used etc so this guidance has been graded expert opinion.

Target audience: National and facility level decision-makers, policy makers, public health and infection prevention and control professionals; healthcare facility administrators, managers and other healthcare workers

The following considerations were highlighted:

- “Medical masks must be changed when wet, soiled or damaged or if the health worker or caregiver removes the mask for any reason (e.g. for eating or drinking or caring for a patient who requires droplet/contact precautions for reasons other than COVID-19).” (pg. 50)
- “The medical mask should not be touched to adjust it or if it is displaced from the face for any reason. If this happens, the mask should be safely removed and replaced and hand hygiene performed.” (pg. 50)

Assessment of evidence
• "The medical mask (as well as other PPE) should be discarded and changed after caring for any patient who requires contact/ droplet precautions for other pathogens, followed by hand hygiene" (pg. 50) Extended mask use: "WHO suggests targeted continuous medical mask use in health-care facilities in situations with minimum to moderate impact of COVID-19 on the health system" • Targeted continuous masking is the practice of wearing a well-fitting medical mask by all health and care workers and caregivers in clinical areas during all routine activities throughout the entire shift, unless otherwise specified (e.g. when performing AGP). In non-patient areas, staff who have no patient contact are not required to wear a medical mask during routine activities." (page 15) "Conditional recommend for, very low certainty evidence" The authors highlight that protective effects of masks outweigh potential harms, referencing studies associating (universal) mask use with decreased risk of SARS-CoV-2 in healthcare settings. Studies referenced in this section were excluded for this or a previous surgical face masks review. Impact on resources is determined as low to moderate.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
World Health Organization (WHO). Interim guidance. Rational use of personal protective equipment for coronavirus disease (COVID-19) and considerations during severe shortages 23 December 2020 WHO REFERENCE NUMBER: WHO/201	Guidance/ expert opinion	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
9-nCoV/IPC_PPE_use/2020.4 Last accessed 06 March 2023					
Assessment of evidence					
Unclear methods used to create this document and later IPC guidance has been published. It is not clear if this is still a recommendation so refers only to recommendations at the time. The following refers to use of 'medical masks' by health and care staff - "use without removing for up to 6 hours, when caring for a cohort of patients with COVID-19" Possible risks outlined – higher contamination of mask, higher likelihood of touching mask, skin issues or damage, lower filtration ability of mask. Removal criteria or precautions to considered: • "Masks must be changed if they become wet, soiled, or damaged; difficult to breathe through; exposed to a splash of chemicals, infectious substances, or body fluids; or if they have been removed for any reason, including when drinking fluids or eating meals.", • "A new medical mask should be worn when providing care outside of a designated cohort of patients with COVID-19." • "Use of the same medical mask by a health care worker between a patient with COVID-19 and a patient who does not have COVID-19 is not recommended owing to the risk of transmission."					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Government of Canada. Infection prevention and control for	Guidance/ Expert opinion	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
COVID-19: Interim guidance for long-term care homes Updated and re-posted 16 June 2021 Last modified 25 January 2022 Last accessed 06 April 2023					

Assessment of evidence

This Canadian interim guidance aimed to provide interim COVID-19 guidance related to IPC, to be considered in conjunction with the Canadian Government's Omicron variant guidance, which does not make any specific reference to removing/changing face masks. It is specific to long-term care homes.

This guidance advises sessional use of surgical masks for source control and advises that masks are changed/removed at the end of a shift. When masks are worn when caring for residents with droplet/contact precautions (including covid-19), they should be changed after care concludes.

Also advises that masks are replaced when they become damaged, wet, damp, or soiled (from the wearer's breathing or external splash), or when they come in direct contact with a resident.

Limitations:

It is not clear if the updates section of this guidance represents current recommendations, or if this section exists for reader's information. Similar wording is used throughout the document, providing further confusion.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Government of Canada.	Guidance/ Expert opinion	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Infection prevention and control for COVID-19: Interim guidance for acute healthcare settings Updated and re-posted 16 June 2021. Last modified 25 January 2022 Last accessed 06 April 2023					

Assessment of evidence

This Canadian interim guidance aimed to provide interim COVID-19 guidance related to IPC, to be considered in conjunction with the Canadian Government's Omicron variant guidance, which does not make any specific reference to removing/changing face masks. It is specific to acute care settings.

08 January 2021 update:

"Given ongoing community spread of COVID-19 within Canada and evidence that transmission occurs from those who have few or no symptoms, masking for the full duration of shifts or visits for all acute healthcare setting staff and visitors is recommended."

"When medical masks for HCWs and visitors (and eye protection for HCWs) are recommended for the full duration of shifts or visits, HCWs and visitors should:

- Just prior to breaks or when leaving the building, remove masks in an area where no patients, staff or visitors are present, and discard them in the nearest no-touch waste receptacle or store them in accordance with facility policy"

"Masks worn as source control, and eye protection worn for the duration of shifts (i.e., not when used for encounters with patients on Additional Precautions), may be worn for extended periods. Masks or N95 or equivalent respirators and eye protection should be replaced

Assessment of evidence
when they become damaged, wet, damp, or soiled (from the wearer's breathing or external splash), or when they come in direct contact with a patient." In summary, this COVID-19 guidance recommends that, when universal masking for source control is in place in acute care settings, medical masks may be removed by staff and visitors before taking a break or leaving the building. Medical masks may also be removed after treating a patient on droplet and contact precautions. Masks should be changed when there is a risk of contamination or when the mask is soiled/damaged. It does not provide any advice/recommendations on mask changing when delivering care to cohorted patients. **Limitations:** It is not clear if the updates section of this guidance represents current recommendations, or if this section exists for reader's information. Similar wording is used throughout the document, providing further confusion.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Government of Canada. Infection prevention and control for COVID-19: Interim guidance for outpatient and ambulatory care settings Updated and re-posted 16 June 2021	Guidance/ Expert opinion	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Last modified 25 January 2022 Last accessed 06 April 2023					

Assessment of evidence

This Canadian interim guidance aimed to provide interim COVID-19 guidance related to IPC, to be considered in conjunction with the Canadian Government's Omicron variant guidance, which does not make any specific reference to removing/changing face masks. It is specific to ambulatory and outpatient care settings. The guidance is broadly in line with acute and long-term care settings guidance. Ambulatory and out-patient care settings should also refer to provincial, territorial and local policies which may differ depending on local epidemiology.

"Medical masks are recommended for all outpatient and ambulatory care setting staff and visitors at all times

- These masks can be removed for breaks or meals, during which a minimum physical distance of 2 metres from others should be maintained, along with minimal numbers of unmasked individuals in any given space. Breaks or meals should occur in larger spaces and at staggered times"

Full shift/visit masking/eye protection:

"Given ongoing community spread of COVID-19 within Canada and evidence that transmission occurs from those who have few or no symptoms, masking for the full duration of shifts or visits for all outpatient and ambulatory care setting staff and visitors (e.g., essential companions or external service providers) is recommended."

"Staff should refer to facility IPC and provincial and territorial guidance on specific recommendations for use of medical masks"

- When masks are recommended for full shifts: just prior to breaks or when leaving the facility, remove masks in an area where no patients, staff or visitors are present, and discard them in the nearest no-touch waste receptacle"

"Masks or N95 or equivalent respirators worn as source control, and eye protection worn for the full duration of shifts (i.e., not when used for encounters with patients on Additional Precautions), may be worn for extended periods. Any extended use policies should be developed with IPC expert consultation or guidance. Masks or N95 or equivalent respirators and eye protection should be replaced when

Assessment of evidence
they become damaged, wet, damp, or soiled (from the wearer's breathing or external splash), or when they come in direct contact with a patient.." "A minimum of Droplet and Contact Precautions should be implemented for all patients who are considered exposed to, have been diagnosed with, or have signs or symptoms of COVID-19. • After seeing a patient on Droplet and Contact Precautions: ○ medical masks and N95 or equivalent respirators should be removed and replaced In summary, this COVID-19 guidance advises that in outpatient and ambulatory settings, when universal masking is in place, masks may be removed by healthcare workers and visitors before breaks or leaving the facility when no one else is present. Medical masks may also be removed after treating a patient on droplet and contact precautions. Masks should be changed when there is a risk of contamination or when the mask is soiled/damaged. **Limitations:** It is not clear if the updates section of this guidance represents current recommendations, or if this section exists for reader's information. Similar wording is used throughout the document, providing further confusion.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
CDC and HICPAC. CDC's Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings Last reviewed 29 November 2022	Guidance/Expert Opinion	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Last accessed 01 December 2022					

Assessment of evidence

An update to the core practices provided by the CDC. It applies across health and care settings as well as across health care workers, patients and visitors, where appropriate. This is considered as expert opinion. The authors describe a process of consulting other CDC materials as well as input from HICPAC in drafted recommendations produced 2014 which were reviewed in October 2022 by "experts within the Division of Healthcare Quality Promotion at CDC" as well as reviewed by HICPAC.

