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Surgical Face Masks Literature Review

Considered Judgement Forms

Version 1.0

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

Version history

Version	Date	Summary of changes
1.0	3 August 2026	First version

Approvals

Version	Date Approved	Group/Individual
1.0	April 2026	National Policies Evidence and Guidance (NPGE) Working Group, Care Home Infection Prevention and Control Working Group (CHIPC), Extraordinary Transmission-based Precautions (TBP) Definitions Working Group (for research question 5 only).

Contents

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

A Quality of evidence

1.1 How reliable is the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4)

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels. If there is insufficient evidence to answer the key question, go to section B.

Comments	Evidence level
Nine documents are included for this research question: • Five regulations graded mandatory. These include the UK Health and Safety at Work Act 1974,[1] the Medical Device Directive Regulations	5 x Mandatory 4 x SIGN 50 Level 4, expert opinion

Comments	Evidence level
(MDD/93/42/EEC),[2] the UK PPE at Work Regulations (PPER),[3] the UK COSHH regulations,[4] and one EU directive (2016/425).[5] • One British Standard[6] graded SIGN 50 level 4 expert opinion based on a lack of detail on the methods utilised to produce these standards. • Three guidance documents[7-9] graded SIGN 50 level 4 expert opinion, one published by the UK HSE to accompany PPE at work regulations.[7] The predominance of standards and legislation over primary research studies is expected and appropriate for this research question. Level 4 guidance is potentially subject to bias as there is often a lack of supporting evidence and an unclear methodology for formulating the guidance.	

1.2 Is the evidence consistent in its conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments
IPC Specific Regulations There are no legislative or other requirements specific to the use of a surgical face mask specifically for infection control purposes (IPC). Relevant, non-IPC specific, legislation includes: the Health and Safety at Work etc. Act (1974),[1] the Control of Substances Hazardous to Health (COSHH) 2002 Regulations (as amended),[4] and the Personal Protective Equipment at Work (Amendment) Regulations (PPER) 2022.[3] **Surgical Face Masks as PPE:** There is some consistency in the included legislation regarding the definition of PPE, with all providing definitions that appear to be inclusive of surgical face masks when they are worn for personal protection:

Comments

- The (mandatory) UK PPER states: “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”.[3]
- The definition of PPE provided by the (mandatory) COSHH Regulations (as amended) defines PPE as “all equipment (including clothing) which is intended to be worn or held by a person at work and which protects that person against one or more risks to his health, and any addition or accessory designed to meet that objective” (Regulation 2).[4] This appears to align with surgical face masks being worn to protect from hazards to health such as exposure to infectious materials. The regulations may apply to employees and others in the health and care setting, where appropriate risk is identified (see regulations for more detail on scope).
- The updated EU Directive 2016/425 for PPE at work 2018 does not list surgical face masks or similar within their list of PPE to which the regulation does not apply (Article 2, Scope).[5] Within this directive, PPE is defined as “equipment designed and manufactured to be worn or held by a person for protection against one or more risks to that person's health or safety” (Article 3, Definitions). This appears to cover surgical face masks when being worn as personal protection.

There is inconsistency in SIGN 50 level 4 UK guidance regarding the status of surgical face masks as PPE:

- The UK Health and Safety Executive (HSE) guidance does not provide clarity regarding the status of surgical face masks as PPE, and these are not listed as PPE within their guidance.[10]
- UKHSA guidance describes surgical face masks as PPE when worn for wearer protection.[9]

Based on the cited legislation, surgical face masks, worn as protection (for example from splash or spray of blood or body fluids) do meet the definition of PPE.

Surgical face masks as medical devices

Surgical masks are described as a medical device (Class I) when worn to protect a patient and therefore subject to mandatory Medical Device Regulations (2002).[2, 9]

In summary, multiple legislations are considered applicable to the use of surgical face masks as PPE in health and care settings. It is clear that medical device legislation also applies to medical masks. It would appear that surgical face masks

Comments
worn for personal protection meet the definition of PPE that is provided by the included legislation. Therefore, the evidence is considered sufficient to support a recommendation for adherence to PPER and other relevant legislation including medical device directives and COSHH. **British Standards** One British Standard (SIGN 50 level 4) details testing requirements for surgical face masks.[6] • The standards allow for the testing of bacterial filtration efficiency (BFE) for inward or outward air flow however it is unclear if manufacturers regularly test both directions and therefore it is unclear whether masks meeting these standards would be compliant with standards for bacterial filtration efficacy with regards to source control, protection of the wearer or both. The standards have a focus on source control. • Specific standards related to surgical face masks are listed within an appendix of the literature review. Standards and legislation should be read in full and are not described in full in this review.

1.3 Is the evidence applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include interventions, comparators or outcomes that are common to Scottish health and care settings?

Comments
The British Standards and UK legislation included for this research question are directly applicable to Scottish health and care settings. The UK legislation is general and not specific to IPC within health and care settings.

1.4 Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
Not applicable as no primary research studies were included.

1.5 Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
The risk of publication bias is expected to be low as this research question focused on standards and legislation.

B Evidence to decision

1.6 Recommendation

What Recommendation(s) or Good Practice Point(s) are appropriate based on this evidence?

Note the following terminology:

- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance
- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present
- **"should consider"** implies that the health and care setting should consider implementing the recommended approach

Recommendation	Grading
R1.1 All UK legislation that is relevant to surgical face mask use (used for personal protection and for source control) must be adhered to, including the PPER, COSHH, the Health and Safety at Work etc. Act and the Medical Device directive (MDD/03/42/EEC).	Recommendation
GPP1.1 Those procuring surgical face masks for use in Scottish health and care settings should ensure the masks are compliant with the relevant standards (listed in appendix 3 of the literature review).	Good Practice Point

1.7 Balancing benefits and harms

Comment here on the potential impact of the Recommendation/Good Practice Point on service users, visitors, and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation/Good Practice Point were followed. Be explicit, clear about pros.

Benefits
R1.1 Adherence to current legislation and regulations supports compliance with associated corporate and social governance responsibilities, including the legal requirements of applicable health and safety measures. GPP1.1 Adhering to industry standards promotes uniformity of the surgical face masks being purchased. GPP1.1 Adhering to industry standards provides an assurance for the organisation and user of the quality of the surgical face mask being provided.

Risks and Harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation/Good Practice Point were followed correctly. Be explicit, clear about cons.

Risks/Harms
R1.1 and GPP1.1 – none identified.

Benefit-Harm assessment

Classify as “benefit outweighs harm” (or vice versa) or a “balance of benefit and harm.” Description of this balance can be from the individual service user/staff/visitor perspective, the societal perspective, or both. Recommendations/Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events (or vice versa).

Benefit-Harm assessment
R1.1 - Only benefits identified. GPP1.1 - Only benefits identified.

1.8 Feasibility

Is the Recommendation/Good Practice Point implementable in the Scottish context?

Describe (if applicable) financial implications, opportunity costs, material or human resource requirements, facility needs, sustainability issues, human factors etc., that may be associated with following a Recommendation/Good Practice Point. State clearly if information on feasibility is lacking.

Feasibility
R1.1 and GPP1.1 Adherence with relevant legislation and standards, aligns with current practice, but there may be ongoing training requirements to ensure that all staff responsible for procurement of surgical face masks are aware of the relevant standards and legislation.

1.9 Expert Opinion

Summarise the expert opinion used in creating the Recommendation/Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining that expert opinion helps users understand their influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
R1.1 -The evidence (mandatory legislation) is considered sufficient to support a recommendation for adherence to PPER and other relevant legislation including medical device directives and COSHH. It is the working group’s opinion that the definitions of PPE provided within the identified legislation appear consistent with surgical face masks being used for personal protection of a wearer. It is also the

working group's view that legislation related to surgical face masks must be complied with in full, and that complying to legislation designed to maintain safety in the workplace should be considered as best practice even where legality is unclear.

GPP1.1 - British, European and International standards (graded SIGN 50 level 4)[6] are considered best practice in UK industry settings, therefore ARHAI Scotland and the working group support that surgical face masks being purchased for Scottish health and care settings adhere to these standards.

1.10 Value judgements

Summarise value judgements used in creating the Recommendation/Good Practice Point; if none were involved, state "none". Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other beliefs and priorities. Clearly outlining value judgements helps users understand their influence on interpreting objective evidence.

Value judgements
R1.1 and GPP1.1 – None to note.

1.11. Intentional vagueness

State reasons for any intentional vagueness in the Recommendation/Good Practice Point; if none was intended, state "none". Recommendations/Good Practice Points should be clear and specific, but if there is a decision to be vague, acknowledging the reasoning clearly promotes transparency. Reasons for vagueness may include inadequate evidence; inability to achieve consensus regarding evidence quality, anticipated benefits/harms, or interpretation of evidence; legal considerations; economic reasons; ethical/ religious reasons.

Intentional vagueness
R1.1 and GPP1.1 – None to note.

1.12 Exceptions

List situations or circumstances in which the Recommendation/ Good Practice Point should not be applied.

Exceptions

R1.1 and GPP1.1 – None to note.

1.13 Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
Expansion of standards pertaining to surgical face masks being used as protection against various infectious particles would be beneficial. Specifically, expansion of the standards to include some additional testing requirements that better mimic exposure risks within real-world settings, where surgical masks are used for source control and personal protection.

Research question 2: What is a surgical face mask?

A Quality of evidence

2.1 How reliable is the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4)

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is insufficient evidence to answer the key question, go to section B.

Comments	Evidence level
Six documents are included to answer this research question: • one guideline (UK EPIC3 guidelines) graded AGREE II 'recommend with provisos'.[11] Limitations included a lack of rigour of development of the guideline, and no update since 2014. • one British Standard, graded SIGN 50 level 4 expert opinion[6]	1 x AGREE II 'Recommend with provisos' 5 x SIGN 50 Level 4, expert opinion

Comments	Evidence level
• four guidance documents graded SIGN 50 level 4 expert opinion.[8, 9, 12, 13] This type of evidence is potentially subject to bias as there is often a lack of supporting evidence and an unclear methodology for formulating the guidance.	

2.2 Is the evidence consistent in its conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments
The literature refers interchangeably to medical, surgical and procedure face masks when referring to surgical face masks. The difference(s) between these (if any) were not well described within the included literature.[6, 8, 9, 12, 13] There was some consistency that a surgical face mask can be described as providing a physical barrier covering the nose and mouth and which should be closely fitted to the face. Definitions suggest a surgical face mask is: • single use[12] • consisting of multiple layers of fabric,[6] • fitted closely to the face,[6] to cover the nose and mouth[6, 11, 12] with a flat or pleated design with straps (elastic loops or ties) which are secured via the head, ears or both.[6, 13]

2.3 Is the evidence applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include interventions, comparators or outcomes that are common to Scottish health and care settings?

Comments
The country or countries in which the guidance was written and/or applies to are as follows: • UK (n=3)[6, 9, 11]

Comments
• US (n=1)[8] • Australia (n=1)[12] • International (n=1)[13] One document was published by the World Health Organization (WHO) and therefore applies internationally.[13] Although two of the guidance documents were published during the SARS-CoV-2 pandemic response, the general descriptions of surgical masks are high level and are applicable to non-pandemic periods.[9, 13] Applicability is not a concern for this research question because the aim is to outline how surgical masks are described in the literature.

2.4 Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
There were no primary studies included therefore generalisability is not applicable.

2.5 Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
Definitions for surgical face masks appear well established, and therefore publication bias is not a concern.

B Evidence to decision

2.6 Recommendation

What Recommendation(s) or Good Practice Point(s) are appropriate based on this evidence?

Note the following terminology:

- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance
- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present
- **"should consider"** implies that the health and care setting should consider implementing the recommended approach

Recommendation	Grading
This research question aimed to outline how surgical face masks are currently described within the literature. It therefore does not have any associated recommendations or good practice points.	Not applicable.

2.7 Balancing benefits and harms

Comment here on the potential impact of the Recommendation/Good Practice Point on service users, visitors, and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation/Good Practice Point were followed. Be explicit, clear about pros.

Benefits
Not applicable.

Risks and Harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation/ Good Practice Point were followed. Be explicit, clear about cons.

Risks/Harms
Not applicable.

Benefit-Harm assessment

Benefit-Harm assessment
Not applicable.

2.8 Feasibility

Is the Recommendation/Good Practice Point implementable in the Scottish context?

Describe (if applicable) financial implications, opportunity costs, material or human resource requirements, facility needs, sustainability issues, human factors etc., that may be associated with following a Recommendation/Good Practice Point. State clearly if information on feasibility is lacking.

Feasibility
Not applicable.

2.9 Expert opinion

Summarise the expert opinion used in creating the Recommendation/Good Practice Point. If none were involved, state “none”. Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining that expert opinion helps users understand their influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
Not applicable.

2.10 Value judgements

Value judgements
Not applicable.

2.11 Intentional vagueness

Intentional vagueness
Not applicable.

2.12 Exceptions

List situations or circumstances in which the Recommendation/Good Practice Point should not be applied.

Exceptions
Not applicable.

2.13 Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
None to note.

Research question 3: What type of surgical face masks are recommended for health and care settings?

A Quality of evidence

3.1 How reliable is the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4)

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is insufficient evidence to answer the key question, go to section B.

Comments	Evidence level
Fourteen documents are included for this research question: • One legislative document, UK PPER, graded mandatory.[3] • Two guidelines graded AGREE II 'recommend with provisos'.[11, 14] Both guidelines had several limitations including a lack of rigour and being published over 10 years ago, meaning they may be out of date. • One BS EN standard (BS EN 14683:2025), graded SIGN 50 level 4 expert opinion.[6] • Ten guidance documents, graded SIGN 50 level 4 expert opinion.[10, 13, 15-22] The evidence base for this research question is generally low quality, consisting mainly of SIGN 50 level 4 expert opinion guidance, which has a high risk of bias related to their applied methodology. There were no high-quality primary studies identified which compared surgical mask types in relevant health and care settings.	1 x Mandatory 2 x AGREE II 'Recommend with provisos' 11 x SIGN 50 Level 4, expert opinion

3.2 Is the evidence consistent in its conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments

There is a lack of consistency within the evidence base (n=11 SIGN 50 level 4, n= 2 AGREE II 'recommend with provisos' and n=1 legislation) regarding the type of surgical face mask that should be worn in health and care settings.

Standards

- The BSI standards (SIGN 50 level 4) for 'medical masks' provide definitions of Type I, Type II and Type IIR surgical face masks based on the level of protection (bacterial filtration efficiency (BFE), and fluid-resistance).[6]
    - According to the BSI, Type I (≥95% BFE, non-fluid resistant) surgical face masks may be appropriate for use by patients and other persons for the purpose of source control during epidemic and pandemic situations but would not be considered appropriate for use by staff during surgical procedures for source control (and presumably for protection against splash and spray although this is not explicitly stated).[6] However, it is stated in Annex E that future revisions of this standard do not intend to refer to Type I surgical face masks.
    - The BSI standard does not provide explicit advice on the use of Type II and Type IIR in healthcare settings.

Legislation

- UK PPER (2022) (mandatory) indicates that "suitable" levels of protection should be provided.[3] The accompanying approved code of practice (ACOP) guidance (SIGN 50 level 4) provided by the UK HSE advises that the "maximum" level of protection be provided for the expected risk, while ensuring minimum discomfort to the wearer.[10] This suggests that where a surgical face mask is used, it should have the highest protection factor available, while considering the discomfort to the wearer, which would be a Type II or IIR surgical face mask.

Comments

Extant guidance regarding fluid resistance:

There is variation in extant guidance (one AGREE II 'recommend with provisos' guideline,[11] 3 SIGN 50 level 4 guidance)[13, 20, 21] regarding the requirement for a surgical mask to be fluid resistant, in part due to the indications for use:

- New Zealand guidance advises fluid resistant masks for all splash and spray producing procedures and 'droplet precautions' and states that non-fluid resistant masks are suitable for source control; either type are advised where protection of the sterile field from healthcare worker exhalations is required.[21]
- The UK EPIC3 guidelines (AGREE II 'recommend with provisos') recommend fluid resistant masks for splash and spray protection and for source control (although only the splash and spray element is a formal recommendation).[11]
- Guidance from the Association of Anaesthetists of Great Britain and Ireland (AAGBI) (SIGN 50 level 4) advise fluid resistance for surgical masks (all patients) as standard precautions.[20]
- Type IIR surgical face masks are recommended by one WHO document (SIGN 50 level 4)[13] that advises fluid resistant Type II or equivalent surgical face masks for the treatment of SARS-CoV-2 patients.

Unclear specification

- One guideline graded AGREE II 'recommend with provisos' did not provide a clear indication of the most appropriate type of mask or level of fluid resistance.[14] Four SIGN 50 guidance, although advising that surgical face masks should provide a physical barrier (for example to protect the wearer from contamination splashes/sprays or similar from blood and body fluids) do not specify a specific type.[17-19, 22]

Transparent face masks:

- One Canadian technical specification (SIGN 50 level 4) recommends that transparent surgical face masks may be worn in health and care settings where they may benefit communication or facial recognition.[15]
- The BSI medical mask standards refer to transparent masks within Annex F of the 2025 revision.[6] The document states that transparent masks support communication and should meet the standards outlined to provide similar protection to Type IIR medical masks (per that document).

3.3 Is the evidence applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include interventions, comparators or outcomes that are common to Scottish health and care settings?

Comments
The country or countries where the guidance was published or to which the guidance applies are as follows: • UK (n=8)[3, 6, 10, 11, 16, 17, 20, 23] • US (n=2)[18, 19] • Canada (n=1)[15] • New Zealand (n=1)[21] • International (n=2)[13, 14] Non-UK guidance may have less applicability to Scottish health and care settings due to possible differences in care provision, mask specifications and policy.

3.4 Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
As primary research was not included, the generalisability of the findings presented is not relevant.

3.5 Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
A formal assessment of publication bias was not conducted. However, a degree of publication bias is expected given the level of expert opinion guidance as well as a lack of high-quality primary studies and unclear non-published data.

B Evidence to decision

3.6 Recommendation

What Recommendation(s) or Good Practice Point(s) are appropriate based on this evidence?

Note the following terminology:

- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance
- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present
- **"should consider"** implies that the health and care setting should consider implementing the recommended approach

Recommendation	Grading
GPP3.1 Surgical face masks required for use in health and care settings to provide personal protection should be Type IIR as per BS EN 14683:2025.	Good Practice Point
GPP3.2 Surgical face masks required for use in health and care settings to provide source control should be Type II or Type IIR as per BS EN 14683:2025.	Good Practice Point
GPP3.3 When there are communication barriers due to mask use in health and care settings, transparent surgical face masks (that meet the specifications of BS EN 146833:2025) should be used.	Good Practice Point

3.7 Balancing benefits and harms

Comment here on the potential impact of the Recommendation/Good Practice Point on service users, visitors, and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation/Good Practice Point were followed. Be explicit, clear about pros.

Benefits
GPP3.1 The use of a surgical face mask that provides fluid resistance in alignment with the BSI standards will provide the greatest protection to the wearer. Currently a Type IIR mask provides the greatest protection factor combined with fluid resistance. Type II masks are not fluid resistant, and Type I masks have a lower bacterial filtration efficiency than Type II. GPP3.1 The selection of the highest level of protection (fluid resistance and bacterial efficiency as per that offered by a Type IIR) promotes a safety culture that values the minimisation of occupational risks. GPP3.2 Having the option of two types of surgical face masks for source control (type II and type IIR) may allow for periods of extended mask use or pandemic preparedness where mask shortages could result in reduced supply of Type IIR masks. GPP3.3 Procuring transparent surgical face masks which meet the same standards and specifications outlined for Type IIR assures the same level of personal protection is provided for the mask wearer as that provided by a type IIR non-transparent mask. GPP3.3 Transparent surgical face masks may help to prevent communication barriers, support an individual's ability to understand and interpret (via lip reading and facial expression), and may minimise suboptimal patient experiences and unintentional distress. GPP3.3 The use of a transparent surgical face mask that meets the BS EN standards provides assurance that suitable protection is provided.

Risks and Harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation/Good Practice Point were followed. Be explicit, clear about cons.

Risks/Harms
GPP3.1 There are no anticipated risks or harms. GPP3.2 It is possible that a non-fluid resistant mask is incorrectly selected where fluid resistance is required. This could occur where there are multiple surgical mask types available and the different types are not clearly denoted or separated

Risks/Harms
to support correct selection. This could result in use of a suboptimal mask and therefore suboptimal protection for the wearer. GPP3.3 There are no anticipated risks or harms.

Benefit-Harm assessment

Classify as “benefit outweighs harm” (or vice versa) or a “balance of benefit and harm.” Description of this balance can be from the individual service user/staff/visitor perspective, the societal perspective, or both. Recommendations/ Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events (or vice versa).

Benefit-Harm assessment
GPP3.1 Only benefits identified. GPP3.2 The working group considered the provision of type II masks an appropriate addition to the overall stock provision in a facility where they would be suitable for scenarios where fluid resistance isn’t required (some sterile procedures, source control during extended mask use in epidemic or pandemic situations) The risk of incorrect mask selection of a type II where a type IIR is required can be mitigated by careful separation/ labelling/ storage. Consequently, the group agreed that the benefits outweigh the risks. GPP3.3 Only benefits identified.

3.8 Feasibility

Is the Recommendation/Good Practice Point implementable in the Scottish context?

