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The effectiveness of surgical face masks: what the literature shows

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ABSTRACT **Lipp, A. (2003) The effectiveness of surgical face masks: what the literature shows. *Nursing Times*; 99: 39, 22–24.**

The use and withdrawal of surgical face masks in recent years has occurred in an ad hoc manner that is incompatible with evidence-based practice. Much of the literature on masks consists of anecdotal evidence or summaries of previous studies. The rationale for wearing masks has shifted from protection of the patient to protection of the health care professional wearing the mask. Currently there is little evidence that wearing a surgical mask provides sufficient protection from all the hazards likely to be encountered in an acute health care setting: the use of a respirator and face shield should be considered depending on the circumstances.

The use of surgical face masks is synonymous with acute health care and is so deeply ingrained that to question it would have been unheard of until recently. However, in some practices the use of masks has been abandoned over recent decades, for example when dressing wounds. Both the use and withdrawal of surgical face masks has occurred in an ad hoc manner that is incompatible with evidence-based practice. This article will discuss the available evidence.

The hierarchy of evidence

Evidence may be categorised according to a hierarchy. At the upper end of the hierarchy (Type Ia) the evidence provides a more reliable base for practice. However, much of the literature on surgical masks is Type IV evidence (at the lowest end of the hierarchy), which includes anecdotal accounts or summaries of previous studies (Belkin, 1996).

Sackett et al (1996) call for the 'conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients'. Such an undertaking could ensure the practice of wearing surgical masks can be adapted, according to circumstances and over time, in line with the latest evidence.

In an earlier definition of evidence-based medicine, Bennett and Sackett (1987) created a simple benchmark of 'doing more good than harm' to measure whether practice is effective. It was formerly presumed that surgical masks do 'more good than harm'; but it has also been suggested that masks may do 'more harm than good'. For example, following a small laboratory study, Schweizer (1976) claimed that mask wiggling caused shedding of skin scales and contamination of an area directly below the masked subjects.

Current devices

Surgical face masks normally comprise three layers – a barrier layer (such as polypropylene) usually separates the inner and outer layer. The most common European design is flat and pleated with horizontal ties and a metal strip shaped over the nasal bridge.

Masks do not filter all particulates from the air inhaled and exhaled by the wearer. Much of the air is drawn in and escapes where there is least resistance to flow, usually around the sides of the mask (venting). The masks do not form a complete seal against the face and are therefore not classed as respirators or personal protective equipment (Stull, 1998).

In practice other equipment may be used instead of face masks depending upon the circumstances. For example, respirators are recommended to reduce the risk of exposure by the wearer to harmful substances. The respirator may be 'valved' providing protection to the wearer, or 'non-valved' providing protection to both the wearer and the patient. Various standards of respirator provide appropriate protection in specific circumstances.

Face shields are thin plastic sheets that either cover the whole of the face in place of a face mask, or are fitted to the top of the face mask with an antifogging device between them to reduce moisture exhalation. Approved goggles or eye protectors may also be worn to supplement the mask to avoid eye splashes.

No single product design on the market today fits all personal preferences and performance needs so it is imperative that the nurse makes a judgement according to the situation. Box 1 (p24) lists the criteria on which the performance of surgical face masks is based.

Cost-effectiveness

Calculating the cost-effectiveness of any procedure is an adjunct to evidence-based practice. However, it is difficult to put a price on the pain, additional treatment and distress that, for example, a surgical site infection can cause. The costs can escalate both in personal and in monetary terms. The cost of wearing surgical masks in theatre in a teaching hospital was estimated to be around £10,000 per annum (Leyland and McCloy, 1993). This is a relatively small outlay, but it can only be justified if the practice is effective.

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Length of effectiveness

A mask wet with exhaled moisture has increased resistance to airflow, is less efficient at filtering bacteria and has increased venting. Current recommendations are that a new surgical mask is used for each surgical case and that they should be changed when wet (National Association of Theatre Nurses, 1998). Some respirators are claimed to be effective for a full shift, although storage to avoid contamination between cases would be problematic (Anon, 1999).

Questioning the rationale

Originally, the rationale for wearing masks was centred on patient protection. More recently, the issue has shifted to protection of the wearer. For example, a recent article in *Nursing Times* shows a nurse practitioner performing minor surgery wearing a visor but no mask (Gallagher, 2002).

