### Review

# Do Anaesthetists Need to Wear Surgical Masks in the Operating Theatre? A Literature Review with Evidence-Based Recommendations

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#### **SUMMARY**

Many operating theatre staff believe that the surgical face mask protects the healthcare worker from potentially hazardous biological infections. A questionnaire-based survey, undertaken by Leyland in 1993 to assess attitudes to the use of masks, showed that 20% of surgeons discarded surgical masks for endoscopic work. Less than 50% did not wear the mask as recommended by the Medical Research Council. Equal numbers of surgeons wore the mask in the belief they were protecting themselves and the patient, with 20% of these admitting that tradition was the only reason for wearing them.

Policies relating to the wearing of surgical masks by operating theatre staff are varied. This indicates some confusion about the role of the surgical mask in modern surgical and anaesthetic practice. This review was undertaken to collate current evidence and make recommendations based on this evidence.

Key Words: SURGICAL MASKS: anaesthesia, postoperative infections

For many years it has been generally accepted that there is a need for operating theatre staff to wear surgical masks. In recent years, new mask materials with different filtering efficiencies have become available. The deflection-type masks reduced bacterial penetration, but were not associated with a reduction in the total bacterial agar plate count in the operating room. With the advancement of surgical techniques in the 1970s, there was a re-examination of sterile procedures, the need for aseptic practice, and the need for improvement in surgical suite air conditioning. Filter-type masks were found to be ineffective in reducing overall airborne contamination. Widespread use of ultraviolet light resulted in a reduction in airborne contamination, but had no effect on the incidence of postoperative wound infection. Laminar flow systems were developed primarily in response to this.

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Air Filtration in the Operating Room

Hospitals have adopted numerous environmental procedures to reduce surgical wound infection rates and to limit the transmission of infection. Airconditioning systems in operating theatres have four main functions:

- —To control air movement within the suite ensuring flow is from clean to dirty areas.
- —To reduce airborne bacterial contamination.
- —To control the temperature and humidity of the theatre.
- —To remove potentially hazardous gases.

In a conventional operating theatre, air is maintained under positive pressure. Air enters high up in the theatre walls or ceiling through filters which render the air clean. The air is then discharged by low level extraction. As new air enters, it mixes with and dilutes the old air, reducing the bacterial count.

Australian Standards<sup>2</sup> require operating theatres to have at least 20 air changes per hour, reducing the bacterial count by one twentieth every three minutes. With this degree of filtration, the chance of airborne transmission between staff and patient is minimal. The efficiency of this system may be affected by the number of individuals in the operating theatre.

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Australian Standards demand that there is a space of 5m<sup>2</sup> for each person in the operating room. Less space per person would reduce the efficiency of the filters. Microorganisms shed by the operating team are the most significant contamination agents in a correctly designed operating room where soil organisms are readily filtered out. In theatres with high efficiency particulate air (HEPA) filters, a large volume of sterile air is flowing into the operating area in a continual downward movement<sup>3</sup>.

Laminar airflow clean room systems operate by unidirectional airflow from a blower through the HEPA filters on entry into the operating room and then through the vents to the air in the outside environment. These filters remove particles >0.5 micron with 99.7% efficiency. This system can provide an air turnover rate of 500 times per hour in conventional operating theatres. Of the two types of airflow systems, vertical and horizontal, the former has greater effect on reducing airborne bacteria in the operating room.

In "steriflow" systems a curtain of air is created around the operating team which prevents contaminated air between the operating area and the outside walls from penetrating into the operating area. Low velocity laminar flow panels directly above the operating team and the patient produce a piston-like action of clean air directly over the operating area and force out contamination that is generated within the curtain. Curtains of sterile air are forced through special plenums and filtered downwards through solid diffusers positioned in the ceiling above the operating table while maintaining positive pressure within the curtain by the piston-effect. Thus the operating team are bathed in a continuous flow of sterile air from the centre panels.

#### **METHOD**

Several literature searches were conducted using Medline, using the index terms "surgical mask", "anaesthetist", "infection control". All original studies published in peer-reviewed journals in the English language were reviewed, with no restrictions on year of publication. Thirty-seven suitable journal articles were obtained, reporting on altogether 44 studies published between 1905 and 2000.

