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Evaluating the protection afforded by surgical masks against influenza bioaerosols

Gross protection of surgical masks compared to filtering facepiece respirators

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Gross protection of surgical masks compared to filtering facepiece respirators

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The UK is preparing for a potential influenza pandemic. The main route of transmission of influenza is believed to be via direct contact with large droplets. The relative importance of aerosols in transmission is considered to be minor, but it cannot be ruled-out. The current UK Pandemic Influenza Infection Control Guidance recommends that workers who are in close contact with patients should wear surgical masks to reduce exposure to large droplets. However, surgical masks are not intended to provide protection against infectious aerosols. The guidance recommends that procedures that are likely to generate aerosols should be minimised, or where unavoidable, workers should wear appropriate respiratory protection. There is a common misperception amongst workers and employers that surgical masks will protect against aerosols. This study aims to evaluate the relative levels of protection provided by both surgical masks and respirators against aerosols.

This study focussed on the effectiveness of surgical masks against a range of airborne particles. Using separate tests to measure levels of inert particles and live aerosolised influenza virus, our findings show that surgical masks provide around a 6-fold reduction in exposure. Live viruses could be detected in the air behind all surgical masks tested. By contrast, properly fitted respirators could provide at least a 100-fold reduction.

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SUMMARY

Background

The UK is preparing for a potential influenza pandemic. The main route of transmission of influenza is believed to be via direct contact with large droplets. The relative importance of aerosols in transmission is considered to be minor, but it cannot be ruled-out. The current UK Pandemic Influenza Infection Control Guidance recommends that workers who are in close contact with patients should wear surgical masks to reduce exposure to large droplets. However, surgical masks are not intended to provide protection against infectious aerosols. The guidance recommends that procedures that are likely to generate aerosols should be minimised, or where unavoidable, workers should wear appropriate respiratory protection. There is a common misperception amongst workers and employers that surgical masks will protect against aerosols. This study aims to evaluate the relative levels of protection provided by both surgical masks and respirators against aerosols.

Main Findings

This study focussed on the effectiveness of surgical masks against a range of airborne particles. Using separate tests to measure levels of inert particles and live aerosolised influenza virus, our findings show that surgical masks provide around a 6-fold reduction in exposure. Live viruses could be detected in the air behind all surgical masks tested. By contrast, properly fitted respirators could provide at least a 100-fold reduction.

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Objectives

The UK is advanced in its preparations for a potential outbreak of human pandemic influenza. The main route of transmission of influenza is believed to be via large droplets or direct contact with secretions and, in some circumstances, exposure to infectious aerosols.

The relative contribution of aerosol transmission in natural influenza transmission is thought to be minor but cannot be ruled-out. The likelihood of infection via this route will increase when in close proximity to the patient and especially when carrying out procedures likely to generate aerosols, such as intubation or dental drilling. Consequently, the current UK Pandemic Influenza Infection Control Guidance recommends the wearing of fluid-repellent surgical masks for those workers who are in close contact with symptomatic patients as protection from droplets/splashes and recommends the use of respiratory protection (i.e. FFP3 respirators) for circumstances in which aerosols are generated as a consequence of medical procedures.

Whilst surgical masks may, in principle, offer adequate protection against large droplets and contact transmission, the level of protection they offer against a residual aerosol risk is poorly understood. They are not designed, or certified, as respiratory protective devices. However, there is a common misperception that they will provide protection against aerosols.

The following study aims to measure the efficiency of surgical masks against airborne particles generated from a simulated sneeze (including those that contain live, infectious influenza virus) so that the contribution of surgical masks in the protection against any residual aerosol risk can be assessed.

Main Findings

Surgical masks and filtering facepiece (FFP) respirators were tested on a human volunteer using an inert aerosol challenge. From the results of this study, it can be concluded that surgical masks will mitigate a mean reduction factor of around 2 against a simulated sneeze of inert airborne particles compared to FFP respirators, which are capable of offering a mean reduction factor of 100 or higher.

