TITLE: Use of Surgical Masks in the Operating Room: A Review of the Clinical Effectiveness and Guidelines

DATE: 19 November 2013

CONTEXT AND POLICY ISSUES

Postoperative wound infections increase length of hospital stay, cost of care, and morbidity.[1] Infections occurring in a wound created by an invasive surgical procedure are referred to as surgical site infections (SSIs). SSIs account for a significant fraction of health care associated infections, however since many of these infections occur after discharge from the hospital their frequency is likely underestimated.[2] While many SSIs cause no additional complications, they can be associated with considerable morbidity, with estimates at over one third of postoperative deaths at least partly attributable to SSIs.[2]

In the operating room (OR) there are procedures and practices in place intended to reduce the probability of infectious material transfer between OR staff and patients.[2] Surgical face masks (SFMs) provide a physical barrier between bacteria of oropharyngeal and nasopharyngeal origin and an open patient wound. Wearing a SFM in the OR is one of many long standing preventative practices, yet controversy exists as to the clinical effectiveness of SFMs in reducing the frequency of SSIs. Additionally, SFMs potentially protect OR staff by providing a physical barrier to infectious bodily fluid splashes from the patient. General purpose disposable SFMs however, are not specifically designed to protect the wearer from airborne infectious particulates.[3,4] A review of clinical effectiveness and evidence-based guidelines for mask use in the OR can inform practice decisions to minimize the occurrence of SSIs and OR staff infections.

The purpose of this report is to retrieve and review the existing evidence on the clinical effectiveness of wearing SFMs in the OR to prevent infections of patients and OR staff.

RESEARCH QUESTIONS

1. What is the clinical evidence regarding the effectiveness of wearing surgical masks in the operating room to reduce bacterial transmission from staff to patients?

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2. What is the clinical evidence regarding the effectiveness of wearing surgical masks in the operating room to reduce bacterial transmission from patients to staff?

3. What are the clinical practice guidelines for the wearing of surgical masks in the operating room?

KEY FINDINGS

The use of surgical face masks by staff in the operating room is presumed to reduce the frequency of surgical site infections. The evidence identified and included in this report finds no evidence basis for this presumption. The consensus of the systematic reviews included in this report is that there is a paucity of data on this topic, and that current evidence is lacking for altering clinical practice. The included guidelines of this report are also in agreement that the long standing practice of wearing surgical face masks in the operating room should continue despite the lack of clinical efficacy evidence.

No evidence was identified that examined a potential role for surgical face masks in protecting staff from infectious material encountered in the operating room. In the absence of available clinical evidence the guidelines recommend wearing masks of a type suitable to the procedure being performed and in accordance with applicable health and safety regulations.

METHODS

Literature Search Strategy

A limited literature search was conducted on key resources including PubMed, The Cochrane Library (2013, Issue 10), University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 1998 and October 21, 2013.

Selection Criteria and Methods

One reviewer screened citations to identify publications that met the inclusion criteria. Potentially relevant articles were retrieved based on the review of titles and abstracts. Full-text articles were considered for inclusion based on the selection criteria listed in Table 1.

Table 1: Selection Criteria

Population	Pediatric and adult patients undergoing surgery in the hospital operating room
Intervention	Surgical masks (all types)
Comparator	No masks
Outcomes	Clinical effectiveness (reduced bacterial transmission from staff to patient and patient to staff, reduced infections, reduced mortality) Benefits and harms (to both patients and staff) Guidelines

Study Designs	Systematic reviews/meta-analyses, heath technology assessments Randomized controlled trials Guidelines

Exclusion Criteria

Guidelines and studies were excluded if they did not meet the selection criteria in Table 1, were duplicate publications, were included in a systematic review, or were published prior to 1998.

Critical Appraisal of Individual Studies

The quality of the included systematic reviews were analyzed using the assessment of multiple systematic reviews (AMSTAR) tool.[5]

Guidelines were assessed for quality using the Appraisal of Guidelines for Research and Evaluation (AGREE) instrument.[6] Scope and purpose, stakeholder involvement, rigor of development, clarity and presentation, applicability and editorial independence were the domains of the AGREE instrument evaluated in this report. The strengths and limitations of systematic reviews and guidelines are described narratively instead of assigning an AGREE or AMSTAR-based numerical score.