#### **RESULTS**

Postoperative Wound Infection Rates

Factors which have been shown to contribute to postoperative wound infection are shown in Table 1.

A significant national study undertaken by McLaws et al<sup>4</sup> in 1988 showed the overall surgical wound

Table 1
Factors that contribute to the rate of postoperative surgical wound infection

- \* duration of preoperative stay
- \* duration of operative stay
- \* patient's age and clinical state
- \* malignancy
- \* obesity
- diabetes
- \* hypovolaemic shock
- \* local ischaemia
- \* immunosuppression
- \* steroid treatment
- \* antibiotic use

- \* surgical technique
- \* preoperative shaving
- use of drains
- \* presence of haematoma
- insertion of prosthesis
- \* aseptic technique
- sterilization techniques
- \* skin preparations
- \* draping rituals and air exchange/air conditioning efficiency

infection rate in Australia to be 4.6%. Earlier studies showed the overall rate to be in the range from 4.1% to 8.8%.

The study demonstrated that certain surgical sites have a greater susceptibility to infection than others. Surgery on skin and subcutaneous tissue had the highest incidence (11.2%), followed by surgery of the musculoskeletal system at 7%, and gastrointestinal surgery at 6.4%. Eye surgery had the lowest infection rate at 0.8%. Operations have been defined as "clean", "clean contaminated" or "contaminated" based upon the degree of contamination that occurred.

It is now clear that the introduction of ultraclean air systems in operating theatres has been a major factor in reducing the postoperative infection rate<sup>5</sup>, despite early findings to the contrary. In 1973 Laufman<sup>6</sup> reported that neither the flow direction nor the cleanliness of air in the operating theatre was thought to have any effect on contact or airborne contamination from the patient or surgical staff members; but in the same year, Charnley<sup>7</sup> hypothesized that postoperative wound infection was related to the operating room environment and not other sources, in his study of postoperative infection after total hip replacement. The rate of postoperative infection in operating theatres with ultraclean air systems fell to that of conventionally well-ventilated operating rooms. The use of appropriate prophylactic antibiotics has also been shown to decrease the implant infection rate, contributing to the overall fall in postoperative infection rates.

#### Surgical Masks and Postoperative Wound Infection

The numbers of airborne bacteria expelled from the nose and mouth are insignificant when compared with the substantial numbers shed from the skin. As early as 1948, Duguid<sup>8</sup> showed that large numbers of bacteria were liberated into the air from desquamated skin and clothing as a result of normal

body activity, and that air in the operating room was contaminated more regularly and to a greater degree by the liberation of dust from clothing than by sneezing. In 1956 Hare9 confirmed that Staphylococcus aureus was carried in the anterior nares in 50% of the population, but found it was generally only expelled from the nose during sneezing and snorting. He concluded this mode of transfer was far less important than its presence in desquamated skin. In 1959 Shooter<sup>10</sup> found that few, if any, nasal bacteria are expelled into the air during quiet breathing, despite heavy nasal colonization. This was confirmed in a study by Mitchell and Hunt<sup>11</sup>. In 1962 Davis<sup>12</sup> showed that desquamated skin, not expelled particulate matter, was the source of most common bacteria dispersed into the air of hospital wards.

In 1975 Ritter<sup>13</sup> studied the effect of wearing surgical masks on the level of airborne microbial contamination in the hallways adjacent to the operating room and in the operating room itself. No significant difference could be found. Ritter showed that, although they did not contain airborne contaminants, masks acted to deflect the droplets out of the sides of the mask when the wearer talked or breathed. A 1999 study, also by Ritter, looked at the environmental effect of various gown protections in a mock operating room setting. He compared a plastic wraparound with cloth hood, face mask and gloves, to a hooded exhaust gown and to scrub clothes. He found that the wearing of a surgical face mask in the hallway or the operating room had no effect on the bacterial counts in either the hallway or the operating room. Both these studies represent Level III-1 evidence. Schweizer's<sup>15</sup> study in 1976 provided evidence that the dissemination of skin bacteria was increased by using masks, due to the friction that occurred between mask and face.

