

Evidence Table

All studies which are critically appraised as part of the literature review are assigned a grade of evidence based on the SIGN 50 methodology grading system (SIGN, 2004), which allows scientific studies to be assessed for quality using a number of reviewing forms (available from the SIGN website - <http://www.sign.ac.uk>). The main conclusions from the studies are summarized along with a brief description of the study quality in an Evidence Table. Studies, which have sufficient quality and specifically answer a defined research question are grouped together to enable formation of a “considered judgment” based on this information. This “considered judgment” is then used as the basis for formulation of recommendations.

This system allows formulation of recommendations supported by good quality observational studies in the case when RCTs are not available for practical or ethical reasons, as is generally found in infection control literature.

Levels of evidence

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

1++ High quality meta analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias

1+ Well conducted meta analyses, systematic reviews of RCTs, or RCTs with a low risk of bias

1- Meta analyses, systematic reviews of RCTs, or RCTs with a high risk of bias

2++ High quality systematic reviews of case-control or cohort studies

High quality case-control or cohort studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is causal

2+ Well conducted case control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal

2- Case control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal

3 Non-analytic studies, e.g. case reports, case series

4 Expert opinion

Question: When should patients wear a FRSM? (SICPs)					
Study	Study type	Evidence level	Intervention	Comparison	Outcome measures
Ref 1387. Baig, S, Rashid, T and Saleem, M. Protection from blood aerosol contamination when managing epistaxis: a study of the effectiveness of a patient mouth mask. 2015. Ear, Nose and Throat Journal. Vol 94 (9) p394-398.	RCT with high risk of bias	3	<p>Patients wearing a mask when being treated for epistaxis via cautery, anterior nasal packing or anterior/posterior packing.</p> <p>(Classic Surgical Mask – Kimberley Clark $\geq 96\%$ (BFE), $\geq 97\%$ (PFE))</p>	Patients not wearing a mask when being treated for epistaxis via cautery, anterior nasal packing or anterior/posterior packing.	Number of blood splatters on physicians eye shield
<p>Assessment of evidence:</p> <p>4 blood splatters (13.3%) in mouth mask group 8 blood splatters (26.7%) in control group</p> <p>No p-values or confidence intervals to indicate levels of statistical significance. Participants were randomly allocated but authors do not indicate how this was done. Lack of information regarding the characteristics of participants.</p> <p>This study suggests that the wearing of surgical masks by epistaxis patients during treatment may reduce the number of blood splashes to HCW facial PPE. However, due to limited information and small sample sizes, conclusions cannot be definitively drawn.</p> <p>It is also unclear whether the need for patients to wear a surgical mask in this scenario is necessary if facial PPE provides adequate protection. This study supports the recommendation that mask/eye protection be worn by HCWs when bodily fluid splashes are anticipated.</p> <p>This study had a high risk of bias as the blood splatters were counted by the physician who had just removed their own mask. Furthermore, this</p>					

method relied on the visual capabilities of the physician alone and this lacks scientific rigour.

Ref 5541. Raad, I, Hanna, H, Osting, C, Hachem, R, Umphrey, J, Tarrand, J, Kantarjian, H and Bodey, G. P. Masking of neutropenic patients on transport from hospital rooms is associated with a decrease in nosocomial aspergillosis during construction. 2002. Infection Control and Hospital Epidemiology. Vol 23 (1) p41-43	Observational study	4	Use of 'high efficiency' masks by patients when transported out of their rooms during hospital construction works.	Non-mask use by patients when transported out of their rooms during hospital construction works.	Nosocomial infection with invasive pulmonary aspergillosis with symptoms appearing at least 14 days after admission. Results of air sampling. Rates of IPA infection of those with haematological malignancy within the community.
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Assessment of evidence:

Graded as level 4 evidence as a 'concise communication' and therefore not peer-reviewed.

The incidence of nosocomial IPA decreased from 0.73 per 1000 hospital patient days to 0.24 per 1000 hospitalised patient days ($p < 0.001$). Incidence decreased significantly for both leukaemia patients ($p < 0.001$) and bone marrow transplant patients ($p = 0.02$). This was despite a significant increase in community acquired IPA in those with haematological malignancy ($p = 0.002$) and a significant increase in aspergillus positive indoor air samples from period 1 to period 2 ($p = 0.003$). Authors were not aware of any other confounding intervention that could have impacted on IPA incidence.