- And "Remove and discard PPE, other than respirators, upon completing a task before leaving the patient's room or care area. If a respirator is used, it should be removed and discarded (or reprocessed if reusable) after leaving the patient room or care area and closing the door".

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
The Association of Anaesthetists of Great Britain and Ireland. Guidelines: Infection Prevention and Control 2020 Last accessed: 16 October 2024	Guidance/Expert Opinion	Level 4	N/A	N/A	N/A

Assessment of evidence

When worn, masks should not be taken down to speak and should be changed if they become damp or contaminated. Masks should only be handled by the ties and should be replaced between patients.

Evidence from previous update(s):

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Coia JE, Ritchie L, Adisesh A, et al. Guidance on the use of respiratory and facial protection equipment. Journal of hospital Infection. 2013 Nov 1;85(3):170-82.	Guidance/ Expert Opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence

This expert consensus guidance provides guidance on surgical masks and respirators. It advises on the standards that both these types of masks should meet in the UK, when they should be worn, how they should be fit checked/tested if necessary and how they should be removed and disposed of. It refers to relevant health and safety/governmental legislation. This document specifies from the outset that the information provided is purely advisory guidance and is not a standard or a regulation.

- After leaving the relevant area where a mask was required ("after leaving the area", pg179). Note the person should have already removed gloves, gown and eye protection followed by hand hygiene inside. The person should handle the ties of the mask e.g. avoid touching the rest of the mask. "Untie or break the bottom ties first, followed by top ties or elastic, and remove by handling ties only." Pg 179. Perform hand hygiene after disposal of the mask.
- Should be changed if they become contaminated with respiratory secretions or if they become damaged.

Caution is advised as this guidance was published in 2014 and some aspects may be out of date.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Department of Health and Health Protection Agency. Pandemic influenza: Summary infection control guidance for ambulance services during an influenza pandemic. 2010	Guidance	**Level 4**	N/A	N/A	N/A
Assessment of evidence					
Guidance provided by England regarding IPC for ambulance settings specific to pandemic influenza. • This guidance highlights that to remove a mask the person should untie or break bottom ties, followed by top ties or elastic and remove by handling ties only. The mask should then be discarded appropriately. • Advises sessional use for cohorted patients. • SFM are outlined as single use but should also “be changed when they become moist” • Surgical face mask is removed last in doffing sequence.					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Department of Health and Health Protection Agency PANDEMIC (H1N1) 2009 INFLUENZA	Guidance	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
A summary of guidance for infection control in healthcare settings. Published 08 January 2010					
Assessment of evidence					
Guidance provided by DoH England regarding IPC for general settings specific to pandemic influenza. "When pandemic influenza patients are cohorted in one area and several patients must be visited over a short time or in rapid sequence, it may be more practical for staff to put on a surgical mask on entry to the area and to keep it on for the duration of the activity or until the surgical mask requires replacement (ie when it becomes wet or damaged)."					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
World Health Organisation (WHO) Infection prevention and control of epidemic-and pandemic-prone acute respiratory infections in health care. 2014 ISBN 978 92 4 150713 4	Guidance/ Expert Opinion	**AGREE: recommend with provisos**	N/A	N/A	N/A

Assessment of evidence
Within this document a medical mask is defined as: • "Wear medical masks fitted tightly to the face, and discard immediately after use (161, 162). If the mask gets wet or dirty with secretions, it must be changed immediately." Please note, that this guidance included systematic reviews and an appropriate consultation process. However, specific details regarding the quality appraisal results were not clear. The studies which were reported as considered for mask related recommendations were limited. The search included studies pre-2000, studies with a bundled approach and studies focused on a community setting. It was also published 2014 and does not consider more recent research or evidence. For these reasons this is considered as level 4 guidance. As such the conclusions made may not apply to health and care settings in Scotland today.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Humphreys H, Bak A, Ridgway EJ, et al. Rituals and behaviours in the operating theatre – joint guidelines of The Healthcare Infection Society and The European Society of Clinical Microbiology and Infectious Diseases. Journal of Hospital Infection. 2023;140:165.e1-165.e28.	Guidance	**AGREE: Recommend with modifications.**	N/A	N/A	N/A

Assessment of evidence
This guideline was conducted using the NICE methodology. The primary evidence which was included for the good practice points (GPP) related to the use of surgical face masks was described as low quality and generally working party and lay person views were considered. These GPP were considered as primarily based on expert opinion. Relevant GPP are as follows: • GPP 11.1: Ensure that all staff working in the operating room wear a head covering and a face mask in accordance with local policies. • GPP 11.2: When face masks are worn, ensure that they are changed periodically." • Possible relevance: "8.12. What is the impact of wearing operating room attire outside the operating theatre complex?": "GPP 12.1: Change or cover operating room attire (e.g. with a single-use disposable gown) and change footwear if leaving the operating theatre complex with the intention of returning." – it is not clear if this applies to masks or only those PPE listed specifically. Changing if SFM is noted in the GPP above. The recommendations are concerned only with theatre staff in a theatre setting. **Limitations:** • Majority of primary evidence were of low quality. All of those related to masks were eligible for exclusion from this review. • The recommendations/GPP provided for mask use were formulated primarily by expert opinion. • Lack of details to ascertain the extent of consultation with the target population (patients, public). It is not clear if those involved in creation of these guidelines reflect the complete spectrum of relevant patient groups. • Lack of specific implementation tools and resources. • The weight of evidence and how it was specially used to form recommendation is not clear. Though expert opinion is provided for the GPP related to mask which support understanding in how these were formed. • The methodology to update this guideline is not clear though it is stated that it is subject to possible future updates. • The GPP related to mask use are somewhat vague ('face masks' rather than TYPE II or TYPE IIR and timeline for changing a mask is not specified) making it difficult to audit/follow.

Assessment of evidence
• It appears that a meta-analysis was conducted as part of the evidence review of mask. The results of this are not well described. The appropriateness of conducting this type of analysis with different study designs and unclear differences in comparator or quality is unclear.

Question 10: Where and how should surgical face masks be donned/put on?

Evidence added to version 2.0 update:

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution Standards Publication. BS EN 14683:2025+AC:2019, ICS 11.140. Medical face masks - Requirements and test methods. March 2025.	British Standards	**Level 4**	N/A	N/A	N/A

Assessment of evidence

This document outlines the British Standards for medical masks (requirements and testing). It is not specific to mask use as PPE and other standards/legislation should be consulted as appropriate. It supersedes EN 14683:2019. The following section(s) are relevant for this research question on donning:

The 2025 revision of this document contains detail regarding donning and doffing of medical face masks.

- “the body of the medical face mask is not touched by the fingers/hands of the wearer”
- “hands are disinfected (full hand disinfection) before donning and after removal of the medical face mask”
- “the nose clip, if present, is fitted on and around the nose to improve the contact between the medical face mask and the face to reduce outward leakage”
- “a medical face mask is worn covering the nose and mouth of the wearer”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health New Zealand. Infection prevention and control Last updated 26 November 2024	Guidance/ Expert Opinion	**Level 4**	N/A	N/A	N/A
Assessment of evidence					
This Guidance published by Health New Zealand includes standard and transmission-based precautions and it includes COVID-19/ mpox guidance (TBPs). The following section(s) are relevant for this research question on when healthcare workers should wear a surgical face mask. Droplet precautions (interacting with people with suspected or known infection or disease spread by droplet): • "Wear a medical mask upon room entry or when interactions mean that physical distancing of 1 metre cannot be maintained"					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Health and Security Agency (UKHSA). Poster: guide to donning and doffing PPE: Droplet Precautions. Gateway number 2020212. Version 1 10 August 2020	Poster/Expert opinion	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Last accessed 02 December 2022					

Assessment of evidence

A poster displaying and describing the steps to donning PPE for droplet precautions an UKSHA publication. An UKSHA publication. It does not appear that this document is COVID-19 specific. It was published at the beginning of the pandemic but refers to 'droplet precautions.

There is no indication of the evidence considered for this poster. It provides the following donning advice:

- Surgical mask donning is therefore second and following HH and donning of a gown.
- Perform hand hygiene before donning any PPE, begin process by donning gown, then surgical mask ("Put on your surgical face mask, if tied, make sure securely tied at crown and nape of neck. Once it covers the nose, make sure it is extended to cover your mouth and chin.") eye protection and finally gloves.

A similar poster exists for airborne precautions but include a respirator and additional steps appropriate for respiratory use.

A similar poster also exists for standard precautions but lists PPE donning and doffing in the same order.