In 1981 Orr<sup>16</sup> completed the first study specifically designed to determine whether the wearing of surgical masks influenced the risk of surgical wound infections. In this study, no surgical masks were worn by surgical staff in the operating room. A total of 1,049 surgical procedures with skin incisions were performed, and a surgical wound infection rate of 1.8% was identified. This rate was significantly lower than that experienced before the trial commenced (P<0.05). It was concluded that the standard practice of wearing surgical masks could be abandoned. In 1984, following Orr's<sup>16</sup> data, Chamberlain and Houang<sup>17</sup> conducted a randomly controlled trial on women having gynaecological surgery. Women were randomly allocated to lists staffed entirely by masked or unmasked teams. The trial was discontinued within a week after the third case of postoperative infection in the unmasked group. This represented three out of five patients. None of four patients developed infections in the masked group. The statistical difference (if any) between the groups was not reported. Furthermore, none of the organisms isolated corresponded to strains isolated from the staff. In addition, Orr's study restricted conversation in theatre, whereas no restriction applied in this study. Ruthman's<sup>18</sup> 1984 study of wounds sutured in an emergency department noted that there was no significant difference in infection rates whether or not masks were worn, while the study by Laslett et al<sup>19</sup> showed no increase in the cases of infection following cardiac catheterization procedures when caps and masks were not worn.

An in vitro study by Berger<sup>20</sup>, not undertaken in a laminar flow environment, looked at the influence of surgical mask position on bacterial contamination of the operative field during cardiac catheterization procedures. In this study the mask position (on, off or below the nose) varied during each procedure. The number of bacterial colonies recoverable was significantly higher in the unmasked population, yet there was no significant difference between "mask on" and "mask below the nose". There was no evidence that the colony count had any correlation to postoperative infection outcome.

In 1992, Phillips et al<sup>21</sup> studied the effectiveness of surgical face masks in reducing bacterial surface contamination produced by dispersal of organisms from the upper airway. The study simulated conditions representative of those occurring in the majority of subarachnoid blocks (i.e., the operator being positioned within 30 cm of the patient undergoing such a procedure). The organisms grown were upper respiratory tract commensals, including coagulase-negative alpha-haemolytic Staphylococci, Streptococci, Micrococci and Moraxella catarrhalis. The unmasked group showed a statistically significant increase in the number of colonies at 30 cm. It is significant that none of the identified cultures included the "common" pathogen for meningitis associated with lumbar puncture. No data was provided on the environmental conditioning systems, and since this study did not involve actual patients, no data on the infection rate in such circumstances was determinable. In view of the low incidence of infection, extremely large numbers of patients would be required to show statistical significance in outcome.

Wildsmith<sup>22</sup> in his 1991 article claimed that masks should be worn when spinal or extradural anaesthesia is performed. He commented on the importance of

the mask, stating that "the anterior nares and mouth are relatively close to, and usually immediately above, the sterile field" in such procedures. His comments were in response to an 1991 article by Lee and Parry<sup>23</sup>, reporting on one case of bacterial meningitis following spinal anaesthesia for caesarean section. The spinal anaesthesia was performed in a theatre setting under "meticulous aseptic techniques". A face mask was not regarded as part of such a technique. Lee and Parry felt that masks could create "a false sense of security" and cited the work of Ritter et al<sup>13</sup> and Orr<sup>16</sup> in defence of its non-use.

In 1993, Leyland¹ hypothesized that masks filter bacteria from the nose and mouth into aggregates of sufficient size as to be affected by gravity, hence falling, rather than remaining atomized and being expelled from the operating theatre by the air change system. The commonest bacterial pathogens in surgical postoperative wound infections include *Staphylococcus aureus*, coagulase-negative *Staphylococci*, *Enterobacter coli*, *Pseudomonas* and *Enterococci*. Few of these are normal oronasal commensals.

