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Review

Respiratory and facial protection: a critical review of recent literature

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S U M M A R Y

Infectious micro-organisms may be transmitted by a variety of routes. This is dependent on the particular pathogen and includes bloodborne, droplet, airborne, and contact transmission. Some micro-organisms are spread by more than one route. Respiratory and facial protection is required for those organisms which are usually transmitted via the droplet and/or airborne routes or when airborne particles have been created during 'aerosol-generating procedures'. This article presents a critical review of the recently published literature in this area that was undertaken by Health Protection Scotland and the Healthcare Infection Society and which informed the development of guidance on the use of respiratory and facial protection equipment by healthcare workers.

Introduction

Infection is caused by a range of micro-organisms including bacteria, viruses and fungi. The route of transmission is dependent on the particular pathogen and the range covers bloodborne, droplet, airborne and contact (direct and indirect) transmission. Droplet transmission is generally accepted as the transfer of large particle droplets (>5 μm) from an infected respiratory tract over a short distance (<1 m).[1–4] Airborne transmission refers to small particles (≤5 μm) which can spread over greater distances and can result in infection without close contact with the source. Some micro-organisms are spread by more than one route. Those that require the use of respiratory and facial protection are usually transmitted via the droplet and/or airborne route by breathing, coughing, sneezing, talking, laughing (particularly if the individual is suffering from respiratory symptoms), or when airborne particles have been artificially created, such as during 'aerosol-generating procedures'.[2,4] Healthcare procedures which generate aerosols include bronchoscopy, respiratory/airway suctioning, and intubation, and there is some evidence of a hierarchy of risk within these categories.[2,4–10] Clearance of aerosols is dependent on ventilation. The greater the number of air changes per hour the faster any aerosols will be diluted, with a single air change removing 63% of particles and each subsequent air change removing a further 63%. It can be estimated therefore that five air changes reduce contamination to <1% of its former level, assuming dispersion has ceased. Due to their ability to access the respiratory tracts of individuals exposed without necessarily having close contact with the source, the use of respiratory and facial protection (as well as other control measures) by healthcare workers may be employed to attempt to reduce the risk of infection transmission.[2]

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Transmission of influenza and respiratory protection

Filtering of inhaled air to protect against influenza has often been regarded as a self-evident tenet of infection prevention philosophy. The 2009 H1N1 influenza pandemic was a significant spur to research in the field of influenza transmission and infection prevention; however, the evidence is still limited.[11] Although it is certain that influenza is transmitted from infected to susceptible people through contaminated exhaled air, the relative importance of droplet and aerosol spread is still debated. A review by Tellier presents evidence to support the role of aerosols in influenza transmission, at least over short distances.[12] If true, an important consequence of this may be the need for effective respiratory protection devices to provide defence against aerosols, not just droplets. In this case, surgical masks are not sufficient since they can only offer protection against droplets. Instead, aerosol-filtering respirators are necessary. However, respiratory protection alone may not be sufficient.[11] A study looking at the ability of facemasks alone, versus facemasks and eye protection combined, to prevent infection from aerosols of live attenuated influenza virus, concluded that trans-ocular transmission was a sufficient and effective route of infection and that eye protection is a necessary adjunct to respiratory protection.[13] Although this observation is significant, it must be remembered that direct splash or splatter contamination, rather than exposure to smaller and lighter respirable particles, remains a primary consideration in the assessment of the requirement for eye protection as a component of respiratory and facial protection.

Surgical masks

There is little good quality evidence to support surgical masks as an effective respiratory infection protection measure, even though they have been used for this purpose since the flu pandemic of 1919. Belkin gives a history of surgical masks from this date to recent years and details US Food and Drug Administration (FDA) standards for surgical masks.[14] He points out that these standards are meant to support the use of masks for their original intended purpose – prevention of surgical infections – not to protect the wearer from respiratory infection. The rationale for the use of surgical face masks is twofold: to protect the wearer from sources of infection, e.g. splashing or spraying of blood, and to protect others from the wearer as a source of infection.[15,16] It has also been recommended that a surgical face mask with attached face shield or a surgical facemask and goggles should be used for the protection of the wearer during aerosol-generating procedures in patients who are not suspected of being infected with an agent for which respiratory protection is otherwise recommended.[2] The use of surgical masks as part of the Transmission Based Precautions (TBPs) is designed to protect healthcare workers from exposure to potentially infective respiratory droplets. Otherwise, mucosal surfaces of the nose and mouth are exposed, providing an easy route of entry to the body for pathogenic micro-organisms.[2]

No standard definition of a surgical facemask was identified in the literature. There appears to be a wide variation in design and quality of masks in use. In terms of design, it is recommended that masks should fully cover the nose and mouth of the wearer.[17–19]