- The guidance also states that before any donning of PPE the person should "Make sure you are hydrated and are not wearing any jewellery, bracelets, watches or stoned rings".
- The location of donning is assumed from the wording of the donning sequence. At the close of donning (step 5) the poster recommends that "you are now ready to enter the patient area" suggesting donning of PPE should be conducted BEFORE entering the patient area.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Department of health and social care. Guidance: Guide to donning (putting on) and doffing (removing) PPE (non-AGP) in adult social care settings (text only version). Updated 1 February 2024 Last accessed 12 December 2024	Expert opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence

Guidance describing the steps to donning PPE for non-AGP PPE in adult social care settings, an Department of health and social care publication.

There is no indication of the evidence considered (if any) for this poster.

- ”Clean your hands and wrists using alcohol-based hand rub or gel, or use soap and water.
- Put on apron and tie at waist.
- Put on face mask.
- Fit mask around nose - cover mouth and chin.
- Put on eye protection.
- Put on gloves if exposure to blood or body fluids is likely (risk assess). Change gloves and clean hands between tasks”.

Assessment of evidence
Limitations: • The methodology for producing this guidance is unclear.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Association of perioperative Registered Nurses (AORN) 2019 Guideline Quick View: Transmission-Based Precautions. 2019 Last accessed 21 November 2022	Guidance/ Expert opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence
An expert opinion guidance. References are not provided for the formation of each section. The guidance is reported to be developed for nursing staff who work in USA. Refers to 'masks' with a picture of a surgical mask. Information gathered from 'mask' section (covers multiple masks) as well as precaution level sections (provides type of mask per 'level of protection'). General guidance (general across mask types): • "Ensure the mask completely covers the mouth, nose, and chin and fits snugly, preventing gaps at the sides of the mask." • "Don a clean mask before each procedure" Contact precautions: • No mention of mask Droplet precautions (ie particles >5μm):

Assessment of evidence
• “don upon entering room or cubicle of a patients with suspected or proven infection transmitted by respiratory droplets (i.e, large particle droplets that are > 5 µm) that are generated by a patient who is coughing, sneezing, or talking” An expert opinion (level 4) guidance designed for use by nursing staff. It states ‘masks’ should be donned “upon entering” a patient room or cubicle where the patient is suspected or confirmed as having a respiratory infection. The guidance also states that a clean mask should be donned before each procedure. It is not clear how this guidance was formed, or which references were used to form the guidance.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
National Health and Medical Research Council (NHMRC) Australian Guidelines for the Prevention and Control of Infection in Healthcare, 2019 2019 (revised 2024, v11.24) Accessed 11 October 2024	Guidance/ Expert opinion	**Level 4**	N/A	N/A	N/A
Assessment of evidence					
Aim: IPC guidance for Australian health and care settings. Target audience: Acute settings but the authors highlight transferability across settings. Methods: Methodologies for reviews are not provided and, except where references are given, guidelines seem to be formed from expert opinion. Recommendations are accompanied by a strength of evidence assessment, based on systematic review.					

Assessment of evidence
Conditional recommendation Updated – "**24. It is suggested that a surgical mask should be worn when entering a patient-care environment to prevent droplet transmission".** The authors suggest the following sequence for donning PPE (sequence for donning PPE updated now to page 129, with vary across healthcare settings and rare outbreak situation now to page 131): • perform hand hygiene • put on gown • put on mask ("secure ties or elastic bands at middle of head and neck") • put on protective eyewear or face shield • put on gloves • They also advise that the sequence of donning may vary across healthcare settings e.g. for surgical and dental procedures, masks are applied first before hand hygiene and/or in a rare outbreak situation (e.g. Ebola) (page 111) – however this would be relevant for the PPE for HCID review. "Sequencing may differ across healthcare settings and any variations to sequencing should be based on a risk assessment relevant to the setting and task being undertaken. Note that for surgical procedures and dentistry, the sequence for putting on PPE differs. In these situations, masks and protective eyewear are applied first prior to hand preparation. Gown and gloves are then put on (see Section 3.5.3)."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
World Health Organization (WHO) How to wear a medical mask safely. 2021 Last updated December 2021	Guidance/ Expert opinion	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Last Accessed: 05 December 2022					
Assessment of evidence					
International guidance appears to be COVID-19 specific. Do's -"Wash hands before touching mask -Inspect the mask for tears or holes -Find the top side, where the metal piece or stiff edge is. -Ensure the coloured side faces outwards. -Place the metal piece of stiff edge over the nose -Cover your mouth, nose or chin -Adjust the mask to your face without leaving gaps on the sides. -Avoid touching the mask -remove the mask from behind the ears or head -Keep the mask away from you and surfaces while removing it -Discard the mask immediately after use preferably into a closed bin -Wash your hands after discarding the mask" Don't's: -"Do not use a ripped or damp mask -Do not wear the mask only over mouth or nose					

Assessment of evidence
-Do not wear a lose mask -Do not touch the front of the mask -Do not remove the mask to talk to someone or do other things that would require touching the mask -Do not leave your mask within the reach of others -Do not re-use the mask". This poster is a part of a series of resource material produced/updated by the WHO in the light of the pandemic. It was last updated in December 2021 and no further update is visible. It provides steps for donning and doffing of medical masks safely by healthcare personnel.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Government of Canada. Infection prevention and control for COVID-19: Interim guidance for acute healthcare settings Updated and re-posted 16 June 2021. Last modified 25 January 2022 Last accessed 24 January 2023	Guidance/ Expert opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence

This Canadian interim guidance aimed to provide interim COVID-19 guidance related to IPC to be considered in conjunction with the Canadian Government's Omicron variant guidance (see above entry) . It is specific to acute settings.

Like the Omicron guidance, this setting-specific guidance also recommends that employers provide information on the steps involved in donning a mask, including the importance of hand hygiene before donning a face mask, available in multiple languages.

Full shift/visit masking/eye protection:

"HCWs should refer to provincial and territorial guidance and facility policies on specific recommendations for use of medical masks, eye protection and other PPE, as well as PPE conservation strategies. When medical masks for HCWs and visitors (and eye protection for HCWs) are recommended for the full duration of shifts or visits, HCWs and visitors should:

- Perform hand hygiene before putting on a mask upon entering the acute healthcare facility (and before putting on eye protection upon entering any patient care area), before and after removing a mask or eye protection, and before putting on a new mask or eye protection"
- Wear the mask securely over their mouth and nose and adjust the nose piece to fit snugly
- Not touch the front of a mask or eye protection during wear (and immediately perform hand hygiene if this occurs)
- Not dangle the mask under their chin, around their neck, off their ear(s), under their nose or place it on top of their head"

In summary, this COVID-19 guidance for acute healthcare settings provides additional guidance on where/how face masks should be donned i.e. hand hygiene before, adjustment around the nose, not touching the front of the mask, and not to be worn around the chin.

Limitations:

- It is not clear between the Canadian Government setting-specific guidance and the Omicron guidance which recommendations are current
- This guidance specifies how masks should be donned when universal masking is being implemented, so guidance on donning masks in other circumstances is not provided

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Government of Canada.	Guidance/ Expert opinion	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Infection prevention and control for COVID-19: Interim guidance for outpatient and ambulatory care settings Updated and re-posted 16 June 2021 Last modified 25 January 2022 Last accessed 25 January 2023					
Assessment of evidence					
This Canadian interim guidance aimed to provide interim COVID-19 guidance related to IPC to be considered in conjunction with the Canadian Government's Omicron variant guidance (see above entry). It is specific to outpatient and ambulance settings. The guidance is broadly in line with acute and long-term care guidance. Like the Omicron guidance, this setting-specific guidance also recommends that employers provide information on the steps involved in donning a mask, including the importance of hand hygiene before donning a face mask, available in multiple languages. Full shift/visit masking/eye protection:					

Assessment of evidence
“Staff should refer to facility IPC and provincial and territorial guidance on specific recommendations for use of medical masks, eye protection and other PPE, as well as PPE conservation strategies. When medical masks for staff and visitors (and eye protection for staff) are recommended for the full duration of shifts or visits, staff and visitors should: • perform hand hygiene before putting on a mask on entry into the facility (and before putting on eye protection on entry into any patient care area), before and after removing a mask or eye protection, and before putting on a new mask or eye protection • wear the mask securely over their mouth and nose and adjust the nose piece to fit snugly • not touch the front of mask or eye protection during wear (and immediately perform hand hygiene if this occurs) • not dangle the mask under their chin, around their neck, off their ear(s), under their nose or place it on top of their head” In summary, this COVID-19 guidance for outpatient and ambulatory settings provides additional guidance on where/how face masks should be donned i.e. hand hygiene before, adjustment around the nose, not touching the front of the mask, and not to be worn around the chin. **Limitations:** • It is not clear between the Canadian Government setting-specific guidance and the Omicron guidance which recommendations are current • This guidance specifies how masks should be donned when universal masking is being implemented, so guidance on donning masks in other circumstances is not provided

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Government of Canada. Infection prevention and control for COVID-19: Interim guidance for long-term care homes Updated and re-posted 16 June 2021 Last modified 25 January 2022 Last accessed 25 January 2023	Guidance/Expert opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence

This Canadian interim guidance aimed to provide interim COVID-19 guidance related to IPC to be considered in conjunction with the Canadian Government's Omicron variant guidance (see above entry). It is specific to long-term care homes. The guidance is broadly in line with acute, outpatient and ambulatory guidance.