Unclear as to what specific type of surgical mask was used but authors state that masks filter to a particle size of $0.1\mu\text{m}$ and are "able to filter 99%

of *Aspergillus* organisms”. Total patient numbers studied is not provided, results are given as per 1000 hospital patient days. The intervention was not applied during the same environmental conditions as masks were not worn during a period of lesser construction and worn during a period of heavy construction. However, intuitively, this should have resulted in an increase in IPA cases not a decrease.

This study weakly supports the recommendation that immunocompromised patients who are being transported out with their room during a period of hospital construction should be given a surgical mask to wear if it can be tolerated.

Question: When should patients wear a FRSM? (TBPs)

Study	Study Type	Evidence Level	Intervention	Comparison	Outcome measure	
Nicola J Rowbotham, Sally C Palser, Sherie J Smith & Alan R Smyth. Infection prevention and control in cystic fibrosis: a systematic review of interventions. 2019. Expert Review of Respiratory Medicine, 13:5, 425-434	Systematic Review	2+	Systematic review assessing the evidence base behind different infection control precautions used to prevent infection in cystic fibrosis patients.	Includes an assessment of evidence concerning the efficacy of face masks in reducing infection for CF patients.	3 included studies. Two studies found face masks to be effective in reducing aerosol PA load and an RCT found no difference in exam room contamination rate.	
<p>Assessment of evidence:</p> <p>The systematic review was well conducted, however, due to the low amount/quality of studies identified, meta-analysis was not conducted. There was no assessment of publication bias. Meta-analysis of the three studies identified was not done/appropriate and although one was an RCT all three measured indirect indicators of infection transmission prevention eg. PA aerosol loads/room contamination. All three studies have been included in the critical appraisal phase of this surgical mask review; Wood et al 2018, Stockwell et al 2018 and Zuckerman et al 2015.</p> <p>This systematic review was completed to a reasonable standard but lacked some key featured that allow for clear interpretation of the results found. The authors did not asses risk of bias in the included publications and there was a lack of detail on the methods applied to combine individual study findings. For these reasons the evidence level applied to this systematic review reflects these lacking elements.</p>						

Wood, M. E, Stockwell, R. E, Johnson, G. R, Ramsay, K. A, Sherrard, L. J, Jabbour, N, Ballard, E, O'Rourke, P., Kidd, T. J, Wainwright, C. E, Knibbs, L. D, Sly, P. D, Morawska, L and Bell, S. C. Face masks and cough etiquette reduce the cough aerosol concentration of pseudomonas aeruginosa in people with cystic fibrosis. 2018. American Journal of Respiratory and Critical Care Medicine. Vol 197 (3) p348-355	Controlled trial study	3	<p>Surgical mask (TECNOL Fluidshield Fog-Free Surgical Mask; Kimberly-Clark Professional) (ASTM Level 3).</p> <p>N95 respirator (N95 Particulate Filter Respirator; Kimberly-Clark).</p> <p>Masks worn by CF patients chronically infected with P. aeruginosa for 5 minute periods of coughing or talking.</p>	Uncovered coughing and talking	<p>1. Percentage of participants with detectable P. aeruginosa following each intervention measured 2m from source</p> <p>2. Log¹⁰ number of P. aeruginosa CFUs collected 2m from source.</p> <p>3. Percentage reduction in aerosol P. aeruginosa concentration (log-transformed CFUs)</p>	
<p>Assessment of evidence:</p> <p>This study showed a statistically significant reduction in numbers of P. aeruginosa CFU detected in aerosols, 2 meters from the source when surgical masks were worn during coughing compared to uncovered coughing. This study also showed that the number of P. aeruginosa CFUs produced during uncovered talking is comparable to that produced when talking whilst wearing a surgical mask.</p> <p>Limitations of this study include the inability to directly link the number of CFUs detected to risk of transmission of infection. The masks used are slightly different to those employed in the UK as they are ASTM level 3 masks. These have greater fluid resistance than an type IIR mask but the same BFE of $\geq 98\%$. Masks were only worn for 9 minutes and the reductive effects provided after this time are unknown.</p> <p>This study adds to the evidence base for coughing CF patients to wear surgical masks when in communal areas with other CF patients although is perhaps not of a high enough quality/size to support a change to recommendations.</p>						
Ref 3069. Bunyan D, Ritchie L, Jenkins D and Coia JE. Respiratory and facial	Expert opinion	4			<p><i>“Johnson et al., who investigated how surgical masks and N95 respirators, worn by patients with confirmed influenza, would</i></p>	