Describe (if applicable) financial implications, opportunity costs, material or human resource requirements, facility needs, sustainability issues, human factors etc., that may be associated with following a Recommendation/Good Practice Point. State clearly if information on feasibility is lacking.

Feasibility
GPP3.1, GPP3.2, GPP3.3 There will remain ongoing costs associated with the continual procurement of surgical face masks. At the time of writing, the cost per Type IIR surgical mask was 1 penny via national procurement, significantly lower than a Type II mask (2.5 pence). GPP3.3 The initial stock requirements, outlay and cost associated with provision of transparent masks are currently difficult to quantify.

Feasibility
GPP3.3 It is currently possible to procure transparent face masks that are of a suitable quality (that meet the requirements outlined in the BS EN standards). GPP3.2 There may be additional resource implications (for example training, storage facilities, and the provision of support to enable appropriate mask selection) where several mask types are procured for use within health and care settings.

3.9 Expert opinion

Summarise the expert opinion used in creating the Recommendation/Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining expert opinion helps users understand their influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
GPP3.1 [Surgical face masks required for use in health and care settings for personal protection should be Type IIR as per BS EN 14683:2025]. • This good practice point is informed by the mandatory UK PPER (2022) which indicates that “suitable” levels of protection should be provided[3] and the accompanying HSE approved code of practice (ACOP) guidance (SIGN 50 level 4) that advises that the “maximum” level of protection be provided for the expected risk, while ensuring minimum discomfort to the wearer.[10] The Working Group have interpreted this to mean that where a surgical face mask is used, it should have the highest protection factor available, while considering the discomfort to the wearer, which would be a Type II or IIR surgical face mask. • Both Type II and Type IIR provide the same bacterial filtration efficiency (BFE) of ≥95%. Type IIR provide fluid resistance, which is an additional element of protection for the wearer. Consequently, the Working Group concluded that a Type IIR would provide the highest level of protection to the wearer when used for personal protection. This aligns with one AGREE II ‘recommend with provisos’ guideline,[11] and three SIGN 50 level 4 guidance[13, 20, 21] that advise fluid resistance for splash and spray/standard precautions/‘droplet’ protection. • Although mandatory legislation (UK PPER 2022) was included, a recommendation did not result as the UK PPER instruction (provision of “suitable” levels of protection) is vague and required interpretation and the

Expert opinion

addition of supplementary instruction which is informed predominantly by SIGN 50 level 4 evidence.

GPP3.2 Surgical face masks required for use in health and care settings to provide source control should be Type II or Type IIR as per BS EN 14683:2025.]

- This GPP is informed by BS EN 14683:2025 which states that Type I (≥95% BFE, non-fluid resistant) surgical face masks may be appropriate for use by patients and other persons for the purpose of source control during epidemic and pandemic situations but should not be considered for use by staff during surgical procedures for source control (and presumably for protection against splash and spray although this is not explicitly stated).[6] This means that staff would require a Type II or Type IIR mask where source control is required. Further, it is stated in Annex E that future revisions of the standard do not intend to refer to Type I surgical face masks.
- Extant guidance is inconsistent; one SIGN 50 level 4 guidance advises that a non-fluid resistant mask is suitable for source control and that either type (fluid resistant or non-fluid-resistant) can be used where protection of the sterile field from healthcare worker exhalations is required.[21] The UK Epic3 guideline (AGREE II 'recommend with provisos') advises fluid resistant masks for source control although this is not a formal recommendation within the guideline.[11] The Working Group acknowledged there may be benefits to specifying only Type IIR for source control, as it would align with GPP3.1 with the subsequent benefit of having only one type of mask (Type IIR) available in healthcare settings. This could reduce the risk of incorrect mask selection (for example, the incorrect selection of Type II where Type IIR is required for personal protection).
- The risk of incorrect mask selection can be reduced by appropriate stock control, storage, and training. Further, provision of both types may support stock provisions and provide resilience during situations where there is an increase in mask use; having Type II available may allow for the prioritisation of Type IIR surgical face masks where required for care provision. The use of a Type II mask where there is not any anticipated need for personal protection does not go against legislation as the UK PPER 2002 is specific to the provision of 'suitable protection'. Whilst the working group agreed the benefits outweigh the harms, the GPP allows for choice of either type, and an element of local decision making.

GPP3.3 [When there are communication barriers due to mask use in health and care settings, transparent surgical face masks (that meet the specifications of BS EN 146833:2025) should be used].

Expert opinion
• This GPP is informed by two SIGN 50 level 4 documents (one British Standard, one guidance) that are consistent in advising that transparent masks may benefit communication or facial recognition.[6, 15] The British Standard in Annex F outlines that such masks should meet the standards as outlined to provide similar protection to Type IIR medical masks. The Working Group are supportive of the use of transparent surgical face masks, as detailed further in 3.10 'value judgements'.

3.10 Value judgements

Summarise value judgements used by the Working Group in creating the Recommendation/Good Practice Point; if none were involved, state "none". Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other beliefs and priorities. Stating them clearly helps users understand their influence on interpreting objective evidence.

Value judgements
GPP 3.1 None to note. GPP3.2 None to note. GPP3.3 When non-transparent face masks are worn in health and care settings there may be negative implications for service users including an experience of distress due to the mask preventing lip reading, hiding facial expression and reducing the volume of speech of the wearer. This can prevent communication and is inequitable for service users that have impaired hearing. Transparent masks may support communication in certain circumstances and reduce distress both for the mask user and/or the person(s) with whom they are communicating. The working group agreed that the provision of transparent masks aligns with the NHS Scotland principles of person-centred care.

3.11 Intentional vagueness

State reasons for any intentional vagueness in the Recommendation/Good Practice Point; if none was intended, state "none". Recommendations/Good Practice Points should be clear and specific, but if the Working Group chooses to be vague, acknowledging their reasoning clearly promotes transparency. Reasons for vagueness may include inadequate evidence; inability to achieve consensus among panel regarding evidence quality, anticipated benefits/harms, or interpretation of evidence; legal considerations; economic reasons; ethical/ religious reasons.

Intentional vagueness
GPP3.1, GPP3.2, GPP3.3 None to note.

3.12 Exceptions

List situations or circumstances in which the Recommendation/ Good Practice Point should not be applied.

Exceptions
GPP3.1, GPP3.2, GPP3.3 None to note.

3.13 Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
While there is no included primary research of sufficient quality that assesses whether there is a difference in the protection offered by different mask types (Type I, Type II, Type IIR), the nature of the exposure may be better explored in a controlled setting. The current tests used by the BSI standards for surgical masks could be improved to better mimic the real-life clinical exposure across a range of particle sizes and a range of infectious agents that are typical of health and care settings. It may also be beneficial to understand if there are any difficulties with transparent surgical face masks meeting the current BSI standards.

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

A Quality of evidence

4.1 How reliable are the studies in the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4)

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is insufficient evidence to answer the key question, go to section B.

Comments	Evidence level
Four documents are included for this research question: • One experimental study graded SIGN 50 level 3[24] • Two guidance documents graded SIGN 50 level 4[15, 25] • One British standard graded SIGN 50 level 4[6] The evidence base for this research question is generally low in quantity and quality, consisting of one SIGN 50 level 3 observational study with a small sample size, and three SIGN 50 level 4 expert opinion guidance. Guidance of this type is at risk of bias due to the methodology and lack of supporting evidence. It is not possible to say with certainty from this evidence whether the features identified will be of benefit and for whom they may benefit.	1 x SIGN 50 Level 3 3 x SIGN 50 Level 4, expert opinion

4.2 Are the studies consistent in their conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments

There was a lack of consistency in the included evidence with regards to the design features desirable for a surgical face mask. The below features were described:
• Nose clips/wire
  ○ The British Standards Institute (BSI) (SIGN 50 level 4) highlights that a surgical face mask fit may be enhanced with a nose clip/wire which contours the mask around the nose.[6]
  ○ One experimental study (SIGN 50 level 3) demonstrated that surgical face masks with a nose wire provided significantly better protection (inward leakage) compared to when a nose wire was not used.[24]
• Anti-fog
  ○ BSI advise that anti-fog functions may be relevant for some settings.6
• Labelling
  ○ In addition to elements such as good breathability, particle filtration and fluid resistance, the WHO (SIGN 50 level 4) recommend that the mask be clearly labelled as to the inner and outer surfaces.[25]
• Ear-loop/ties
  ○ The use of loops or ties as a method to secure a surgical face mask and in relation to IPC is not well addressed within the literature.
• Transparency
  ○ Guidance from the Canadian Government (SIGN 50 level 4) describe transparency feature of transparent face masks, usually made of plastic, as well as other design features for transparent masks such as a foam strip or other material to facilitate fit to the wearer's face.[15]

4.3 Are the studies applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include similar target populations, interventions, comparators, or outcomes as those common to Scottish health and care settings?

Comments
The country or countries in which the guidance/research was published and/or applies to are as follows: • UK (n=1)[6] • International (n=1)[25] • Canada (n=1)[15]

Comments
• Japan (n=1)[24] The BSI standards apply to Scottish health and care settings. The applicability of the one primary study, graded as SIGN 50 level 3, was considered as limited.[24] Applicability was impacted by several factors including use of N95 duckbill masks as a comparator (not recommended for use within the UK), fixed experimental conditions (lack of applicability to real world settings), no unmasked control, only one type of surgical mask and it was unclear if this would meet BSI standards for the UK.

4.4 Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. For example, if all the studies include adults only, their findings may not be generalisable to neonates.

Comments
There was one included primary study which had limited generalisability.[24] Limitations included a small sample size (n= 54) which may not have representativeness of different facial shapes and sizes.

4.5 Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
A formal analysis of publication bias was not conducted. However, it is recognised that there may be publication bias which led to the non-publication of primary studies regarding desirable features for surgical face masks which were not published, for example based on non-significant results.

B Evidence to decision

4.6 Recommendation

What Recommendation(s) or Good Practice Point(s) does the Working Group agree are appropriate based on this evidence?

Note the following terminology:

- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present.
- **"could consider/may consider"** implies that the health and care settings could consider implementing the recommended approach.
- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance.

Recommendation	Grading
GPP4.1 When selecting or procuring surgical face masks, preference should be given to masks that have an integral nose clip or wire to ensure a good fit.	Good Practice Point
GPP4.2 When selecting or procuring surgical face masks, preference should be given to masks that have an easily identifiable inner and outer surface.	Good Practice Point
GPP4.3 When selecting or procuring surgical face masks, masks with ear loops or ties can be selected.	Good Practice Point

4.7 Balancing benefits and harms

Comment here on the potential impact of the Recommendation/Good Practice Point on service users, visitors and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation/Good Practice Point were followed. Be explicit, clear about pros.

Benefits
GPP4.1 A surgical face mask which enables a closer fit (which the nose clip or wire is anticipated to provide) may increase the masks' protective properties. GPP4.1 A nose wire may provide additional comfort to the wearer and is likely to minimise fogging of spectacles or eye wear. GPP4.2 Surgical face masks with an easily identifiable inner and outer surface may support the user to correctly don (put on), wear and doff (take off). GPP4.3 Provision of both types of surgical face mask (those with ear loops or ties) increases the likelihood that a mask can be securely fitted to the face, accounting for variation in the size of the wearers face (for example distance between ears and chin) and any variation in ear size, shape or presence.

Risks and Harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation/Good Practice Point were followed. Be explicit, clear about cons.

Risks/Harms
GPP4.1 Mask users may experience discomfort and/or skin irritation or abrasion if the nose wire is applied or conformed too tightly or there are prolonged periods of mask use. GPP4.2 No harms to note. GPP4.3 No harms to note.

Benefit-Harm assessment

Classify as "benefit outweighs harm" (or vice versa) or a "balance of benefit and harm." Description of this balance can be from the individual service user/staff/visitor perspective, the societal perspective, or both. Recommendations/Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events (or vice versa).

Benefit-Harm assessment
GPP4.1 Whilst there is a risk of abrasion or discomfort if nose clips or wires are fitted too tightly to the wearers face, it is anticipated that donning training and ongoing experience of donning this type of mask correctly may mitigate this risk. Discomfort due to prolonged mask use with a nose clip or wire could be mitigated by regular breaks. Consequently, the working group agreed that the benefits outweigh the harms.

Benefit-Harm assessment
GPP4.2 Only benefits identified. GPP4.3 Only benefits identified.

4.8 Feasibility

Is the Recommendation/Good Practice Point implementable in the Scottish context?

Describe (if applicable) financial implications, opportunity costs, material or human resource requirements, facility needs, sustainability issues, human factors etc., that may be associated with following a Recommendation/Good Practice Point. State clearly if information on feasibility is lacking.

Feasibility
GPP4.1 Nose wire/clip are integral and manufactured as standard within most fluid repellent surgical face masks. It is therefore not expected that this feature would encounter procurement difficulties or additional costs. GPP4.2 There are noticeable differences between the inner and outer surfaces of surgical face masks as standard with most brands (colour differences, a clear hem on the inside, a clear concave shape with obvious pleating) therefore there should be no issues with procurement. GPP4.3 There will be a requirement for those procuring surgical face masks to ensure sufficient stock levels of the types required/preferred by staff.

4.9 Expert opinion

Summarise the expert opinion used in creating the Recommendation/Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining expert opinion helps users understand their influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
GPP4.1 [When selecting or procuring surgical face masks, preference should be given to masks that have an integral nose clip or wire]. • Nose wires are considered as integral to most surgical face masks and their use is supported by the British standards (SIGN 50 level 4) for surgical masks.[6] One SIGN 50 level 3 experimental study indicated a benefit, although the sample size was small, and further research would be necessary to confirm this.[24] This evidence was considered insufficient for a recommendation. However, both ARHAI Scotland and the working group considered it good practice to select a surgical face mask with an integral

Expert opinion
nose wire to enhance the closeness of the masks fit. The risk of discomfort is likely to be low and should be mitigated by training and reminders for good donning practice and by taking regular breaks, when mask use is prolonged. GPP4.2. [When selecting or procuring surgical face masks, preference should be given to masks that have an easily identifiable inner and outer surface]. • This GPP is supported within one limited international guidance document, graded as SIGN 50 level 4.[25] This may ensure the mask is worn correctly as per manufacturer's instructions. Both ARHAI Scotland and the working group support the use of surface identification or a similar design feature on surgical masks to denote which is the intended inner and outer (fluid resistant) surfaces. GPP4.3 • There was no evidence available to assess ear loops versus ear ties. There were mixed views and no clear preference provided by stakeholders at consultation. Reasons for a preference for ear loops included that masks are easier and faster to don and doff, and that patients and service users are more likely to be able to wear masks with ear loops; masks with ties may become undone or may be incorrectly tied which can make doffing challenging. One reported downside related to the use of masks with ear loops was that they may become painful if worn for long durations. There is a requirement to provide for variation in the size of the wearers face including distance between ears and chin, and any variation in ear size, shape or presence. Eye wear/ spectacles may compromise the placement of ear loops. Ear loops may also dislodge hearing aids. • Consequently, the good practice point provides for either mask type to be selected.

4.10 Value judgements

Summarise value judgements used by the Working Group in creating the Recommendation/Good Practice Point; if none were involved, state "none".

Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other beliefs and priorities. Stating them clearly helps users understand their influence on interpreting objective evidence.

Value judgements
GPP 4.1, GPP 4.2, GPP4.3 None to note.

4.11 Intentional vagueness

State reasons for any intentional vagueness in the Recommendation/Good Practice Point; if none was intended, state “none”. Recommendations/Good Practice Points should be clear and specific, but if the Working Group chooses to be vague, acknowledging their reasoning clearly promotes transparency. Reasons for vagueness may include inadequate evidence; inability to achieve consensus among panel regarding evidence quality, anticipated benefits/harms, or interpretation of evidence; legal considerations; economic reasons; ethical/ religious reasons.

Intentional vagueness
GPP4.1, GPP4.2, GPP4.3 None to note.

4.12 Exceptions

List situations or circumstances in which the Recommendation/ Good Practice Point should not be applied.

Exceptions
GPP 4.1 Surgical face masks with an integral metal nose clip or wire would require to be risk assessed in any areas within which metal objects are not permitted, for example during MRI scanning. GPP4.2 None to note. GPP4.3 None to note.

4.13 Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
Desirable design features of surgical masks could be researched within higher-quality controlled or comparative studies which consider major confounding factors. The UK HSE published a safety notice regarding the use of respiratory protective equipment (RPE, respirators) which have ear loops as they were not considered to “provide protection as tightly fitting RPE”.[26] This safety notice is not applicable to surgical face masks which do not require to form a tight seal or have formal fit checks and assessments. However, it may indicate possible differences in the type of ties used and the associated closeness of fit of a surgical face mask. This may be a useful area for undertaking future research.

Research question 5: When should health and care workers wear a surgical face mask?

A Quality of evidence

5.1 How reliable are the studies in the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4)

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is insufficient evidence to answer the key question, go to section B.

Comments	Evidence level
Forty-one evidence sources are included for this research question: • Four guidelines published by WHO, Humphreys et al., and Loveday et al., graded as AGREE II 'recommend with provisos'.[11, 14, 27, 28] • Nine SIGN 50 level 3 experimental/ observational studies.[29-37] • Twenty-eight guidance documents graded SIGN 50 level 4 expert opinion.[12, 13, 16-21, 23, 38-56] ○ These documents did not report sufficient details of a rigorous systematic review process for developing their evidence-base. The following limitations are noted for the AGREE II (recommend with provisos) graded guidelines: • The WHO (2014) guidance is specific to epidemic/pandemic-prone respiratory illnesses.[14] The recommendations related to surgical face mask use were based on limited studies with a high risk of bias including those focused on community settings, bundled approaches, and flawed methodologies. The details regarding grading per included study are unclear. The procedure for guideline development was unclear,	4 x AGREE II 'Recommend with provisos' 9 x SIGN 50 Level 3 28 x SIGN 50 Level 4, expert opinion

Comments	Evidence level
as were the methods for systematic review and criteria for selecting evidence. • The WHO (2024) guideline is specific to prevention of blood stream infections associated with intravascular catheters.[28] The search strategy was not accessible, and no pilot took place. • The EPIC3 guidelines published by Loveday et al. (2014) also has several limitations including limited rigour of development including a lack of detail regarding the systematic methods used to search evidence as well as for selecting evidence.[11] The references supporting the surgical face mask recommendations had a high risk of bias. This was based on the limitations of the included studies within the included four systematic reviews which considered surgical face masks. • Humphreys et al., (2023) provided an update to the rituals and behaviours in the operating theatre guidance for the UK.[27] The guidance was developed using NICE methodology. However, the good practice points for mask use were based on low quality evidence and expert opinion. Other limitations included a lack of clarity on consultations with patients/ public, vagueness in some good practice points and lack of detail on the results of a meta-analysis. The included evidence graded as SIGN 50 level 3 had many limitations, including a lack of applicability and generalisability.[29-37] The differences in experimental setup, including the size of nebulised particles expelled, the use of viral particles (those showing mask efficacy) or use of radiolabelled saline (those showing mask ineffectiveness), flow rate, temperature, humidity, and distance from source are likely to impact the results of such experimental studies. It is therefore not possible to ascertain any conclusions from these four studies which differ significantly in their experimental setup and findings. There was a moderate volume of evidence for this research question. The evidence base for the use of surgical face masks by HCW is generally low quality,	

Comments	Evidence level
consisting mainly of SIGN 50 level 3 experimental studies and SIGN 50 level 4 expert opinion guidance, which have a high risk of bias related to their methodology.	

5.2 Is the evidence consistent in its conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments

Protection against splash and spray
• Two guidelines graded AGREE II 'recommend with provisos', (WHO, 2014; Loveday, 2014)[11, 14] and seven SIGN 50 level 4 guidance documents[12, 16-19, 44, 57] are consistent in advising the use of a fluid resistant surgical face mask or unspecified face mask for any care activity where there is anticipated splash or spray of blood or body fluids. The masking recommendations in the two guidelines were based primarily on low quality evidence and/ or expert opinion.[11, 14]
• No primary scientific evidence was included to inform the use of surgical masks for protection against splash and spray.
Use to maintain a sterile field
• Surgical scrub team
  ○ No primary scientific evidence of sufficient quality was identified to inform use of surgical masks by scrubbed surgical staff. There is uncertainty regarding the impact of using a surgical face mask to maintain a sterile field.
  ○ Acknowledging a lack of evidence in support of surgical face mask use by staff within the operating room, the updated theatre rituals and behaviours guidance by Humphreys et al. 2023 (graded AGREE II 'recommend with provisos') provided no recommendation.[27] Instead, these guidelines provide a good practice point based on expert opinion which advises the use of a surgical face mask by all staff working in the operating room, in accordance with local policies. This suggests all staff may wear surgical face masks but that local polices may differ and therefore the requirements to wear a surgical face mask may differ.