Like the Omicron guidance, this setting-specific guidance also recommends that employers provide information on the steps involved in donning a mask, including the importance of hand hygiene before donning a face mask, available in multiple languages.

Full shift/visit masking/eye protection:

"LTCHs should refer to facility IPC and provincial and territorial guidance on specific recommendations for use of medical masks, eye protection and other PPE, as well as PPE conservation strategies. When medical masks and eye protection are recommended for the full duration of shifts or visits, staff and visitors should:

- Perform hand hygiene before putting on a mask on entry into the facility (and before putting on eye protection on entry into any resident care area), before and after removing a mask or eye protection, and before putting on a new mask or eye protection

Assessment of evidence
• Wear the mask securely over their mouth and nose and adjust the nose piece to fit snugly • Not touch the front of the mask or eye protection during wear (and immediately perform hand hygiene if this occurs) • Not dangle the mask under their chin, around their neck, off their ear(s), under their nose or place it on top of their head” In summary, this COVID-19 guidance for long-term care settings provides additional guidance on where/how face masks should be donned i.e. hand hygiene before, adjustment around the nose, not touching the front of the mask, and not to be worn around the chin. **Limitations:** • It is not clear between the Canadian Government setting-specific guidance and the Omicron guidance which recommendations are current • This guidance specifies how masks should be donned when universal masking is being implemented, so guidance on donning masks in other circumstances is not provided

Evidence from previous update(s):

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Coia JE, Ritchie L, Adisesh A, et al. Guidance on the use of respiratory and facial protection equipment. Journal of hospital Infection. 2013 Nov 1;85(3):170-82.	Guidance/Expert Opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence

Methods: Coia et al., (2014) is a summary of Coia et al (2013) and Bunyan et al (2013) was the review that informed ref Coia et al (2013). Reference of interest is Coia 2013. Full references of supporting documents: Coia, et al. Use of respiratory and facial protection. 2014. Nursing Times. Vol 110 (4) p18-20. Coia, JE, et al, The Healthcare Infection Society Working Group on Respiratory and Facial Protection. Guidance on the use of respiratory and facial protection. Journal of hospital infection 85 (2013) 165-169. Bunyan D et al, Respiratory and facial protection: a critical review of recent literature. 2013. Journal of Hospital Infection. Vol 85 p165-169.

This expert consensus guidance provides guidance on surgical masks and respirators. It advises on the standards that both these types of masks should meet in the UK, when they should be worn, how they should be fit checked/tested if necessary and how they should be removed and disposed of. It refers to relevant health and safety/governmental legislation. This document specifies from the outset that the information provided is purely advisory guidance and is not a standard or a regulation. This differs from the legal obligations of employers and employees that are found within other OSHA documents such as the OSHA standards or the *Occupational Safety and Health Act* (OSH Act).

Within the dos and don't section of the report the authors state:

- DO "Ensure the eye protection, surgical face mask or FFP respirator is worn correctly, completely covering the eyes, nose and mouth and secured on to the face according to the manufacturer's instructions."

Assessment of evidence
• DON'T "Fiddle with eye protection, surgical face mask or respirator while in position on the face." Caution is advised as this guidance was published in 2014 and some aspects may be out of date.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Department of Health and Health Protection Agency. Pandemic influenza: Summary infection control guidance for ambulance services during an influenza pandemic. 2010	Guidance	**Level 4**	N/A	N/A	N/A
Assessment of evidence					
"Surgical mask (or FFP3 respirator for an AGP): • Secure ties or elastic bands at middle of head and neck. • Fit flexible band to nose bridge. • Fit snug to face and below chin."					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Department of Health and Health Protection Agency PANDEMIC (H1N1) 2009 INFLUENZA A summary of guidance for infection control in healthcare settings. Published 08 January 2010	Guidance	**Level 4**	N/A	N/A	N/A

Assessment of evidence

Report providing information on IPC recommendations for influenza. Published 2010.

“Surgical masks should:

– cover both nose and mouth

– not be allowed to dangle around the neck after or between each use

– not be touched once put on

– be changed when they become moist or damaged

– be worn once and then discarded as clinical waste

– hand hygiene must be performed after disposal”.

“PPE should be put on before entering a side room or cohorted area”

“1. Gown (or apron if not a potentially infectious aerosol-generating procedure) 2. FFP3 respirator (or surgical mask if not a potentially infectious aerosol-generating procedure) 3. Eye protection, i.e goggles or face shield (for a potentially infectious aerosol-generating procedure and as appropriate after risk assessment) 4. Disposable gloves.”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centres for Disease Control. (CDC) Sequence for putting on Personal Protective Equipment (PPE) and how to safely remove Personal Protective Equipment (PPE). 2019.	Poster/ Expert opinion	**Level 4**	N/A	N/A	N/A
Assessment of evidence					
"Mask or Respirator • Secure ties or elastic bands at middle of head and neck • Fit flexible band to nose bridge • • Fit snug to face and below chin"					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Association for Professionals in Infection control and Epidemiology (APIC), American Nurses Association,	Poster	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Association of Occupational Health Professionals in Healthcare Association of periOperative registered nurses (AORN). Do's and don'ts for wearing procedure masks in non-surgical healthcare settings. 2015.					
Assessment of evidence					
“Check to make sure the mask has no defects, such as a tear or torn strap or ear loop.” “Bring both top ties to the crown of head and secure with a bow; tie bottom ties securely at the nape of neck in a bow”					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
World Health Organization (WHO) How to put on, use, take off and dispose of a mask. 2020	Poster/ Expert opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence
• “Before putting on a mask, wash hands with alcohol-based hand rub or soap and water” • “Cover mouth and nose with mask and make sure there are no gaps between your face and the mask” • “Avoid touching the mask while using it; if you do, clean your hands with alcohol-based hand rub or soap and water”

Question 11: Where and how should surgical face masks be doffed/taken off?

Evidence added to version 2.0 update:

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution Standards Publication. BS EN 14683:2025+AC:2019, ICS 11.140. Medical face masks - Requirements and test methods. March 2025.	British Standards	**Level 4**	N/A	N/A	N/A

Assessment of evidence

This document outlines the British Standards for medical masks (requirements and testing). It is not specific to mask use as PPE and other standards should be consulted. It supersedes EN 14683:2019. The following section(s) are relevant for this research question on doffing:

The 2025 revision of this document contains detail regarding donning and doffing of medical face masks.

- “the body of the medical face mask is not touched by the fingers/hands of the wearer”
- “hands are disinfected (full hand disinfection) before donning and after removal of the medical face mask”

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
World Health Organization (WHO) Infection prevention and control in the context of coronavirus disease (COVID-19): A living guideline Last updated 21 December 2023 Last accessed 15 October 2024	Guidance/ Expert opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence

A living guidance document which includes recommendations for mask use in health and care settings in light of the SARS-CoV-2 pandemic.

Methodology: Consensus approach described with GRADE and evidence searched. However, there are no details on how literature was searched, what terms were used etc. so this guidance has been graded expert opinion.

Target audience: National and facility level decision-makers, policy makers, public health and infection prevention and control professionals; healthcare facility administrators, managers and other healthcare workers

- “Remove the mask using the appropriate technique. Do not touch the front of the mask; rather, untie it from behind.”
- “Do not store the mask around the arm or wrist or pull it down to rest around the chin or neck.”

A living guidance document published by WHO and funded by CDC. It did not provide sufficient detail to be considered AGREE recommend but was included as level 4 expert opinion level evidence. While it is reported that multidisciplinary experts were involved in the development of these guidelines it is not clear how evidence was identified or selected and therefore it is subject to bias. Medical face

Assessment of evidence
masks are recommended to be removed using the loops and untied from the back with care not to touch the front of the mask. Hands should be washed after discarding a medical face mask.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Health and Security Agency (UKSHA) Poster: guide to donning and doffing PPE: Droplet Precautions. Gateway number 2020212. Version 1 10 August 2020 Last accessed 02 December 2022	Poster/ Expert opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence
A poster displaying and describing the steps to doffing PPE for droplet precautions an UKSHA publication. An UKSHA publication. It does not appear that this document is COVID-19 specific. It was published at the beginning of the pandemic but refers to 'droplet precautions' generally. There is no indication of the evidence considered for this poster. • Contact: Remove gloves first, perform hand hygiene, remove apron, remove goggles, perform hand hygiene and then remove surgical face masks and then wash hands with soap and water. • "Surgical masks are single session use, gloves and apron should be changed between patients"

Assessment of evidence
A similar poster exists for airborne precautions but include a respirator and additional steps appropriate for respiratory use. A similar poster also exists for standard precautions but lists PPE donning and doffing in the same order.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Department of health and social care. Guidance: Guide to donning (putting on) and doffing (removing) PPE (non-AGP) in adult social care settings (text only version) Updated 1 February 2024 Last accessed 12 December 2024	Guidance/ Expert opinion	**Level 4**	N/A	N/A	N/A
Assessment of evidence					
Guidance describing the steps to donning PPE for Non-AGP PPE in adult social care settings, a Department of health and social care publication. **"Taking off PPE** • To take off your PPE safely and correctly: • Remove gloves - do not touch the outside front of the gloves, they will be contaminated. • Clean hands and wrists (and forearms if necessary) with alcohol-based hand rub or gel, or use soap and water. • Remove apron - do not touch the outside front of the apron, this will be contaminated.					