protection: a critical review of recent literature. 2013. Journal of Hospital Infection. Vol 85 p165-169.					<i>prevent the generation of infectious airborne particles. Surgical masks and N95 respirators appeared to be equally and highly effective in filtering out influenza-contaminated particles when worn by infected patients.⁴² This small study did not investigate whether masks or respirators worn by patients reduced the numbers of cross-infection events in a real clinical setting, which would be the decisive test for this approach.”</i>
<p>Assessment of evidence:</p> <p>This expert opinion is based on a review. The document provides guidance on surgical masks and respirators. It advises on the standards that both these types of masks should meet in the UK, when they should be worn, how they should be fit checked/tested if necessary and how they should be removed and disposed of.</p> <p>It refers to relevant health and safety/governmental legislation.</p> <p>Caution is advised as this guidance was published in 2014 and some aspects may be out of date.</p> <p>NOT TO BE USED FOR FORMAL RECOMMENDATIONS</p>					
Ref ID 6107 Milton, D. K., Fabian, M. P., Cowling, B. J., Grantham, M. L., McDevitt, J. J. 2013. Influenza virus aerosols in human exhaled breath:	Controlled experimental study	3	Participants donned a ear-loop surgical mask (Kimberly-Clark, Roswell, GA).	Participants did not don a surgical mask	<i>“relative risk for any virus detection with mask versus without a mask was 0.85 and borderline statistically significant (CI 0.72 to 1.01; McNemar’s test p =0.06).”</i>

<p>particle size, culturability, and effect of surgical masks. <i>PLoS Pathogens</i>. Volume 9(3). p: e1003205</p>					<p>(p: 2)</p> <p><i>“The geometric mean copy number in the fine particle fraction without a facemask was 110 (95% CI 45 to 260) and the facemasks produced a 2.8 fold reduction in copy number (95% CI 1.5 to 5.2, $p= 0.001$)”(p: 2)</i></p> <p><i>“Combining the coarse and fine fractions, we detected viral RNA in 29 (78%) subjects when wearing facemasks and 35 (95%) when not wearing facemasks (McNemar’s test $p= 0.01$). Surgical masks produced a 3.4 (95% CI 1.8 to 6.3) fold reduction in viral copies in exhaled breath.” (p:2)</i></p> <p><i>“This finding supports current Centers for Disease Control and Prevention recommendations that healthcare facilities encourage patients with influenza-like illness to don surgical facemasks as one component of an influenza infection control program” (p:3)</i></p>
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Assessment of evidence:

Low quality, small study that lacks validity, reliability and generalisability in relation to answering the research question it is most relevant to. However, as the authors state, the findings do support the CDC recommendation for healthcare facilities to encourage use of facemasks by patients with ILI as part of a wider IPC effort.

Limitations:

- The sampler used in the study was specifically for fine and ultrafine particles which would therefore mean it would not detect large droplets (>50 µm).
- Sample was of volunteers from the community, most of whom were either students or staff at the university of Massachusetts. Not healthcare professionals.
- No further details of participant demographics assessed
- Lacks validity and generalisability
- Measured results of forced coughs
- the mask description does not include enough detail to confirm the exact mask model and associated properties of the mask (FRSM?)