Comments

- Extant guidance (n=3), graded SIGN 50 level 4 expert opinion, advises that scrubbed surgical team members should wear a surgical mask to protect the surgical field.[18, 19, 27] There was a lack of evidence of the impact this has on surgical site infection or other infections.
- One guidance document (SIGN 50 level 4) advises a risk assessment to guide surgical face mask use in surgical settings or for surgical procedures.[17]

- Non-scrub surgical team
  - No primary scientific evidence of sufficient quality was identified to inform use of surgical masks by non-scrubbed surgical staff.
  - Extant guidance is vague:
    - The Association of Anaesthetists of Great Britain and Ireland (AAGBI) (SIGN 50 level 4 expert opinion) advise use of a surgical mask 'by members of the surgical team'.[20] They do not specify if this includes both scrubbed and non-scrubbed staff.
    - Humphreys et al. (2023) (AGREE II 'recommend with provisos') provided a good practice point stating that "all" staff in the operating room should wear a surgical face mask, where it aligns with local policy.[27] This suggests that this may not be essential and should be dependent on local policy. This good practice point was based on expert opinion and was not based on evidence.
  - Surgical face masks are also used in surgery to protect against splash and spray of blood and body fluids. See above section on splash and spray that applies to all staff, across settings.
- Invasive procedures
  - No primary scientific evidence of sufficient quality was identified to inform the use of surgical masks during specific invasive procedures.
  - Three AGREE II 'recommend with provisos' guidelines[11, 27, 28] and five SIGN 50 level 4 guidance[20, 38, 50, 52, 57] are consistent in advising the use of a surgical face mask during invasive procedures. The guidelines (graded AGREE II 'recommend with provisos') were based on low quality evidence and relied on expert opinion. There is inconsistency in the types of invasive procedures noted as requiring surgical face mask use: preparing and injecting solution into an intracapsular space (joint),[50] spine lumbar puncture,[50] catheter insertion,[20, 52, 57] injections into the epidural space,[20, 57] invasive spinal procedures,[20] intra-articular injections.[20]

Comments

- The EPIC3 guidelines, graded AGREE II 'recommend with provisos',[11] also supports the use of a surgical mask during some invasive procedures for example as part of maximal sterile barrier precautions for the insertion of central venous access devices. However, the references supporting the surgical face mask recommendations have a high risk of bias. This is based on the limitations of the included studies within the included four systematic reviews which considered surgical face masks.

Use as source control against respiratory infection

- Eight experimental research studies, graded SIGN 50 level 3, assessed the source control (for respiratory infections) efficacy of surgical masks.[29-32, 34-37] Together they suggest that surgical face masks may provide some level of protection through source control. However, the results have limited generalisability and applicability.
- Surgical face mask use by healthcare workers for respiratory infection source control is suggested across six included guidance documents graded as SIGN 50 level 4.[17, 19, 39, 42, 47, 49] This expert opinion guidance describes surgical face masks as protecting others from the wearer's source of infection, including a health or care worker.

Protection against respiratory infection

- Four experimental studies, graded SIGN 50 level 3, assessed surgical face mask efficacy as a form of personal protection against respiratory particles emitted from a source within fixed condition experiments.[30, 33, 34, 37] Two of these *in vitro* studies demonstrated a statistically significant reduction in exposure to the receiver when the emitter wore a surgical face mask.[30, 33] Two in vitro studies did not.[34, 37]
- The results from these studies are inconclusive; in addition, it is not possible to extrapolate conclusions to real-life settings due to the in vitro nature and limitations of the studies.
- Extant guidance (eight SIGN 50 level 4[12, 18, 23, 41, 43, 53-55] and one AGREE II 'recommend with provisos' guideline published by the WHO)[14] is generally consistent in advising the use of a surgical face mask when caring for patients with a suspected or confirmed respiratory infection which is considered as spread by the 'droplet route' or specifically for respiratory infections such as influenza.[54] The WHO guideline has limitations and is based on evidence with a high risk of bias.
    - There is a lack of clarity regarding the definition of 'droplet' or the example pathogens that may require 'droplet' precautions.

Comments

  - The following infection types were considered: GAS,[44, 53] influenza,[14, 18, 22, 44, 54] new influenza,[14] SARS,[14] adenovirus,[18] parainfluenza,[18] human metapneumonvirus,[18] meningitis,[44] Bordetella pertussis,[44] necrotising facitis,[53] syncytial virus.[18] These lists were non-exhaustive.
- Other guidance documents did not provide example pathogens or clearly define 'droplets'. Generally, similar terms can be used with lack of a clear definition, including large droplet, respiratory droplet, and respiratory aerosol.[14] The term 'droplet' is traditionally used to define particles of certain sizes, usually larger than 5μm[14, 18, 55] that usually travel short distances.[14]

In summary, the extant guidance (8 SIGN 50, 1 AGREE II 'recommend with provisos') is consistent in recommending that surgical face masks should be worn by HCW when caring for patients with a variety of infectious agents which require 'droplet precautions'. However, there is a lack of consistency regarding the infectious agents they use as examples to demonstrate infectious agents spread by the droplet route. The examples include respiratory syncytial virus, parainfluenza, adenovirus, influenzas, human metapneumovirus, GAS infection, influenzas, SARS, or other ARI viruses. However, these lists were non-exhaustive. Generally, these guidance documents refer to surgical face masks as part of 'droplet' precautions.

Extended use

- No primary scientific evidence of sufficient quality was included to inform extended or prolonged use of surgical masks.
- Two UK guidance documents (published 2009, 2010) graded as SIGN 50 level 4 recommend surgical face mask specifically for pandemic influenza control at all times in cohort areas for practical purposes (inclusive of non-clinical staff).[22, 54]
- Guidance (SIGN 50 level 4) by five international organisations regarding SARS-CoV-2,[13, 42, 49] or more generally for respiratory infections, including SARS-CoV-2,[40, 56] published more recently (2023 onwards) continues to recommend extended mask use for source control and/ or during a cluster/ outbreak or high local prevalence, following a risk assessment, and/ or based on HCW or facility preferences.
  - Factors for risk assessment described in three guidance documents include:
    - Epidemiological - increasing community transmission/ higher prevalence periods,[42, 49, 56] facility outbreaks,[42, 56] increasing hospitalisations/ ICU admissions,[42] increasing staff cases.[42]

Comments
▪ Clinical - presence of high-risk/immunocompromised persons (cancer/transplant/dialysis patients), working in high transmission risk units for example emergency departments, open space critical care areas, oncology units, outbreak wards, medical/ surgical assessment units.[42, 49, 56] **Personal preference** • Two guidance (SIGN 50 level 4) provide for personal preference of HCWs to choose to wear a surgical mask based on their risk of developing severe respiratory infection.[49, 56] The CDC SARS-CoV-2 guidance states this choice may be informed by "their perceived level of risk for infection based on their recent activities (e.g. attending crowded indoor gatherings with poor ventilation)" which would be more relevant for source control masking rather than masking for PPE.

5.3 Are the studies applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include interventions, comparators or outcomes that are common to Scottish health and care settings?

Comments
The countries where the studies were conducted, or in which the guidance applies, include: • Australia (n=3),[12, 31, 43] • Canada (n=1),[42] • New Zealand (n=3),[21, 41, 56] • Europe (n=2),[39, 40] • international (published by the WHO) (n=4),[13, 14, 28, 51] • Japan (n=2),[30, 33] • UK (n=11),[11, 16, 17, 20, 22, 27, 45, 47, 52-54] • US (n=15).[18, 19, 29, 32, 34-38, 44, 46, 48-50, 55] The included guidance documents produced by internationally recognised associations may be relevant to Scottish health and care settings. Guidance produced for specific countries may have less applicability.

Comments
Experimental studies (SIGN 50 level 3) can provide an indication of mask efficacy in specific, often laboratory-based, settings however, the results may not apply to real-world settings.[29-37] The experimental studies included in this review have limited applicability as they are specific to the fixed environment in which they were conducted. This includes the specific mask type used (which is not always stated), temperature, humidity, ventilation, persons in the room, and sampling technique. These factors may alter the behaviour of particles and therefore the measured efficacy of a mask is specific to this setting. Most of the studies did not state with certainty if the mask was fluid resistant similar to standards used within the UK. Additionally, seven sources are specific to a SARS-CoV-2 response.[13, 39, 42, 43, 45-47] Some guidance included in this review was produced for specific settings, including: acute,[11, 38, 53] ambulance,[22] adult social care,[16] operating theatres/ surgical settings.[27, 51]

5.4 Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
The findings of three primary studies (SIGN 50 level 3) may lack generalisability as they included healthy volunteers,[58, 59] or volunteers with SARS-CoV-2.[29] These studies include small sample sizes, focused on a range of participants and for two studies healthy volunteers. Therefore, the results are unlikely to generalise fully to patients in health and care settings who have a respiratory infection. Five studies had low generalisability as they did not include human participants and instead included manikins at a fixed distance, or a novel vacuum sampling setup.[30, 32, 34, 35, 60] These studies should be considered with caution as they may not reflect human participants. None of these studies took place in a clinical setting, therefore, the findings may not generalise to real clinical settings. The findings are unlikely to generalise given the limitations of the studies including small sample sizes, lack of representative samples and use of human-proxies, e.g., manikins.

5.5 Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
A formal assessment of publication bias was not conducted. However, it should be noted that a degree of publication bias is expected given the level of expert opinion guidance included for this research question as well as a lack of high-quality primary studies. During the SARS-CoV-2 pandemic response, evidence was often rapidly produced and limited to a pandemic period. It is difficult to assess if there could be eligible data that is, as yet, unpublished. Many guidance documents cite the same randomised controlled trials or systematic reviews which are based on these trials that have been excluded from this review (as per the NIPCM exclusion criteria).

B Evidence to decision

5.6 Recommendation

What Recommendation(s) or Good Practice Point(s) does the Working Group agree are appropriate based on this evidence?

Note the following terminology:

- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present.
- **"could consider/may consider"** implies that the health and care settings could consider implementing the recommended approach.
- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance.

Recommendation	Grading
GPP5.1 A Type IIR fluid resistant surgical face mask should be worn by health and care workers when splashing or spraying of blood or body fluids is anticipated.	Good Practice Point
GPP5.2 A Type IIR fluid resistant surgical face mask should be worn by scrubbed members of the theatre surgical team during surgical procedures.	Good Practice Point
GPP5.3. Non-scrubbed members of the theatre team should consider wearing a Type IIR surgical face mask.	Good Practice Point
GPP5.4 A Type IIR fluid resistant surgical face mask should be worn when preparing equipment for, and performing invasive clinical procedures, for example: intra-articular (joint) injections, central venous catheter insertion, invasive spinal procedures (such as myelography, lumbar puncture and spinal anaesthesia).	Good Practice Point

Recommendation	Grading
GPP5.5 Health and care workers should wear a Type IIR surgical face mask as a minimum when delivering care to patients who are suspected or confirmed to be infected with an R1* respiratory infectious agent. *R1 = respiratory infectious agents that can cause human disease and may be a hazard to employees but are unlikely to spread to the community and there is usually effective prophylaxis or treatment available.	Good Practice Point
GPP5.6 The extended use of Type IIR surgical face masks by health and care workers should be considered as an enhanced infection prevention and control measure during epidemics or periods of high rates of local transmission of respiratory infectious agents.	Good Practice Point
GPP5.7 Heath and care workers should wear a Type IIR surgical face mask when providing care to severely immunocompromised service users where protective isolation is indicated, as determined by the clinical team.	Good Practice Point
GPP5.8 Where a patient presents with symptoms indicative of a transmissible respiratory infection and the likely causative agent cannot be determined, health and care workers should (as a minimum) wear a Type IIR surgical face mask.	Good Practice Point

5.7 Balancing benefits and harms

Comment here on the potential impact of the Recommendation/Good Practice Point on service users, visitors and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation/Good Practice Point were followed. Be explicit, clear about pros.

Benefits
GPP5.1, GPP5.2, GPP5.3, GPP5.4, GPP5.5, GPP5.6, GPP5.9 - The use of a Type IIR surgical mask may help to minimise occupational exposure, which may reduce the potential impacts on clinical services, and the risk of nosocomial infection transmission. GPP5.1 – Use of Type IIR surgical face masks when splashing and spraying of blood or body fluids is anticipated is expected to reduce the exposure risk from potentially infectious material and as a result may reduce the risk of HAI for the healthcare worker wearing the mask. GPP5.2 – Use of Type IIR surgical face masks by scrubbed members of the theatre team may reduce contamination of the sterile field from the wearer's respiratory emissions and debris, and this may reduce the risk of HAI for the patient. It would also provide protection from splash and spray. GPP5.3 – The use of a surgical face mask by non-scrubbed surgical team members may reduce exposure of the sterile field to respiratory emissions and debris from the face of the wearer and may assure these team members are protected for unexpected spray and splash of blood and body fluids. GPP5.4 – A Type IIR surgical face mask worn when preparing for and performing invasive procedures should reduce the risk of contamination of the sterile field which may reduce the risk of HAI for the patient. GPP 5.5. - Use of a Type IIR surgical face mask as a minimum when delivering care to patients suspected or confirmed to be infected with an R1 respiratory infectious agent will reduce the risk of exposure to infectious agents. The benefits of wearing surgical masks in this scenario include that they do not require fit testing, meaning any staff member can quickly don, and therefore a minimum level of protection can be provided. Staff may be more likely to comply with masking in these situations if the minimum requirement is a surgical face mask rather than a respirator, due to ease of application, greater comfort and ease of wear with the surgical mask. GPP5.6 - The extended use of surgical face masks may reduce the risk of exposure from some pre-symptomatic/ unidentified sources as it creates a physical barrier against the expulsion / emission of particles from individuals not wearing masks and prevents emission of particles from the mask wearer. GPP5.7 Use of surgical face masks by healthcare workers when caring for severely immunocompromised service users where protective isolation is indicated may reduce the risk of these patients acquiring infection from healthcare workers that may be asymptomatic or presymptomatic. GPP5.8 Use of a Type IIR surgical face mask when a patient presents with symptoms indicative of a transmissible respiratory infection and the likely causative agent cannot be determined, may reduce the risk of transmission.

Risks and Harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation/Good Practice Point were followed. Be explicit, clear about cons.

Risks/Harms
GPP5.1, GPP5.2, GPP5.3, GPP5.4, GPP5.5, GPP5.6, GPP5.7, GPP5.8 -The use of surgical face masks can reduce the ability to communicate as the masks may impact the volume of speech and reduce the ability to lip-read and see facial expression. This may lead to an emotional, behavioural, or psychological impact for HCWs, patients/service users and visitors. This risk may be greater for GPP5.6 and GPP5.7 - which involve extended use of a surgical mask. There is also a risk that wearers may perceive surgical masks as a 'silver-bullet' in terms of transmission prevention and therefore place less importance on the other suite of IPC measures. GPP5.5, GPP5.6, GPP5.7, GPP5.8 There is a risk that respirable particles may breach a surgical face mask directly or via breaches where the mask is not well fitted to the face. This could result in transmission of infection to the mask wearer. GPP5.5 There is a risk that staff may perceive use of surgical masks as suboptimal protection when caring for patients with suspected or confirmed infection with a R1 respiratory infectious agent. This may increase staff anxiety and reduce staff confidence in the employer's ability to protect employees. GPP5.5, GPP5.8 If a patient with a suspected R1 respiratory infection (or unknown respiratory infection) is later confirmed as infected with an R2 or R3 infectious agent (and therefore RPE is indicated), the use of the surgical face mask may have provided insufficient protection against transmission. This may increase the risk of the healthcare worker acquiring infection with an R2 or R3 infectious agent. GPP5.6 If surgical mask use is increased as part of extended use, there may be an increased risk of poor communication due to the mask blocking speech and lip-reading/ facial recognition. GPP5.6, GPP5.7, GPP5.8 - Wearing a surgical face mask for extended periods may increase the likelihood of touching the mask, which can increase the risk of cross-contamination. GPP 5.6 The use of a surgical face mask while within a cohort area of patients with respiratory infection may result in lack of consideration for the indications to change a surgical mask, which would still apply (for example when soiled, contaminated, damp, etc.). This could negatively impact the integrity of the mask and increase the risk of exposure to infectious agents.

Risks/Harms
GPP5.6, GPP5.7, GPP5.8 - The use of a surgical face mask over a prolonged period of time may increase the risk of occupational skin irritation/ damage.

Benefit-Harm assessment

Classify as “benefit outweighs harm” (or vice versa) or a “balance of benefit and harm.” Description of this balance can be from the individual service user/staff/visitor perspective, the societal perspective, or both. Recommendations/Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events (or vice versa).

Benefit-Harm assessment
GPP5.1 Although surgical masks can negatively impact communication, the anticipated benefits of preventing exposure to splash and spray outweigh this harm. The use of a transparent mask, as appropriate, may further reduce this harm. GPP5.2, GPP5.3 Although surgical masks can negatively impact communication, the anticipated benefits of protecting the sterile field and protection against splash and spray outweigh this harm. The impact on communication is less of a risk for the patient if they are sedated or anaesthetised during surgery. GPP5.4 Although surgical masks can negatively impact communication, the anticipated benefits of protecting the sterile field and protection against splash and spray outweigh this harm. The use of a transparent mask, as appropriate, may further reduce this harm. GPP5.5 [**Health and care workers should wear a Type IIR surgical face mask as a minimum when delivering care to patients who are suspected or confirmed to be infected with an R1* respiratory infectious agent**]. Healthcare workers may choose to wear RPE instead of surgical face masks (based on personal preference or per occupational risk assessment) where indicated for R1 care as per the RPE literature review; this may in part reduce any anxiety associated with concerns that surgical masks provide suboptimal protection against transmission. The working group consider that these additional considerations support the benefits associated with this GPP to outweigh the risks. GPP5.6 The working group agreed that the benefits of implementing extended use of surgical face masks as an enhanced infection prevention and control measure during epidemics or periods of high rates of local transmission of respiratory infectious agents, outweigh the risks.

Benefit-Harm assessment
GPP5.7 The working group agreed that the benefits of healthcare workers wearing masks (reduced risk of infection acquisition in vulnerable patient cohort) outweighs the risks (discomfort during wear, reduced communication). GPP5.8 Although there is a risk that surgical face masks may provide insufficient protection if the service user is later confirmed to be infected with an R2 or R3 respiratory infectious agent, the working group agreed that this risk is low. It was noted that typically, there is some pre-assessment information which would generate suspicion of an R2 or R3 infection in advance of contact with the symptomatic individual, indicating the need for RPE. Use of a surgical face mask where the infectious agent is unknown in conjunction with pre-assessment screening is a practical measure in the absence of RPE use for all suspected or confirmed respiratory infectious agents and the harms associated with this. Further, healthcare workers at risk of severe outcomes may be advised to wear RPE instead of surgical masks. The working group consider that these additional considerations support the benefits associated with this GPP to outweigh the risks.

5.8 Feasibility

Is the Recommendation/Good Practice Point implementable in the Scottish context?

Describe (if applicable) financial implications, opportunity costs, material or human resource requirements, facility needs, sustainability issues, human factors etc., that may be associated with following a Recommendation/Good Practice Point. State clearly if information on feasibility is lacking.

Feasibility
• There are costs associated with ensuring maintenance of stock and supply of surgical face masks. This is an ongoing feasibility implication for all the proposed recommendations and good practice points. If mask use is increased so too may the cost of masks (such as for GPP5.6). • There may be ongoing training requirements and supportive promotional materials to support compliance with recommended surgical face mask use. This is a feasibility implication for all the proposed good practice points. • There may be a requirement for ongoing occupational workplace support and monitoring for employee health & safety. This is a feasibility implication for all the proposed recommendations and good practice points. • GPP5.5 There will be requirement for HCWs to know which infectious agents are categorised as R1 and also to determine (based on patient symptoms, presentation, history) whether a patient has or may have an R1

Feasibility
infection. Guidance will need to clearly provide this information, and there will be a need for supportive education and training resources. • GPP5.6 If the use of masks is increased during periods where extended or prolonged use of a surgical face mask is recommended, there will be increased waste management considerations associated with this. • GPP5.6 There may be supplemental procurement requirements during increased demand during epidemics or periods of high rates of local transmission of respiratory infections. • GPP5.6 It may be difficult to operationalise this good practice point given the complexities in quantifying the local burden of infection. There may be resource and surveillance requirements at board level to monitor local rates to support risk assessment for this GPP. • GPP5.7 There may be a requirement for staff to explain to patients why healthcare workers are wearing masks.

5.9 Expert opinion

Summarise the expert opinion used in creating the Recommendation or Good Practice Point. If none were involved, state “none”. Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining that expert opinion helps users understand their influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
GPP5.1 - **[A Type IIR fluid resistant surgical face mask should be worn by health and care workers when splashing or spraying of blood or body fluids is anticipated**] This GPP is informed by two guidelines graded as AGREE II ‘recommend with provisos’, (WHO, 2014; Loveday, 2014)[11, 14] and seven SIGN 50 level 4 guidance documents.[12, 16-19, 44, 57] This evidence was considered as insufficient to make a recommendation but was used to support the formation of a GPP. It is the view of ARHAI Scotland and the working group that the use of a surgical face mask by health and care workers, when there is a risk of splash and spray of blood and body fluids, is appropriate as a physical barrier to prevent contact of potentially infectious material with the mouth and nose of the wearer. As outlined in research question 3 surgical face masks used for splash and spray of fluids should be fluid resistant. GPP5.2 - [**A Type IIR fluid resistant surgical face mask should be worn by scrubbed members of the theatre surgical team during all surgical procedures**]. This GPP is informed by three SIGN 50 level 4 guidance,[18, 19, 27] and

Expert opinion

one AGREE II 'recommend with provisos' guideline (published by the Healthcare Infection Society (HIS) and the European Society of Clinical Microbiology and Infectious Diseases).[27] This evidence was considered insufficient to support a recommendation. The HIS guideline recommended surgical face masks for scrubbed members of the theatre team but this was based on expert opinion as there was a lack of evidence demonstrating effectiveness of masks at reducing surgical site infections (SSI). ARHAI and the working group agreed that surgical face masks may assist in maintaining a sterile field, even though there is a paucity of evidence to support this.