SUMMARY OF EVIDENCE

Quantity of Research Available

The literature search strategy identified 124 articles. Full text retrieval of 30 articles followed screening of titles and available abstracts. Upon review two systematic reviews met the selection criteria (Table 1). The excluded 28 studies consisted of one that was included in a systematic review, one that was included in an updated version, eight were reviews, seven were correspondence, five were editorials, two were case reports, two examined an irrelevant outcome, one was a survey study and another was a prospective cohort study. An additional 4 publications were identified through search of the grey literature. Two of the four grey literature publications identified were relevant guidelines, one publication was a duplicate while the other was a review article. A PRISMA flowchart summarizes the selection procedure of the included studies of this review (Appendix 1).

Summary of Study Characteristics

Systematic Reviews

The characteristics of included systematic reviews are summarized in Appendix 2.

Study design

Two systematic reviews were identified as meeting the selection criteria.[1,7] One of these reviews was originally published in 2002 and subsequently updated in 2006 and 2012.[7] The updated 2012 review includes an additional RCT published in 2010,[8] and two quasi-RCTs that were included in the original 2002 publication. The quasi-RCTs are referred to as quasi-RCT because of unclear allocation concealment.[7] The second identified systematic review included the

original 2002 publication of Lipp and Edwards, the two quasi-RCTs identified in that study, and one prospective cohort study published in 1981.[1] In total, the evidence from the included systematic reviews includes one RCT, one prospective cohort study, and two quasi-RCTs included in both systematic reviews. It is important to note therefore that the two quasi-RCTs are over represented in the evidence presented in this report.[1,7]

Population

The population included in the systematic review by Lipp and Edwards were patients undergoing elective clean surgery.[7] Clean surgery is defined as surgery where no inflammation is encountered and the alimentary, respiratory and genitourinary tracts are not entered.[7] The authors hypothesize that a clean surgical wound is less likely to become infected postoperatively and thus SSIs could be more reasonably attributable to other factors in the OR such as the use of SFM by OR staff. The systematic review by (Bahli 2009), included data from all elective surgeries.[1] Both included systematic reviews exclusively examined elective surgeries as emergency surgeries have a higher chance of other confounding sources of wound contamination.[1,7] One of the trials included in both systematic reviews examined only women undergoing elective gynaecological surgery.[1,7]

Intervention and Comparators

The included systematic reviews examined the wearing of disposable SFMs by staff in the OR compared to OR staff not wearing a SFM.[1,7] Neither of the included systematic reviews attempted to differentiate between different disposable SFMs.[1,7] Potential sources of intervention heterogeneity between studies included the type of disposable surgical face mask, restriction of nonscrubbed staff to the comparator group, and design of the OR (eg. air flow rates).

Outcomes

The primary outcome examined in the included systematic reviews was the frequency of SSIs following OR procedures. Individual study authors used different definitions of infection, which were inconsistent across studies. The follow up time was inconsistent both across studies and within studies included in the systematic reviews, with follow-up typically done until hospital discharge which differed depending on the procedure performed.[1,7]

Guidelines and Recommendations

Included guideline characteristics are tabulated in Appendix 3.

Origin of reports

The two selected guidelines and recommendations were both published in 2008.[2,9] The selected guidelines represent combined contributions from the National Collaborating Centre for Women's and Children's Health (NCC-WCH), the National Institute for Health and Clinical Excellence (NICE),[2] the Betsy Lehman Centre for Patient Safety and Medical Error Reduction (BLC), JSI Research and Training Institute, Inc. (JSI-RTI), and the Massachusetts Department of Public Health (MDPH).[9] The guidelines formulated by NCC-WCH, NICE regarding the use of SFM in the OR cites the systematic review by Lipp and Edwards updated in 2005, which is also

included in this report as evidence.[2,7] There were no Canadian guidelines identified meeting the selection criteria (Table 1).

Interventions

One of the guidelines had a broad focus on the prevention and control of healthcare-associated infections[9] while the other was focused on the prevention and treatment of SSIs.[2] Both guidelines provide recommendations specific to SFMs in the OR.[2,9]

Grading of recommendations and levels of evidence

The guidelines and recommendations reviewed are evidence based. The methodology of literature selection was described in both identified guidelines.[2,9] Additionally, both guidelines provided a level of evidence ranking, however only one provided a grade for recommendations.[9] The grading systems used to assign levels of evidence and strength of recommendations for the included guidelines are summarized in Appendix 4.