Ref XX. Department of Health and Health Protection Agency. Pandemic influenza: Summary infection control guidance for ambulance services during an influenza pandemic. 2009.	Guidance	4			<p>“When transporting a patient with symptoms of influenza, the patient should be encouraged to wear a surgical mask to minimise droplet dispersal. The mask should be worn throughout the period of transport.”</p> <p>“If the patient cannot tolerate a mask, good respiratory hygiene should be encouraged and a tissue or similar can be offered to hold against their mouth and nose to ‘catch’ secretions</p>
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					from coughing, sneezing or blowing the nose.”	
HICPAC and Centres for Disease Control. Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings – Recommendations of the Healthcare Infection Control Practices Advisory Committee. 2017.	Expert opinion/consensus	4				
<p>Assessment of evidence:</p> <p><i>“Prompt patients and visitors with symptoms of respiratory infection to contain their respiratory secretions and perform hand hygiene after contact with respiratory secretions by providing tissues, masks, hand hygiene supplies and instructional signage or handouts at points of entry and throughout the facility”</i></p>						
Ref XX. Occupational Safety and Health Act (OSHA). Guidance on Preparing Workplaces for an Influenza Pandemic. 2009.	Guidance / Expert opinion	4			<p><i>“Surgical/procedure masks are used for several different purposes, including the following: [...] Placed on sick people to limit the spread of infectious respiratory secretions to others.”</i></p> <p>(pp 21)</p>	

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

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

“Surgical masks are not designed or certified to prevent the inhalation of small airborne contaminants. These small airborne contaminants are too little to see with the naked eye but may still be capable of causing infection. Surgical/procedure masks are not designed to seal tightly against the user’s face. During inhalation, much of the potentially contaminated air passes through gaps between the face and the surgical mask, thus avoiding being pulled through the material of the mask and losing any filtration that it may provide. Their ability to filter small particles varies significantly based upon the type of material used to make the surgical mask, and so they cannot be relied upon to protect employees against airborne infectious agents.” (pp 22)

“Note: Additional respirator and surgical mask guidance for healthcare workers has been developed and is available at www.pandemicflu.gov/plan/healthcare/maskguidancehc.html. This document, “Interim Guidance on Planning for the Use of Surgical Masks and Respirators in Health Care Settings during an Influenza Pandemic,” provides details on the differences between a surgical mask and a respirator, the state of science regarding influenza transmission, and the rationale for determining the appropriate protective device.” (pp 26)

Ref XX. World Health Organisation (WHO). 2014. Infection prevention and control of epidemic-and pandemic-prone acute respiratory infections in health care. [Online]. Available at: https://apps.who.int/iris/bitstream/handle/10665/112656/9789241507134_eng.pdf;jsessionid=90E49145E816EB70914AF47FFF7EC42E?sequence=1	Guidance	Agree: recommend	NA	NA	Medical masks should be part of a number of IPC supplies that are accessible within the healthcare environment. <i>“In people with ARIs, encourage the use of respiratory hygiene (i.e. covering the mouth and nose during coughing or sneezing with a medical mask [surgical or procedure mask], cloth mask, tissue, sleeve or flexed elbow), followed by hand hygiene, to reduce the dispersal of respiratory secretions containing potentially</i>
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					<p><i>infectious particles (Strong recommendation, very low quality of evidence)... ” (pp 31)</i></p> <p>It is recommended that patients with Acute Respiratory Infection or TB should always don a medical mask when outside of isolation areas.</p> <p><i>“Encourage the use of medical masks by patients with ARI during transport or when care is necessary outside of the isolation room or area” (pp 18)</i></p>
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Assessment of evidence:

Within this document a medical mask is defined as: “**Medical mask**

Also known as a surgical or procedure mask. As personal protective equipment, a facial mask is intended to protect caregivers and health-care workers against droplet-transmitted pathogens, or to serve as part of facial protection for patient-care activities that are likely to generate splashes or sprays of blood, body fluids, secretions or excretions (Annex A provides details of usage and standards for medical masks). In this document, the term refers to disposable masks only.” (pp xviii).