Mitchell<sup>11</sup> published a study of the effectiveness of a variety of surgical masks in 1991. This study was undertaken in modern operating rooms, which had modern air-conditioning systems with high efficiency particulate air units filtering air under positive pressure. The study concluded that operating room staff not immediately in the vicinity of the surgical site do not pose an infection hazard, and that it is not necessary for these staff to wear surgical masks.

A well constructed, randomized prospective con-

trolled study conducted over two years was reported by Tunevall in 1991<sup>24</sup>. It looked at the correlation between surgical masks and the incidence of post-operative wound infection, using three different brands of mask. A total of 3088 patients were included in the study during a period of 115 weeks. Procedures were denoted "masked" or "unmasked". Of 1537 surgical procedures performed with masks, the surgical wound infection rate was 4.7% (3.7 to 5.8%, 95% confidence limit). Of 1551 surgical procedures performed without masks, the surgical wound infection rate was 3.5% (2.6 to 4.5%). The bacterial culture from both groups was similar.

A 1992 study, again by Tunevall<sup>25</sup>, looking at the wearing of masks and the number of colony forming units of bacteria, supported these results. He found almost identical air counts of aerobic and anaerobic skin bacteria whether or not masks were worn by operating staff. No postoperative infections were found during the study, involving 22 operations. This represents level II evidence.

Table 2 summarizes the studies by Orr<sup>16</sup>, Mitchell<sup>11</sup> and Tunevall<sup>24</sup>.

Mask Filtering Efficiency and its Effect Upon the Wearer of the Mask

Surgical masks have two functions: the first to protect the patient from a potential source of infection—the wearer; the second, to protect the wearer from another potential source of infection—the patient.

The latter function, that of protecting staff from patients, has been increasingly a focus of health care policy within medical facilities. However, it has not

Table 2
Summary of later studies on postoperative wound infection and surgical mask use

Study	Design	Results	Recommendations	Level of Evidence
Orr <sup>15</sup> , 1981	Comparison of wound infection rates with "no-masks" versus "masks" in ALL theatre staff. No restrictions in staff talking or moving. General surgical patients used	Infection rate significantly less (P<0.05) in "no-mask" versus "mask" group	The wearing of a mask has very little relevance to the wellbeing of patients undergoing routine surgery and is a standard that can be abandoned	Level III-3
Mitchell <sup>11</sup> , 1991	Comparison of oral microbial flora dispersion in the OR in unmasked volunteers in a modern laminar flow theatre.	Colony forming airborne microbial dispersal from the noses of volunteers was zero	Operating theatre staff not immediately in the vicinity of surgical site do not pose an infection risk. It is NOT necessary to wear masks	Level III-2
Tunevall <sup>22</sup> , 1991	2 year prospective study correlating masked versus unmasked operating theatre staff on postoperative wound infection rate	3,088 patients over 115 weeks. 1537 "masked" patients, infection rate 4.5% 1551 "unmasked" patients infection rate 3.5% Culture was the same	No significant difference in infection rate	Level II

been properly established that masks are effective in protecting the wearer from infection transmission.

From as early as 1918, various studies, both in vitro and in vivo, have looked at the filtering efficiency of masks. Neither type of study can fully assess mask leakage, and hence there is a wide discrepancy in the results of controlled testing of mask efficiency.

Huller and Colwell's<sup>26</sup> 1918 study found extreme variations in the numbers of layers and quality of gauze of which masks were made. They undertook a series of tests to determine how many layers were needed to provide complete filtration. This study was the first to produce a specification for surgical masks. Further tests undertaken during this period indicated that the distance droplets were carried in the air was dependent principally on the force with which they were driven. It was demonstrated that gauze would remove bacteria from a moist spray and that the efficiency with which this occurred was directly proportional to the density of the weave and the number of layers27. Kellogg and MacMillan28 undertook an array of tests on masks in 1920, and concluded that masks had not been demonstrated to have a degree of efficiency that would warrant mandatory use. Tests have been performed under stringent conditions and monitored by qualitative sampling<sup>29,30</sup>, but a standard method for determining the efficiency of masks, variously reported from 15.6% to 99.7%, has yet to be adopted universally. Improving the filtering efficiency of masks is thought to improve outcome, yet no published evidence exists to support this theory.