Summary of Critical Appraisal

The quality of the systematic reviews in this report is limited by the size and number of included studies and reflect a paucity of evidence.[1,7] Two quasi-RCTs identified as having unclear allocation concealment are included in both systematic reviews. Bahli includes an additional prospective cohort study (PCS) while Lipp also includes a more recent RCT from 2010.[1,7] The systematic review by Lipp and Edwards provided an analysis of risk of bias, quantified conclusions and performed an examination of the statistical power of the included studies.[7] Both systematic reviews had defined literature search methodology with predetermined exclusion criteria while neither pooled data from the included trials. The review by Bahli is described as a systematic review, however one author performed screening and review of the included articles, introducing a greater risk for bias. Critical appraisal of these systematic reviews is tabulated in Appendix 5.

The included guidelines have clearly stated, easily identifiable recommendations.[2,9] Both guidelines are a result of a clear evidence selection criteria by guideline development groups representative of relevant interest groups, however neither guideline included any patient perspective.[2,9] Both guidelines also include references to special patient populations, including pediatric patients and those at higher risk of being antibiotic resistant bacteria carriers. No recommendations regarding SFMs included reference to these special patient populations.[2,9] A summary of individual guideline strengths and limitations is provided in Appendix 6.

Summary of Findings

Key findings of the included systematic reviews are summarized in Appendix 7.

Both systematic reviews highlight a lack of trials on this topic and a lack of evidence on the effectiveness of SFMs for prevention of SSIs. One included trial was terminated by the authors before completion due to a high SSI incidence in the comparator group, while one statistically significant finding from a prospective cohort study suggested that SFM use increased SSI incidence.[1] Although the design of SFMs is intended to prevent contamination there are possible mechanisms by which SFMs could contribute to SSIs. These possible mechanisms

include incorrect use of the SFMs, incorrect removal or touching of the SFM and subsequent contamination of hands or gloves, exhalation of moist air causing venting, wicking of bacteria through the SFM and skin scale dispersal through friction of the SFM against the face.[7] All other trials included in the systematic reviews did not demonstrate any statistically significant differences in SSI frequency between the masked and unmasked groups.

The only outcome examined in the included systematic reviews was postoperative wound infection therefore no evidence as to the effectiveness of SFMs in protecting OR staff from infection is presented.

Recommendations of the included guidelines are summarized in Appendix 8.

The two identified guidelines present recommendations for SFM use by OR staff with regards to the prevention of SSIs and OR staff safety. Both guidelines recommend SFM use by staff in the OR.

The guideline from NCC-WCH and NICE cites a level of evidence supporting the single recommendation for all staff to wear SFMs in the OR as 1+ (see Appendix 4 for Grading of Recommendations and Levels of Evidence). The evidence statement supporting the recommendation states, “Evidence from two quasi-RCTs show that there is no difference in the rate of SSI when face masks are worn during clean or dirty surgery. [EL = 1+]” (p. 29) The guideline development group's (GDG) interpretation follows: ”Although there is limited evidence concerning the use of specific non-sterile theatre wear (scrub suits, masks, hats and overshoes), the GDG consensus was that wearing non-sterile theatre wear is important in maintaining theatre discipline and may therefore contribute to minimising [sic] the risk of SSI.” (p. 29)[2] Therefore this recommendation is based on an EL=4 (i.e. expert opinion, formal consensus). This evidence level is also consistent with the recommendations of BLC, JSI-RTI and MDPH.[9]

Two recommendations, from one guideline, address the prevention of OR staff infection through the use of SFM. The guideline recommends OR staff wear SFM and other suitable PPE during OR procedures whenever splashes, spray, spatter or droplets of potentially infectious material may be generated. These recommendations are graded B (i.e. recommended for implementation) based on expert opinion, evidence level IV and are in keeping with occupational health and safety regulations.[9] The recommendations from NCC-WCH and NICE state that the protection of OR staff from exposure to patients' body fluids was beyond the scope of the guidelines and is covered by health and safety regulations.[2]

Limitations

This report presents overlapping evidence of two quasi-RCTs included in both systematic reviews. The repetition of these studies suggests a greater quantity of available evidence and presents a duplication of the data from these studies.