Respirators

Medical devices designed to protect the wearer from airborne infectious aerosols transmitted directly from the patient or when artificially created such as during aerosol-generating procedures (e.g. bronchoscopy) are termed respirators.[2,4,6,7] Many different respirators are available including half-face (mouth and nose both covered) and full-face (eyes are covered in addition to mouth and nose) respirators and they vary in their nominal ability to resist penetration by aerosols. The respirators most frequently used in healthcare settings are filtering face piece (FFP) respirators. Inhaled air is drawn through a split polypropylene fibre filter enhanced with a static electric charge to increase their filtering capabilities. There are different grades of FFP respirator distinguished by labels such as FFP2 (UK designation, equivalent to North American N95 respirators) and FFP3 (N99). Healthcare workers in the UK are required to wear a respirator complying with the European standard EN149:2001 FFP3.[20–22] However, there is a dearth of studies focusing on the use of the FFP3 respirator, the majority being centred on the N95 respirator. Although vaguely comparable, due to the N95 having a lower particulate efficacy rating, it would be helpful (especially for healthcare workers in the UK) for researchers to use FFP3 respirators in future studies.

Powered air-purifying respirators (PAPRs) use a power source to drive ambient air through a high-efficiency particulate air (HEPA) filter prior to inhalation by the wearer, increasing the filtration performance over FFP respirators. However, PAPR devices are expensive, cumbersome, noisy and require the wearer to be specially trained in their use. A summary of the properties of masks and respirators, including PAPRs, is given by Tompkins and Kerchberger.[23]

Surgical masks versus respirators

Ultimately the effectiveness of both surgical masks and respirators is liable to be associated with their consistent and correct usage.[11] While the preceding arguments may suggest it is reasonable to assume that respirators should give greater protection than surgical masks against influenza infection, there are only two recent studies that test this assumption. Neither demonstrated the superiority of N95 respirators over surgical masks. Loeb *et al.* looked at rates of influenza infection in nurses in Ontario, Canada, who were randomized to wear either N95 respirators or surgical masks when providing care to patients with febrile respiratory illnesses during the 2008–2009 influenza season.[24] There was no significant difference in influenza infection rates between the two groups – both were close to 23%. Similarly, MacIntyre *et al.* compared N95 respirators to surgical masks for their ability to protect nurses in Beijing, China, against respiratory viral infections.[25] In contrast to the Loeb study, subjects in the MacIntyre *et al.* trial were required to wear their respiratory protection throughout their shifts for four weeks. The results of this study were more suggestive that N95 respirators provided protection against respiratory viral infections, achieving significance for the group of illnesses broadly classed as clinical respiratory illness, but failing to demonstrate significant protection against influenza infection. While neither study included a formal 'no-masks' group, because of ethical concerns, MacIntyre *et al.* compared their subjects to a convenience no-masks group of nurses working in hospitals where mask use was not routine; they concluded that rates of respiratory infection were higher in this no-mask group compared with either the mask or respirator study arms. The report by Loeb *et al.* drew a number of comments and criticisms including questions relating to variations in the filtering efficiencies of different makes of respirators and masks, training in N95 respirator use, poor compliance with respirator use, problems in ensuring a proper respirator fit, and infection with influenza in settings outside the workplace.[26–28]

Fit-testing of respirators

The fitting of N95 respirators has been the subject of many publications. The effective functioning of N95 respirators requires a seal between the mask and the face of the wearer. Variation in face size and shape and different respirator designs mean that a proper fit is only possible in a minority of healthcare workers for any particular mask. Winter *et al.* reported that, for any one of three widely used respirators, a satisfactory fit could be achieved by fewer than half of the healthcare workers tested, and for 28% of the participants none of the masks gave a satisfactory fit.[29] Fit-testing is a laborious task, taking around 30 min to do properly and comprises qualitative fit-testing (testing whether the respirator-wearing healthcare worker can taste an intensely bitter or sweet substance sprayed into the ambient air around the outside of the mask) or quantitative fit testing (measuring the ratio of particles in the air inside and outside the breathing zone when wearing the respirator). Attempts have been made to circumvent the requirement for fit testing, and it has been suggested that self-testing for a seal by the respirator wearer (see http://youtu.be/pGXiUyAoEd8a for a video demonstration) is a sufficient substitute for fit-testing. However, self-checking for a seal has been demonstrated to be a highly unreliable technique in two separate studies so that full fit-testing remains a necessary preliminary requirement before respirators can be used in the healthcare setting.[30,31] Operationally, this presents significant challenges to organizations with many healthcare workers who require fit-testing. Chakladar *et al.* pointed out that, in addition to the routine need for repeat testing over time to ensure that changes in weight or facial hair have not compromised a good fit, movements of healthcare workers between organizations using different makes of respirators would necessitate additional repeat fit-testing.[32] Fit-testing is likely to remain problematic to healthcare organizations for the foreseeable future. In addition to the requirement for fit-testing, 'fit-checking' is also required each time the respirator is donned to ensure there are no air leaks.[33]

Finding a respirator that fits a healthcare worker is not the only challenge. Many healthcare workers find that respirators are uncomfortably hot and interfere with breathing and communication.[34] Female healthcare workers were found to be more likely to complain than males.[35] However, objective studies of the impact of respirators on performance and communication show few significant effects, although hearing clarity was impaired in users of PAPRs.[36–38] Physiological measurements during simulations of clinical workloads in subjects wearing N95 respirators recorded some deviation from normal values in transcutaneously measured carbon dioxide levels, possibly linked to the measured increases and decreases in respirator dead space of carbon dioxide and oxygen levels respectively.[39] The possible consequences of these changes are unknown, although probably clinically insignificant.