GPP5.3 - [**Non-scrubbed members of the theatre team should consider wearing a Type IIR surgical face mask**] This GPP is informed by one guidance document (SIGN 50 level 4)[20] and one AGREE II 'recommend with provisos' guideline.[27] Evidence lacked clear recommendations for non-scrubbed staff and was considered as insufficient to from recommendations. The Association of Anaesthetists of Great Britain and Ireland (AAGBI) (SIGN 50 level 4) advises use of a surgical mask 'by members of the surgical team'.[20] They do not specify if this includes both scrubbed and non-scrubbed staff. The AGREE II-graded guideline published by the Healthcare Infection Society (HIS) and the European Society of Clinical Microbiology and Infectious Diseases)[27] advises masking by all members of the surgical team, based on expert opinion and not based on evidence. It is the view of ARHAI Scotland and the working group that non-scrubbed staff members may consider the use of a surgical face mask during surgical procedures. But that this should be in accordance with local policy. This GPP does not specifically mention splash and spray in surgical settings as this is already captured within GPP 5.1 which applies to all staff across settings, including during surgical procedures.

GPP5.4 - [**A Type IIR fluid resistant surgical face mask should be worn when preparing equipment for and performing invasive clinical procedures, for example: intra-articular (joint) injections, central venous catheter insertion, invasive spinal procedures (such as myelography, lumbar puncture and spinal anaesthesia).**] This GPP was informed by three AGREE II 'recommend with provisos' guidelines[11, 27, 28] and five SIGN 50 level 4 guidance[20, 38, 50, 52, 57] that were consistent in advising the use of a surgical face mask during various invasive procedures. The types of invasive procedures noted as requiring surgical face mask use include: preparing and injecting solution into an intracapsular space (joint),[50] spine lumbar puncture,[50] catheter insertion,[20, 52, 57] injections into the epidural space,[20, 57] invasive spinal procedures,[20] intra-articular injections. It was the view of ARHAI Scotland and the working group that based on a benefit-harms assessment that wearing a surgical face mask during these and any similar procedures should be undertaken by a HCW using a surgical face mask.

Expert opinion

GPP5.5 [**Healthcare workers should wear a Type IIR surgical face mask as a minimum when delivering care to patients suspected or confirmed to be infected with an R1 respiratory infectious agent**].

Evidence regarding the effectiveness of surgical masks at reducing nosocomial respiratory infection is insufficient. Evidence from experimental manikin or simulation studies, whilst demonstrating the mechanistic effect of the mask as a barrier, is inconsistent.[30, 33, 34, 37] Two of these in vitro studies demonstrated a statistically significant reduction in exposure to the receiver when the emitter wore a surgical face mask.[30, 33] Two in vitro studies did not.[34, 37]

Extant guidance (eight SIGN 50 level 4[12, 18, 23, 41, 43, 53-55] and one AGREE II 'recommend with provisos' guideline published by the WHO)[14] is generally consistent in advising the use of a surgical face mask when caring for patients with a known or suspected respiratory infection which is considered as spread by the 'droplet route' or for specific respiratory infections.

The following infection types were considered within this extant guidance: GAS,[44, 53] influenza,[14, 18, 22, 44, 54] new influenza,[14] SARS,[14] adenovirus,[18] parainfluenza,[18] human metapneumonvirus,[18] meningitis,[44] *Bordetella pertussis*,[44] necrotising facitis,[53] syncytial virus.[18] These lists were non-exhaustive.

The TBP Definitions literature review has recommended a move away from the droplet-airborne dichotomy framework for TBPs and has proposed the introduction of R1, R2, R3 respiratory TBP categories – further detail of which is provided within that literature review. Consequently, extant guidance that is based on the droplet-airborne dichotomy, has not been used to inform this GPP.

The working group discussed the potential harms associated with this GPP (respirable respiratory particles may breach a surgical face mask; use of a surgical face mask where subsequent confirmation of infection indicates the need for RPE; staff anxiety related to the perception that surgical face masks provide suboptimal protection compared to RPE). These harms could have significant consequence if infection results in severe infection in the healthcare worker. Application of this GPP to R1 infectious agents (those that can cause disease; may be a hazard if exposed; unlikely to spread to the community; there is usually effective prophylaxis or treatment available) considers that severe infection in the healthcare worker is unlikely. The working group agreed that HCWs would be more likely to adhere to surgical mask use for R1 indications (compared to RPE); this ensures a level of protection against potentially infectious exposures. The working group agreed the benefits outweigh the risks, where provision of an additional good practice point within the RPE literature review will provide for selection of RPE during provision of care for patients with suspected or confirmed R1 respiratory infection based on occupational health or personal preference.

Expert opinion

Expert opinion was sought from the UK Health and Safety Executive (Biohazards team), who stated that, although they would maintain that surgical face masks such as Type IIR are not RPE and should not be considered as such (as they provide 'incidental' protection to the wearer) they considered the working group's benefit-harm assessment to be very thorough and are supportive of the risk assessment approach for mask selection (FRSM and RPE).

GPP5.6 - **[The extended use of Type IIR surgical face masks by health and care workers should be considered as an enhanced infection prevention and control measure during epidemics or periods of high rates of local transmission of respiratory infectious agents.**] This GPP is informed by five guidance documents (SIGN 50 level 4)[13, 40, 42, 49, 56] which advise that surgical face masks may be considered for extended use during outbreaks, high community cases, based on a risk assessment and/or based on HCW or facility preference. The working group agreed that local risk assessment by the organisation/ board should consider the balance of benefit and harm when determining the requirement for prolonged or extended use of surgical face masks in these scenarios. The use of a transparent face mask may reduce the potential harms associated with communication where masks are worn across a facility. The working group discussed the inclusion of 'pandemics' within this GPP however agreed that separate guidance would provide for masking indications during pandemics.

GPP5.7 This GPP is informed by the expert opinion of the working group who consider it a precautionary measure for HCWs to don surgical face masks when providing care to severely immunocompromised patients where protective isolation is indicated. The working group discussed the challenge of providing a clear definition for severely immunocompromised patients and agreed that clinical judgement was required. The need for the clinical team to determine this is to take account of the individual patient's condition and risk factors. Protective isolation for patients with a 'very poor immune system (neutropenia)' is detailed within SHTM 03-01 Part A (bone marrow transplant units, haematology/ oncology wards, organ and tissue transplant units). The working group agreed that there might not be protective isolation available for these patients even where it is needed; hence the wording 'where protective isolation is indicated' was added to account for this. Although the HCW would technically be wearing a surgical mask to provide source control, the group did not want 'source control' to feature within the GPP as it could be incorrectly interpreted to mean the HCW was working whilst knowingly symptomatic/ infectious.

GPP5.8 **[Where a patient presents with symptoms indicative of a transmissible respiratory infection and the likely causative agent cannot be determined, health and care workers should (as a minimum) wear a Type IIR surgical face mask]**. This good practice point was informed by the expert opinion of the working group who consider it good practice to wear a surgical mask as a

Expert opinion
precautionary measure. For many healthcare settings, determination of the causative infectious agent may not be sought because the presentation is not related, the healthcare visit is short (for example in GP surgeries) or the setting is not one that provides such testing (for example, dental surgeries). In these scenarios, the working group consider that surgical face masks are sufficient.

5.10 Value judgements

Summarise value judgements used by the Working Group in creating the Recommendation/ Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other beliefs and priorities. Stating them clearly helps users understand their influence on interpreting objective evidence.

Value judgements
GPP5.6. Extended/prolonged surgical face mask use may be considered as an enhanced infection prevention and control measure where appropriate and aligns with the hierarchy of controls approach within the context of future epidemics or period of outbreaks or high community transmission of respiratory infectious agents. GPP5.7 The use of surgical face masks by healthcare workers when caring for severely immunocompromised patients where protective isolation is indicated is informed by the precautionary principle, acknowledging that these patients are particularly vulnerable to infection and therefore enhanced IPC measures are justified.

5.11 Intentional vagueness

State reasons for any intentional vagueness in the Recommendation/Good Practice Point; if none was intended, state “none”. Recommendations/Good Practice Points should be clear and specific, but if the Working Group chooses to be vague, acknowledging their reasoning clearly promotes transparency. Reasons for vagueness may include inadequate evidence; inability to achieve consensus among panel regarding evidence quality, anticipated benefits/harms, or interpretation of evidence; legal considerations; economic reasons; ethical/ religious reasons.

Intentional vagueness
GPP5.1, GPP5.2, GPP5.3, GPP5.4, GPP5.6, GPP5.7, GPP5.8 - None to note.

Intentional vagueness
GPP5.5 This GPP has not specified which infectious agents are categorised as R1; this information is provided within the TBP Definitions literature review and will need to be clearly detailed within guidance. GPP5.7 This GPP has not specified which patients are considered to be severely immunocompromised and requiring protective isolation – this is because local decision-making by the clinical team for each individual patient is required.

5.12 Exceptions

List situations or circumstances in which the Recommendation/ Good Practice Point should not be applied.

Exceptions
GPP5.1, GPP5.5, GPP5.6 - Where RPE is already being worn and there is anticipated splash spray, a surgical mask is not required. GPP5.1, GPP5.2, GPP5.3, GPP5.4, GPP5.5, GPP5.6, GPP5.8 - When guidance or legislation is implemented due to the emergence of a novel infectious agent, enactment of an emergency or pandemic response or there is an altered assessment of occupational hazards present or the adequacy of control measures. GPP5.1, GPP5.2, GPP5.3, GPP5.4, GPP5.5, GPP5.6, GPP5.8 - Where occupational health has assessed and supported a risk assessment which advises against a HCW using a surgical face mask, reasonable adjustments require to be made.

5.13 Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
The efficacy of surgical face masks in reducing surgical site infections remains under-researched and based on expert opinion. More research in this area may increase understanding. High quality primary research regarding the effectiveness of surgical face masks in preventing transmission of respiratory infections may assist in understanding within which scenarios a HCW should use a surgical face mask or not. However, it may be challenging to conduct such a study given the ethical and practical issues of including a no mask control group when wearing a surgical mask is currently/ historically recommended. The majority of observational, case study, outbreak report and cohort studies, particularly those published during the COVID-19 pandemic response, considered bundled measures (for example other PPE, testing and/ or behavioural

Recommendations for research
interventions), which included but was not limited to surgical face masks. Studies which focus specifically on surgical masks and not on PPE ensembles or bundled IPC measures would assist in understanding their adequacy and the settings in which a surgical mask may be an effective control measure. However, not using a bundle may be impractical and unethical where other measures such as other PPE and enhanced cleaning are required. Research in this area should attempt to control for as many confounding variables/ factors as possible to decrease the risk of bias. The feasibility of such studies to ascertain the effectiveness of surgical face masks as source control, to maintain a sterile field and as personal protection is limited, particularly as current / accepted IPC practices consist of bundled approaches. This type of study would also struggle to obtain the necessary ethical approval.

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

A Quality of evidence

6.1 How reliable are the studies in the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4)

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is insufficient evidence to answer the key question, go to section B.

Comments	Evidence level

Twenty-four evidence sources are included for this research question:
• Eight experimental studies graded SIGN 50 level 3. [29-32, 34-37]
  ○ These studies compared simulated mask use with non-mask use. These studies had many limitations including a lack of generalisability and applicability.
• Thirteen guidance documents graded SIGN 50 level 4 expert opinion.[12, 13, 18, 19, 22, 39, 41, 42, 44, 47, 49, 54, 57]
  ○ This guidance did not include evidence of a systematic review and/ or relied on expert opinions or consensus, meaning it is subject to bias and reflects the opinion of the organisation or creators of the guidance. The underpinning evidence for much of this literature was not provided or was based on limited or unclear methods.
• One British Standard graded SIGN 50 level 4 expert opinion[6]
• Two guidance documents published by NICE (2016)[61] and WHO (2014),[14] graded AGREE II 'recommend with provisos'.
	8 x SIGN 50 Level 3
	14 x SIGN 50 Level 4, expert opinion
	2 x AGREE II 'Recommend with provisos'

Comments	Evidence level
○ The WHO (2014) guidance is specific to epidemic/ pandemic-prone respiratory illnesses. The details regarding grading per included study are unclear. The procedure for guideline development was unclear, as were the methods for systematic review and criteria for selecting evidence. The recommendations related to surgical face mask use were based on limited studies with a high risk of bias including those focused on community settings, bundled approaches, and flawed methodologies. ○ The NICE guidelines are of sufficient quality but are specific to the management of TB and may not apply to other conditions. The guidelines were developed in 2016 and are over-due an update, per the provided protocol. It is also not clear what the external consultation involved. The evidence base for this research question is generally low quality, consisting mainly of SIGN 50 level 3 experimental studies and SIGN 50 level 4 expert opinion guidance, which have a high risk of bias related to their methodology.	

6.2 Is the evidence consistent in its conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments
Source control • The eight experimental studies (SIGN 50 level 3) demonstrate that surgical face masks were effective forms of source control within the novel/ fixed experimental settings in which they were tested.[29-32, 34-37] • Two AGREE II 'recommend with provisos' graded guidelines,[14, 61] 13 SIGN 50 level 4 expert opinion guidance,[12, 13, 18, 19, 22, 39, 41, 42, 44, 47, 49, 54, 57] and one

Comments

British Standard[6] are consistent in advising that patients should wear a surgical face mask as a form of source control.

- There is consistency across five guidance documents graded as SIGN 50 level 4[12, 41, 42, 44, 49] and one guideline graded as AGREE II 'recommend with provisos'[61] regarding the use of a surgical mask by patients with a confirmed/ suspected respiratory infection, and eight (SIGN 50 level 4)[18, 22, 39, 41, 44, 48, 49, 54] and one guideline (AGREE II 'recommend with provisos')[14] that this applies specifically to those patients with symptoms of a respiratory infection (such as coughing or sneezing).
- A guidance document published by WHO (2014)[14] and graded as AGREE II 'recommend with provisos' and specific to 'pandemic-prone' or epidemic respiratory infections, recommends that surgical face masks be worn as part of cough etiquette by a symptomatic person. This recommendation was based on evidence described as "very low quality".
- The British Standard specifically advises Type 1 surgical face masks for use particularly in epidemic or pandemic situations.[6]

- Patients' surgical face mask use is also advised (within eight SIGN 50 level 4 guidance,[12, 13, 18, 44, 49, 54, 62] 1 AGREE II guideline[14]) during transfer/ transport of patients including during ambulatory care, and when outside of their room.[41]

In summary, extant guidance is consistent in advising that surgical masks should be worn by patients with respiratory infections (suspected or confirmed) or respiratory symptoms. This includes during transfer of patients between departments within ambulatory care settings or movement outside of their rooms. Evidence in support of this consisted of experimental studies that demonstrate the mechanistic efficacy of surgical masks in fixed experimental settings, there was no evidence available to assess the impact on infection or transmission rates in real-life settings.

Extended/prolonged use (pandemic control)

- There is a degree of consistency across 5 documents (1 AGREE II 'recommend with provisos' guideline,[14] 4 SIGN 50 level 4 guidance)[13, 39, 42, 49] that patients should wear a surgical face masks as part of extended or universal masking precautions during pandemic situations.
  - Four guidance (SIGN 50 level 4) regarding SARS-CoV-2 management advise that patients should wear a surgical face mask as part of extended or universal masking precautions where appropriate (for example, during periods of high community

Comments
transmission, or where there is a significant impact on the health system).[13, 39, 42, 49]

6.3 Are the studies applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include interventions, comparators or outcomes that are common to Scottish health and care settings?

Comments
The evidence included for this research question was produced for the following countries: • Australia (n=2)[12, 31] • New Zealand (n=1)[41] • Canada (n=1)[42] • International (n=2) [13, 14] • Europe (n=1)[39] • Japan (n=1)[30] • UK (n=5) [6, 22, 47, 54, 61] • US (n= 11)[18, 19, 29, 32, 34-37, 44, 49, 57] The non-UK guidance may have less applicability to a Scottish health and care setting. Experimental studies (SIGN 50 level 3) can provide an indication of mask efficacy in specific, often laboratory-based settings however, the results may not apply to real-world settings.[29-32, 34-37] The experimental studies have limited applicability as they are specific to the fixed environment in which they were conducted. This includes the specific mask type used (which is not always stated), temperature, humidity, ventilation, persons in the room, and sampling technique. These factors may alter the behaviour of particles and therefore the measured efficacy of a mask is specific to this setting. The completion of the studies in a non-health care setting (usually a laboratory or room) may not fully replicate Scottish health and care settings. The outcomes across the studies varied with limited focus on the size of particles and infectivity of particles and the relationship this may have with exposure or transmission risk. While the studies provide an indication of mask effectiveness, they lack applicability.

Comments
Guidance produced specifically for SARS-CoV-2 may not be applicable to other patient infections.[13, 39, 42, 47, 49] The WHO and UK Department of Health documents are specific to acute pandemic/ epidemic-prone respiratory infections or pandemic influenza, respectively.[14, 22, 54] The recommendations may be specific to these settings. Guidance published over 10 years ago may have limited applicability to a Scottish health and care settings.[14, 19, 22, 54] This is because health and care as well as IPC practices may have changed over time and the underpinning research may have been updated but not captured. Further general methodological limitations which may reduce the applicability of the findings relate to the kind of mask used including: • differing or unspecified mask types used. • the definition of 'surgical', 'medical' and 'procedure' mask across the literature is not well defined and these terms are used interchangeably, while the masks used in experimental studies appeared to generally meet bacterial filtration efficiency of Type II masks, the fluid resistance is often not clear or surmised based on an internet search.

6.4 Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
The findings of three primary studies (SIGN 50 level 3) may lack generalisability as they included healthy volunteers,[58, 59] or volunteers with SARS-CoV-2.[29] These studies included small sample sizes, and lacked representativeness. Therefore, the results are unlikely to generalise fully to patients in health and care settings who have a respiratory infection. The remining five studies had low generalisability as they did not include human participants.[30, 32, 34, 35, 60] These studies should be considered with caution as they may not reflect human participants as they included manikins as a human proxy. All of the included experimental studies were graded as SIGN 50 level 3 and included fixed conditions with variable temperature, humidity, and room ventilation across the studies. Therefore, the findings may not apply to patient-health care workers or other interactions that happen within health and care settings. Manikin studies also lack generalisability as they represent a

Comments
controlled air flow (often one way from source to receiver) which does not reflect real life where multiple persons would be inhaling/exhaling.

6.5 Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
A formal assessment of publication bias was not conducted. However, it should be noted, that a degree of publication bias is expected given the level of expert opinion guidance for this research question as well as a lack of high-quality primary studies.

B Evidence to decision

6.6 Recommendation

What Recommendation(s) or Good Practice Point(s) does the Working Group agree are appropriate based on this evidence?

Note the following terminology:

- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present.
- **"could consider/may consider"** implies that the health and care settings could consider implementing the recommended approach.
- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance.

Recommendation	Grading
GPP6.1 Where it does not compromise clinical care and is tolerable, patients/ service users who have a suspected or confirmed respiratory infection should wear a Type II or Type IIR surgical face mask when outside their dedicated room and when a healthcare worker enters their room.	Good practice point
GPP6.2 The extended use of surgical face masks, within health and care settings, by all patients/ service users should be considered, where they are tolerable and do not compromise clinical care, as an enhanced infection prevention and control measure during epidemics or periods of high rates of local transmission of respiratory infectious agents.	Good Practice Point
GPP6.3 Severely immunocompromised patients should wear a type II or type IIR surgical face mask when outside protective environments, where they are tolerable and do not compromise clinical care.	Good Practice Point

6.7 Balancing benefits and harms

Comment here on the potential impact of the Recommendation/Good Practice Point on service users, visitors and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation/Good Practice Point were followed. Be explicit, clear about pros.

Benefits
GPP6.1, GPP6.2, GPP6.3 The use of surgical face masks can minimise exposure risk, clinical service impacts, and the risk of transmission. GPP6.2 Extended use of a surgical face mask allows for an additional IPC measure which may be easily implemented by boards. GPP6.2 The use of surgical face masks as an extended infection control measure may prevent transmission from pre-symptomatic/ unknown sources as it creates a physical barrier for the expulsion/ emission of any infectious particles. GPP6.3 The use of a surgical face mask by severely immunocompromised patients, as appropriate, may provide additional protection (by application of a physical barrier) in settings where there is a risk of exposure to potentially infectious particles. GPP6.1, GPP6.2, GPP6.3 It is possible that the use of a surgical face mask by patients who are at greater risk of infection as well as by patients who have a respiratory infection, may result in a positive impact on wellbeing if patients feel a sense of protection of themselves (from others) and others (from themselves), respectively.

Risks and Harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation/Good Practice Point were followed. Be explicit, clear about cons.

Risks/Harms
GPP6.1, GPP6.2 and GPP6.3. The use of surgical face masks can impact on the ability to communicate effectively. This may lead to an adverse emotional, behavioural, or psychological impact for patients or others (staff, visitors/care givers). This may be a particular issue for GPP6.1 and GPP6.2 during increased mask use.