The included studies only examine general and gynaecological surgeries and the results may not be applicable to the wide range of procedures performed in the OR. In addition to the limitations of the included guidelines and systematic reviews, this report is limited to an examination of the role of SFMs in prevention of infection both of the patient and the OR staff. The role of SFMs in protecting OR staff from other potential hazards of the operating room (eg

surgical smoke and aerosols) is beyond the scope of this report.[10] There was no identified evidence comparing clinical effectiveness of different types of SFMs, and the exact type of SFM in the included trials is a source of heterogeneity between studies.

None of the reviewed guidelines included Canadian stakeholders and therefore the recommendations may have limited applicability in a Canadian setting.

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING

There was a lack of evidence identified in this report demonstrating any statistically significant effects of the use of SFMs on SSI frequency. Three RCTs and one PCS reported in two systematic reviews examine the clinical efficacy of SFMs to reduce SSIs. The authors of both included systematic reviews suggested the quality, limitations and findings of these studies were insufficient to guide any alteration of current clinical practice.[1,7] Studies exist, which do not describe clinical outcomes and therefore did not meet the criteria for this report, and have been cited in support of SFMs where filtration efficiency of SFMs and bacterial contamination of the surgical field is quantified using settle plates, however the clinical relevance of this indirect evidence is questionable.[7]

There was consensus of the guidelines identified and included in this report recommending SFM use by staff in the OR. These recommendations acknowledged a lack of clinical evidence and instead are based upon expert opinion. In the face of a lack of clinical evidence for SFMs prevention of SSIs, the use of SFMs is more recently advocated as a barrier for the protection of OR staff from patients. However, there was also no data identified that examined the use of SFMs for this purpose.[7]

The included trials in this report examine a small fraction of the breadth of procedures performed in the OR. It is possible that SFM use may have more a significant impact on infections occurring in the OR in particular procedures or situations. There were no identified studies regarding the use of SFMs in branches of surgery where SSIs could cause serious adverse events such as surgeries using implants or grafts.[1] Some procedures in the OR are unique in their potential hazards to OR staff. For example, procedures producing surgical smoke and aerosols, including cautery devices, laser ablation and others that cause disruption and vaporization of tissue, are such potential hazards. Viable bacteria and viruses, including HIV, have been found in surgical smoke, however there was no identified evidence that these findings are clinically significant.[10] Although a SFM may not be an effective tool against surgical smoke and aerosols, a SFM used correctly can achieve a 95-99% bacterial filtration efficiency and a 91-95% particulate filtration efficiency.[3,4,10]

Interestingly, one Canadian survey-based study suggested that age and profession in the OR are the dominant variables in the acceptance of SFMs as evidenced based practice to prevent SSIs. Younger OR physicians generally perceive SFMs as only a tradition in the OR, yet this group also is more amenable to using SFMs to protect themselves from exposure to blood or bodily fluids. Their senior counterparts in the OR are more likely to believe that SFMs are a legal and ethical responsibility of OR staff to prevent the spread of disease. Surgeons in the OR are much more likely to believe that SFMs are a legal and ethical responsibility than anaesthetists in the OR.[11] Knowledge of these demographic perspectives and changing attitudes could aid discussions of SFM use with OR staff. The findings of the survey may also suggest a need for

clarification regarding evidence based practices, occupational health and safety, and legal and ethical obligations.

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REFERENCES

1. Bahli ZM. Does evidence based medicine support the effectiveness of surgical facemasks in preventing postoperative wound infections in elective surgery? J Ayub Med Coll Abbottabad. 2009 Apr;21(2):166-70.

2. National Collaborating Centre for Women's and Children's Health. Surgical site infection: prevention and treatment of surgical site infection [Internet]. London: National Institute for Health and Clinical Excellence (NICE); 2008 Oct. (Clinical Guideline). [cited 2013 Nov 1]. Available from: http://www.nice.org.uk/nicemedia/live/11743/42378/42378.pdf

3. Skinner MW, Sutton BA. Do anaesthetists need to wear surgical masks in the operating theatre? A literature review with evidence-based recommendations. Anaesth Intensive Care. 2001 Aug;29(4):331-8.

4. Kunachak S, Sobhon P. The potential alveolar hazard of carbon dioxide laser-induced smoke. J Med Assoc Thai. 1998 Apr;81(4):278-82.