“A.2.3 Medical mask standards

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

- *Fluid resistance:*
 - *American Society for Testing and Materials (ASTM) F 1862–00a: standard test method for resistance of surgical mask to penetration by synthetic blood.*
- *Filtration efficiency:*
 - *particulate filtration efficiency (PFE) – 0.1 µ polystyrene latex sphere;*
 - *bacterial filtration efficiency (BFE) – ASTM F 2101–01: standard test method for evaluating the BFE of surgical masks using a biological aerosol of Staphylococcus aureus.*
- *Air exchange (differential pressure, delta-P):*
 - *measure of breathability and comfort of surgical masks.*
- *Flammability:*
 - *Class 1 and Class 2 flammability rating material for use in the operating room (OR);*
 - *Class 4 flammability rating is not appropriate for use in the OR (would be labelled as “not for OR use”).*
- *Biocompatibility.*” (pp 41)

<p>Siegel, J. D., Rhinehart, E., Jackson, M. and Chiarello, L. et al. Health Care Infection Control Practices Advisory Committee (HICPAC). 2007. 2007 guideline for isolation precautions: preventing transmission of infectious agents in health care settings. <i>American Journal of Infection Control</i>. 35:S65-164.</p>	Guidance	AGREE: Recommend	NA	NA	<p>“Respiratory hygiene/cough etiquette (source containment of infectious respiratory secretions in symptomatic patients, beginning at initial point of encounter, eg, triage and reception areas in emergency departments and physician offices)” ... in this instance healthcare workers should ...</p> <p>“Instruct symptomatic persons to cover mouth/nose when sneezing/ coughing; use tissues and dispose in no-touch receptacle; observe hand hygiene after soiling of hands with respiratory</p>
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					<p><i>secretions; wear surgical mask if tolerated or maintain spatial separation, .3 feet if possible.” (pp S74)</i></p> <p>Recommendation: surgical mask when: <i>“placed on coughing patients to limit potential dissemination of infectious respiratory secretions from the patient to others (ie, respiratory hygiene/cough etiquette).” (S99)</i></p> <p>Transportation of patients: <i>“When transport is necessary, applying appropriate barriers on the patient (eg, mask, gown, wrapping in sheets or use of impervious dressings to cover the affected areas) when infectious skin lesions or drainage are present, consistent with the route and risk of transmission.” (pp S103)</i></p>
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Assessment of evidence:

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

Ref XX. Internal Clinical Guidelines Team. Tuberculosis – Prevention, diagnosis, management and service organisation. NICE NG33. Methods, evidence and recommendations (2016).	Guidance	AGREE: Recommend			
<p>Assessment of evidence:</p> <p><i>“1.5.1.12 Explain to inpatients with suspected infectious or confirmed pulmonary or laryngeal TB that they will need to wear a surgical mask in the hospital whenever they leave their room. Ask them to continue wearing it until they have had at least 2 weeks of treatment. [2016]” (pp 45)</i></p>					
<p>Ref 1879. Coia JE, Ritchie L and Fry C. Use of respiratory and facial protection. 2014. Nursing Times. Vol 110 (4) p18-20.</p> <p>AND</p> <p>Ref 2987. J.E. Coia, L. Ritchie, A. Adishes, C. Makison Booth, C. Bradley, D. Bunyan, G. Carson, C. Fry, P. Hoffman, D. Jenkins, N. Phin, B. Taylor, J. S. Nguyen-Van-Tam, M. Zuckerman, The Healthcare Infection Society Working</p>	Expert consensus	4			

<p>Group on Respiratory and Facial Protection. Guidance on the use of respiratory and facial protection. Journal of hospital infection 85(2013) 165-169</p> <p>AND</p> <p>Ref 3069. Bunyan D, Ritchie L, Jenkins D and Coia JE. Respiratory and facial protection: a critical review of recent literature. 2013. Journal of Hospital Infection. Vol 85 p165-169.</p>					
<p>Ref 1879 is a summary of ref 2987 and ref 3069 was the review that informed ref 2987.</p> <p>To protect others from the wearer as a source of infection.</p> <p>This expert consensus provides guidance on surgical masks and respirators. It advises on the standards that both these types of masks should meet in the UK, when they should be worn, how they should be fit checked/tested if necessary and how they should be removed and disposed of.</p> <p>It refers to relevant health and safety/governmental legislation.</p> <p>Caution is advised as this guidance was published in 2014 and some aspects may be out of date.</p>					
<p>Epic3: National Evidence-Based Guidelines for Preventing Healthcare-Associated Infections in NHS Hospitals in England. H.P. Loveday, J.A. Wilson,</p>	<p>Guidance/expert opinion</p>	<p>AGREE: recommend (but level 4 here)</p>			