Risks/Harms
GPP6.2 Extended or prolonged use of surgical face masks can increase the risk of skin irritation/damage. GPP6.2. Extended use of a surgical face mask may result in a negative impact on some people's psychological wellbeing.

Benefit-Harm assessment

Classify as "benefit outweighs harm" (or vice versa) or a "balance of benefit and harm." Description of this balance can be from the individual service user/staff/visitor perspective, the societal perspective, or both. Recommendations/Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events (or vice versa).

Benefit-Harm assessment
GPP6.1 - It was determined that the benefits may outweigh the harms when additional patient factors are considered (i.e., being tolerable and not compromising clinical care). The potential risk of negatively impacted communication should be limited for this GPP which would include mask use as appropriate (for example, when outside of room or during transport) and not for prolonged periods of time and may be reduced further through the use of a transparent face mask as appropriate. GPP6.2 - It was determined that the benefits may outweigh the harms where an assessment of risk identifies the requirement for extended surgical face mask use in clinical care settings. This is due to the potential for reduced exposure to infectious agents and associated transmission risk. While it is possible that extended use of a surgical mask negatively impacts communication, it is expected that this harm may be reduced through the use of transparent face masks, as appropriate. It is an exception to this and the other GPP within this research question that the surgical face mask should be tolerable and not compromise clinical care. GPP6.3 – While there is a risk that the use of a surgical face mask could negatively impact communication, it is expected that the use of a transparent surgical face mask may reduce this risk. It was also considered that the use of a surgical mask by severely immunocompromised patients/ service users has the potential to reduce their exposure to infectious particles as well as a possible perceived sense of protection. It was therefore concluded that benefits outweigh the harms assuming that the mask is tolerable and does not compromise clinical care.

6.8 Feasibility

Is the Recommendation/Good Practice Point implementable in the Scottish context?

Describe (if applicable) financial implications, opportunity costs, material or human resource requirements, facility needs, sustainability issues, human factors etc., that may be associated with following a Recommendation/Good Practice Point. State clearly if information on feasibility is lacking.

Feasibility
• GPP6.1, GPP6.2, GPP6.3 There are costs associated with ensuring maintenance of stock and supply of surgical face masks. • GPP6.1, GPP6.2, GPP6.3 There may be training requirements for HCW or promotional materials required regarding when to encourage patients/ service users to wear a surgical face mask. • GPP6.1, GPP6.2, GPP6.3 The explanation by staff to patients/ service users regarding all aspects of wearing surgical face masks may have resource implications. This includes why a mask is required, selection of certain types, where and how this should be donned/ doffed, when this should be changed/ removed, and where to place or dispose of used masks. • GPP6.1, GPP6.2, GPP6.3 It is possible that patient/ service users may refuse to wear a mask or find them intolerable (note this is an exception to patient mask use, see below section on exceptions). It is also possible that the patient is unable to provide informed consent. This may result in additional resource from staff to conduct risk assessment or enact other mitigation measures, as appropriate. • GPP6.2 There may be supplemental procurement requirements during increased demand for outbreak/ incident response. • GPP6.2 If the use of masks is increased, during periods where extended or prolonged use of a surgical face mask is recommended, there will be waste management considerations and costs associated with this. • GPP6.3 Ongoing training requirements and supportive promotional materials may be needed to support HCWs in conducting patient/ service user risk assessment and promoting surgical mask use and adherence. • GPP6.1, GPP6.2, GPP6.3 Supporting materials may need to be developed or interpreter availability may need to be considered for non-English speakers. • GPP6.1, GPP6.2, GPP6.3 Appropriate facilities which allow for the safe donning and doffing of surgical face masks will need to be made available to reduce the risk of cross-contamination, particularly for GPP6.2.

Feasibility
• GPP6.1, GPP6.2, GPP6.3 Facilities and processes which allow for the distribution of surgical face masks at the appropriate place and time for patients/ service user use, should be considered. • GPP6.2 It may be difficult to operationalise this good practice point given the complexities in quantifying the local burden of infection.

6.9 Expert Opinion

Summarise the expert opinion used in creating the Recommendation (R) or Good Practice Point (GPP). If none were involved, state “none”. Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining that expert opinion helps users understand their influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
• GPP6.1 [Where it does not compromise clinical care and is tolerable, patients/ care recipients who have a suspected or confirmed respiratory infection should be encouraged to wear a surgical face mask] This good practice point (GPP) is informed by two AGREE II ‘recommend with provisos’ graded guidelines,[14, 61] 12 SIGN 50 level 4 expert opinion guidance,[12, 13, 18, 19, 22, 39, 42, 44, 47, 49, 54, 57] and one British Standard.[6] This evidence is generally supportive of the use of surgical face masks as source control, for example by patients with suspected or confirmed respiratory infections with eight specifically noting surgical face masks for patients with symptoms. There is an absence of high-quality evidence in real-life settings therefore a good practice point instead of a recommendation is supported. ARHAI Scotland and the Working Group support the view that surgical face masks should be used by patients/ service users who have a suspected or confirmed respiratory infection. It was considered that this may act as a mitigation measure for emissions of potentially infectious particles within the health and care environment. The use of a surgical face mask by patients as part of cough etiquette is an established practice. Therefore, to an extent patients and staff should already be familiar with being offered, or offering a surgical face mask, respectively. However, this GPP is made only where it would not compromise clinical care and where it is tolerated by the patient/ service user, to prevent unintended harms. • GPP6.2 [The extended use of surgical face masks by all patients/care recipients may be considered, where they are tolerable and do not compromise clinical care, as an enhanced infection prevention and control measure during epidemics or periods of high rates of community transmission of respiratory infectious agents] This GPP is informed by five documents (1 AGREE II

Expert opinion

'recommend with provisos' guideline,[14] 4 SIGN 50 level 4 guidance)[13, 39, 42, 49] which provide consistency regarding there being a place for patient use of surgical face masks as part of extended or prolonged use of masks. This includes during pandemic periods, for periods of high community transmission or after a risk assessment. The use of a surgical face mask as part of extended or prolonged use may act as a physical barrier both for the protection of patients/ service users from external sources of potentially infectious particulate and protection from emissions from patients/ service users. It is the view of ARHAI Scotland and the working group that an assessment of the risk is advised as part of this good practice point to account for the variance of operational risks across multiple facilities and clinical settings. This GPP is considered as applicable only where the use of a surgical face mask would not compromise the clinical care of the patient/ service user and where they are tolerated. Pandemics were not specified within this GPP because mask indications for pandemics will be covered in separate guidance.

- GPP6.3 [Severely immunocompromised patients should wear a type II or type IIR surgical face mask when outside protective environments, where they are tolerable and do not compromise clinical care.] It is the view of ARHAI Scotland and the working group that the use of surgical face masks should be considered as an active control measure where there may be a risk of infection transmission for severely immunocompromised patients and should include an individual risk /harm assessment. This would include during any construction or refurbishment projects which is both precautionary and protective. 'Protective environments' refers specifically to rooms that have specialised ventilation and air filtering, for example those in haemato-oncology wards, bone marrow transplant units and critical care wards. This GPP was considered as applicable only where the use of a surgical face mask would not compromise the clinical care of the patient/ service user and where they are tolerated by the patient/service user.

6.10 Value judgements

Summarise value judgements used by the Working Group in creating the Recommendation(R)/ Good Practice Point (GPP); if none were involved, state "none". Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other beliefs and priorities. Stating them clearly helps users understand their influence on interpreting objective evidence.

Value judgements

GPP6.1, GPP6.2, GPP6.3 – None to note.

6.11 Intentional vagueness

State reasons for any intentional vagueness in the Recommendation/Good Practice Point; if none was intended, state “none”. Recommendations/Good Practice Points should be clear and specific, but if the Working Group chooses to be vague, acknowledging their reasoning clearly promotes transparency. Reasons for vagueness may include inadequate evidence; inability to achieve consensus among panel regarding evidence quality, anticipated benefits/harms, or interpretation of evidence; legal considerations; economic reasons; ethical/ religious reasons.

Intentional vagueness
GPP 6.1, GPP6.2, GPP6.3 - None to note.

6.12 Exceptions

List situations or circumstances in which the Recommendation/Good Practice Point should not be applied.

Exceptions
GPP6.1, GPP6.2, GPP6.3 Surgical mask should not be worn by the following service users: • neonatal and paediatric patients (age 0-5) • those who cannot tolerate a surgical face mask • those for whom it is not clinically appropriate or feasible to wear a surgical face mask (where the wearing of a mask would compromise clinical care) • those who refuse the request to wear surgical face masks or are unlikely or unable to adhere with the request • those who are unable to provide informed consent

6.13 Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
• Controlled comparison studies to consider surgical face mask effectiveness in reducing or preventing onward transmission of infections. • High quality primary research to determine the effectiveness of surgical face masks in preventing transmission of respiratory infections may assist in

Recommendations for research

understanding which scenarios a patient should use a surgical face mask or not.

- The majority of observational, case study, outbreak report and cohort studies, particularly those published during the SARS-CoV-2 pandemic response, considered bundled measures (for example other PPE and/or behavioural interventions), which included but was not limited to surgical face masks. Studies which focus specifically on surgical masks and not on PPE ensembles or bundled IPC measures would assist in understanding their adequacy and the settings within which a surgical mask may be an effective control measure. However, the feasibility of such studies is very limited as current/accepted IPC practices consist of bundled approaches. This type of study might also struggle to obtain the necessary ethical approvals.

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

A Quality of evidence

7.1 How reliable are the studies in the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4)

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is insufficient evidence to answer the key question, go to section B.

Comments	Evidence level
Twenty-one evidence sources are included for this research question: • One AGREE II 'recommend with provisos' guideline.[27] • Eight SIGN 50 level 3 experimental studies.[29-32, 34-37] These studies lack generalisability and applicability to real world Scottish health and care settings. These studies have several limitations and are unable to provide evidence regarding the absolute transmission risk with or without surgical masks. • Twelve guidance documents graded SIGN 50 level 4 expert opinion. [13, 18, 39, 42, 44, 47, 49, 53, 54, 56, 57, 63] These documents did not report sufficient details of a rigorous systematic review process for developing their evidence base. The evidence base for this research question is generally low quality, consisting mainly of SIGN 50 level 3 experimental studies and SIGN 50 level 4 expert opinion guidance, which have a high risk of bias related to their methodology.	1 x AGREE II 'Recommend with provisos' 8 x SIGN 50 Level 3 12 x SIGN 50 Level 4, expert opinion

7.2 Are the studies consistent in their conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments

Source control

- Eight experimental studies (SIGN 50 level 3) were consistent in demonstrating the effectiveness of a face mask as a form of source control compared to no mask, within varied fixed experimental conditions.[29-32, 34-37]
- However, this was not specific to visitors and was set to the fixed experimental condition of the individual studies which included either healthy volunteers,[31, 36] volunteers with a positive SARS-CoV-2 sample[29] or manikins.[30, 32, 34, 35, 37]
- Two extant guidance advise source control; for the prevention of respiratory infection transmission as part of respiratory hygiene (CDC, SIGN 50 level 4),[57] and to protect surgical patients when entering the operating room (HIS guidance, AGREE II 'recommend with provisos).[27]

Personal protection

- Evidence on effectiveness is inconsistent: two experimental studies suggest that masks may significantly reduce exposure for a mask wearer.30, 33 However, in two studies there was minimal reduction in exposure at the receiver manikin except for N95 respirators sealed with Vaseline.34, 37 These studies have several limitations and are unable to provide evidence regarding the absolute transmission risk with or without surgical masks. Furthermore, none are specific to visitors or mask use by visitors.
- Four SIGN 50 level 4 guidance are consistent in advising masks for visitors when visiting a patient with a suspected/confirmed respiratory infection.44, 53, 54, 63
    - Three recommend visitor mask use when 'droplet' precautions for a patient are in place.[44, 53, 63]
    - UK Department of Health pandemic guidance is specific to visitor mask use when in cohort areas.[54]

Extended use

Expert-opinion (n= 6, SIGN 50 level 4) including guidance from public health organisations ECDC, WHO, and CDC, highlight that during periods of high respiratory virus transmission, visitors in health and care facilities should be encouraged to wear a surgical face mask.[13, 39, 42, 47, 49, 56]

Comments

Specific indications for masking include:

- where community transmission is high[13, 49, 56]
- where clusters/outbreaks are high[13, 56]
- where there is significant impact on the health system[13]
- during winter months[56]
- as a pandemic control measure[39, 47] including where physical distancing is not possible[39]

With regards to use during winter months where prevalence of respiratory viruses may be higher, Health New Zealand recommends mask use when visiting settings with vulnerable patients/ residents (immunocompromised individuals, for example those in cancer and transplant units, dialysis units, especially if "units [are] known to have suboptimal physical environment (including ventilation)".[56]

7.3 Are the studies applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include interventions, comparators or outcomes that are common to Scottish health and care settings?

Comments

The country or countries for which the guidance was produced were as follows:

- Australia (n=1)[31]
- Canada (n=1)[42]
- International/European (n=2)[13, 39]
- Japan (n=1)[30]
- New Zealand (n=1)[56]
- UK (n= 4)[27, 47, 53, 54]
- US (n=11)[18, 29, 32, 34-37, 44, 49, 57, 63]

Four of the guidance documents included were created for a UK setting. These are applicable to Scottish settings. The COVID-19 guidance is specific to that infectious agent, [13, 39, 42, 47, 49] or and where appropriate, pandemic periods.[39, 47] The remaining guidance is broadly appliable for Scottish health and care settings.[44, 56]

Comments
Experimental studies (SIGN 50 level 3) can provide an indication of mask efficacy in specific, often laboratory-based settings however, the results may not apply to real-world Scottish settings and should be considered with caution. The experimental studies have limited applicability as they are specific to the setting in which they were conducted. This includes the specific mask type used (which is not always stated), temperature, humidity, ventilation, persons in the room, and sampling technique. These factors may alter the behaviour of particles and therefore, the measured efficacy of a mask is specific to this setting. Ueki et al compared viral load and viral titres of Vero E6/ SARS-CoV-2 cells which has some applicability in a Scottish setting which may encounter SARS patients.[64] The outcomes across the studies varied with limited focus on the size of particles and infectivity of particles and the relationship this may have with transmission risk. Therefore, the results may not apply to Scottish health and care settings which have different conditions (temperature, humidity, particle flow etc). While the studies provide an indication of mask effectiveness, they are specific to the fixed experimental settings in which they were conducted.

7.4 Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
Two of the experimental studies included healthy adult participants.[31, 36] However, the sample size was small, the results may not apply to patients with a respiratory infection. One study included volunteers with a positive SARS-CoV-2 sample.[29] The sample size of this study was small, the stage of infection or severity was unclear. In all three studies the results have limited generalisability.

7.5 Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
A formal assessment of publication bias was not conducted. However, it should be noted, that a degree of publication bias is expected given the level of expert opinion guidance for this research question as well as a lack of high-quality primary studies. During the COVID-19 pandemic response research was often rapidly produced or limited to a pandemic period. It is difficult to assess if there could be eligible data that is, as yet, unpublished

B Evidence to decision

7.6 Recommendation

What Recommendation(s) or Good Practice Point(s) does the Working Group agree are appropriate based on this evidence?

Note the following terminology:

- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present.
- **"could consider/may consider"** implies that the health and care settings could consider implementing the recommended approach.
- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance.

Recommendation	Grading
GPP7.1 Visitors should wear a surgical face mask when visiting a patient who has a suspected or confirmed respiratory infection.	Good Practice Point
GPP7.2 Visitors should wear a surgical face mask when there is a risk of splash and spray of blood or body fluids from the patient, if participating in patient care.	Good Practice Point
GPP7.3 The extended use of surgical face masks by visitors should be considered as an enhanced infection prevention and control measure during epidemics or periods of high rates of local transmission of respiratory infectious agents.	Good Practice Point
GPP7.4 Health and care settings should consider the provision of surgical face masks for visitors when visiting any patient who is severely immunocompromised or being cared for in protective isolation.	Good Practice Point
GPP7.5 During enablement of essential visiting, visitors with a suspected or confirmed respiratory infection should wear a surgical face mask on entry to the facility.	Good Practice Point

7.7 Balancing benefits and harms

Comment here on the potential impact of the Recommendation/Good Practice Point on service users, visitors and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation/Good Practice Point were followed. Be explicit, clear about pros.

Benefits
GPP7.1, GPP7.2, GPP7.3, GPP7.4 Use of a surgical face masks by visitors when visiting a patient who has a suspected or confirmed respiratory infection reduces the risk of exposure of the wearer to infectious agents. GPP7.2 The use of a surgical face mask by a visitor when providing direct care to a patient where there is anticipated spray or splash of blood and body fluids may reduce the risk of exposure of the wearer to potentially infectious agents. GPP7.3 The use of surgical face masks by visitors as an enhanced control measure may reduce the risk of transmission to and from visitors and therefore reduce the overall burden of infection in the healthcare facility GPP7.3. The use of surgical face masks by visitors as an enhanced control measure may reduce the risk of transmission from some pre-symptomatic or asymptomatic sources as it creates a physical barrier for the emission of any infectious particles. GPP7.4 The use of surgical face masks by visitors when visiting patients who are severely immunocompromised or in protective isolation may reduce the risk of infection in these vulnerable high-risk patients. GPP7.5 Use of surgical face masks by visitors who have respiratory infection during essential visits may reduce the risk of transmission to other individuals within the facility, including those they are visiting. Facilitating visiting is beneficial for the patient as it provides support whilst receiving care which promotes wellbeing. Benefits for the individuals visiting include a feeling of reassurance, ongoing connection with the person they are visiting, and the ability to provide support.

Risks and Harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation/ Good Practice Point were followed. Be explicit, clear about cons.

Risks/Harms
GPP7.1, GPP7.2, GPP7.3, GPP 7.4, GPP7.5 - The use of surgical face masks can reduce the ability of individuals to communicate which may negatively impact patient/ visitor psychological wellbeing. GPP 7.1-7.5 There is a risk that visitors may not wish to wear a mask and may respond negatively when asked to wear one. Staff morale may be decreased where there is resistance or refusal by the visitor to comply with the request to wear a surgical face mask as a prevention and control measure. GPP7.3. Extended or prolonged use of surgical face masks can increase the risk of skin irritation/ damage. GPP7.5 There is a risk that infectious visitors may transmit respiratory infection even whilst wearing a surgical face mask, if the mask does not prevent escape of all respiratory emissions.

Benefit-Harm assessment

Classify as “benefit outweighs harm” (or vice versa) or a “balance of benefit and harm.” Description of this balance can be from the individual service user/staff/visitor perspective, the societal perspective, or both. Recommendations/ Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events (or vice versa).

Benefit-Harm assessment
GPP7.1. Benefits outweigh harm as the need to prevent transmission to the visitor is considered greater than the unintended possible harm of impaired communication. This risk may be reduced where a transparent mask is used, as appropriate. GPP7.2 The use of a surgical face mask by visitors where there is an anticipated splash and spray risk if participating in provision of care is considered uncommon. However, to protect visitors in this scenario from exposure to potentially infectious agents this GPP was added. The impact on communication was considered to be low as the mask would be worn during the period of care where the splash and spray risk was present. Transparent mask use may also prevent communication issues where relevant. GPP7.3. Benefits were determined to outweigh harms where a mask is worn as part of extended mask use where risk assessment identifies the requirement for extended surgical face mask use in clinical care settings. While there may be an unintended negative impact on communication and discomfort to the wearer, these are considered as likely reduced through use of a transparent mask as appropriate and via regular breaks to mask use, as appropriate.

Benefit-Harm assessment
GPP 7.4 Benefits outweigh harms where the patient is considered as vulnerable to acquiring infection due to being severely immunocompromised. This should be based on a clinical assessment of the risk. While there is a risk of negative impact on the patient and visitor due to the mask reducing communication, the potential benefit (reduced risk of infection in the patient) outweighs this risk. These patient groups are highly vulnerable to infection and the impact of infection on their treatment and recovery could be significant. GPP 7.5. It was determined that the benefit (patient and visitor wellbeing) outweighs the harms (masks negatively impacting communication) where essential visitation is required. A further benefit is adherence to the key principles set out in Scottish Government guidance regarding essential visitation (hospital visiting guidance and adult care home visiting guidance), and adherence to Anne's Law.

7.8 Feasibility

Is the Recommendation/Good Practice Point implementable in the Scottish context?

Describe (if applicable) financial implications, opportunity costs, material or human resource requirements, facility needs, sustainability issues, human factors etc., that may be associated with following a Recommendation/Good Practice Point. State clearly if information on feasibility is lacking.

Feasibility
• GPP7.1, GPP7.2, GPP7.3, GPP 7.4, GPP7.5 There are costs associated with ensuring the maintenance of stock and supply of surgical face masks. • GPP7.3. If the use of masks is increased, during periods where extended or prolonged use of a surgical face mask is recommended, there will be waste management considerations and costs associated with this. • GPP7.1, GPP7.2, GPP7.3, GPP7.5 Supplemental procurement and availability of masks may be required during increased demand for outbreaks. • GPP7.1, GPP7.2, GPP7.3, GPP 7.4 Health promotion materials, training or activities may be required to assist staff in supporting and encouraging visitors using surgical face mask use. • GPP7.1, GPP7.2, GPP7.3, GPP 7.4, GPP7.5 Staff resource is required to encourage visitor mask use and to ensure masks are made available and can be offered when required. This includes provision of explanations as to why a mask is required, where and how they should be donned/doffed,

Feasibility

when they should be changed/ removed, and where to place or dispose of used masks.