5. Shea BJ, Grimshaw JM, Wells GA, Boers M, Andersson N, Hamel C, et al. Development of AMSTAR: a measurement tool to assess the methodological quality of systematic reviews. BMC Med Res Methodol [Internet]. 2007 [cited 2013 Nov 5];7:10. Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1810543/pdf/1471-2288-7-10.pdf

6. Brouwers M, Kho ME, Browman GP, Burgers JS, Cluzeau F, Feder G, et al. AGREE II: advancing guideline development, reporting and evaluation in healthcare. CMAJ [Internet]. 2010 Dec [cited 2013 Nov 5];182(18):E839-E842. Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3001530/pdf/182e839.pdf

7. Lipp A, Edwards P. Disposable surgical face masks for preventing surgical wound infection in clean surgery. Cochrane Database Syst Rev. 2002;(1):CD002929.

8. Webster J, Croger S, Lister C, Doidge M, Terry MJ, Jones I. Use of face masks by non-scrubbed operating room staff: a randomized controlled trial. ANZ J Surg. 2010 Mar;80(3):169-73.

9. Betsy Lehman Center for Patient Safety and Medical Error Reduction, JSI Research and Training Institute, Inc. Surgical attire and drapes [Internet]. In: Prevention and control of healthcare-associated infections in Massachusetts. Part 1: final recommendations of the Expert Panel. Boston: Massachusetts Department of Health; 2008. p. 66-7 [cited 2013 Nov 1]. Available from: http://www.mass.gov/eohhs/docs/dph/patient-safety/haipcp-final-report-pt1.pdf.

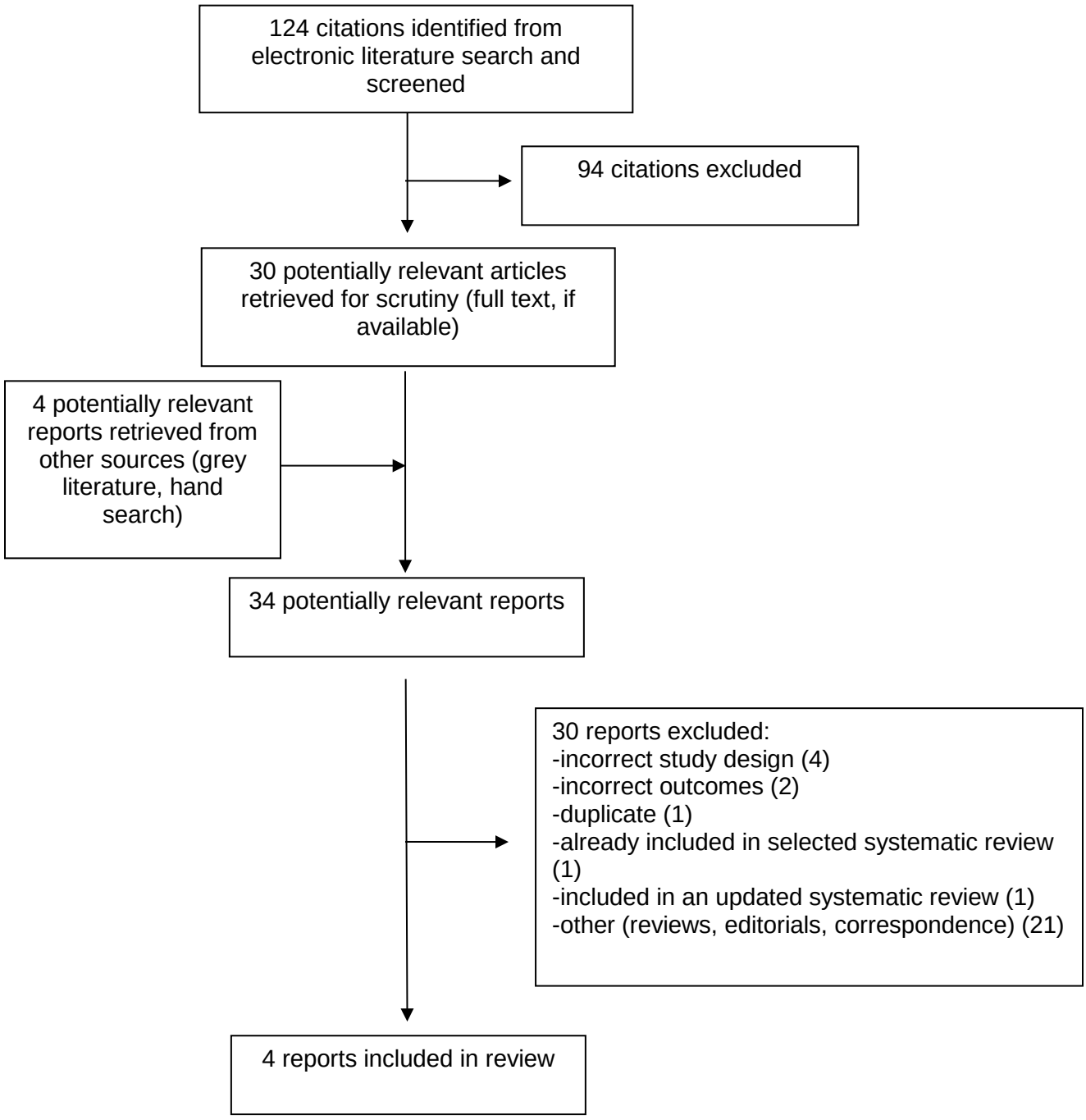
10. Fan JK, Chan FS, Chu KM. Surgical smoke. Asian J Surg. 2009 Oct;32(4):253-7.