The use of surgical masks has been advocated to protect clinicians from inhaled aerosols containing organic and inorganic particles. In 1987, Pippin et al<sup>31</sup> examined the ability of a 22-micron tracer particle to breach the filters of two commonly used face masks. Pippin found that masks worn in the normal manner allow inhaled air to enter around the periphery of the mask, circumventing the filtration of airborne contaminants.

Concern regarding respiratory protection for healthcare professionals in the operating suite is increasing, particularly because of the growing use of equipment that may increase the risk of patient-to-staff infection transmission. For instance, it has been shown that viable material and DNA are released during CO<sub>2</sub> laser surgery<sup>32,34</sup>; the laser plume fragments had a median aerodynamic diameter of 0.31 microns. The use of surgical power tools generates aerosols with aerodynamic diameters of 0.07 microns<sup>35</sup>. Both of these are considerably smaller than the droplets of approximately 4 microns expelled from masks by medical staff.

In 1993 Weber et al<sup>36</sup>, studied the aerosol penetration and the leakage characteristics of masks used in the healthcare industry. Eight different masks were tested for aerosol particle penetration and penetration through masks with induced face seal leaks. Filter penetration ranged from 20 to 100% for submicrometer-sized particles. The study concluded that surgical masks offer insufficient protection to staff in environments containing potentially hazardous aerosols.

Table 3

Viral and bacterial particle diameters (microns) in relation to the filtration properties of surgical masks

, , , ,	
Hepatitis C virus	0.03 - 0.06
Hepatitis B	0.042
Adenovirus	0.07 - 0.09
Orthomyxovirus	0.08 - 0.12
HIV	0.18
Cytomegalovirus	0.12 - 0.2
Laser plume droplets*	0.31
High Filtration Mask filter	0.60
Pseudomonas aeruginosa	$0.6 \times 2.0$
Mycobacterium tuberculosis	$0.4 \times 3.0$
Staphylococcus aureus	1.0
Escherichia coli	0.5 x 2.0

\*0.31 micron (range 0.1 to 0.8) sized droplets found in laser plume. Viruses are not free-floating but are usually found on the surface of these droplet nuclei.

Table 3 represents the diameters of viral and bacterial particles in relation to the filtration properties of surgical masks.

#### The Effect of Surgical Visors

Kouri's<sup>37</sup> 1993 study recommended that obstetricians should wear face shields or eyeglasses to protect against facial contamination, reporting that obstetricians commonly received blood or amniotic fluid splashes to the face during deliveries (50% during caesarean delivery and 32% during vaginal delivery). In the same year, Berridge looked at contamination of a surgical mask incorporating a splash shield. It was shown that 51% of the visors and 42% of the masks of the principal surgeons were contaminated. This was reduced down to 10% and 4% respectively for the scrub nurse. No data were presented for nonscrubbed operating theatre occupants. It was concluded that eye protection should be worn. However, Norman's<sup>38</sup> 1995 study showed no significant difference in the infection rate between surgical mask users and staff wearing surgical visors.

#### Policy Relating to Surgical Masks

National Health and Medical Research Council Guidelines<sup>39</sup> recommend that masks must always be

## Table 4 Levels of evidence

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

- Level I Evidence obtained from a systematic review or metaanalysis of all relevant randomised controlled trials.
- Level II Evidence obtained from at least one properly designed randomized controlled trial.
- Level III-1 Evidence obtained from well-designed pseudorandomized controlled trials (alternate allocation or some other method).
  - -2 Evidence obtained from comparative studies with historical control 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

worn in the operating theatre. This appears to be a change from a patient-protective standpoint to a healthcare worker-protective standpoint, and no evidence is cited to support this change. The Australian Confederation of Operating Room Nurses (ACORN) Standards and Policy Statement for operating suite attire stipulates that high-filtration masks are worn in "designated areas", a term which is not defined in the Policy Statement. Neither of the Policy Guidelines mentions the relative contribution of the efficiency of the operating room air conditioning system, a factor that far outweighs the contribution of face mask use in environmental infection control