Assessment of evidence
• Clean hands and wrists again with alcohol-based hand rub or gel, or use soap and water. • When at least 1 meter from the client, carefully remove eye protection by the sidearms or side straps. Discard (or disinfect for next use). • Clean hands and wrists again with alcohol-based hand rub or gel, or use soap and water. • Remove mask - do not touch the front of the mask but remove by the ear loops or ties. • Clean hands and wrists again with alcohol-based hand rub or gel, or use soap and water. • If required, put on a clean face mask before contact with others in a care setting or service". There is no indication of the methodology used to produce this guidance or the evidence considered (if any) for this poster.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Association of perioperative Registered Nurses (AORN) 2019 Guideline Quick View: Transmission-Based Precautions. 2019 Last accessed 21 November 2022	Guidance/ Expert opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence
An expert opinion guidance. References are not provided for the formation of each section. The guidance is reported to be developed for nursing staff who work in USA. Refers to ‘masks’ with a picture of a surgical mask. Information gathered from ‘mask’ section (covers multiple masks). Droplet precautions described as used in addition to standard precautions to be implemented when a patient has a “known or suspected infection transmitted by respiratory droplets (e.g., adenovirus, group A Streptococcus, influenza, Neisseria meningitides, Bordetella pertussis, rhinovirus)” which are considered as “i.e. greater than 5µm”. General guidance (general across mask types): • “Remove the mask last when it is worn in combination with other PPE” • “Remove the mask by touching only the ties and without touching the front of the mask” An expert opinion (level 4) guidance designed for use by nursing staff in US settings. The guidance states, masks should be removed last in the sequence if other PPE is donned. To remove the mask the ties or loops should be touched, only. The front of the mask should not be touched. It is not clear how this guidance was formed, or which references were used to form the guidance.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
World Health Organization (WHO) How to wear a medical mask safely. 2021 Last updated: December 2021 Last Accessed: 05 December 2022	Poster/ infographic	**Level 4**	N/A	N/A	N/A

Assessment of evidence
International guidance, produced for public but includes specific infographics for medical mask use in the context of COVID-19. Do’s -Wash hands before touching mask -Inspect the mask for tears or holes -Find the top side, where the metal piece or stiff edge is. -Ensure the coloured side faces outwards. -Place the metal piece of stiff edge over the nose -Cover your mouth, nose or chin -Adjust the mask to your face without leaving gaps on the sides. -Avoid touching the mask -remove the mask from behind the ears or head -Keep the mask away from you and surfaces while removing it -Discard the mask immediately after use preferably into a closed bin -Wash your hands after discarding the mask Don’t’s: -Do not use a ripped or damp mask -Do not wear the mask only over mouth or nose -Do not wear a lose mask -Do not touch the front of the mask -Do not remove the mask to talk to someone or do other things that would require touching the mask -Do not leave your mask within the reach of others -Do not re-use the mask.

Assessment of evidence
This poster is a part of a series of resource material produced by the WHO in the light of the pandemic. It was last updated in December 2021 and remains valid/current. No further update is visible. It provides steps for donning and doffing of medical masks safely by healthcare personnel.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
National Health and Medical Research Council (NHMRC) Australian Guidelines for the Prevention and Control of Infection in Healthcare, 2019 2019 (revised 2024, v11.24) Accessed 11 October 2024	Guidance/ Expert opinion	**Level 4**	N/A	N/A	N/A
Assessment of evidence					
Aim: IPC guidance for Australian health and care settings. Target audience: Acute settings but the authors highlight transferability across settings. Methods: Methodologies for reviews are not provided and, except where references are given, guidelines seem to be formed from expert opinion. Recommendations are accompanied by a strength of evidence assessment, based on systematic review. Methods: Methodologies for reviews are not provided and, except where references are given, guidelines seem to be formed from expert opinion. Recommendations are accompanied by a strength of evidence assessment, based on systematic review.					

Assessment of evidence
The authors suggest the following sequence for doffing PPE (sequence for doffing PPE updated now to page 129, with vary across healthcare settings and rare outbreak situation now to page 131): • remove gloves • perform hand hygiene • remove gown (or remove gloves and gown in one step then perform hand hygiene) • remove protective eyewear or face shield (perform hand hygiene at least if PPE was contaminated) • remove mask ("front of mask is contaminated – DO NOT TOUCH! Grasp bottom, then top ties or elastics and remove. Discard in waste container.") • perform hand hygiene They also highlight that this sequence may vary across healthcare settings and/or in a rare outbreak situation (e.g. Ebola) Authors also advise: "Removal of a face shield, protective eyewear and surgical mask can be performed safely after gloves have been removed and hand hygiene performed. The ties, earpieces and/or headband used to secure the equipment to the head are considered 'clean' and therefore safe to touch with bare hands. The front of a mask, protective eyewear or face shield is considered contaminated."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
European Centre for Disease Prevention and Control (ECDC). Guidance for wearing and removing personal protective equipment in healthcare settings	Guidance/ Expert Opinion	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
for the care of patients with suspected or confirmed COVID-19. **2020**					

Assessment of evidence

This EU document aims to provide guidance for the removal of PPE for COVID-19 patients. It COVID-19 specific and relevant to the COVID-19 pandemic. It may not be applicable to non-COVID-19 pandemic settings. This was still referred to in the final update of the ECDC guidance for the management of COVID-19 patients.

- After a patient has been examined PPE should be removed in the following order:
- Gloves first (use of ABHR before glove removal may be considered), hand hygiene after glove removal is then recommended followed by the donning of a new pair of gloves, the gown should be removed next with assistance from a second person (who should wear gloves and a mask) where appropriate, goggles should then be removed avoiding touching the front and where possible using the straps only. The respirator or mask may then be removed using the straps avoiding touching the face with disposal immediately after removal without touching using the straps only where possible. The final pair of gloves can then be doffed followed by hand hygiene.

This expert opinion level guidance document was produced early 2020 in response to the emergence of SARs-CoV-2 infections across the world. This document provides more specific details on donning and doffing for suspected or confirmed COVID-19 patients. This ECDC document recommends doffing in the following order: doff gloves, perform hand hygiene, don new gloves, doff gown, doff goggles, doff mask, doff gloves, perform hand hygiene. When removing a face mask care should be taken not to touch the front and straps should be used. The mask should be disposed of immediately.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
CDC and HICPAC.	Guidance/Expert Opinion	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
CDC's Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings Last reviewed 29 November 2022 Last accessed 01 December 2022					
Assessment of evidence					
An update to the core practices provided by the CDC. It applies across health and care settings as well as across health care workers, patients and visitors, where appropriate. This is considered as expert opinion. The authors describe a process of consulting other CDC materials as well as input from HICPAC in drafted recommendations produced 2014 which were reviewed in October 2022 by "experts within the Division of Healthcare Quality Promotion at CDC" as well as reviewed by HICPAC. • Within the 'risk assessment with appropriate use of PPE' section it states: "Remove and discard PPE, other than respirators, upon completing a task before leaving the patient's room or care area. If a respirator is used, it should be removed and discarded (or reprocessed if reusable) after leaving the patient room or care area and closing the door".					

Evidence from previous update(s):

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Association for Professionals in Infection control and	Poster	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Epidemiology (APIC), American Nurses Association, Association of Occupational Health Professionals in Healthcare Association of periOperative registered nurses (AORN). Do's and don'ts for wearing procedure masks in non-surgical healthcare settings. 2015.					

Assessment of evidence

A poster published by AORN/APIC 2015 regarding the ‘Dos’ and ‘Don’ts’ of wearing a ‘procedure’ mask. The authors state this is also referred to as an ‘isolation’ mask. And defines it as a “disposable mask that protects the wearer from droplets that might be infectious”.

- Do not touch face of mask or let it hang around the neck.
- “remove the mask when no longer in clinical space and the patient intervention is complete”
- Change mask if soiled or damaged.
- Single use, dispose after one use.