11. Davis PJ, Spady D, Forgie SE. A survey of Alberta physicians' use of and attitudes toward face masks and face shields in the operating room setting. Am J Infect Control. 2007 Sep;35(7):455-9.

List of Abbreviations

BLC	Betsy Lehman Centre for Patient Safety and Medical Error Reduction
CI	confidence interval
COI	conflict of interest
CRD	University of York Centre for Reviews and Dissemination
GDG	guideline development group
JSI-RTI	JSI Research and Training Institute, Inc.
MDPH	Massachusetts Department of Public Health
NCC-WCH	National Collaborating Centre for Women's and Children's Health
NICE	National Institute for Health and Clinical Excellence
ODR	odds ratio
OR	operating room
OSHA	occupational safety and health administration
PCS	prospective cohort study
PPE	personal protective equipment
RCT	randomized controlled trial
SARS	severe acute respiratory syndrome
SFM	surgical face mask
SSI	surgical site infection
UK	United Kingdom
USA	United States of America

APPENDIX 1: Selection of Included Studies



APPENDIX 2: Summary of Characteristics Of Included Systematic Reviews

First Author, Publication Year	Study Design	Patient Characteristics, Sample Size (n)	Intervention	Comparator	Clinical Outcomes
Lipp and Edwards, 2002 (updated 2012)[7]	1 RCT 2 quasi-RCTs FU=until discharge	Patients undergoing clean surgery (n=2113)	OR staff wearing SFM during clean surgery	OR staff not wearing SFM during clean surgery	Postoperative wound infection
Bahli, 2009[1]	1 SR 1 PCS 2 quasi-RCTs FU=until discharge	Patients undergoing elective surgery (n=unclear)	OR staff wearing SFM during elective surgery	OR staff not wearing SFM during elective surgery	Postoperative wound infection

OR=operating room; **PCS**=prospective cohort study; **RCT**=randomized controlled trial; **SFM**=surgical face mask; **SR**=systematic review

APPENDIX 3: Summary of Characteristics of Included Guidelines

Guideline Society or Institute	Origin, Publication Year	Interventions of Interest	Grading (see Appendix 4)	Target Population
NCC-WCH, NICE[2]	London, UK, 2008	SFMs and related non-sterile theatre wear	Level of Evidence Ranked (1++ to 4)	Healthcare professionals, healthcare policy makers and surgical patients in England, Wales and Northern Ireland in particular
BLC, JSI-RTI, MDPH[9]	Massachusetts, USA, 2008	SFMs and related PPE	Level of Evidence Ranked (EL I to EL V) Recommendations Graded (A to D, UI and NR)	Hospital staff and policy makers

BLC, JSI-RTI, MDPH=Betsy Lehman Centre for Patient Safety and Medical Error Reduction, JSI Research and Training Institute, Inc., the Massachusetts Department of Public Health; **EL**=evidence level; **NCC-WCH, NICE**=National Collaborating Centre for Women's and Children's Health, National Institute for Health and Clinical Excellence; **NR**=no recommendation **PPE**=personal protective equipment; **SFM**=surgical face mask; **UI**=unresolved issue; **UK**=United Kingdom; **USA**=United States of America