- GPP7.1, GPP7.2, GPP7.3, GPP 7.4, GPP7.5 Appropriate facilities which allow for the safe donning and doffing of surgical face masks will need to be made available to reduce the risk of cross-contamination.
- GPP7.1, GPP7.2, GPP7.3, GPP 7.4, GPP7.5 Facilities and processes which allow for the distribution of surgical face masks at the appropriate place and time to the appropriate visitors should be considered.
- GPP 7.3, GPP7.4, GPP7.5 There would be additional training, time and other resources required to assure that local risk is accurately considered to inform the implementation of these GPPs.
- GPP7.3 It may be difficult to operationalise this good practice point given the complexities in quantifying the local burden of community infection.

7.9 Expert Opinion

Summarise the expert opinion used in creating the Recommendation or Good Practice Point. If none were involved, state “none”. Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining that expert opinion helps users understand their influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion

GPP7.1 **[Visitors should be encouraged to wear a surgical face mask when visiting a patient who has a suspected or confirmed respiratory infection]**.

- This GPP was informed by four experimental studies (SIGN 50 level 3) which demonstrated inconsistent results; it is not possible to draw conclusions regarding mask efficacy from this evidence.[30, 33, 34, 37] Additionally, four SIGN 50 level 4 guidance are consistent in advising masks for visitors when visiting a patient with a suspected/confirmed respiratory infection.[44, 53, 54, 63] It is the view of ARHAI Scotland and the Working Group that a surgical face mask may support essential visitation by providing a physical barrier for visitors while within a health and care setting where a patient has a suspected or confirmed respiratory infection. The benefits of the potential protection provided from a mask are considered to outweigh the potential harms. While there may be some feasibility considerations, the use of a mask for this purpose aligns with current practice in Scottish health and care settings and therefore the impact is expected to be minimal.

Expert opinion

GPP7.2 **[Visitors should be encouraged to wear a surgical face mask when there is a risk of splash and spray of blood and body fluids]**

- This GPP is informed by expert opinion from ARHAI Scotland and the working group. It is their view that visitors who may be exposed to splash and spray of blood or body fluids should be encouraged to wear a surgical face mask to prevent unnecessary exposure to potentially infectious fluids.

GPP7.3 **[The extended/prolonged use of surgical face masks by visitors may be considered as an enhanced infection prevention and control measure during epidemics or periods of high rates of community transmission of respiratory infectious agents.]**

- This GPP is informed by six guidance documents graded as SIGN 50 level 4, expert opinion.[13, 39, 42, 47, 49, 56] These documents outline that there is a place for extended use of surgical face masks by visitors in some settings which include where community transmission is high,[13, 49, 56] where clusters/ outbreaks are high,[13, 56] during winter months,[56] and as a pandemic control measure[39, 47] including where physical distancing is not possible.[39] It is the view of ARHAI Scotland and the Working Group that surgical face masks may provide an effective source control measure in these scenarios where there is a risk of asymptomatic or pre-symptomatic transmission. The operational challenges are noted but are considered a lesser harm in comparison to the transmission risk and infection burden that could arise in a vulnerable healthcare population. Pandemics have not been noted in this GPP because mask indications for pandemic scenarios will be covered in separate guidance.

GPP7.4 **[Health and care settings should consider the provision of surgical face masks for visitors when visiting any patient who is severely immunocompromised or being cared for in protective isolation]**.

- This good practice point is informed by one SIGN 50 level 4 guidance. With regards to use during winter months where prevalence of respiratory viruses may be higher, Health New Zealand recommends mask use when visiting settings with vulnerable patients/residents (immunocompromised individuals, for example those in cancer and transplant units, dialysis units, especially if “units [are] known to have suboptimal physical environment (including ventilation)”.[56] It is the view of ARHAI Scotland and the working group that the use of a surgical face mask by visitors when visiting severely immunocompromised patients or patients being cared for in protective isolation may support safe visiting by reducing the risk of transmission to these vulnerable patient groups. This is a precautionary approach.

Expert opinion
GPP7.5 **[During enablement of essential visiting, visitors with a suspected or confirmed respiratory infection should wear a surgical face mask on entry to the facility]** - • This GPP was not informed by evidence included within this review. It is the view of ARHAI Scotland and the working group that the use of a surgical face mask by visitors who have a suspected or confirmed respiratory infection should be considered to support essential visitation, as outlined by the Scottish Government guidance regarding essential visitation (hospital visiting guidance and adult care home visiting guidance), and mandated by Anne's Law.

7.10 Value judgements

Summarise value judgements used by the Working Group in creating the Recommendation/ Good Practice Point; if none were involved, state "none". Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other beliefs and priorities. Stating them clearly helps users understand their influence on interpreting objective evidence.

Value judgements
GPP7.5 – The working group consider it appropriate to support the guiding principles of essential visiting and to align with the Scottish Government hospital visiting guidance and adult care home visiting guidance wherever feasible. This GPP also supports adherence to Anne's Law.

7.11 Intentional vagueness

State reasons for any intentional vagueness in the Recommendation/Good Practice Point; if none was intended, state "none". Recommendations/Good Practice Points should be clear and specific, but if the Working Group chooses to be vague, acknowledging their reasoning clearly promotes transparency. Reasons for vagueness may include inadequate evidence; inability to achieve consensus among panel regarding evidence quality, anticipated benefits/harms, or interpretation of evidence; legal considerations; economic reasons; ethical/religious reasons.

Intentional vagueness
GPP 7.1, GPP7.2, GPP7.3, GPP7.4, GPP7.5 - None to note.

7.12 Exceptions

List situations or circumstances in which the Recommendation/ Good Practice Point should not be applied.

Exceptions
The following exceptions apply across all GPPs, indicating where a surgical face mask should not be used by a visitor: • If the visitor is a child or neonate (aged 0-5) • If unable to tolerate a mask or is medically exempt. • If the visitor refuses to wear a mask or is unlikely to adhere with the request due to their comorbidities or cognitive understanding.

7.13 Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
Research regarding visitors' surgical face mask use in health and care settings as an IPC measure is limited. Controlled comparison studies are required to consider mask effectiveness in reducing or preventing onward transmission of infections in both symptomatic and non-symptomatic individuals.

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

No considered judgement form is required for this question, because evidence and recommendations regarding eye and face protection use have already been considered within the Eye and Face Protection Literature Review.

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

A Quality of evidence

9.1 How reliable are the studies in the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4)

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is insufficient evidence to answer the key question, go to section B.

Comments	Evidence level
Eighteen evidence sources are included for this research question: • Two guidelines graded AGREE II 'recommend with provisos'[14, 27] ○ Humphreys et al., (2023) provided an update to the rituals and behaviours in the operating theatre guidance for the UK.[27] The guidance was developed using NICE methodology. However, the good practice points for mask use were based on low quality evidence and expert opinion. Other limitations included a lack of clarity on consultations with patients/ public, vagueness in some good practice points and lack of detail on the results of a meta-analysis. ○ The WHO (2014) guidance is specific to epidemic/pandemic-prone respiratory illnesses.[14] The details regarding grading per included study is unclear. The procedure for guideline development was unclear, as were the methods for systematic review and criteria for selecting evidence. The recommendations related to surgical face mask use were based on limited studies with a high risk of bias including those focused on community settings, bundled approaches, and flawed methodologies.	2 x AGREE II 'Recommend with provisos' 16 x SIGN 50 Level 4, expert opinion

Comments	Evidence level
• Fifteen guidance documents graded SIGN 50 level 4 expert opinion.[12, 13, 16, 17, 20, 22, 39, 44, 49, 54, 57, 65-68] • One British Standard graded SIGN 50 level 4 expert opinion.[6] No primary research of sufficient quality was included for this research question. The evidence base for this research question is generally low quality, consisting mainly of SIGN 50 level 4 expert opinion guidance, which has a high risk of bias related to its methodology.	

9.2 Are the studies consistent in their conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments
Compromised mask integrity as an indication for removal • There is consistency across five guidance documents, graded SIGN 50 level 4, that a surgical face mask should be removed/ changed each time it becomes contaminated, soiled, damaged or wet/ damp.[12, 16, 17, 20, 44] • These recommendations also feature within seven (SIGN 50 level 4) SARS-CoV-2 specific literature[13, 39, 49, 65-68] two pandemic influenza guidance (SIGN 50 level 4)[22, 54] and one pandemic ARI guideline (AGREE II 'recommend with provisos')[14] which recommend extended or prolonged face mask use. **Completion of a task as an indication for removal** • Two extant guidance and one British Standard (all SIGN 50 level 4) are consistent in advising that surgical face masks are removed/ changed after the completion of a patient care task/ procedure or an 'episode of care'.[6, 16, 57] **Between patients as an indication for removal** • Five guidance documents (SIGN 50 level 4), three of which are an organisation 'bundle' of COVID-19 guidance, are consistent in advising

Comments

removal or replacement of surgical masks between patients, to reduce the risk of cross infection.[12, 20, 66-68]

Indications to change during extended/ prolonged use

- When worn for source control, extant guidance (four SIGN 50 level 4) is consistent in advising that masks should be changed if soiled, damaged, wet, damp, or hard to breathe through.[49, 66-68]
    - If at any time when worn for source control, the mask is worn when delivering care to a patient with suspected/ confirmed COVID-19 or is 'on contact/ droplet precautions', the mask should be changed.[49, 66-68]
- Two COVID-19 guidance published by WHO (SIGN 50 level 4) advise a mask change when moving between patients in a cohort, only if moving from a COVID-19 patient to a patient with another 'droplet/ contact' infection[13] (or vice-versa) or if the patients have other 'healthcare transmissible infections'.[65]

There was no consistency across extant guidance (two SIGN 50 level 4, one AGREE II 'recommend with provisos') regarding the total time (before removal/ change) a mask may be worn during periods of prolonged or extended surgical face mask use:

- Humphreys et al (2023, AGREE II recommend with provisos) indicate that in surgical settings surgical masks should be changed "periodically" however a specific indication for what would conclude a 'period' or a specific timeline is not provided.[27]
- Two sources provide specific durations of wear:
    - WHO interim pandemic guidance (2020) (SIGN 50 level 4) reported that a surgical mask can be worn for 6 hours, yet in later documents no time frame is provided and it is recommended that the mask be changed after each patient when worn for personal protection.[69]
    - The UK Department of Health and Social Care (SIGN 50 level 4) advise a wear time of no longer than a 4-hour period.16

9.3 Are the studies applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include interventions, comparators or outcomes that are common to Scottish health and care settings?

Comments
The literature included for this research question consisted of guidance. These were created for the following country or countries: • Australia (n=1)[12] • Canada (n=3) [66-68] • International/ European (n=4)[13, 14, 39, 65] • UK (n=7)[6, 16, 17, 20, 22, 27, 54] • US (n=3) [44, 49, 57] Guidance which is not produced for a UK or Scottish health and care setting may have reduced applicability. Four of the guidance documents were published 10-15 years ago which may limit applicability to health and care settings in Scotland today as more recent evidence may not have been considered.[14, 17, 22, 54] Five guidance documents were produced to inform a specific setting including care homes,[68] acute care,[66] outpatient/ambulance settings,[67] and surgical/ theatre settings.[27] They may have limited applicability to other settings. SARS-CoV-2 pandemic guidance and recommendations provided within the included literature should be considered as reduced in their applicability to non-pandemic periods or other infectious agents.

9.4 Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
The evidence included in this question was guidance and therefore generalisability is not applicable.

9.5 Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
A formal assessment of publication bias was not conducted. However, it should be noted, that a degree of publication bias is expected as there was a lack of high-quality primary studies and unclear non-published data.

B Evidence to decision

9.6 Recommendation

What Recommendation(s) or Good Practice Point(s) does the Working Group agree are appropriate based on this evidence?

Note the following terminology:

- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present.
- **"could consider/may consider"** implies that the health and care settings could consider implementing the recommended approach.
- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance.

Recommendation	Grading
GPP9.1 Surgical face masks should be removed or changed if they become damaged, damp, wet, soiled or contaminated.	Good Practice Point
GPP9.2 Surgical face masks should be removed following the completion of a clinical procedure/ task.	Good Practice Point
GPP9.3 Surgical face masks should be changed between patients unless sessional use is indicated.	Good Practice Point
GPP9.4 When worn for prolonged periods (sessional or extended use), surgical face masks should be changed when moving between clinical areas (e.g. wards) and when moving from a clinical to a non-clinical area.	Good Practice Point
GPP9.5 Where indicated for personal protection during the care of (or while visiting) patients with suspected or confirmed respiratory infection, surgical face masks should be removed after exiting the patient/ service user's room.	Good Practice Point

9.7 Balancing benefits and harms

Comment here on the potential impact of the Recommendation/Good Practice Point on service users, visitors and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation/Good Practice Point were followed. Be explicit, clear about pros.

Benefits
GPP9.1 Removal/changing of a mask when it has lost its integrity due to contamination or moisture may reduce the wearers exposure to potentially contaminated material. GPP9.2 Removal of a surgical face mask at the end of a clinical procedure/ task may prevent onward transmission from masks which have become contaminated. GPP9.3 The benefit of changing surgical masks between patients is to reduce the risk of cross-transmission should the mask be contaminated. The benefit of not changing masks between patients when worn sessionally is that it may reduce the amount of hand contact with the face associated with mask changing and saves time that would have been spent exiting the room to safely doff and don new masks when caring for multiple patients with the same infectious pathogen within a cohort. It may also reduce the risk of far-field exposure to infectious particles, that could be encountered if the mask is changed between patients whilst in the cohort. GPP9.4 Removal of surgical masks when moving between clinical areas and when moving from a clinical to non-clinical area when worn sessionally or for extended use, may prevent cross-contamination and transmission from contaminated masks. GPP9.5 Removal of surgical masks (when worn for personal protection during the care of (or while visiting) patients with suspected or confirmed respiratory infection), after exiting the patient or service user's room ensures the wearer is not exposed to any respiratory particles whilst in the room. Removal after use also ensures the wearer does not continue to wear the mask when not indicated and reduces the risk of cross-contamination from the worn mask.

Risks and Harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation/ Good Practice Point were followed. Be explicit, clear about cons.

Risks/Harms
GPP9.1, GPP9.2, GPP9.4, GPP9.5 – none to note. GPP9.3 – There is a risk that infection may be transmitted between patients via contaminated masks if a mask is not changed between patients when worn sessionally. There is also a risk that staff may assume that other items of PPE can be worn sessionally and not changed between patients, for example aprons.

Benefit-Harm assessment

Classify as “benefit outweighs harm” (or vice versa) or a “balance of benefit and harm.” Description of this balance can be from the individual service user/staff/visitor perspective, the societal perspective, or both. Recommendations/Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events (or vice versa).

Benefit-Harm assessment
GPP9.1, GPP9.2, GPP9.4, GPP9.5 - only benefits identified. GPP9.3 The working group consider that the risk of indirect transmission, from one patient to another via a contaminated surgical mask, is low as it is unlikely that a patient will directly touch a healthcare workers mask. Hand hygiene performed between patients will also reduce the risk of transmission to patients via the healthcare worker touching a contaminated mask. Appropriate guidance and training may reduce the risk of inappropriate use of other PPE items. Consequently, the benefits are considered to outweigh the potential risks.

9.8 Feasibility

Is the Recommendation/Good Practice Point implementable in the Scottish context?

Describe (if applicable) financial implications, opportunity costs, material or human resource requirements, facility needs, sustainability issues, human factors etc., that may be associated with following a Recommendation/Good Practice Point. State clearly if information on feasibility is lacking.

Feasibility
GPP9.1, GPP9.2, GPP9.3, GPP9.4, GPP9.5 There may be a requirement for ongoing training, education and promotional materials to support decision-making and compliance with the recommended indications for surgical face mask removal.

Feasibility
GPP9.3 There will be a requirement for ongoing training, education and promotional materials to support staff compliance with hand hygiene and appropriate mask use (including compliance with changing masks when contaminated), to ensure that this good practice point can be implemented safely. GPP9.5 There may be a need for staff to prompt visitors to remove their masks when leaving the room.

9.9 Expert Opinion

Summarise the expert opinion used in creating the Recommendation or Good Practice Point. If none were involved, state “none”. Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining that expert opinion helps users understand their influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
GPP9.1 [Surgical face masks should be removed/changed when they become damaged, damp, wet, soiled or contaminated]: • This GPP was informed by 14 SIGN 50 level 4 guidance,[12, 13, 16, 17, 20, 22, 39, 44, 49, 54, 65-68] and one AGREE II ‘recommend with provisos’ guideline[14] which are consistent in advising that surgical masks should be removed or changed when contaminated, wet, damaged or damp. ARHAI Scotland and the Working Group support the view that a contaminated, soiled, damp, wet mask may have reduced integrity and therefore should be removed and changed as required. This GPP would apply regardless of the wear time (sessional or extended use). GPP9.2 [Surgical face masks should be removed following the completion of a clinical procedure/task]: • This GPP is informed by two guidance documents and one British Standard (all SIGN 50 level 4) that are consistent in advising that single use surgical face masks be removed/ changed after each use, including after completion of patient care episodes or a relevant procedure/ care task.[6, 16, 57] ARHAI Scotland and the Working Group support this. GPP9.3 [Surgical face masks should be changed between patients unless sessional use is indicated]: • This GPP is informed by five guidance documents (SIGN 50 level 4), three of which are an organisation ‘bundle’ of COVID-19 guidance, that are consistent in advising removal or replacement of surgical masks between

patients, to reduce the risk of cross infection.[12, 20, 66-68] This is specific to care of individual patients with suspected or confirmed infection.

- Extant guidance regarding mask change between patients during sessional use is limited. Two COVID-19 guidance published by WHO (SIGN 50 level 4) advise a mask change when moving between patients in a cohort, only if moving from a COVID-19 patient to a patient with another 'droplet/ contact' infection[13] (or vice-versa), or if the patients have other 'healthcare transmissible infections'.[65]
- Regarding the use of surgical masks when caring for cohorted patients, the risk of indirect transmission - from one patient to another via a contaminated surgical mask - is considered by ARHAI Scotland and the working group to be low, as it is unlikely that a patient will directly touch a healthcare workers mask. Further, if touched or contaminated, the mask should be changed and hand hygiene should be performed. This good practice point would not override application of GPP9.1 or GPP9.2, where masks should be removed if contaminated and at the conclusion of a clinical task for which splash/spray was anticipated, even when worn sessionally within a cohort.

GPP9.4 [Removal of surgical masks when moving between clinical areas and when moving from a clinical to non-clinical area when worn sessionally or for extended use, may prevent cross-contamination and transmission from contaminated masks]. This GPP is informed by expert opinion from the working group which consider it good practice to remove masks between clinical areas and when leaving a clinical area to enter a non-clinical area, as it may reduce the risk of cross-contamination if the mask has become contaminated during wear.

GPP9.5 This GPP is informed by the expert opinion of ARHAI Scotland and the working group who consider it good practice to remove masks after exit, to prevent exposure to any respiratory particles that may be present in the room. Removal of masks when no longer indicated may also prevent cross-contamination from the mask.

9.10 Value judgements

Summarise value judgements used by the Working Group in creating the Recommendation/Good Practice Point; if none were involved, state "none". Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other beliefs and priorities. Stating them clearly helps users understand their influence on interpreting objective evidence.

Value judgements
GPP 9.1, GPP9.2, GPP9.3, GPP9.4, GPP9.5 - None to note.

9.11 Intentional vagueness

State reasons for any intentional vagueness in the Recommendation/Good Practice Point; if none was intended, state “none”. Recommendations/Good Practice Points should be clear and specific, but if the Working Group chooses to be vague, acknowledging their reasoning clearly promotes transparency. Reasons for vagueness may include inadequate evidence; inability to achieve consensus among panel regarding evidence quality, anticipated benefits/harms, or interpretation of evidence; legal considerations; economic reasons; ethical/religious reasons.

Intentional vagueness
GPP 9.1, GPP9.2, GPP9.3, GPP9.4, GPP9.5 - None to note.

9.12 Exceptions

List situations or circumstances in which the Recommendation/ Good Practice Point should not be applied.

Exceptions
GPP 9.1, GPP9.2, GPP9.3, GPP9.4, GPP9.5 - None to note.

9.13 Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
High quality studies considering best practice for changing or removing a surgical face mask when worn generally as well as when worn for extended/prolonged periods.

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

A Quality of evidence

10.1 How reliable are the studies in the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4)

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is insufficient evidence to answer the key question, go to section B.

