EVIDENCE CENTRE CRITICAL APPRAISAL

Does the wearing of face masks by non-scrub team operating theatre staff affect surgical wound infection rates?

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SUMMARY STATEMENT:

Publication of materials - please use the following format when citing this article:

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REQUEST:

Does the wearing of face masks by non-scrub team operating theatre staff affect surgical wound infection rates?

REQUESTED BY:

Ms Frances Frederic, Accredited Charge Nurse, Operating Theatre, Monash Medical Centre Clayton.

METHODOLOGY

Search Strategy

The Centre for Clinical Effectiveness defines the 'best available evidence' as that research we can identify that is least susceptible to bias. We determine this according to pre-defined NHMRC criteria (see Appendix).

First we search for systematic reviews, evidence-based clinical practice guidelines or health technology assessments, and randomised controlled trials. If we identify sound, relevant, material of this type the search stops. Otherwise, our search strategy broadens to include studies that are more prone to bias, less generalisable, or have other methodological difficulties. We include case-control and longitudinal cohort studies in our critical appraisal reports. While we cite observational and case series studies, and narrative reviews and consensus statements, in our reports we do not critically appraise them. Such studies can produce accurate results but they are generally too prone to bias to allow determination of their validity beyond their immediate setting.

Details Of Evidence Request

Subjects	non-scrub team operating theatre staff
Interventions	wearing of face mask
Comparisons	non-wearing of face masks
Outcomes	reduced surgical wound infection rates

Search terms

'mask' terms: mask/s

'wound infection' terms: surgical wound infection, risk for infection, infection control, infection, antisepsis, sterilization

'operating theatre staff' terms: operating room personnel, operating rooms, operating theatre/s,

Resources Searched

Cochrane Library CD-ROM

Ovid Medline

PubMed

Ovid CINAHL

Ovid Biomedical Fulltext collection

Ovid Nursing Collection

Refinements, Searching & Reporting Constraints

We have included only English language articles published in the past ten years, as mask materials have changed over time. Our electronic searching was completed on 1 September 1999.

Studies on wearing of masks by scrub team members only eg surgeons were not appraised for this report, nor was the protection of operating personnel considered. Level IV evidence articles (narrative reviews or expert opinion) have not been included as studies of better methodological design have been obtained.

The articles appraised for this report include studies of post-operative wound infections and studies of bacterial growth on culture plates in simulated operating theatre scenarios with and without wearing of masks by theatre staff personnel.

RESULTS:

From our sources we identified 4 articles which we categorised as follows:

Evidence-based clinical practice guidelines	1
Randomised controlled trials	2
Controlled trials, cohort or case-control analytic studies	1

We are reasonably confident that these articles represent the most important findings published to date based on our refinements, searching and reporting constraints.

EVIDENCE SUMMARIES

Format

Evidence summaries are in the form of spreadsheets reproduced at the end of this report. Each spreadsheet contains the article citation, the study design with level of evidence available according to NHMRC guidelines (1998), patient description, scientific validity of the article, results and pertinent remarks from the authors and Centre for Clinical Effectiveness reviewer.

ARTICLES CRITICALLY APPRAISED FOR THIS REPORT

Evidence-based clinical practice guidelines

Mangram AJ, Horan TC, Pearson ML, Silver LC and Jarvis WR. Guideline for prevention of surgical site infection. AJIC American journal of infection control. 1999; 27:97-113.

Randomised controlled trials

Tunevall TG. Postoperative wound infections and surgical face masks: a controlled study. World journal of surgery. 1991; 15:383-388

Tunevall TG and Jörbeck H. Influence of wearing masks on the density of airborne bacteria in the vicinity of the surgical wound. European journal of surgery. 1992; 158:263-266.

Controlled trials, cohort or case-control analytic studies

Mitchell NJ and Hunt S. Surgical face masks in modern operating rooms – a costly and unnecessary ritual? Journal of hospital infection. 1991; 18:239-242.