APPENDIX 4: Guideline Grading of Recommendations and Levels of Evidence

Guideline Society or Institute	Recommendation	Level of Evidence
NCC-WCH, NICE[2]	N/A	**EL 1++** : High quality MAs, SRs of RCTs or RCTs with very low risk of bias **EL 1+** : Well conducted MAs, SRs of RCTs or RCTs with a low risk of bias **EL 1-** : MAs, SRs of RCTs or RCTs with a high risk of bias **EL 2++** : High quality SRs of other study designs with a very low risk of bias and a high probability that the relationship is causal **EL 2+** : Well conducted studies with a low risk of bias and a moderate probability that the relationship is causal **EL 2-** : Studies with a high risk of bias and a significant risk the relationship is not causal **EL 3** : Non-analytical studies **EL 4** : Expert opinion, formal consensus
BLC, JSI-RTI, MDPH[9]	**A**: Strongly recommended **B**: Recommended for implementation **C**: Consider for implementation **D**: Recommended against implementation **UI**: Unresolved issue **No recommendation**: Unresolved issue. Practices for which insufficient evidence or no consensus regarding efficacy exists.	**I**: Strong evidence from at least one well-designed RCT **II**: Evidence from well-designed non-randomized trials; cohort or case-controlled analytic studies; multiple time-series studies **III**: Well-designed descriptive studies from more than one source **IV**: Opinions of authorities (eg. guidelines), clinical evidence; reports of expert committees **V**: No quality studies or expert guidance

BLC, JSI-RTI, MDPH=Betsy Lehman Centre for Patient Safety and Medical Error Reduction, JSI Research and Training Institute, Inc., the Massachusetts Department of Public Health; **EL**=evidence level; **MA**=meta-analysis; **N/A**=not applicable; **NCC-WCH, NICE**=National Collaborating Centre for Women's and Children's Health, National Institute for Health and Clinical Excellence; **RCT**=randomized controlled trial; **SR**=systematic review;

APPENDIX 5: Summary of Critical Appraisal of Systematic Reviews Using AMSTAR[5]

First Author, Publication Year	Strengths	Limitations
Lipp and Edwards, 2002 (updated 2012)[7]	● Statement of no COI ● Literature search selection/exclusion methodology clearly described ● Study methodology quality assessed and tabulated ● Risk of bias assessed ● Data extraction performed ● Table of included/excluded studies ● Table of characteristics of included studies ● Statistical power calculations of included studies examined ● Quantified conclusions	●Limited by size and number of included studies ●Publication bias could not be assessed due to the small number of included studies ●Heterogeneity of included studies prevented pooling of data and meta-analysis ●No standard followup time of included studies
Bahli, 2009[1]	●Literature search selection/exclusion methodology described ●Level of evidence defined and tabulated ●Included recommendations	●Limited by size and number of included studies ●No statement of COI ●No explicit exclusion criteria ●No examination of risk of bias ●Recommendations not assigned a level of evidence ●No acknowledgement that the included SR (Lipp and Edwards, 2005) included the same studies. The same data was examined twice.[7] ●No standard followup time of included studies ●No meta-analysis ●One author
COI=conflict of interest		

APPENDIX 6: Summary of Critical Appraisal of Guidelines Using AGREE[6]

Guideline Society, Country, Author and Year	Strengths	Limitations
NCC-WCH, NICE, UK, 2008[2]	●Stakeholder representation in guideline development group ●Detailed COI statement ●Literature search methodology outlined ●Guidance for implementation ●Evidence development strategy ●Recommendations linked to supporting evidence level	●No grey literature searched ●No clear included literature publication date limits ●No summary of limitations ●No inclusion of patient views ●Recommendations relevant to SFMs do not reflect the associated supporting evidence level
BLC, JSI-RTI, MDPH, USA, 2008[9]	●Stakeholder representation in guideline development group ●Evidence development methodology outlined ●Level of evidence evaluated and linked to graded recommendations ●Guidance for local implementation ●Integration of other guidelines and regulations (eg CDC, OSHA)	●Potential COI NR ●No inclusion of patient views ●No summary of limitations ●Literature search limited to studies conducted in the USA