Stockpiling of respirators

An additional operational challenge is ensuring sufficient stock of respirators. While surgical masks are used in large numbers in surgical procedures outside flu outbreak seasons, N95 respirators have very few indications other than respiratory protection against influenza and tuberculosis. Consequently, there is an element of feast or famine in their use. Outside a flu outbreak, the need for respirators is small. During an outbreak, the numbers of respirators used may soar. As an illustration, during the severe acute respiratory syndrome (SARS) outbreak in 2003, 18,000 N95 respirators were used in one Toronto hospital alone every day. Manufacturers are unable to ramp up respirator production quickly enough to meet such sudden demand and so a number of countries have built up national stockpiles of respirators. The possibility that these may not be used for several years has prompted investigations of performance after prolonged storage. Happily, it appears that filtration performance is not significantly degraded by storage of up to 10 years in warehouse conditions, although this general conclusion may not be true for all makes of respirators or for attachments such as face straps.[40]

Use of masks by patients and visitors

A few reports have focused on putting the mask on the infected patient, rather than a healthcare worker. This copies the common practice of placing masks on patients with respiratory tuberculosis when they need to leave their isolation room. Diaz and Smaldone developed a bench model to explore the relative importance of dilution, deflection and filtration of infectious particles by respiratory protection when worn either by healthcare workers or patients. They concluded that deflection of exhaled particles by a mask placed over the nose and mouth of a patient, coupled with sufficient air exchanges (around six per hour) was an effective protective mechanism, providing greater protection to healthcare workers than wearing masks themselves.[41] Clinical support for this approach was provided by Johnson *et al.*, who investigated how surgical masks and N95 respirators, worn by patients with confirmed influenza, would prevent the generation of infectious airborne particles. Surgical masks and N95 respirators appeared to be equally and highly effective in filtering out influenza-contaminated particles when worn by infected patients.[42] This small study did not investigate whether masks or respirators worn by patients reduced the numbers of cross-infection events in a real clinical setting, which would be the decisive test for this approach.

The use of a mask by visitors is a contentious issue and should be decided by the level of interaction between them and the patient, i.e. during contact with a patient with known or suspected infection with a micro-organism spread wholly or partly by the droplet route while the patient is considered infectious.[2]

Removal and disposal of respirators

Finally, the possibility that removal and disposal of used, potentially contaminated, respirators may be an infection risk was addressed in a pair of papers looking at particle release from respirators during removal and when dropped from height during disposal. Taking off a mask causes it to be temporally stressed but these tensions do not appear to cause significant particle release from respirators, whereas dropping used respirators into a bin seems to release only very small numbers of particles.[43,44] However, it is important that respirators are taken off using a procedure to avoid self-contamination and disposed of appropriately.[2,33]

Conclusion

The lack of clear superiority of respirators over facemasks in the studies of Loeb *et al.* and MacIntyre *et al.* may result from poor respirator face seals, poor compliance due to discomfort, lack of recognition of infectious patients and consequent inappropriate non-use of respirators, infection arising from infectious co-workers, trans-ocular infection despite appropriate respirator use but no eye protection, or infection from sources outside the healthcare setting.[24,25] Regardless of the reason for failure, the high rate of infection in both of the groups in the Loeb study is impressive and reinforces the need to consider how protection can be strengthened. In relation to aerosol-generating procedures the results of a recent review concluded that, although there are a number of these procedures listed under this heading, few have sufficient evidence to confirm they actually do produce aerosols – therefore further research in this area is warranted.[4] The view that cross-infection may be reduced by placing masks on potentially infectious patients, supported by bench and clinical studies, opens up an additional approach to protection. The demonstration of trans-ocular infection by aerosols needs further investigation and suggests that eye protection may be required as a component of respiratory and facial protection, not only to mitigate risks associated with direct splash or splatter contamination, but also to prevent aerosol exposure. Finally, as pointed out by Srinivasan and Perl, and also by a recent Department of Health scientific review, the use of masks and respirators should be considered as the last line of defence in the hierarchy of infection prevention measures.[11,45] These include vaccination (when available), hand hygiene (always), environmental measures including sufficient ambient ventilation, the provision of single occupancy rooms, and administrative practices that emphasize early recognition of infectious patients and their removal from others.

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