R.J. Pratt, M. Golsorkhi, A. Tingle, A. Bak, J. Browne, J. Prieto, M. Wilcox. 2014. Journal of Hospital Infection. S1-S70					
<p>Authors state that healthcare workers may use “standard fluid repellent masks to prevent respiratory droplets from the mouth or nose being expelled into the environment”, although this is not included in their formal recommendations. This would suggest that masks worn by symptomatic patients to prevent dissemination of infectious particles should be fluid resistant but this is based on interpretation and is not specifically outlined in any sources and so has been given a level 4 (expert opinion) grading.</p>					
Leung N.H.L. et al. Respiratory virus shedding in exhaled breath and efficacy of face masks. Nature Medicine, 3 April 2020.	Randomised controlled trial	1-	Respiratory droplet and respiratory aerosol samples were collected for 30 mins with participants wearing a type II mask whilst they sat naturally breathing with allowance for any natural coughing.	Control: Respiratory droplets and respiratory aerosols samples were collected for 30 mins whilst they sat naturally breathing with allowance for any natural coughing.	<p>Viral load (log10 virus copies per sample) detected in aerosol samples and droplet samples.</p> <p>Detection of virus in aerosol samples and droplet samples.</p>
<p>Effect of wearing a surgical mask (equivalent to type II) on detection of viral seasonal influenza, seasonal coronavirus or seasonal rhinovirus particles detected on exhalation from infected participants. Respiratory droplets or respiratory aerosols were collected for 30 mins with participants either wearing or not wearing a mask whilst they sat naturally breathing with allowance for any natural coughing. Of 246 - 122 randomised to not wearing a facemask, 124 randomised to wearing a facemask. Of 246 participants – 111 had seasonal coronavirus (n=17), influenza (n=43) or rhinovirus (n=54). [3 participants had multiple infections].</p> <p>No coronavirus virus was detected in respiratory droplets or aerosols collected from participants wearing face masks (n=11), this detection and viral load difference was significant in aerosols (p=0.04). Surgical face masks significantly reduced detection and viral load of influenza virus RNA in respiratory droplets. While not wearing a mask, viral RNA was only identified from 30% (corona), 26% (influ) and 28% (rhino) of respiratory droplet samples and 40% (corona), 35%(influ) and 56% (rhino) of aerosol samples. Reduced detection of virus is an indirect measure of reduced</p>					

transmission from symptomatic patients.

Authors report that viable influenza particles were detected in aerosols following collection of samples from both those wearing and not wearing masks highlighting this as a potential mode of transmission. Among the eight participants who had influenza virus detected by RT-PCR from without-mask aerosols, five were tested by viral culture and four were culture-positive. Among the six participants who had influenza virus detected by RT-PCR from with-mask aerosols, four were tested by viral culture and two were culture-positive.

It is unclear as to the impact that widespread use of this intervention would have, especially as it appears that a proportion of patients may not exhale any detectable virus whilst infected.

This study suggests that type II surgical masks may significantly reduce coronavirus virus (exhaled from symptomatic mask wearers in the form of droplets and/or aerosols) to undetectable levels. However, sample sizes are too small to draw definitive conclusions.

This study suggests that type II surgical masks may significantly reduce influenza virus (exhaled from symptomatic mask wearers in the form of droplets). However, sample sizes are too small to draw definitive conclusions.

This study suggests that type II surgical masks may not be effective in significantly reducing rhinovirus virus (exhaled from symptomatic mask wearers in the form of droplets and/or aerosols). However, sample sizes are too small to draw definitive conclusions.

This study suggests that type II surgical masks may not be effective in significantly reducing influenza virus (exhaled from symptomatic mask wearers in the form of aerosols). However, sample sizes are too small to draw definitive conclusions.

This study is limited and provides very weak evidence that surgical face masks could be used by symptomatic people to reduce onwards transmission of respiratory pathogens.

Ref XX. DoH and HPA 2009. PANDEMIC (H1N1) 2009 INFLUENZA A summary of guidance for infection control in healthcare settings.	Guideline	4			
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“The provision of surgical masks to patients with suspected or confirmed pandemic influenza to be worn from the point of assessment or triage in

any healthcare setting (except when in a dedicated influenza area) should be considered.”