APPENDIX

Copyright

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The information in this report is a summary of that available and is primarily designed to give readers a starting point to consider currently available research evidence. Whilst appreciable care has been taken in the preparation of the materials included in this publication, the authors and Southern Health Care Network do not warrant the accuracy of this document and deny any representation, implied or expressed, concerning the efficacy, appropriateness or suitability of any treatment or product. In view of the possibility of human error or advances of medical knowledge the authors and Southern Health Care Network cannot and do not warrant that the information contained in these pages is in every aspect accurate or complete. Accordingly, they are not and will not be held responsible or liable for any errors of omissions that may be found in this publication. You are therefore encouraged to consult other sources in order to confirm the information contained in this publication and, in the event that medical treatment is required, to take professional expert advice from a legally qualified and appropriately experienced medical practitioner.

Levels Of Evidence

As Defined By "A Guide To The Development, Implementation And Evaluation Of Clinical Practice Guidelines" (National Health & Medical Research Council, Canberra, 1998):

Level I		Evidence obtained from a systematic review or meta-analysis of all relevant randomised controlled trials.
Level II		Evidence obtained from at least one properly designed randomised controlled trials.
Level III	-1	Evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method).
	-2	Evidence obtained from comparative studies with concurrent controls and allocation not randomised (cohort studies), case control studies or interrupted time series with a control group.
	-3	Evidence obtained from comparative studies with historical control, two or more single-arm studies or interrupted time series without a parallel control group.
Level IV		Evidence obtained from case series (either post-test or pre-test and post-test), opinions of respected authorities (narrative reviews), descriptive studies, reports of expert (i.e. consensus) committees, case studies.

EVIDENCE SUMMARY THERAPY Surgical face masks in operating theatres.	**STUDY DESIGN & NHMRC LEVELS OF EVIDENCE**	**VALIDITY:** Methodology, rigour, selection, opportunity for bias.	**RESULTS:** Generally favourable or unfavourable, specific outcomes of interest, estimate of experimental effect and precision if appropriate	**AUTHORS' COMMENTS:** Risk/benefit, limitations	**REVIEWERS' COMMENTS:** Risk/benefit, methodology, conclusions
Mangram A et al. Guideline for prevention of surgical site infection. AJIC American journal of infection control. 1999; 27:97-113.	Evidence based guidelines, Level II, III, and IV evidence on face masks.	"Recommendations supported by some experimental, clinical or epidemiological studies and strong theoretical rationale."	"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. Wear the mask throughout the operation."	.." some studies have raised questions about the efficacy and cost-benefit of surgical masks in reducing SSI risk. Nevertheless wearing a mask can be beneficial since it protects the wearer's nose and mouth from inadvertant exposures (ie splashes) to blood and other body fluids."	The recommendation in this guideline is made on the basis of protection of the wearer rather than the patient.

EVIDENCE SUMMARY THERAPY Face masks and surgical wound infection rates.	**STUDY DESIGN & NHMRC LEVELS OF EVIDENCE**	**DESCRIPTION:** Subjects, Interventions, Comparisons, Outcomes, Inclusion & Exclusion Criteria	**VALIDITY:** Methodology, rigour, selection, opportunity for bias.	**RESULTS:** Generally favourable or unfavourable, specific outcomes of interest, estimate of experimental effect and precision if appropriate	**AUTHORS' COMMENTS:** Risk/benefit, limitations	**REVIEWERS' COMMENTS:** Risk/benefit, methodology, conclusions
Mitchell NJ et al. Surgical face maks in modern operating rooms - a costly and unnecessary ritual?. Journal of hospital infection. 1991; 18:239-242.	Comparative study with concurrent control Level III-2	**Subjects:** Volunteers speaking aloud one metre from operating table. **Intervention:** No masks worn. **Comparison:** Masks worn. **Outcomes:** Number of colony forming units grown on exposed blood agar plates placed on and beside an operating table. **Inclusion & Exclusion Criteria:** Not applicable.	This study is based on measurements of CFUs growing on agar plates following single exposure by masked or unmasked subjects speaking out loud. A total of six subjects participated. **Potential for bias:** Very small sample size.	There was no contamination when up to four volunteers recited together standing one metre from the table. No colonies grew on any of three settle plates when subjects were tested individually or as a group of four, with and without masks in a fully ventilated operating theatre.	"These observations suggest that oral bacteria normally conveyed in droplets into the air during ordinary talking by non-scrubbed staff, who are not within the immediate vicinity of the operation site, do not pose an infection hazard and the wearing of masks is unnecessary."	This study includes the consideration of direction of airflow in the operating theatre, a factor which could influence wound infection rates.