BLC, JSI-RTI, MDPH=Betsy Lehman Centre for Patient Safety and Medical Error Reduction, JSI Research and Training Institute, Inc., the Massachusetts Department of Public Health; **CDC**=Centres for Disease Control and Prevention; **COI**=conflict of interest; **NCC-WCH, NICE**=National Collaborating Centre for Women's and Children's Health, National Institute for Health and Clinical Excellence; **NR**=not reported; **OSHA**=Occupational Safety and Health Administration; **UK**=United Kingdom; **USA**=United States of America

Appendix 7: Summary of Systematic Review Findings

First Author, Publication Year	Main Study Findings	Author's Conclusions
Lipp and Edwards, 2002 (updated 2012)[7]	**2106 patients in three trials – no statistically significant differences found** **Postoperative Wound Infections – Clean Surgery Only** **ODR<1 favours SFM** 2 quasi-RCTs 1. ODR(95%CI): 1.34 (0.58, 3.07) 2. ODR(95%CI): 0.07 (0.00, 1.63) 1 RCT 1. ODR(95%CI):1.17 (0.70, 1.97)	"From the limited results, it is unclear whether the wearing of surgical face masks by the surgical team either increases or reduces the risk of surgical site infection in patients undergoing clean surgery."[7] (p. 10)
Bahli, 2009[1]	**8311 patients in three trials** **Postoperative Would Infections** 2 quasi-RCTs – no statistically significant differences 1. 3.5% without SFM, 4.7% with SFM 2. 30% without SFM, 0% with SFM 1 PCS – statistical significance favouring no SFMs 1. 1.8% without SFM, 4.4% with SFM (P<0.05)	"Evidence regarding effectiveness of surgical facemasks in preventing postoperative wound infection in elective surgery is inconclusive. It is difficult to alter current clinical practice of wearing facemasks in theatres on the basis of current evidence."[1] (p. 170)

CI=confidence interval; **ODR**=odds ratio; **PCS**=prospective cohort study; **RCT**=randomized controlled trial; **SFM**=surgical face mask

APPENDIX 8: Summary of Recommendations by Source

Guideline Society or Institute, Year	Directly Quoted Recommendations [recommendation grade, level of evidence]
NCC-WCH, NICE, 2008[2]	●"All staff should wear specific non-sterile theatre [includes scrubs suits, surgical caps/hoods, shoe covers and masks] wear in all areas where operations are undertaken." [N/A, 1+] (p. 29)
BLC, JSI-RTI, MDPH, 2008[9]	●"Use PPE to protect the mucous membranes of the eyes, nose and mouth during procedures and patient-care activities that are likely to generate splashes or sprays of blood, body fluids, secretions and excretions. Select masks, goggles, face shields and combinations of each according to the need anticipated by the task performed." [B, IV] (p. 44) ●"During aerosol-generating procedures (e.g., bronchoscopy, suctioning of the respiratory tract [if not using in-line suction catheters], endotracheal intubation) in patients who are not suspected of being infected with an agent for which respiratory protection is otherwise recommended (e.g., M. tuberculosis, SARS or hemorrhagic fever viruses), wear one of the following: a face shield that fully covers the front and sides of the face, a mask with attached shield, or a mask and goggles (in addition to gloves and gown)." [B, IV] (p. 45) ●"Wear a surgical mask when placing a catheter or injecting material into the spinal canal or subdural space (i.e., during myelograms, lumbar puncture and spinal or epidural anesthesia)." [B, IV] (p. 49) ●"Wear a surgical mask that fully covers the mouth and nose when entering the operating room if an operation is about to begin or already under way or if sterile instruments are exposed or a sterile field has been established. Wear the mask throughout the operation. (This recommendation is in keeping with OSHA regulations that "require masks in combination with protective eyewear, such as goggles or glasses with solid shields, or chin-length face shield be worn whenever splashes, spray, spatter, or droplets of blood or other potentially infectious material may be generated and eye, nose, or mouth contamination can be reasonably anticipated" in addition to "longstanding surgical tradition".)" [B, IV] (p. 66)

BLC, JSI-RTI, MDPH=Betsy Lehman Centre for Patient Safety and Medical Error Reduction, JSI Research and Training Institute, Inc., the Massachusetts Department of Public Health; **NCC-WCH, NICE**=National Collaborating Centre for Women's and Children's Health, National Institute for Health and Clinical Excellence; **OSHA**=occupational safety and health administration; **PPE**=personal protective equipment; **SARS**=severe acute respiratory syndrome