Protecting the patient

Most of the evidence on the effectiveness of surgical masks relates to the protection of the patient, although the endpoint measured varies. Some studies measure surgical site infection (SSI) rates and others either measure contamination of the surgical site or settle plates close to the surgical site. Contamination studies may be performed in the laboratory or the operating theatre. Distinguishing the endpoint is important, as some studies have claimed that contamination will inevitably lead to infection and this cannot be established unless infection rates are measured.

Measuring contamination

In their laboratory study on surgical masks McLure et al (2000) found that bacterial shedding from people with beards was increased. They suggest that bearded males should avoid mask wiggling and recommend the removal of beards. Like the study by Schweizer (1976), this is an example of contamination being extrapolated to infection without measuring the endpoint of infection.

A study that measured oral and nasal contamination of settle plates in a forced ventilation theatre was limited to five subjects. Despite contamination, the article cites dated and speculative studies to claim that the routine wearing of masks should be abandoned (Mitchell and Hunt, 1991). This research displays the faults of similar studies in that substantial claims arise from a very small sample studied under laboratory conditions.

Alwitry et al's (2002) study on contamination in cataract surgery maintains that masks should continue to be worn. The researchers combine the two deficits of a small sample size and extrapolation from contamination to infection 'despite the unproven link between bacterial load and endopthalmitis rate' (Alwitry et al, 2002).

Measuring infection

A more reliable indicator of whether surgical masks are likely to cause an SSI is to measure the infection rate. In support of discarding surgical masks for the protection of the patient, a study by Orr (1981) looked at over 1,000 patients undergoing a variety of surgery over a period of six months. According to Orr there was a significant decrease in the infection rate during the period when masks were not used. Although this study is lacking in scientific rigour, it has encouraged the abandonment of the use of surgical masks.

The author and a colleague have undertaken a systematic review of the use of surgical masks via the Cochrane Wound Group (Lipp and Edwards, 2002). In an attempt to gain a definitive answer on mask effectiveness, this evidence focused on clean surgery. Despite retrieving 97 papers for examination, only 13 had potential relevance. Two studies met the criteria for inclusion (Tunevall, 1991; Chamberlain and Houang, 1984). As these were quasi-randomised controlled trials, it is acknowledged that neither was without flaws, but a judgement was made that they were sufficiently valid for inclusion. 'From the limited results it is unclear whether wearing surgical face masks results in harm or benefit to the patient undergoing clean surgery' (Lipp and Edwards, 2002).

A critique of Tunevall's study cites it as lacking 'control' and lists the 'five Ds of surgical infection control' (Laufman, 1992) as:

- Discipline;
- Defence mechanisms;
- Drugs;
- Design;
- Devices.

This amounts to almost 100 variables as diverse as length of operation, patient age, prophylactic antibiotics, ventilation and aseptic barriers, such as masks, respectively (Laufman, 1992).

Laufman (1992) advocates the use of in vitro testing to exclude some of these variables. This would inevitably move the end point from infection to contamination, which was not the aim of Tunevall's study. If the independent variables cannot be excluded then a controlled trial must ensure they are evenly distributed via baseline comparability (Sanderson et al, 2001). Tunevall (1991) assured this was the case in terms of age, acute and elective surgery, although not for comorbidity. He enlisted a large sample, which is more representative of the general population of patients undergoing surgery and could therefore be more easily applied to other similar situations. Having developed his argument based on variables and sample size, Laufman (1992) then changes tack and advocates wearing masks for the protection of health care staff, if not the patient.

Specialist surgery, such as transplantation and orthopaedics, is often cited as a special case, where wearing a mask to protect the patient is crucial to avoid deep infection. In these types of surgery, infection is more likely to have grave repercussions. The risks of not wearing a mask are arguably too great. Crucially, there are no randomised controlled trials that demonstrate a link between wearing or not wearing a mask and SSIs in these specialisms. The major evidence in this field is based on contamination (Friberg et al, 2001; Hubble et

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al, 1996; Ha'eri and Wiley, 1980). The argument for wearing a surgical mask in this sphere of surgery could more rationally be based on staff protection, as sub-micron-sized particles are likely to be present.