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Tunevall TG. Postoperative wound infections and surgical face masks: a controlled study. World journal of surgery. 1991; 15:383-388.	Randomised controlled trial. Level II	**Patients:** General surgery patients at a Swedish hospital between March 1984 and May 1986. **Intervention:** Masks not worn by staff in operating theatre. **Comparison:** Masks worn by all staff in operating theatre. **Outcomes:** Number of postoperative wound infections. **Inclusion & Exclusion Criteria:** All general surgery patients operated on through intact skin and sutured by primary intention. Exclusions: anal procedures, outpatient, orthopedic, urologic, synthetic graft operations and patients with haemolytic disease	**Randomisation:** Random list, weeks designated "masked" or "unmasked", inversed for second and part of third year of study. **All patients accounted for:** Yes n=3088 **Patients treated equally:** Although a range of different operations was performed, randomisation and the sample size should have allocated similar groupings for the masked and unmasked operations. **Similar groups:** Average age for acute groups was 38 years (masked and unmasked), for the elective operations 58 years for the "masked" group and 57 years for the "unmasked" group. **Potential for bias:** Three different types of face mask were used over the period of the trial. No information is provided on infection rates after unmasked operations compared with rates after use of a particular type of mask.	There was no statistically significant difference in wound infections after operations with or without face masks. In the "masked" group of operations the infection rate was 4.7% (3.7 - 5.8%, 95% confidence limit) compared to 3.5% (2.6-4.5%) in the "unmasked" group. For 277 operations where 1 or 2 people wore face masks because of common cold or allergis rhinitis only 4 infections occurred. Breakdown of figures by type of operation and by acute vs clean elective or non-clean elective operations also revealed no statistical difference between masked vs non-masked operations (see Tables 1 and 2 in paper for details.) Staphyloccal infection rates corrected for differences in missed cultures were 1.5% for the unmasked operations and 2.2% for the masked operations.	"It has not been possible to demonstrate any advantages for the patient when the surgical team wears face masks."	It should be noted that operating staff wore face masks during "unmasked" operations if they had a common cold or suffered from allergic rhinitis (1-2 people in 18% of unmasked operations.)

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Tunevall TG and Jörbeck H. Influence of wearing masks on the density of airborne bacteria in the vicinity of the surgical wound.European journal of surgery. 1992; 158:263-266.	Randomised controlled trial. Level II	**Patients:** Following a pilot study, main study of 14 patients undergoing operations on the thyroid gland. **Intervention:** Period during operation in which masks were not worn by any members of the operating team. **Comparison:** Period during operation in which masks were worn by all members of the operating team. **Outcomes:** Number of colony forming units (CFU) grown from air filters placed 20 cm above surgical wound. **Inclusion Criteria:** Operations which were planned to last more than one hour.	**Randomisation:** Operations began with a masked or non-masked period determined by "random list." **Similar groups:** There were 17 periods in which masks were worn and 28 periods when masks were not worn. Anaerobic and aerobic CFU were counted for each of these periods. **Potential for bias:** The authors draw attention to their method of counting bacterial colonies as a possible source of bias but suggest that as comparisons were made from numbers obtained in the same way their conclusions are valid.	The 14 thyroid operations produced similar counts of aerobic and anaerobic bacteria from the air filters whether or not masks were worn. No postoperative wound infections were encountered during the study. The total mean CFU (categorised by bacterial type) for the 17 masked periods was 15 CFU/m^3 and for the 28 unmasked periods 13 CFU/m^3. (see Table 1 of paper for breakdown by bacterial type and range of CFU/m^3)	"We conclude that the use of masks during operations does not influence the number of potentially pathogenic bacteria in the air close to the operation wound…. However, the importance of masks on surgical staff members with respiratory tract infections remains to be studied."	