Assessment of evidence
• Remove the mask from the side, with head tilted forward and only touch the loops or ties (bottom then top tie for removal). Handle the straps only. Hand hygiene after removal. Method for developing this poster is not clear. References are provided.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Coia JE, Ritchie L, Adisesh A, et al. Guidance on the use of respiratory and facial protection equipment. Journal of hospital Infection. 2013 Nov 1;85(3):170-82.	Guidance/Expert Opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence
Methods: Coia et al., (2014) is a summary of Coia et al (2013) and Bunyan et al (2013) was the review that informed ref Coia et al (2013). Reference of interest is Coia 2013. Full references of supporting documents: Coia, et al. Use of respiratory and facial protection. 2014. Nursing Times. Vol 110 (4) p18-20. Coia, JE, et al, The Healthcare Infection Society Working Group on Respiratory and Facial Protection. Guidance on the use of respiratory and facial protection. Journal of hospital infection 85 (2013) 165-169. Bunyan D et al, Respiratory and facial protection: a critical review of recent literature. 2013. Journal of Hospital Infection. Vol 85 p165-169. This expert consensus guidance provides guidance on surgical masks and respirators. It advises on the standards that both these types of masks should meet in the UK, when they should be worn, how they should be fit checked/tested if necessary and how they should be removed and disposed of. It refers to relevant health and safety/governmental legislation. This document specifies from the outset that the information provided is purely advisory guidance and is not a standard or a regulation. This differs from the legal obligations of employers and employees that are found within other OSHA documents such as the OSHA standards or the Occupational Safety and Health Act (OSH Act).

Assessment of evidence
• After leaving the work area (having already removed gloves, gown and eye protection followed by hand hygiene inside). Handle mask by ties only. Untie or break bottom ties first followed by top ties. Perform hand hygiene after disposal.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Department of Health and Health Protection Agency. Pandemic influenza: Summary infection control guidance for ambulance services during an influenza pandemic. 2010	Guidance	**Level 4**	N/A	N/A	N/A
Assessment of evidence					
• Untie or break bottom ties, followed by top ties or elastic and remove by handling ties only and discard appropriately. • Surgical face mask is removed last in doffing sequence.					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Centres for Disease Control. (CDC) Sequence for putting on Personal Protective	Poster/ Expert opinion	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Equipment (PPE) and how to safely remove Personal Protective Equipment (PPE). 2019.					
Assessment of evidence					
• Mask should be removed last in doffing sequence. • Wash hands or use an ABHR after removing PPE. • Do not touch the front of the mask. • If your hands become contaminated during doffing immediately wash them. • Untie bottom ties before top.					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Loveday HP, et al., Epic3: National evidence-based guidelines for preventing healthcare-associated infections	Guidance/ Expert opinion	**AGREE: recommend with provisos**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
in NHS hospitals in England. J Hosp Infect. 2014 Jan;86 Suppl 1:S1-70.					
Assessment of evidence					
A guidance document published 2014 detailing core IPC principles. The document includes some evidence. PPE should be removed in the following order: 1. gloves; 2. apron; 3. eye protection (when worn); and 4. mask/respirator (when worn). 5. Conduct hand hygiene once all PPE removed. EPIC guidance no longer being updated. Last update published 2014 and should be considered with caution.					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
World Health Organization (WHO) Infection prevention and control of epidemic-and pandemic-prone acute respiratory	Guidance/ Expert Opinion	**AGREE: recommend with provisos**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
infections in health care. 2014 ISBN 978 92 4 150713 4					
Assessment of evidence					
• "Wear medical masks fitted tightly to the face, and discard immediately after use (161, 162). If the mask gets wet or dirty with secretions, it must be changed immediately." (pp 26) • "remove the mask or particulate respirator last (by grasping the ties and discarding in a rubbish bin);" Within this document a medical mask is defined as: "Medical mask Also known as a surgical or procedure mask. As personal protective equipment, a facial mask is intended to protect caregivers and health-care workers against droplet-transmitted pathogens, or to serve as part of facial protection for patient-care activities that are likely to generate splashes or sprays of blood, body fluids, secretions or excretions (Annex A provides details of usage and standards for medical masks). In this document, the term refers to disposable masks only.					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Statutory Instrument. Control of Substances Hazardous to Health (COSHH) L5 6th Edition. 2002.	Regulation / Legislation	**Mandatory**	N/A	N/A	N/A

Assessment of evidence
This document contains the Control of Substances Hazardous to Health Regulations 2002 (as amended) (COSHH) regulations. Regulation (6) “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.”

Question 12: How should surgical face masks be disposed of?

Evidence added to version 2.0 update:

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
British Standards Institution Standards Publication. BS EN 14683:2025+AC:2019, ICS 11.140. Medical face masks - Requirements and test methods. March 2025.	British Standards	**Level 4**	N/A	N/A	N/A
Assessment of evidence					
This document outlines the British Standards for medical masks (requirements and testing). It is not specific to mask use as PPE and other standards should be consulted. It supersedes EN 14683:2019. The following section(s) are relevant for this research question on disposal: • "a used medical face mask should be disposed of or placed into suitable collection containers when no longer needed. Medical face masks should be changed between procedures"					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
World Health Organization (WHO).	Guidance/ Expert opinion	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Infection prevention and control in the context of coronavirus disease (COVID-19): A living guideline, 13 January 2023 Last updated 21 December 2023 Last accessed 15 October 2024					

Assessment of evidence

A living guidance document which includes recommendations for mask use in health and care settings in light of the SARS-CoV-2 pandemic. It is considered as expert opinion as it did not meet the standards of AGREE recommend.

Methodology: Consensus approach described with GRADE approach and evidence searched. However, there are no details on how literature was searched, what terms were used etc so this guidance has been graded expert opinion.

Target audience: National and facility level decision-makers, policy makers, public health and infection prevention and control professionals; and other healthcare professionals.

- “Either discard the mask or place it in a clean plastic resealable bag where it is kept until it can be washed and cleaned. Do not store the mask around the arm or wrist or pull it down to rest around the chin or neck. Wash hands immediately after discarding a mask.”
- “Do not reuse single-use masks. • Discard single-use masks after each use and properly dispose of them immediately upon removal.”

Assessment of evidence
A living guidance document published by WHO and funded by CDC. While it is reported that multidisciplinary experts were involved in the development of these guidelines it is not clear how evidence was identified or selected and therefore it is subject to bias. Single use medical face masks should be disposed of immediately and should not be reused.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Association of perioperative Registered Nurses (AORN) 2019 Guideline Quick View: Transmission-Based Precautions. 2019 Last accessed 21 November 2022	Guidance/ Expert opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence
An expert opinion guidance. References are not provided for the formation of each section. The guidance is reported to be developed for nursing staff who work in USA. Refers to 'masks' with a picture of a surgical mask. Information gathered from 'mask' section (covers multiple masks). General guidance (general across mask types): • "Discard the mask in a waste receptacle and perform hand hygiene" and "Do not wear the mask hanging around your neck" An expert opinion (level 4) guidance designed for use by nursing staff in US settings. The guidance states, surgical masks should be discarded in waste receptacle followed by hand hygiene. It is also recommended that wearers not wear their mask around their neck. It is not clear how this guidance was formed, or which references were used to form the guidance.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
National Health and Medical Research Council (NHMRC) Australian Guidelines for the Prevention and Control of Infection in Healthcare, 2019 2019 (revised 2024, v11.24) Accessed 11 October 2024	Guidance/ Expert opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence

Aim: IPC guidance for Australian health and care settings.

Target audience: Acute settings but the authors highlight transferability across settings.

Recommendations are based on evidence and knowledge from a range of sources which differs per recommendation. The methodologies for the relevant reviews are not provided and, except where references are given, guidelines seem to be formed from expert opinion. Recommendations are accompanied by a strength of evidence assessment, based on systematic review.

In the surgical mask section of the guidelines, considerations proposed include “masks should never be reapplied after they have been removed”, “masks should not be left dangling around the neck”, and “hand hygiene should be performed upon touching or discarding a used mask”.