Comments	Evidence level
Sixteen evidence sources are included for this research question: • 15 guidance graded SIGN 50 level 4, expert opinion[12, 17, 22, 41, 44, 54, 66-68, 70-75] • One British Standard graded SIGN 50 level 4 expert opinion[6] This type of evidence is potentially subject to bias as there is often a lack of supporting evidence and an unclear methodology for formulating the guidance.	16 x SIGN 50 Level 4, expert opinion

10.2 Are the studies consistent in their conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments
How to don/put on a surgical face mask SIGN 50 Level 4 sources provide best practice for donning a surgical face mask and these are listed below: • If being donned/ put on as part of an ensemble of other protective equipment, three documents (SIGN 50 level 4) advise that a surgical face mask be donned second in the sequence (for example after performing

Comments

hand hygiene and donning an apron/gown).[12, 70, 71] However, the donning sequence may differ in surgical settings.[12]

- Perform hand hygiene prior to donning a mask (9 SIGN 50 level 4).[6, 12, 66-68, 70-72, 75]
- Examine the mask for holes and/ or tears (2 SIGN 50 level 4).[72, 74]
- Ensure the fluid repellent coloured side is facing outwards.[72]
- For ear loops, secure the loops behind the ears or for ties, bring the top ties to the crown of the head and secure; then tie bottom ties at the nape of the neck and secure (5 SIGN 50 level 4).[12, 22, 70, 73, 74]
- Mould the flexible nose piece/metal strip over the bridge of the nose (4 SIGN 50 level 4).[6, 22, 72, 73]
- Once covering the nose, extend to cover the mouth and chin making sure there are no gaps between the face and the mask (12 SIGN 50 level 4),[17, 22, 44, 54, 66-68, 70-73, 75] with adjustment mask to reduce gaps at the side (3 SIGN 50 level 4).[44, 72, 75]
- Do not wear the mask hanging around the neck (4 SIGN 50 level 4).[54, 66-68]

Location of donning

The optimum location to perform surgical face mask donning was unclear within most of the included literature:

- Seven guidance documents (SIGN 50 level 4) provide advice to don before[54] or upon[12, 41, 44, 66-68] entering a patient's care area or room. Both 'before' and 'upon' suggest a need to don the mask before or at the point of entry to a care area.
    - The Australian NHMRC IPC guidance (SIGN 50 level 4) provides a conditional recommendation that surgical masks should be worn "when entering a patient-care environment".[12]

10.3 Are the studies applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include interventions, comparators or outcomes that are common to Scottish health and care settings?

Comments
The included evidence was created for the following country/countries: • UK (n=6)[6, 17, 22, 54, 70, 71] • US (n=3)[44, 73, 74] • Australia (n=1)[12] • New Zealand (n=1)[41] • International (n=2)[72, 75] • Canada (n=3)[66-68] UK guidance published by UKHSA, the UK Department of Health and Coia et al. consider a UK context and are applicable to Scottish health and care settings. Whilst non-UK guidance may differ due to variations in care provision and policy across countries, it remains applicable due to the high-level focus of this research question being on donning practice and location.

10.4 Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
There were no primary studies included in relation to this research question therefore issues such as sample size and methods of sample selection are not relevant.

10.5 Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
A formal assessment of publication bias was not conducted. However, there were no primary studies found in relation to this research question.

B Evidence to decision

10.6 Recommendation

What Recommendation(s) or Good Practice Point(s) does the Working Group agree are appropriate based on this evidence?

Note the following terminology:

- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present.
- **"could consider/may consider"** implies that the health and care settings could consider implementing the recommended approach.
- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance.

Recommendation	Grading
GPP10.1 Hand hygiene should be performed before donning (putting on) a surgical face mask.	Good Practice Point
GPP10.2 The surgical face mask should be examined before donning; if there is any visible damage or defect (holes or tears) it should not be used.	Good Practice Point
GPP10.3 Where indicated for personal protection during the care of patients with suspected or confirmed respiratory infection, a surgical face mask should be donned (put on) prior to entering the care area (rooms, bays or cohort areas) and kept on whilst in the care area.	Good Practice Point
GPP10.4 The following steps should be followed when donning a surgical face mask: • Ensure the fluid repellent side is facing outwards • For masks with ear loops, secure ear loops by placing the loops behind the ears • For masks with ties, bring the top ties to the crown of the head and secure with a bow, then tie the bottom ties at the nape of the neck	Good Practice Point

Recommendation	Grading
• If present, shape the flexible nose wire/clip over the bridge of the nose for a secure fit • Extend and adjust the mask so that it covers the nose, mouth and chin, without gaps.	
GPP10.5 The front of a surgical face mask should not be touched once fitted to the face; if this should occur, hand hygiene should be performed.	Good Practice Point
GPP 10.6 A surgical face mask should be worn only on the face and not, for example, hanging around the neck or from an ear.	Good Practice Point
GPP10.7 When multiple items of PPE are required, surgical face masks should be donned second in the sequence following an apron / gown.	Good Practice Point

10.7 Balancing benefits and harms

Comment here on the potential impact of the Recommendation/Good Practice Point on service users, visitors and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation/Good Practice Point were followed. Be explicit, clear about pros.

Benefits
• GPP10.1, GPP10.2, GPP10.3, GPP10.4, GPP10.5, GPP10.6, GPP10.7, Donning surgical face masks correctly, minimises occupational exposure risks and may reduce the risk of transmission of infectious agents. • GPP10.1 Undertaking hand hygiene prior to donning may reduce cross contamination from the hands to the mask. • GPP10.2 Identifying issues with a surgical face mask before donning may prevent discomfort, identify issues with functionality or integrity and minimise unintended consequences introduced by donning substandard surgical face masks. • GPP10.3. Donning a surgical face mask before entering a room, bay, patient area or bed space may reduce exposure to infectious agents

Benefits
potentially present. Keeping the mask on whilst in the room may reduce the risk of far-field exposure to respiratory particles. • GPP10.4 Having the fluid resistant side of the mask facing outwards ensures the correct side is facing the fluid exposure. Ensuring that the mask is donned and secured correctly supports a closer fit of the surgical face mask to the contours of the wearers face. • GPP10.5 Undertaking hand hygiene if the front of the mask is touched once in situ, should reduce the risk of cross contamination of the wearer's hands from the mask. • GPP10.6 Wearing a surgical face mask correctly (not allowing the mask to hang around the neck or from an ear) will reduce risk of cross contamination from the mask and may decrease the risk of exposure to infectious agents.

Risks and Harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation Good Practice Point were followed. Be explicit, clear about cons.

Risks/Harms
GPP10.1, GPP10.2, GPP10.4, GPP10.5, GPP10.6, GPP10.7 - None to note. GPP10.3 There is a risk that keeping a surgical face mask on at all times when within a cohort area could lead to cross-transmission between patients if the mask is contaminated between patients.

Benefit-Harm assessment

Classify as "benefit outweighs harm" (or vice versa) or a "balance of benefit and harm." Description of this balance can be from the individual service user/staff/visitor perspective, the societal perspective, or both. Recommendations/Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events (or vice versa).

Benefit-Harm assessment
GPP10.1, GPP10.2, GPP10.4, GPP10.5, GPP10.6, GPP10.7 - Only benefits identified. GPP10.3 The benefit (reduced risk of far-field exposure to respiratory particles) outweighs the potential harm (cross-transmission between patients if the mask is contaminated between patients). The risk can be reduced by changing masks

Benefit-Harm assessment
between patients in the event that they become damaged, damp, wet, soiled or contaminated.

10.8 Feasibility

Is the Recommendation/Good Practice Point implementable in the Scottish context?

Describe (if applicable) financial implications, opportunity costs, material or human resource requirements, facility needs, sustainability issues, human factors etc., that may be associated with following a Recommendation/Good Practice Point. State clearly if information on feasibility is lacking.

Feasibility
• GPP10.1, GPP10.2, GPP10.3, GPP10.4, GPP10.5, GPP10.6, GPP10.7, Generally, surgical face masks are readily available within / throughout most health and care facilities. However, there may be costs and resources required to maintain a stock and supply of surgical face masks to assure the product is readily available where/when demand fluctuates. • GPP10.1, GPP10.2, GPP10.3, GPP10.4, GPP10.5, GPP10.6, GPP10.7 - Appropriate facilities which allow for the safe donning of surgical face masks (near to the point of care) will need to be made available to reduce the risk of exposure. This includes facilities for hand hygiene. • GPP10.1, GPP10.2, GPP10.3, GPP10.4, GPP10.5, GPP10.6, GPP10.7 - There will be an ongoing requirement for training, education and supportive promotional materials to support compliance with recommended surgical mask donning.

10.9 Expert opinion

Summarise the expert opinion used in creating the Recommendation or Good Practice Point. If none were involved, state “none”. Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining that expert opinion helps users understand their influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
GPP10.1 [Perform hand hygiene before donning (putting on) a surgical face mask] This was consistently outlined within nine SIGN 50 level 4 guidance sources.[6, 12, 66-68, 70-72, 75] It is the view of ARHAI Scotland and the working group that hand

Expert opinion

hygiene should be conducted before donning a surgical face mask to prevent cross contamination of the mask from the hands.

GPP10.2 [The surgical face mask should be examined before donning; if there is any visible damage or defect (holes or tears) it should not be used.] This GPP was informed by two SIGN 50 level 4 guidance documents.[72, 74] ARHAI Scotland and the working group support the view that surgical face masks with defects or damage should not be used, and an integrity check should be completed before donning. Compromised or damaged masks may may not provide sufficient protection to the wearer.

GPP10.3 [Where indicated for personal protection during the care of patients with suspected or confirmed respiratory infection, a surgical face mask should be donned (put on) prior to entering the care area (rooms, bays or cohort areas) and kept on whilst in the care area]. Six guidance documents (SIGN 50 level 4) provide advice to don before[54] or upon[12, 44, 66-68] entering a patient's care area or room. Both 'before' and 'upon' suggest a need to don the mask before or at the point of entry to a care area. The working group agreed that donning prior to entry, and keeping the mask on at all times when in the care area, provides the safest scenario and is a precautionary measure where patients with respiratory symptoms indicative of transmissible infection have yet to be formally diagnosed.

GPP10.4 (Specific steps/instructions for donning a surgical mask). As per Part A, this GPP is informed by best practice advice from 14 SIGN 50 level 4 guidance and one British Standard[6, 12, 17, 22, 44, 54, 66-68, 70-75] The Working Group are supportive of these instructions, no additional expert opinion to note.

GPP10.5 [The front of a surgical face mask should not be touched once fitted to the face; if this should occur, hand hygiene should be performed] The Working Group considered anecdotal evidence and observations made during the SARS-CoV-2 pandemic response to develop this GPP. This GPP provides a reminder that the front of a surgical face mask should not be touched once donned, to reduce the risk of cross-transmission. Performing hand hygiene (if the mask is touched) is a precaution to reduce the risk.

GPP10.6 [A surgical face mask should be worn only on the face and not, for example, hanging around the neck or from an ear.] This GPP was informed by four guidance documents (SIGN 50 level 4).[54, 66-68] The Working Group considered anecdotal evidence and observations made during the COVID-19 pandemic response of masks being worn in this manner. It is their view that wearing or re-wearing masks in this manner presents a risk of cross contamination. This GPP includes for extended/ prolonged (sessional) use of a surgical face mask.

GPP10.7 [When multiple items of PPE are required, surgical face masks should be donned second in the sequence following an apron / gown.] It was highlighted in three guidance documents (SIGN 50 level 4)[12, 70, 71] that for standard care a mask

Expert opinion
would be donned second in the sequence (for example after performing hand hygiene and donning an apron/ gown). The Working Group continue to support the view that surgical masks should be donned after a gown or apron to prevent unintended mask dislodgment and achieve intended bacterial filtration efficacy.

10.10 Value judgements

Summarise value judgements used by the Working Group in creating the Recommendation/ Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other beliefs and priorities. Stating them clearly helps users understand their influence on interpreting objective evidence.

Value judgements
GPP10.1, GPP10.2, GPP10.3, GPP10.4, GPP10.5, GPP10.6, GPP10.7 - None to note.

10.11 Intentional vagueness

State reasons for any intentional vagueness in the Recommendation/Good Practice Point; if none was intended, state “none”. Recommendations/Good Practice Points should be clear and specific, but if the Working Group chooses to be vague, acknowledging their reasoning clearly promotes transparency. Reasons for vagueness may include inadequate evidence; inability to achieve consensus among panel regarding evidence quality, anticipated benefits/harms, or interpretation of evidence; legal considerations; economic reasons; ethical/ religious reasons.

Intentional vagueness
GPP10.1, GPP10.2, GPP10.3, GPP10.4, GPP10.5, GPP10.6, GPP10.7 - None to note.

10.12 Exceptions

List situations or circumstances in which the Recommendation/ Good Practice Point should not be applied.

Exceptions
GPP10.1, GPP10.2, GPP10.3, GPP10.4, GPP10.5, GPP10.6, GPP10.7 - None to note.

10.13 Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
Further high-quality research may consider contamination risk and infection exposure risks in practice where surgical face masks are donned correctly (individually and as part of an ensemble). As well as comparative studies comparing the donning of the surgical face mask before, upon or after entering a relevant patient room or area.

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

A Quality of evidence

11.1 How reliable are the studies in the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4)

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is insufficient evidence to answer the key question, go to section B.

Comments	Evidence level

Sixteen documents are included for this research question:
• one regulation graded mandatory[4]
• two guidelines graded AGREE II 'recommend with provisos[11, 14] These documents may not include the most up-to-date research and had several limitations including with the rigour of development:
  ○ The EPIC3 guidelines published by Loveday et al. (2014) also had several limitations including limited rigour of development including a lack of detail regarding the systematic methods used to search evidence as well as for selecting evidence.[11]
  ○ The WHO (2014) guidance is specific to epidemic/pandemic-prone respiratory illnesses.[14] The details regarding grading per included study were unclear. The procedure for guideline development was unclear, as were the methods for systematic review and criteria for selecting evidence. The recommendations related to surgical face mask use were based on limited studies with a high risk of bias including those focused on community settings, bundled approaches, and flawed methodologies.
	1 x Mandatory
	2 x AGREE II 'Recommend with provisos'
	13x SIGN 50 Level 4, expert opinion

Comments	Evidence level
• 12 guidance graded SIGN 50 level 4 expert opinion.[12, 13, 17, 22, 44, 57, 70-74, 76] This type of evidence is potentially subject to bias as there is often a lack of supporting evidence and an unclear methodology for formulating the guidance. • One British Standard graded SIGN 50 level 4 expert opinion.[6]	

11.2 Are the studies consistent in their conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments
Removing the straps/ties • Two documents, graded as SIGN 50 level 4, advise that the front of surgical face masks are considered to be contaminated after use.[12, 71] • Six guidance documents and a British Standard (SIGN 50 level 4) are consistent in advising that the front of the mask should not be touched during removal.[6, 12, 13, 44, 71, 73, 76] • Nine of the guidance (n= 8 SIGN 50 level 4[12, 13, 17, 22, 44, 71, 74, 76] and n= 1 AGREE II 'recommend with provisos')[14] were consistent in advising that that surgical face masks should be doffed/ removed by handling the straps or ties only. • Five documents (SIGN 50 level 4) are consistent in describing how masks should be removed; surgical face masks with loops should be removed using the elastic ear loops[12] and masks with ties should be removed by untying bottom ties first followed by top ties,[17, 22, 73, 74] one document advised this should be achieved with the head tilted forwards.[74] **Order of ensemble removal** • When worn as part of an ensemble, it is consistently advised within seven expert opinion guidance documents[12, 22, 44, 70, 71, 73, 76] and one guideline (AGREE II 'recommend with provisos')[11] that surgical face masks be the last item of protective equipment to be removed.

Comments

- There was consistency across nine expert opinion (SIGN 50 level 4) [6, 12, 17, 70-74, 76] and one guideline (AGREE II 'recommend with provisos')[11] that the removal of a face mask should be followed by hand hygiene.
- Four guidance documents, graded as SIGN 50 level 4,[12, 70, 71, 76] and one guideline graded as AGREE II 'recommend with provisos'[11] advise the order of removal as gloves, hand hygiene, apron/ gown, eye protection, surgical face mask and then hand hygiene.

Where to remove the mask

The optimal location for face mask doffing (removal) was uncertain within the included literature (3 SIGN 50 level 4 expert opinion,[17, 57, 74] one mandatory UK regulation).[4]

Guidance, graded as SIGN 50 level 4, suggests that the mask be removed either:

- after leaving a "work area"[17], or when no longer in the clinical space[74]
- before leaving the patients room or care area[57]

The COSHH regulation (6) states that; "Personal protective equipment which may be contaminated by a substance hazardous to health shall be removed on leaving the working area and kept apart from uncontaminated clothing and equipment."[4]

The definition of work/care area was unclear in this context.

11.3 Are the studies applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include interventions, comparators or outcomes that are common to Scottish health and care settings?

Comments

The country or countries for which the guidance was created was as follows:

- UK (n=7)[4, 6, 11, 17, 22, 70, 71]
- Australian (n=1)[12]
- US (n=4)[44, 57, 73, 74]
- International or European (n=4)[13, 14, 72, 76]

One guidance document is specific to adult social care settings,[71] one for ambulance settings,[22] however there are no specific concerns about applicability.

Comments
Of the three guidance documents that provide information regarding location of doffing, one is from the UK,[17] two are from the US.[57, 74] There are no concerns about applicability of the US guidance to Scottish settings. Two of the documents are specific to SARS-CoV-2,[13, 76] one is pandemic influenza-specific,[22] and one is focused on pandemic/ epidemic prone respiratory infections.[14] These documents are applicable as these infectious agents can appear in Scottish settings.

11.4 Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
There were no primary studies found in relation to this research question therefore issues such as sample size and methods of sample selection are not applicable.

11.5 Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
A formal assessment of publication bias was not conducted. However, as there were no primary studies found in relation to this research question, publication bias is difficult to determine.

B Evidence to decision

11.6 Recommendation

What Recommendation(s) or Good Practice Point(s) does the Working Group agree are appropriate based on this evidence?

Note the following terminology:

- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present.
- **"could consider/may consider"** implies that the health and care settings could consider implementing the recommended approach.
- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance.

Recommendation	Grading
GPP11.1 Surgical face masks should be removed by handling the loops or ties only and any direct contact with the front of the mask should be avoided as it may be contaminated.	Good Practice Point
GPP11.2 Surgical face masks with ties should be removed by untying or breaking the bottom ties first followed by the top ties. Masks with ear loops should be removed from each side, with the head tilted forward.	Good Practice Point
GPP11.3 Hand hygiene should be performed immediately before and after removal of a surgical face mask.	Good Practice Point
GPP11.4 A surgical face mask should be doffed (removed) at the nearest disposal point; this should be following exit from the care area (room, bay or cohort area) when worn for the care of patients with suspected or confirmed respiratory infection.	Good Practice Point

11.7 Balancing benefits and harms

Comment here on the potential impact of the Recommendation/Good Practice Point on service users, visitors and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation/Good Practice Point were followed. Be explicit, clear about pros.

Benefits
• GPP11.1, GPP11.2, GPP11.3, GPP11.4 Doffing (taking off) surgical face masks correctly, may minimise exposure risks and the transmission of infectious agents. • GPP11.3 Engaging in hand hygiene as part of doffing may reduce cross contamination of the hands following contact with a potentially contaminated mask. • GPP11.4 Removal of a surgical face mask at the nearest disposal point reduces the risk of cross-transmission from the mask. Removal of a surgical face mask following exit from the care area (room, bay or cohort area) when worn for the care of patients with suspected or confirmed respiratory infection, is a precautionary measure to reduce the risk of exposure to respiratory particles that could occur if the mask were removed whilst till in the care area.

Risks and Harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation/ Good Practice Point were followed. Be explicit, clear about cons.

Risks/Harm
GPP11.1, GPP11.2, GPP11.3, GPP11.4 - None to note.

Benefit-Harm assessment

Classify as “benefit outweighs harm” (or vice versa) or a “balance of benefit and harm.” Description of this balance can be from the individual service user/staff/visitor perspective, the societal perspective, or both. Recommendations/ Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events (or vice versa).

Benefit-Harm assessment
GPP11.1, GPP11.2, GPP11.3, GPP11.4- Only benefits identified.

11.8 Feasibility

Is the Recommendation/Good Practice Point implementable in the Scottish context?

Describe (if applicable) financial implications, opportunity costs, material or human resource requirements, facility needs, sustainability issues, human factors etc., that may be associated with following a Recommendation/Good Practice Point. State clearly if information on feasibility is lacking.

Feasibility
• GPP11.1, GPP11.2, GPP11.3, GPP11.4, Appropriate facilities (including hand hygiene and waste disposal) which allow for safe doffing of surgical face masks will need to be made available at doffing locations. • R11.1, GPP11.1, GPP11.2, GPP11.3, GPP11.4, There may be ongoing training requirements and supportive promotional materials to support risk assessment and compliance with recommended surgical mask doffing, including for non-English speakers.

11.9 Expert opinion

Summarise the expert opinion used in creating the Recommendation or Good Practice Point. If none were involved, state “none”. Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining that expert opinion helps users understand their influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
GPP11.1 **[Surgical face masks should be removed by handling the loops or ties only and contact with the front of the mask should be avoided as it may be contaminated]:** • This GPP was informed by six guidance documents and a British Standard (SIGN 50 level 4) that are consistent in advising that the front of the mask should not be touched during removal.[6, 12, 13, 44, 71, 73, 76] Further, nine guidance (n= 8 SIGN 50 level 4[12, 13, 17, 22, 44, 71, 74, 76] and n= 1 AGREE II ‘recommend with provisos’)[14] are consistent in advising that surgical face masks should be doffed/ removed by handling the straps or ties only. The Working Group support the view that a used surgical face mask may be

Expert opinion

contaminated and that this is likely to be concentrated on the face/ front of the mask, therefore only the loops and ties should be handled during removal.