In protecting the patient, it is important to ascertain who should wear a surgical mask. Should it be limited to the person performing the procedure, or to all personnel present? Mitchell and Hunt's (1991) laboratory study found no contamination of settle plates when personnel spoke at a distance of 1m. This indicates that staff in the vicinity of a procedure need not wear masks. However, due to the small sample size of five and a lack of validity, it is difficult to have confidence in these findings.

Immunocompromised patients may be advised to wear surgical masks. This practice may provide reassurance for both patient and staff, but it cannot be justified unless it is based on evidence. To date there have been no randomised controlled trials that establish this practice to be effective.

Protection for the wearer

Operating techniques and clinical situations that create aerosolised hazardous agents pose a potential threat to staff. To evaluate mask effectiveness against aerosolised hazardous agents, Weber et al (1993) tested eight types of masks for aerosol particle penetration either through the mask or via a leak (venting). In this laboratory study, they predict that the surgical masks provide insufficient protection against potentially hazardous submicron-sized particles (Weber et al, 1993).

The need to protect staff from contamination by patients has become more urgent. A recent study of 40 hospital staff who contracted severe acute respiratory syndrome (SARS) in Hong Kong found that all staff had worn masks with a minimum bacterial filtration efficiency (see Box 1) of 95 per cent. Staff did not use respirators and only 28 per cent had used eye shields. The implication from these findings is that surgical masks alone do not provide sufficient protection against SARS (Ho et al, 2003). It is inevitable due to the acute circumstances that this study only rates as a well-designed, non-experimental study (level III in the hierarchy). To date this is the only study that links protection of staff to the use of surgical masks and the risk of infection.

Professional organisations in the USA and the UK recognise that the link between protection of the patient and wearing a surgical mask is tenuous. However, they provide cautious advice on the use of surgical face masks, respirators and eye shields when the wearer is at risk of contamination (Mangram et al, 1999; Association of Operating Room Nurses, 1998; National Association of Theatre Nurses, 1998).

Future research

A useful phrase to remember is that 'lack of evidence of benefit does not equate to evidence of lack of benefit'. Staff protection is a relatively recent concern and robust research still needs to be undertaken. One could argue that randomising staff into masked and non-masked ascertained whether wearing a surgical mask affects infection rates this would create an ethical dilemma equivalent to randomising patients into such groups.

To determine the effectiveness of masks, a randomised controlled trial would have to be large enough to give a statistically significant result. It would have to specify the aim as either patient or staff protection. Controlling the independent variables would mean creating a balance between selecting clean cases with no comorbidity and gaining more valid results by including subjects with varying comorbidity, reflecting the general population.

Conclusion

The rationale for wearing surgical face masks has shifted from protection of the patient to protection of the health professional. Despite this there remains a need to base the decision to wear a mask on the best available evidence (Sackett et al, 1996). Unfortunately, there is a lack of robust evidence for protecting nurse and patient.

Currently there is little evidence that wearing a surgical mask provides sufficient protection from all the hazards encountered in an acute health care setting. For this reason, the use of a respirator and face shield should be considered depending on the situation. ■

BOX 1. MEASURING THE PERFORMANCE OF SURGICAL FACE MASKS

Performance is based on the following properties:

- Fluid resistance: tests measuring the amount of fluid a mask is able to withstand;
- Bacterial filtration efficiency (BFE): bacteria of a specific size are projected through the mask into a sieve sampler at a specified concentration and flow rate. Higher per cent efficiency = a more effective mask (minimum of 95% BFE recommended);
- Particulate (submicron) filtration efficiency: minute particles, for example diathermy smoke, are measured being drawn through the mask at a specific concentration and rate. Greater resistance to particles = a more effective the mask. Efficiency of 95 per cent is expected although venting can occur;
- Pressure drop: test of breathability where air is passed through the mask at 50 litres per minute and the resistance to airflow is measured. The higher the resistance = a greater resistance to breathing;
- Flammability: measurement of the time taken for a flame to move across mask material in controlled conditions. A rate of flame spread of greater than four seconds is the standard;
- Biocompatibility: mask must be non-irritating to skin. Tests for cytotoxicity, skin sensitisation and dermal irritation should be negative.

(Based on Stull, 1998)

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