Surgical masks were also tested on a breathing dummy head and subjected to an aerosol challenge containing live influenza virus. Infectious, viable virus could be detected in the air behind all surgical masks challenged. A mean reduction factor of 6 was measured.

Recommendations

In principle, surgical masks that are worn correctly should provide adequate protection against large droplets, splashes and contact transmission. They may also reduce to some degree any residual aerosol risk, although this level of protection might not sufficiently reduce the likelihood of transmission via this route. Consequently they should not be used in situations where close exposure to infectious aerosols is likely.

With this in mind, it is recommended that HSE draw the results of this research to the attention of DH/HPA so that it can be considered as part of the wider issue of modes of influenza transmission.

1 INTRODUCTION

1.1 BACKGROUND

There is growing concern that an H5N1 avian influenza virus currently causing global outbreaks of disease in wild and domestic poultry could be a candidate virus for a human pandemic. This is partially due to the ability of this virus to cause serious and often fatal diseases in humans who have been in close contact with infected birds. Although no human-to-human transmission of the H5N1 virus has yet been observed, its ability to replicate in humans might permit adaptation, resulting in an antigenically novel virus that could cause a global epidemic, excess hospitalisations and fatalities. In any event, pandemics occur sporadically and even if the current H5N1 candidate fails to adapt to humans, it is widely expected that another strain of the virus will do so in due course.

Health protection organisations worldwide are making preparations for such an outbreak and national risk assessments and pandemic contingency plans are at an advanced stage in the UK (HPA 2005; DH 2007a; NHS 2007). Many of these plans offer advice to healthcare workers regarding precautions to take in order to avoid exposure to infectious aerosols generated by people suffering from pandemic influenza, or from certain medical procedures carried out on them. Clearly, there is a need for front-line healthcare workers to be adequately protected in the event of such an outbreak, which will require organisational, environmental and procedural controls and may rely heavily on effective protective equipment (Yassi *et al.*, 2005).

In theory, influenza can be transmitted via three major routes

- Large droplets (>5μm diameter)– these settle rapidly on surfaces
- Manual inoculation/direct contact or contact with secretions
- Aerosols – small droplets (<5μm diameter) that remain airborne for protracted periods

Prevailing expert opinion is that the balance of evidence points to large droplet and direct/indirect contact as being the most important routes of influenza transmission. The relative contribution of aerosols in natural transmission of the virus is unknown, but is believed to be minor (Brankston *et al.,* 2007; Bell, 2006; Bridges *et al.*, 2003; Gardam and Lemeiux 2007; Lee 2007; DH 2007b). Consequently, many pandemic planning bodies, including those in the UK, have placed less importance on infectious aerosols as being a natural feature of influenza transmission and indicate personal protection against bioaerosols only for certain aerosol generating procedures (HPA 2005; DH 2007a; NHS 2007). This view of transmission is based upon the rarity of long-range infections, which suggests that the ability of the virus to remain viable in aerosols is limited. However, the rarity of long-range infections does not preclude a role for bioaerosols in the transmission of influenza virus in close proximity. The evidence for an aerosol component to natural transmission of influenza virus was recently reviewed and it was concluded that they may have a role (Tellier, 2006; Toner, 2006; see also Tellier 2007; Tang and Li 2007). Influenza can be transmitted to both humans and mice via artificially generated aerosols (Alford *et al.*, 1966; Loosli *et al.*, 1943; Schulman, 1967) and via the air between mice and birds in a laboratory setting (Schulman, 1968; Webster *et al.*, 2002). Therefore, the three modes of transmission are not mutually exclusive and it is difficult to separate them in order to draw conclusions as to the relative importance of each. Whilst the absence of long-range infections is evidential for large droplet and contact transmission in a common infection, it remains that it is reasonable to consider that multiple routes of transmission may be possible and that infectious aerosols, regardless of their relative importance in the context of other modes, should not be discounted.

Given the potential severity of the consequences associated with contracting a pandemic strain of influenza, it is clear that exposure of healthcare workers and others that are to work in close proximity to infected individuals should be minimised, that includes the selection of adequate protective equipment that is suitable for the tasks required.