“In common waiting areas or during transport, symptomatic patients may wear surgical masks to minimise the dispersal of respiratory secretions and reduce environmental contamination.”

Considered judgement form



Health
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Question: When should patients wear a FRSM? (SICPs)	Evidence Table Ref: 6a
1. Volume of Evidence - Quantity of evidence on this topic and quality of method	

1 low quality RCT which assesses the merit of patients wearing surgical masks during treatment of epistaxis 1 observational study which assesses the impact of immunocompromised patients wearing masks when being transported out with their rooms during constructions periods.	
2. Applicability – in Scotland	
Applicable	
3. Generalisability - How reasonable it is to generalise from the available evidence	
Due to the low number of studies it would be inappropriate to generalise from the available evidence.	
4. Consistency - Degree of consistency demonstrated by the available evidence	
N/A	
5. Potential Impact of the intervention	
Asking patients to wear masks may be unnecessary, impact on pt comfort, inhibit communication and be a waste of resources if not required.	
6. Other factors to consider while assessing the evidence base	
7. Evidence Statement – synthesis of the evidence relating to this question	Evidence level

<p>Scientific findings are limited and based on observational studies. Recommendations are based on expert opinion and the concept that masks are low cost interventions therefore recommending their use may be based on a precautionary approach</p> <p>Leukaemia and bone marrow transplant patients, who are being transported out with their room, during a period of hospital construction, should be given a surgical mask to wear if it can be tolerated.</p> <p>As there is only one study to support each patient mask wearing event, conclusions and thus recommendations cannot currently be drawn.</p>	3
8. Recommendation -	Grade of Recommendation
No recommendations can currently be made regarding patients wearing surgical masks in line with SICPs.	N/A

Question: When should patients wear a FRSM? (TBPs)	Evidence Table Ref: 6b
1. Volume of Evidence - Quantity of evidence on this topic and quality of method	
<p>There is a paucity of evidence on when patients should wear surgical masks. However, there does appear to be some consensus between the Guidance available from UK sources which focus on prevention of spreading of the aerosol or droplet infection whilst the patient is accessing communal areas (out of their room).</p> <p>1 systematic review was inconclusive regarding need for CF patients to wear surgical masks in communal areas (studies assessed were indirect measures of infection control)</p> <p>1 controlled experimental study suggested that masks can filter out/reduce influenza particles produced by infectious patients</p> <p>1 piece of UK guidance (B) gave advice re mask wearing by TB patients</p> <p>1 UK expert opinion/guidance (C), 2 x US expert opinion guidance (C), WHO guidance (B) and US guidance (B) gave advice re: mask wearing by patients known or suspected to be infected with droplet transmitted pathogens.</p>	
2. Applicability – in Scotland	

Most studies are low quality, conducted in the US or experimental in nature. Expert opinion is partly derived from UK based authors.	
3. Generalisability - How reasonable it is to generalise from the available evidence	
Due to the low quality/experimental nature of the studies it is inappropriate to generalise from the available evidence.	
4. Consistency - Degree of consistency demonstrated by the available evidence	
Recommendations are limited but fairly consistent.	
5. Potential Impact of the intervention	
Asking patients to wear masks may be unnecessary, impact on comfort, inhibit communication and be a waste of resources if not required.	
6. Other factors to consider while assessing the evidence base	
7. Evidence Statement – synthesis of the evidence relating to this question	Evidence level
Scientific findings are limited and based on observational/experimental studies. Recommendations are based on expert opinion and the concept that masks are low cost interventions therefore recommending their use may be based on precautionary measures	3/4
8. Recommendation -	Grade of Recommendation

<p>If it can be tolerated, an FRSM may be worn by a patient known or suspected to be infected with a microorganism spread by the droplet route during patient transportation from one clinical area to another.</p> <p>Patients with pulmonary or laryngeal Tuberculosis should be made aware by the healthcare team caring for them that a surgical mask should be worn when they leave their room and that this precaution applies until they have received a minimum of 2 weeks of treatment (NICE 2016).</p>	<p>B/C</p>
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