The National Health and Medical research council guidance advises that used masks should be discarded and this should be followed by hand hygiene but there is a lack of clarity regarding how to discard the mask.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
CDC and HICPAC. CDC's Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings Last reviewed 29 November 2022 Last accessed 01 December 2022	Guidance/Expert Opinion	**Level 4**	N/A	N/A	N/A
Assessment of evidence					
An update to the core practices provided by the CDC. It applies across health and care settings as well as across health care workers, patients and visitors, where appropriate. This is considered as expert opinion. The authors describe a process of consulting other CDC materials as well as input from HICPAC in drafted recommendations produced 2014 which were reviewed in October 2022 by "experts within the Division of Healthcare Quality Promotion at CDC" as well as reviewed by HICPAC. • Within the 'risk assessment with appropriate use of PPE' section it states: "Remove and discard PPE, other than respirators, upon completing a task before leaving the patient's room or care area. If a respirator is used, it should be removed and discarded (or reprocessed if reusable) after leaving the patient room or care area and closing the door".					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Government of Canada. Infection prevention and control for COVID-19: Interim guidance for long-term care homes Updated and re-posted 16 June 2021 Last modified 25 January 2022 Last accessed 24 January 2023	Guidance/ Expert opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence

This Canadian interim guidance aimed to provide interim COVID-19 guidance related to IPC, to be considered in conjunction with the Canadian Government's Omicron variant guidance, which does not make any specific reference to disposal of face masks. It is specific to long term care. The guidance is broadly in line with acute and outpatient/ambulance guidance.

Recommendations for SARS-CoV-2 variants of concern:

"As noted in previous guidance, a foundational concept in IPC practice is that disposable medical masks should not be re-worn." This point is re-iterated under the heading "Handling resident care equipment", but about reusable equipment in general.

Under the heading "Infection prevention and control preparedness", it is also recommended that no-touch waste receptacles "are sufficient and appropriately placed" for PPE disposal, and "available and easily accessible to staff and residents".

Assessment of evidence
Under the heading “Access points”, alongside guidance to minimise potential access points, on when masks should be worn on entry, and when hand hygiene should be performed when wearing a mask, “all staff, residents and visitors who are asked to wear a mask should be … provided with access to … a no-touch waste receptacle for proper mask disposal“. Under the heading “Masking and eye protection for the full duration of shifts or visits”, it is advised that when masks are removed where no one else is present, they are disposed of in the “nearest no-touch waste receptacle”. Further, under the heading “Handling resident care equipment”, it is stated that single-use disposable equipment should be disposed of “into a no-touch waste receptacle immediately after use”. Guidance produced by the Canadian Government for across long term care settings detailing IPC considerations considering SARS-CoV-2. It was last modified in January 2022. The guidance suggests that a no-touch waste receptacle be used when disposing of a surgical face mask, straight after use, and that these receptacles are readily available for staff and residents. Please note that the use of a non-touch waste receptacle was also advised within the published Canadian guidance that was specific to acute, outpatient and ambulance settings. **Limitations:** It is not clear if the updates section of this guidance represents current recommendations, or if this section exists for reader’s information. Similar wording is used throughout the document, providing further confusion.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Government of Canada. Infection prevention and control for COVID-19: Interim guidance for acute healthcare settings	Guidance/ Expert opinion	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Updated and re-posted 16 June 2021. Last modified 25 January 2022 Last accessed 24 January 2023					

Assessment of evidence

This Canadian interim guidance aimed to provide interim COVID-19 guidance related to IPC, to be considered in conjunction with the Canadian Government's Omicron variant guidance, which does not make any specific reference to disposal of face masks. It is specific to acute settings. Acute healthcare facilities should also refer to provincial, territorial and local policies which may differ depending on local epidemiology.

Recommendations:

- "All staff, visitors, and patients who are asked to wear a mask should be informed about the importance of performing hand hygiene prior to putting on, and after removing or touching their mask, to reduce the risk of self-contamination, and on clean handling and storage of masks.
- "… and a no-touch waste receptacle for proper disposal of the mask." This recommendation is included under the heading "Triage, patient and healthcare worker access points".

Recommendations for SARS-CoV-2 variants of concern:

"As noted in previous guidance, a foundational concept in IPC practice is that disposable medical masks should not be re-worn." This point is not mentioned again throughout the guidance, but the "Handling patient care equipment" section mentions that single-use disposable equipment in general should be disposed of in a no-touch receptacle after use.

Engineering controls:

Facilities should be designed to include:

Assessment of evidence
• "An adequate number of no-touch waste receptacles for disposal of paper towels, tissues, masks and PPE" Administrative controls: Policies should include: • "Proper … disposal of single-use PPE in no-touch waste receptacles." Under the heading "Masking and eye protection for the full duration of shifts or visits", it is recommended that when healthcare workers and visitors are required to wear medical masks for full shifts/visits, they should "discard them in the nearest no-touch waste receptacle". This guidance included IPC considerations within a SARS-CoV-2 context. The guidance is specific to acute settings and mirrors the guidance within the wider published guidance from the Canadian Government suggesting masks should be disposed of in a non-touch waste receptacle. **Limitations:** It is not clear if the updates section of this guidance represents current recommendations, or if this section exists for reader's information. Similar wording is used throughout the document, providing further confusion.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Government of Canada. Infection prevention and control for COVID-19: Interim guidance for outpatient and ambulatory care settings	Guidance/Expert opinion	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Updated and re-posted 16 June 2021 Last modified 25 January 2022 Last accessed 25 January 2023					

Assessment of evidence

This Canadian interim guidance aimed to provide interim COVID-19 guidance related to IPC,, to be considered in conjunction with the Canadian Government's Omicron variant guidance, which does not make any specific reference to disposal of face masks. It is specific to outpatient and ambulance settings. The guidance is broadly in line with acute and long-term care guidance. Outpatient and ambulatory care settings should also refer to provincial, territorial and local policies which may differ depending on local epidemiology.

Recommendations:

"All staff, visitors, and patients who are asked to wear a mask should be informed about the importance of performing hand hygiene prior to putting on, and after removing or touching their mask, to reduce the risk of self-contamination, and of clean handling and storage of masks."

"They should also be informed about the steps for proper hand hygiene, and be provided with access to a dedicated hand hygiene sink with soap or alcohol-based hand rub (ABHR), and a no-touch waste receptacle for proper disposal of the mask." This recommendation is included under the heading "Access points".

Recommendations:

SARS-CoV-2 variants of concern:

"As noted in previous guidance, a foundational concept in IPC practice is that disposable medical masks should not be re-worn." This point is not repeated throughout the guidance, but the "Handling patient care equipment" section does highlight that single-use disposable equipment should be used if possible and disposed of into a no-touch waste receptacle "immediately after use".

Assessment of evidence
IPC preparedness, actions for outpatient and ambulatory care setting operators: “Respiratory hygiene products (e.g., medical masks, tissues, ABHR, no-touch waste receptacles) are available and easily accessible to staff, patients, and visitors” “Patient (and essential companion) screening and management at presentation”: It is stated that a no-touch waste receptable should be available outside patient exam rooms Full shift/visit masking/eye protection: “just prior to breaks or when leaving the facility, remove masks in an area where no patients, staff or visitors are present, and discard them in the nearest no-touch waste receptacle” This guidance included IPC considerations within a SARS-CoV-2 context. The guidance is specific to ambulatory and outpatient settings and mirrors the guidance within the wider published guidance from the Canadian Government suggesting masks should be disposed of in a non-touch waste receptacle, straight after use, and that these receptacles are readily available. **Limitations:** It is not clear if the updates section of this guidance represents current recommendations, or if this section exists for reader’s information. Similar wording is used throughout the document, providing further confusion.

Evidence from previous update(s):

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Coia JE, Ritchie L, Adisesh A, et al. Guidance on the use of respiratory and facial protection equipment.	Guidance/ Expert Opinion	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Journal of hospital Infection. 2013 Nov 1;85(3):170-82.					

Assessment of evidence

Methods: Coia et al., (2014) is a summary of Coia et al (2013) and Bunyan et al (2013) was the review that informed ref Coia et al (2013). Reference of interest is Coia 2013. Full references of supporting documents: Coia, et al. Use of respiratory and facial protection. 2014. Nursing Times. Vol 110 (4) p18-20. Coia, JE, et al, The Healthcare Infection Society Working Group on Respiratory and Facial Protection. Guidance on the use of respiratory and facial protection. Journal of hospital infection 85 (2013) 165-169. Bunyan D et al, Respiratory and facial protection: a critical review of recent literature. 2013. Journal of Hospital Infection. Vol 85 p165-169.

This expert consensus guidance provides guidance on surgical masks and respirators. It advises on the standards that both these types of masks should meet in the UK, when they should be worn, how they should be fit checked/tested if necessary and how they should be removed and disposed of. It refers to relevant health and safety/governmental legislation. This document specifies from the outset that the information provided is purely advisory guidance and is not a standard or a regulation. This differs from the legal obligations of employers and employees that are found within other OSHA documents such as the OSHA standards or the Occupational Safety and Health Act (OSH Act).

Within the do's and don't section the authors state:

DO: "Dispose of single-use eye protection, surgical face mask or FFP respirator immediately after removal and in accordance with local policy. Perform hand hygiene after removing PPE".