1.2 RESPIRATORY PROTECTIVE EQUIPMENT

The Control of Substances Hazardous to Health Regulations 2002 (COSHH) covers not only exposure to hazardous chemicals but also biological agents. The regulations assert that '*every employer shall ensure that the exposure of his employees to substances hazardous to health is either prevented or, where this is not reasonably practicable, adequately controlled'*. HSE recommends a hierarchy of principles for the control of exposure to airborne hazardous substances to underpin this requirement. These are:

- Elimination
- Substitution
- Physical separation
- Use of personal protective equipment (PPE)

Vaccination can be added to this list of control measures but should not be seen as a primary measure as it might preclude the principles of controlling exposure to an organism.

Where PPE is employed as a control measure then it should be '*adequate'* for the anticipated exposure levels and '*suitable'* for the task, for the environment and for the wearer. In addition the PPE must be:

- "CE" marked to the European PPE Directive
- Selected, used and maintained by properly trained people
- Correctly maintained, examined and tested
- Correctly stored

The British Standard BS EN 149:2001 covers disposable filtering facepiece (FFP) respirators. FFP respirators are classified as FFP1, FFP2 and FFP3 according to the level of protection afforded as assessed by specified laboratory tests, with FFP3 offering the most protection. In order to aid the correct selection of '*adequate'* RPE assigned protection factors (APF) have been derived, and for FFP respirators these are 4, 10 and 20 respectively. The APF is the ratio of pollutant outside the device to that inside the device and is defined by British Standard BS EN 529:2005 as the '*level of respiratory protection that can realistically be expected to be achieved in the workplace by 95% of adequately trained and supervised wearers using a properly functioning and correctly fitted respiratory protective device and is based on the 5th percentile of the Workplace Protection Factor (WPF) data'*. APFs are published by both BS EN 529:2005 and by HSE in its RPE guidance HSG53 (HSE 2005a). Table 1 shows the efficiency requirement levels for the three classes of filtering facepieces from British Standards, together with their assigned protection factors.

Disposable filtering facepieces can only be said to be suitable for the wearer if they have been subject to, and have passed, a 'Fit Test' on the intended wearer. A fit test is a means of

assessing the goodness of fit of the facepiece to the wearer's face. HSE Operational Circular OC282/28 provides further information (HSE 2004).

The European PPE Directive 89/686/EEC covers Respiratory Protective Equipment. This Directive excludes surgical masks and they are not certified for use as RPE in the UK. Surgical masks can be certified compliant with the Medical Devices Directive and be 'CE' marked. However, the placing of a 'CE' mark on a surgical mask does not denote the ability to provide respiratory protection under the PPE Directive. Whilst surgical masks do provide a degree of protection against droplets and splashing, the British Standard covering surgical masks (BS EN 14683:2005) categorically states that '*The surgical masks intended to be used in operating theatres and health care settings with similar requirements are designed to protect the working environment and not the wearer. When the primary intention is to protect the wearer from infection, the use of respiratory protective devices should be considered'*. As surgical masks are not intended to offer protection against airborne particles, they are not designed to fit closely to the wearers face or designed to have the filtering efficiencies required for adequate respiratory protection. Furthermore, no protection factors are assigned to surgical masks, as they are not designed to offer respiratory protection. However, there is a common misperception that they will provide protection against aerosols.

Table 1. Efficiency requirement for filtering facepieces and their assigned protection factors

Class	Max permitted total inward leakage	Max permitted filter penetration	Min filter efficiency ▯	Nominal Protection Factor ††	Assigned Protection Factor
FFP1	22%	20	80%	4.5	4
FFP2	8%	6	94%	12.5	10
FFP3	2%	1	99%	50	20

▯ Figure derived from the maximum filter penetration allowed by BS EN 149:2001
▯ Figure derived from the maximum total inward leakage allowed by BS EN 149:2001