Precedent exists to discontinue use of surgical masks by non-scrub staff. In 1993, based on published evidence, the Royal Alexandra Hospital in Alberta, Canada, released the circulating nurses and anaesthetists from wearing surgical masks in theatre during surgery unless they were closely observing the surgical site<sup>40</sup>. This policy change generated substantial discussion, and it was eventually agreed that, in all surgery where implants were being used, all operating theatre staff would wear masks. This change is partially supported by the data published by Hubble et al<sup>41</sup> in 1996. In this study bacterial counts were higher in non-masked surgeons in close proximity to the wound in laminar flow theatres. No data, however, was given on the postoperative infection rate in this group. It would be incorrect, therefore, to conclude that the increase in count reflects a higher infection

rate. To date, infection control monitoring in the Royal Alexandra Hospital shows no sign of increase in the rate of postoperative infection, nor is their rate significantly different from comparable regional institutions performing similar procedures.

The number of masks used annually in a 470-bed public hospital facility in Australia averages at over 65,000 (personal communication). The total average yearly cost of masks in such a facility is \$12,000. This sum is a relatively small proportion of the expenditure of a single facility, but when extrapolated on a national scale it can be seen that the usage of surgical masks creates considerable expense. Discontinuation of use would represent a large saving for the national health budget.

#### DISCUSSION

The surgical mask was introduced to protect patients from being infected by large pathogen-containing aerosol droplets emitted by health personnel. The enormous advances made in the design of operating theatres have minimized the risk of airborne contamination by micro-organisms. Laminar flow/steriflow systems provide the greatest reduction in environmental contamination, and in this environment other variables such as duration of procedure, operating theatre personnel and their attire, including masks, have insignificant impact from an infection control viewpoint.

A decision to eliminate masks would generate much discussion. The evidence for discontinuing the use of surgical face masks would appear to be stronger than the evidence available to support their continued use. In this climate of economic justification it would appear prudent to say that the use of surgical face masks by non-scrub operating theatre staff cannot be scientifically justified.

It is essential that anaesthetists use appropriate standard precautions to reduce the potential for transmission of infectious agents to patients. Equally important is the protection of the anaesthetist in this environment.

There is little evidence to suggest that the wearing of surgical face masks by staff in the operating theatre decreases postoperative wound infections. Published evidence indicates that postoperative wound infection rates are not significantly different in unmasked versus masked theatre staff. However, there is evidence indicating a significant reduction in postoperative wound infection rates when theatre staff are unmasked. Currently there is no evidence that removing masks presents any additional hazard to the

patient. There is no published data on the effect of unmasking the anaesthetist alone.

Orr<sup>16</sup> Mitchell<sup>11</sup> and Tunevall's<sup>24</sup> studies represent levels of evidence of level III-3, level III-2 and level II respectively. These studies provide sound scientifically-based evidence that, in the setting of a modern operating theatre with laminar flow/steriflow systems, surgical masks should no longer be considered mandatory for anaesthetists and non-scrub staff during most surgical procedures.

The available evidence indicates that, for the wearer, surgical masks offer incomplete protection from airborne bacteria and viruses. Protection of the anaesthetist from infection by the patient may better be accomplished with the use of plastic face shields, which afford a higher level of protection from contamination.

On the basis of the scientific evidence presented, recommendations concerning the use of surgical masks in the operating theatre may be made.

# RECOMMENDED GUIDELINES FOR THE USE OF FACE MASKS BY ANAESTHETISTS IN THE OPERATING THEATRE

#### Guideline One\*

During any surgery other than surgery identified in Guideline 2:

- Surgical mask to be worn by scrub team.
- Surgical masks NOT required by other OR staff.

#### **Guideline Two\***

Masks with eye protection or visor mask protection should be worn during

- implant insertion surgery
- during the use of surgical power tools.
- trauma management
- (\*Assuming that theatre air conditioning meets Australian Standards and that standard infection control and transmission-based precautions apply.)

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