This expert opinion guidance suggests surgical masks should be disposed of immediately after use in a waster receptacle and this should be followed by hand hygiene. Caution is advised as this guidance was published in 2014 and some aspects may be out of date.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Department of Health and Health Protection Agency Pandemic influenza: Summary infection control guidance for ambulance services during an influenza pandemic. 2010	Guidance	**Level 4**	N/A	N/A	N/A
Assessment of evidence					
“discarded in an appropriate receptacle as clinical waste – hand hygiene must be performed after disposal is complete.”					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Association for Professionals in Infection control and Epidemiology (APIC), American Nurses Association, Association of Occupational Health Professionals in Healthcare	Poster	**Level 4**	N/A	N/A	N/A

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Association of periOperative registered nurses (AORN). Do's and don'ts for wearing procedure masks in non-surgical healthcare settings. 2015.					
Assessment of evidence					
A poster published by APIC 2015 regarding the ‘Dos’ and ‘Don’ts’ of wearing a ‘procedure’ mask. The authors state this is also referred to as an ‘isolation’ mask. And defines it as a “disposable mask that protects the wearer from droplets that might be infectious”. • Handle only by ear loops/ties. • Perform hand hygiene after removing and disposing a surgical mask.					

Question 13: How should surgical face masks be stored?

Evidence added to version 2.0 update:

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
National Health and Medical Research Council (NHMRC) Australian Guidelines for the Prevention and Control of Infection in Healthcare, 2019 2019 (revised 2024, v11.24) Accessed 11 October 2024	Guidance/ Expert opinion	**Level 4**	N/A	N/A	N/A
Assessment of evidence					
Aim: IPC guidance for Australian health and care settings. Target audience: Acute settings but the authors highlight transferability across settings. Methods: For this recommendation/guidance the methodologies for reviews are not provided and, except where references are given, guidelines seem to be formed from expert opinion. Recommendations are accompanied by a strength of evidence assessment, based on systematic review. The authors state that “It is [also] essential that all areas of the facility are designed to facilitate appropriate use of PPE. All rooms should have dedicated and accessible areas for storage of gowns, aprons, gloves, masks and protective eyewear.” (no reference provided). Australian IPC guidance inclusive of COVID-19 considerations but not specific to that setting. The guidance states that there should be dedicated, accessible areas for the storage of masks and other PPE.					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Government of Canada. Infection prevention and control for COVID-19: Interim guidance for long-term care homes Updated and re-posted 16 June 2021 Last modified 25 January 2022 Last accessed 24 January 2023	Guidance/ Expert opinion	**Level 4**	N/A	N/A	N/A

Assessment of evidence

This Canadian interim guidance aimed to provide interim COVID-19 guidance related to IPC to be considered in conjunction with the Canadian Government's Omicron variant guidance, which does not make any specific reference to storage of face masks. It is specific to long term care. The guidance is broadly in line with acute and outpatient/ambulance guidance.

PPE:

"All PPE (e.g., gloves, gowns, medical masks, N95 or equivalent respirators, eye protection) should be supplied in adequate amounts and sizes in all resident care areas, and placed so it is readily accessible at the point-of-care for all staff and visitors. Additional supplies of PPE should be stored in clean supply rooms that are clearly separated from any soiled utility areas."

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Government of Canada. Infection prevention and control for COVID-19: Interim guidance for acute healthcare settings Updated and re-posted 16 June 2021. Last modified 25 January 2022 Last accessed 24 January 2023	Guidance/ Expert opinion	**Level 4**	N/A	N/A	N/A
Assessment of evidence					
This Canadian interim guidance aimed to provide interim COVID-19 guidance related to IPC, to be considered in conjunction with the Canadian Government's Omicron variant guidance, which does not make any specific reference to storage of face masks It is specific to acute settings. PPE: "All PPE (e.g., gloves, gowns, medical masks, N95 or equivalent respirators, eye protection) should be supplied in adequate amounts and sizes in all patient care areas, and stored so it is readily accessible at the point-of-care for all HCWs and permitted visitors."					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Government of Canada. Infection prevention and control for COVID-19: Interim guidance for outpatient and ambulatory care settings Updated and re-posted 16 June 2021 Last modified 25 January 2022 Last accessed 25 January 2023	Guidance/ Expert opinion	**Level 4**	N/A	N/A	N/A
Assessment of evidence					
This Canadian interim guidance aimed to provide interim COVID-19 guidance related to IPC to be considered in conjunction with the Canadian Government's Omicron variant guidance, which does not make any specific reference to storage of face masks. It is specific to outpatient and ambulance settings. The guidance is broadly in line with acute and long-term care guidance. PPE: "All PPE (e.g., gloves, gowns, medical masks, N95 or equivalent respirators, eye protection) should be supplied in adequate amounts and sizes in all patient care areas, and placed so it is readily accessible at the point-of-care for all staff. Additional supplies of PPE should be stored in clean supply rooms that are clearly separated from any soiled utility areas."					

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Statutory Instrument. Personal Protective equipment (PPE) at work regulations from 06 April 2022. ISBN 978-0-34-823083-3. 2022.	Regulation	**Mandatory**	N/A	N/A	N/A

Assessment of evidence

2022 updates (previously 1992 regulations, PPER 1992) to PPE at work regulations -cite as PPER 2022. Relevant amendments are listed below, please note extension or clarification to working for “employer” and “workers” as well as extension to include limb (b) workers and updates to other references such as the updated COSHH regulations. These are not described in detail below but are highlighted as amended and required. Employers and employees must adhere to all aspects of PPE at work regulations, where appropriate.

It is stated that:

- Employers/self-employed should “ensure that any personal protective equipment provided to his employees is maintained (including replaced or cleaned as appropriate) in an efficient state, in efficient working order and in good repair”.
- “Where an employer or self-employed person is required, by virtue of regulation 4, to ensure personal protective equipment is provided, he shall also ensure that appropriate accommodation is provided for that personal protective equipment when it is not being used.”
- “Every employee and self-employed person who has been provided with personal protective equipment by virtue of regulation 4 shall take all reasonable steps to ensure that it is returned to the accommodation provided for it after use”
- “Every employee who has been provided with personal protective equipment by virtue of regulation 4(1) shall forthwith report to his employer any loss of or obvious defect in that personal protective equipment.”

Assessment of evidence
However it is noted that this is the 1992 wording and amendments in line with the 2022 update the legislation are outstanding and listed on the legislation.uk website here: The Personal Protective Equipment at Work Regulations 1992 (legislation.gov.uk) see here for changes to be implemented The Personal Protective Equipment at Work (Amendment) Regulations 2022 (legislation.gov.uk). Including changes to the wording and meaning of ‘employee’ (to worker) and pronouns.

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE) ACOP. Personal protective equipment at work. The Personal Protective Equipment at Work Regulations 1992 (as amended) Guidance on Regulations. (version 4). ISBN 9780717667468. 2022 (Fourth Edition) Accessed 17 October 2024	Guidance	**Level 4**	N/A	N/A	N/A
Assessment of evidence					
This document contains the “Approved Code of Practice (ACOP) for Health and safety regulations ‘ PPE at work’ for the UK. Health and safety guidance and interpretation of the health and safety at work regulations which were amended in April 2022. Within the maintenance section it states:					

Assessment of evidence
“PPE must be properly looked after and stored when not in use, for example in a dry, clean cupboard. If it is reusable it must be cleaned and kept in good condition”. “Think about: using the correct replacement parts, following the manufacturer’s replacement schedule keeping replacement PPE available who is responsible for maintenance and how they should do this”

Evidence from previous update(s):

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
UK Statutory Instrument Control of substances hazardous to health (COSHH). The Control of Substances Hazardous to Health Regulations 2002 (as amended).	Regulation	**Mandatory**	N/A	N/A	N/A

Assessment of evidence
Employers should ensure that PPE “is maintained in an efficient state, in efficient working order, in good repair and in a clean condition” **Regulation 9 (5), (6), and (7)** “Regulation 9 Maintenance, examination and testing of control measures (5) Every employer shall ensure that personal protective equipment, including protective clothing, is: a) properly stored in a well-defined place;

Assessment of evidence
b) checked at suitable intervals; and c) when discovered to be defective, repaired or replaced before further use. (6) 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) The employer shall ensure that the equipment referred to in paragraph (6) is subsequently decontaminated and cleaned or, if necessary, destroyed"

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure
Health and Safety Executive (HSE). Control of Substances Hazardous to Health L5 6th Edition. Guidance. 2013.	Regulation and Guidance	**Level 4**	N/A	N/A	N/A
Assessment of evidence					
This document contains the "Approved Code of Practice (ACOP) to the Control of Substances Hazardous to Health Regulations 2002 (as amended) (COSHH) and covers all substances to which the Regulations apply.". It provides guidance produced to assist with understanding of the COSHH regulations: "198 Employers should ensure that accommodation is provided for PPE so that it can be safely stored or kept when it is not in use... The storage should be adequate to protect the PPE from contamination, loss or damage by, for example, harmful substances, damp or sunlight."					