1.3 RPE IN HEALTHCARE AND PANDEMIC PLANNING

Healthcare workers are exposed to infectious agents as a consequence of their work. In the context of the COSHH Regulations, elimination, substitution, and physical separation are not possible in the healthcare setting. Since physically preventing exposure of healthcare workers to the virus is not feasible, it is important to minimise the likelihood that they will become infected, as far as is reasonably practicable, whilst still ensuring they are able to undertake their duties effectively. What is both reasonable and practicable will change during a pandemic, although the duty of control will still be based upon applying protective measures appropriate to the activity and consistent with the risk assessment. The UK Pandemic Influenza Infection Control Guidance identifies approaches, systems of work and infection control measures to protect healthcare workers. This places a heavy reliance on the use of personal protective equipment (including RPE) and vaccination. In the first waves of a pandemic, it is unlikely that a protective vaccine will be available. Therefore, PPE (including RPE) will play a major part in the control programme. As a result, it is important to be able to correctly select the appropriate type and class of PPE and RPE and to be aware of any limitations that may exist in the protection it affords.

The type of RPE that is considered to be most suitable for use by healthcare workers are FFP respirators. The use of FFP respirators would necessitate correct maintenance, correct storage,

fit testing and use by trained personnel. These aspects, as well as respirator supply, would clearly present a planning challenge to the healthcare sector.

The current UK Pandemic Influenza Infection Control Guidance (HPA 2005; NHS 2007), and the draft framework for responding to an influenza pandemic (DH 2007a) recommends the wearing of class FFP3 disposable respirators when carrying out clinical procedures likely to generate aerosols of respiratory secretions from infected patients (e.g. dental drilling, intubations, aspiration). For those workers who may be in close or frequent contact with symptomatic patients (i.e. within one metre), the use of fluid-repellent surgical masks is recommended as protection from large droplets or splashes. Therefore, the guidance recognises there may be a hazard from infectious aerosols from certain procedures and prescribes suitable control measures. However, there is concern that natural processes such as coughing, sneezing and talking may also generate infectious aerosols resulting in a residual risk of infection. Whether this is sufficient to cause an infection is unknown.

The scant data regarding the distribution of particle sizes in coughs and sneezes was recently reviewed by Nicas *et al* (Nicas *et al.*, 2005) and analysed in relation to the likelihood of infection via the inhalation route. A single sneeze contains more particles than a single cough, but particles in both a sneeze and a cough are thought to vary in size from <1 to >2000μm, with the large majority being in the <20μm range. These could be inhaled and therefore pose a risk of infection. In addition, a fraction of larger particles (droplets) expelled by coughing or sneezing will shrink in size by evaporation and hence will become aerosols (droplet nuclei) thus increasing the total aerosol content. However, 99.9% of the fluid volume is contained in larger droplets and, as a consequence, this is also where an equivalent proportion of emitted pathogens would be. This supports the argument that the most likely route of infection would be large droplets, or subsequent contact with them after they have settled onto surfaces. However, this does not necessarily mean that infection by inhalation is highly unlikely. This probability is affected by a number of parameters, including the infectious dose and titre of the pathogen in secretions. Both of these parameters are unknown for future pandemic influenza strains.

Unlike exposure to industrial chemicals whereby Workplace Exposure Levels (WELs) exist, there is no specified safe exposure level for biological agents. Whilst the numbers of organisms required to establish different infections varies, the general requirement is to reduce the exposure to as low as reasonably practicable. HSE's current stance is that where there is a respiratory risk of infection use of FFP3 devices represents best practice, and where these are not available then FFP2 may be an acceptable, pragmatic compromise. Hence, HSEs guidance on working with poultry suspected of being infected with highly pathogenic avian influenza prescribes the use of FFP3 respirators (HSE 2005b) due to the absence of an effective vaccine and the severity of the consequences relating to exposure. This also acknowledges the widely held belief that H5N1 avian influenza is transmitted to humans in airborne particles, although it is thought that a large dose is required. Whilst human-to-human transmission of the H5N1 avian influenza virus has not been observed, for the virus to adapt to growth in humans and cause a pandemic, there would be a prerequisite for the infectious dose to become reduced. The precise impact of the pandemic virus is difficult to predict, but levels of morbidity and mortality are expected to be considerably higher than for seasonal influenza outbreaks (NHS 2005; DH 2007a). Furthermore, the relative properties of transmission of this virus may also differ from those that cause outbreaks of seasonal influenza.