GPP11.2 [Surgical face masks with ties should be removed by untying or breaking the bottom ties first followed by the top ties. Masks with ear loops should be removed from each side, with the head tilted forward]:

- This GPP was informed by five documents (SIGN 50 level 4) that are consistent in describing how masks should be removed; surgical face masks with loops should be removed using the elastic ear loops[12] and masks with ties should be removed by untying bottom ties first followed by top ties,[17, 22, 73, 74] one document advised this should be achieved with the head tilted forwards.[74] With only benefits associated with the removal of a mask as stated in this GPP it is supported by the Working Group.

GPP11.3 [Hand hygiene should be performed before and after removal of a surgical face mask]:

- This GPP was informed by nine expert opinion (SIGN 50 level 4)[6, 12, 17, 70-74, 76] and one guideline (AGREE II 'recommend with provisos')[11] that are consistent in advising that the removal of a face mask should be followed by hand hygiene. It is the view of the Working Group that hand hygiene should be conducted both before and following the removal of a surgical face mask to avoid cross contamination. This GPP also aligns with moment 3 (after blood or body fluid exposure risk) of the WHO 5 moments of hand hygiene. For practicality, the post removal hand hygiene step would be performed following the masks disposal as indicated by GPP12.1.

GPP11.4 This GPP is informed by two SIGN 50 level 4 guidance that advise removal of masks after leaving the care area ("work area",[17] "clinical space"),[74] one that advises removal before leaving the patients room or care area,[57] and the UK COSHH regulation which instructs removal of PPE on leaving the working area. Acknowledging the inconsistency in extant guidance, the working group agreed that if a mask is removed after leaving the care area it could reduce the risk of any occupational respiratory exposures that could occur if the mask was removed whilst still in the care area, and therefore within proximity of the source. This approach does not contradict with the UK COSSH instructions. It is the expert opinion of the working group that it is best practice to remove a surgical face mask at the nearest point of disposal to reduce cross-transmission from masks that may be contaminated with blood and body fluids.

11.10 Value judgements

Summarise value judgements used by the Working Group in creating the Recommendation/ Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other beliefs and priorities. Stating them clearly helps users understand their influence on interpreting objective evidence.

Value judgements
GPP11.1, GPP11.2, GPP11.3, GPP11.4 - None to note.

11.11 Intentional vagueness

State reasons for any intentional vagueness in the Recommendation/Good Practice Point; if none was intended, state “none”. Recommendations/Good Practice Points should be clear and specific, but if the Working Group chooses to be vague, acknowledging their reasoning clearly promotes transparency. Reasons for vagueness may include inadequate evidence; inability to achieve consensus among panel regarding evidence quality, anticipated benefits/harms, or interpretation of evidence; legal considerations; economic reasons; ethical/ religious reasons.

Intentional vagueness
GPP11.1, GPP11.2, GPP11.3, GPP11.4 - None to note.

11.12 Exceptions

List situations or circumstances in which the Recommendation/ Good Practice Point should not be applied.

Exceptions
GPP11.1, GPP11.2, GPP11.3, GPP11.4 - None to note.

11.13 Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
Further high-quality research may consider contamination risk and infection risk where surgical face masks are doffed correctly (individually and as part of an ensemble), as well as comparative studies comparing the removal of the surgical face mask before or after leaving a relevant patient room or area.

Research question 12: How should surgical face masks be disposed of?

A Quality of evidence

12.1 How reliable are the studies in the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4)

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is insufficient evidence to answer the key question, go to section B.

Comments	Evidence level
Eleven documents are included for this research question: • Ten guidance documents graded SIGN 50 level 4 expert opinion[12, 13, 17, 22, 44, 57, 66-68, 74] • One British Standard graded SIGN 50 level 4 expert opinion[6] The evidence base for this research question is generally low quality, consisting of SIGN 50 level 4 expert opinion guidance which has a high risk of bias due to the lack of supporting evidence and an unclear methodology for formulating the guidance. However, it may represent the established practices for surgical mask use.	11 x SIGN 50 Level 4, expert opinion

12.2 Are the studies consistent in their conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments
Immediate disposal • Disposing of a surgical face mask immediately after it has been removed is advised by two guidance documents (SIGN 50 level 4).[13, 17]

Comments
Waste receptacle • Disposal of a face mask in an “appropriate” or “suitable collection container” is advised by UK pandemic guidance[22] and a British Standard respectively.[6] • Non-touch features are advised by a suite of Canadian SARS-CoV-2 guidance (SIGN 50 level 4).[66-68] **Hand hygiene** • Four guidance (SIGN 50 level 4) are consistent in advising hand hygiene following the removal and disposal of a surgical face mask.[12, 17, 22, 74] **Technique** • The APIC (2015) guidance (SIGN 50 level 4) advises that only the ties should be handled when disposing of a surgical mask.[74] This is in line with the evidence considered in research question 11 (where and how should surgical face masks be doffed (removed)).

12.3 Are the studies applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include interventions, comparators or outcomes that are common to Scottish health and care settings?

Comments
The country or countries for which this evidence was developed are as follows: • UK (n=3)[6, 17, 22] • Canada (n=3) [66-68] • US (n=3)[44, 57, 74] • International (n=1)[13] • Australia (n=1)[12] Only two of the guidance documents were created with a UK context in mind.[17, 22] Some of the guidance is specific to a particular setting or population. For example, the three Canadian guidance documents were published for the SARS-CoV-2 pandemic response in Canada.[66-68] While guidance created for a specific setting or a specific country may lack applicability to Scottish settings, this guidance on disposal is high level and does not appear to be setting specific (i.e., specific

Comments
actions dependant on a setting). Therefore, there are no concerns with applicability.

12.4 Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
There were no primary studies found in relation to this research question therefore issues such as sample size and methods of sample selection are not applicable.

12.5 Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
A formal assessment of publication bias was not conducted. However, as there were no primary studies found in relation to this research question, publication bias is difficult to determine.

B Evidence to decision

12.6 Recommendation

What Recommendation(s) or Good Practice Point(s) does the Working Group agree are appropriate based on this evidence?

Note the following terminology:

- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present.
- **"could consider/may consider"** implies that the health and care settings could consider implementing the recommended approach.
- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance.

Recommendation	Grading
GPP12.1 Used surgical face masks should be disposed of immediately after their removal into an appropriate waste receptable.	Good Practice Point
GPP12.2 Used surgical face masks should only be handled by the ties or loops during disposal.	Good Practice Point
GPP12.3 Hand hygiene should be performed immediately after disposal of a surgical face mask.	Good Practice Point

12.7 Balancing benefits and harms

Comment here on the potential impact of the Recommendation/Good Practice Point on service users, visitors and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation/Good Practice Point were followed. Be explicit, clear about pros.

Benefits
GPP12.1, GPP12.2, GPP12.3 Disposal of surgical face masks correctly may reduce potential exposure to infectious agents and by extension transmission risks.

Risks and Harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation/ Good Practice Point were followed. Be explicit, clear about cons.

Risks/Harms
GPP12.1, GPP12.2, GPP12.3 - None to note.

Benefit-Harm assessment

Classify as “benefit outweighs harm” (or vice versa) or a “balance of benefit and harm.” Description of this balance can be from the individual service user/staff/visitor perspective, the societal perspective, or both. Recommendations/Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events (or vice versa).

Benefit-Harm assessment
GPP12.1, GPP12.2, GPP12.3 - Only benefits identified

12.8 Feasibility

Is the Recommendation/Good Practice Point implementable in the Scottish context?

Describe (if applicable) financial implications, opportunity costs, material or human resource requirements, facility needs, sustainability issues, human factors etc., that may be associated with following a Recommendation/Good Practice Point. State clearly if information on feasibility is lacking.

Feasibility
• GPP12.1, GPP12.2, GPP12.3 To facilitate safe surgical face mask disposal, health and care services may need to consider the provision and placement of clinical waste receptacles and hand hygiene facilities. This could have financial, training and material implications. • GPP12.1, GPP12.2, GPP12.3 There may be requirements to develop and deliver ongoing training and education and supportive promotional materials including for non-English speakers.

12.9 Expert opinion

Summarise the expert opinion used in creating the Recommendation or Good Practice Point. If none were involved, state “none”. Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining that expert opinion helps users understand their influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
GPP12.1 **[Surgical face masks should be disposed of immediately after their removal into an appropriate waste receptacle]** This good practice point is informed by two guidance documents (SIGN 50 level 4) that advise immediate disposal after removal[13, 17] and two SIGN 50 level 4 documents (one UK pandemic guidance,[22] one British Standard)[6] that advise disposal into an appropriate or suitable container. It is the view of the Working Group that disposal of a mask immediately after removal takes a precautionary approach (reducing likelihood or exposure risk) and aligns with well-established guidance. Details regarding waste streams and suitability of waste containers or bags (including design features) is covered separately in the NIPCM ‘Safe disposal of waste’ literature review; the working group agreed that this detail is not required here. GPP12.2 **[Surgical face masks should only be handled by the ties or loops during disposal]** This GPP is informed by one guidance published by APIC (SIGN 50 level 4) that advises that only the ties should be handled when disposing of a surgical mask.[74] It is the view of the Working Group that this GPP aligns with established practice and supports a precautionary approach as it may minimise the risk of exposure to infectious agents. GPP12.3 **[Hand hygiene should be performed immediately after disposal of a surgical face mask]** This GPP is informed by four guidance (SIGN 50 level 4) that are consistent in advising hand hygiene following the removal and disposal of a surgical face mask.[12, 17, 22, 74] It is the view of the Working Group that this GPP aligns with a precautionary approach as it may minimise the risk of cross transmission of and exposure to infectious agents. This aligns with moment 3 of the WHO 5 moments of hand hygiene (after blood or body fluid exposure risk). Although GPP11.3 advises hand hygiene immediately after removal, this would incorporate the action of disposal at the same time as per GPP12.1; therefore, in practice the hand hygiene would be performed once (immediately after the mask has been removed and disposed of). Stakeholders requested this to be made clear in final guidance.

12.10 Value judgements

Summarise value judgements used by the Working Group in creating the Recommendation/ Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other beliefs and priorities. Stating them clearly helps users understand their influence on interpreting objective evidence.

Value judgements
GPP12.1, GPP12.2, GPP12.3 – none to note.

12.11 Intentional vagueness

State reasons for any intentional vagueness in the Recommendation/Good Practice Point; if none was intended, state “none”. Recommendations/Good Practice Points should be clear and specific, but if the Working Group chooses to be vague, acknowledging their reasoning clearly promotes transparency. Reasons for vagueness may include inadequate evidence; inability to achieve consensus among panel regarding evidence quality, anticipated benefits/harms, or interpretation of evidence; legal considerations; economic reasons; ethical/ religious reasons.

Intentional vagueness
GPP12.1, GPP12.2, GPP12.3 - None to note.

12.12 Exceptions

List situations or circumstances in which the Recommendation/ Good Practice Point should not be applied.

Exceptions
GPP12.1, GPP12.2, GPP12.3 - None to note.

12.13 Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
The absence of primary research in this area (disposal of surgical masks) is reflective of disposal being driven primarily by logic and common sense and in

Recommendations for research
alignment with established waste management guidance. There is no requirement for any further research specific to disposal of surgical masks

Research question 13: How should a surgical face mask be stored?

A Quality of evidence

13.1 How reliable are the studies in the body of evidence?

(see SIGN 50, section 5.3.1, 5.3.4)

Comment here on the quantity of evidence available on this topic and its methodological quality. Please include citations and evidence levels.

If there is insufficient evidence to answer the key question, go to section B.

Comments	Evidence level
Eight documents are included for this research question: • Two UK legislative regulations graded mandatory.[3, 4] • Six guidance documents, graded as SIGN 50 level 4 expert opinion.[7, 12, 66-68, 77] This type of evidence is potentially subject to bias as there is often a lack of supporting evidence and an unclear methodology for formulating the guidance. The evidence base for this research question consists of legislation and extant guidance, some of which accompanies the legislation.[7, 77] This is expected for this research question.	2 x Mandatory 6 x SIGN 50 Level 4

13.2 Are the studies consistent in their conclusions?

(see SIGN 50, section 5.3.2)

Comment here on the degree of consistency demonstrated by the evidence. Where there are conflicting results, indicate how the group formed a judgement as to the overall direction of the evidence.

Comments
Dedicated area • An accessible (point of use) and dedicated room or space for mask storage is consistently advised by four guidance (SIGN 50 Level 4).[12, 66-68]

Comments
Two of the six guidance documents are consistent with the mandatory legislation that they accompany: • UK PPE at work (Amendment) 2022 regulations (mandatory) state that "appropriate accommodation" for PPE must be provided,[3] the UK HSE guidance (SIGN 50 level 4) that accompanies this legislation provides the example of a clean, dry cupboard.[7] • The UK COSHH regulations (mandatory) states that a "well-defined place" should be identified for PPE but specifics are not provided.[4] The UK HSE guidance (SIGN 50 level 4) for this regulation states that storage should be "adequate" to provide protection from "contamination, loss or damage".[77]

13.3 Are the studies applicable to Scottish health and care settings?

(see SIGN 50, section 5.3.3)

For example, do the studies include interventions, comparators or outcomes that are common to Scottish health and care settings?

Comments
The evidence included for this research question was created for the following country/countries: • UK (n=4)[3, 4, 7, 77] • Canada (n=3)[66-68] • Australia (n=1)[12] The UK legislation included for this research question are applicable to Scottish health and care settings. The UK legislation is general and not specific to IPC within health and care settings. Of the UK-specific literature the two UK HSE guidance documents[7, 77] are specific to the regulations which they accompany, COSHH, (as amended) and PPER (amendment). Some of the guidance is specific to a particular setting or population. For example, the three Canadian guidance documents were published for the SARS-CoV-2 pandemic response.[66-68] While guidance created for a specific setting may lack applicability to some other settings, the storage of masks is applicable across all settings.

13.4 Are the studies generalisable to the target population?

Comment here on sample size and methods of sample selection. Is the sample representative of the specific population/group of interest? Generalisability is only relevant to primary research studies.

Comments
There were no primary studies found in relation to this research question therefore issues such as sample size and methods of sample selection are not relevant.

13.5 Are there concerns about publication bias?

(see SIGN 50, section 5.3.5)

Comment here on whether there is a risk in the evidence base that studies have been selectively published based on their results (and thus a risk that results from published studies are systematically different from unpublished evidence).

Comments
A formal assessment of publication bias was not conducted. However, it should be noted, that a degree of publication bias is expected given the level of expert opinion guidance for this research question as well as a lack of high-quality primary studies.

B Evidence to decision

13.6 Recommendation

What Recommendation(s) or Good Practice Point(s) does the Working Group agree are appropriate based on this evidence?

Note the following terminology:

- **"should"** implies that the health and care setting "should" implement the recommended approach unless a clear and compelling rationale for an alternative approach is present.
- **"could consider/may consider"** implies that the health and care settings could consider implementing the recommended approach.
- **"must"** implies that the health and care setting must implement the recommended approach and is used where a recommendation has been directly lifted from legislation or mandatory guidance.

Recommendation	Grading
R13.1 Appropriate storage arrangements in a well-defined space must be provided for PPE to protect it from contamination, loss or damage.	Recommendation
GPP13.1 Surgical face masks should be stored within their original packaging in an appropriate dedicated room or allocated space that is accessible and near to the intended point of use, outside of patient rooms/ zones.	Good Practice Point

13.7 Balancing benefits and harms

Comment here on the potential impact of the Recommendation/Good Practice Point on service users, visitors and staff. Benefits and harms include considerations beyond IPC.

Benefits

List the favourable changes in outcome that would likely occur if the Recommendation/Good Practice Point were followed. Be explicit, clear about pros.

Benefits
R13.1 Protection of surgical face masks from contamination, damage and loss will reduce the risk of cross-transmission and exposure of the wearer to any contaminant and should ensure that masks are providing their intended protection. GPP13.1 Storage of masks within their original packaging may prevent contamination of the mask that could occur from handling during repackaging into storage areas. Ensuring that masks are accessible and near to the point of use may support compliance with mask use and quick donning. Having a dedicated space for storage may support staff in knowing where to locate surgical face masks when required. Storage outside of patient rooms/ zones may reduce the risk of contamination.

Risks and Harms

List the adverse events or other unfavourable outcomes that may occur if the Recommendation/ Good Practice Point were followed. Be explicit, clear about cons.

Risks/Harms
R13.1, GPP13.1, - None to note.

Benefit-Harm assessment

Classify as “benefit outweighs harm” (or vice versa) or a “balance of benefit and harm.” Description of this balance can be from the individual service user/staff/visitor perspective, the societal perspective, or both. Recommendations/ Good Practice Points are possible when clear benefit is not offset by important harms, costs or adverse events (or vice versa).

Benefit-Harm assessment
R13.1, GPP13.1 - Only benefits identified.

13.8 Feasibility

Is the Recommendation/Good Practice Point implementable in the Scottish context?

Describe (if applicable) financial implications, opportunity costs, material or human resource requirements, facility needs, sustainability issues, human factors etc., that may be associated with following a Recommendation/Good Practice Point. State clearly if information on feasibility is lacking.

Feasibility
• R13.1, GPP13.1 - To facilitate safe and appropriate storage, there will be a requirement to consider the provision and availability or repurposing of appropriate dedicated rooms or spaces. This may require time resource, materials and cost.

13.9 Expert opinion

Summarise the expert opinion used in creating the Recommendation or Good Practice Point. If none were involved, state “none”. Translating evidence into action often involves expert opinion where evidence is insufficient. Clearly outlining that expert opinion helps users understand their influence on interpreting objective evidence. Expert opinion may also be required where there is no evidence available.

Expert opinion
R13.1 **[Appropriate storage arrangements in a well-defined space must be provided for PPE to protect it from contamination, loss or damage].** This recommendation is informed by COSHH/PPER legislation which is considered mandatory in Scotland.[3, 4] GPP13.1 **[Surgical face masks should be stored within their original packaging in an appropriate dedicated room or allocated space that is accessible and near to the intended point of use, outside of patient rooms/ zones].** This GPP is informed by SIGN 50 level 4 guidance from Australia[12] and Canada[66-68] that advises accessible (point of use) and dedicated room or space for mask storage. The suggestion to store masks within their original packaging is informed by the expert opinion of the working group as a reasonable means of reducing the risk of contamination that could occur during transfer of masks from their packaging to storage.

13.10 Value judgements

Summarise value judgements used by the Working Group in creating the Recommendation/ Good Practice Point; if none were involved, state “none”. Translating evidence into action often involves value judgements, which include guiding principles, ethical considerations, or other beliefs and priorities. Stating them clearly helps users understand their influence on interpreting objective evidence.

Value judgements
R13.1, GPP13.1– None to note.

13.11 Intentional vagueness

State reasons for any intentional vagueness in the Recommendation/Good Practice Point; if none was intended, state “none”. Recommendations/Good Practice Points should be clear and specific, but if the Working Group chooses to be vague, acknowledging their reasoning clearly promotes transparency. Reasons for vagueness may include inadequate evidence; inability to achieve consensus among panel regarding evidence quality, anticipated benefits/harms, or interpretation of evidence; legal considerations; economic reasons; ethical/ religious reasons.

Intentional vagueness
R13.1, GPP13.1 – ‘Appropriate storage arrangements’ are not further defined as this may vary according to the local setting. The focus is on the storage arrangement ensuring the surgical masks are protected from any contamination, damage or loss.

13.12 Exceptions

List situations or circumstances in which the Recommendation/ Good Practice Point should not be applied.

Exceptions
R13.1, GPP13.1 - None to note.

13.13 Recommendations for research

List any aspects of the question that require further research.

Recommendations for research
The absence of primary research in this area (storage of surgical masks) is reflective of storage being driven primarily by logic and common sense and in alignment with established facilities guidance (e.g., HAI-SCRIBE). There is no requirement for any further research specific to storage of surgical masks.

Appendix 1 - Definitions

Term used	Description	Evidence
Recommendation	In general, 'Recommendations' should be supported by high- to moderate-quality evidence. In some circumstances, however, 'Recommendations' may be made based on lower quality evidence when high-quality evidence is impossible to obtain, and the anticipated benefits strongly outweigh the harms or when the Recommendation is required by Legislation or Mandatory Guidance.	Sufficient evidence (SIGN 50 level 1++, 1+, 2++, 2+, 3, 4* AGREE II Recommend Recommend (with Modifications)) Legislation, or mandatory guidance
Good Practice Point	Insufficient evidence or a lack of evidence to make a recommendation but identified best practice based on the clinical/technical experience (expert opinion) of the Working Group, with a clear balance between benefits and harms.	Insufficient evidence + Working Group expert opinion OR No evidence + Working Group expert opinion
No Recommendation	Both a lack of pertinent evidence and an unclear balance between benefits and harms.	No evidence

* A Recommendation cannot be developed when there is only SIGN 50 level 4 evidence available.

The considered judgement form and recommendation system are adapted from the following three sources:

- Update to the Centers for Disease Control and Prevention and the Healthcare Infection Control Practices Advisory Committee Recommendation Categorization Scheme for Infection Control and Prevention Guideline Recommendations. (2019)

- Scottish Intercollegiate Guidelines Network (SIGN). A guideline developer's handbook. (2019)

- Grading of Recommendations, Assessment, Development and Evaluation (GRADE) Handbook. (2013)

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