The issue of protecting healthcare workers against infectious respiratory viruses was highlighted following outbreaks of Severe Acute Respiratory Syndrome (SARS) in the Far East and Canada in 2002-2003 (reviewed by Gamage *et al.*, 2005). Significant numbers of healthcare workers were infected with the virus that causes SARS (Hogg & Huston, 2006; Loeb *et al.*, 2004; Ofner-Agostini *et al.*, 2006; Seto *et al.*, 2003), which is also thought to be spread primarily via large

droplets and direct contact, similarly to Influenza virus (CDC 2005). Retrospective studies on the clinical attack rates of SARS during the management of outbreaks in the hospital setting suggested that surgical masks afforded some protection, but this was not enough to significantly reduce the risk of infection. The studies also suggested that N95 respirators may have provided added protection (Loeb *et al.*, 2004; Seto *et al.*, 2003) and they, or better RPE, may be required to adequately protect healthcare workers from SARS (Gamage *et al.*, 2005). Consequently, N95-rated respirators are the minimum recommendation for healthcare workers who are in proximity to SARS patients due to the residual risk of aerosol transmission (CDC 2005). It is reasonable to assume that the same characteristics may apply to outbreaks of influenza, and the pandemic planning authorities in the USA make similar recommendations for work with pandemic influenza patients (CDC 2006). The USA APF for N95 is similar to the APF of 10 for UK FFP2. A recent published study on the performance of N95 filtering facepieces found that the workplace protection factor (WPF) for microorganisms with a mean aerodynamic diameter <5um were less than the APF of 10, concluding that even N95 respirators are inappropriate for protection against infectious bioaerosols (Lee *et al.*, 2005).

Epidemics of seasonal influenza occur frequently and explosive outbreaks are not uncommon in hospitals (reviewed in Salgado *et al.*, 2002). Clearly, healthcare workers are at increased risk of contracting influenza during such an outbreak, and this can be extrapolated to the situation expected during a pandemic. As no immunity to the pandemic virus will exist, increased attack rates, mortality and hospital admissions are expected. It is predicted that 25% of the UK population will be affected during a pandemic (as compared to 5-10% during seasonal influenza epidemics), resulting in 50,000 excess deaths and an increase in hospital admissions of 25% (NHS 2005). It is anticipated that excessive strain will be placed on front-line healthcare and community services and further disruption would also be expected if healthcare workers become ill. Some evidence indicates that unvaccinated healthcare workers do contract influenza during seasonal outbreaks with attack rates exceeding those of the rest of the population (Elder *et al.*, 1996; Horcajada *et al.*, 2003; Salgado *et al.*, 2002). Furthermore, vaccination of healthcare workers against seasonal influenza probably reduces the number of recorded absence days (Wilde *et al.*, 1999).

Similar infection control measures to those used in nosocomial outbreaks of influenza would be introduced during a pandemic. This will probably include isolation of infected patients in a dedicated private room or cohort ward, the use of droplet precautions (including PPE and increased levels of hygiene) that includes the wearing of surgical masks. Historically, surgical masks were worn by healthcare workers for the purpose of reducing the likelihood of nosocomial infection in patients and have been shown to be effective for the retention of expelled droplets originating from the wearer (Inouye *et al.*, 2006, Weber *et al.*, 1993). However, their value in specifically protecting a worker from an airborne infection hazard is less well defined.

The Department of Health Pandemic Influenza Scientific Advisory Group recently reviewed the evidence base for the use of facemasks during an influenza pandemic (DH 2007b). This includes the use of surgical masks in various settings, including their use by healthcare workers.

Much work has been done to characterise RPE protection against non-biological, or inert, particles and some of the early work was used to establish the tests that form the basis for the European Standard for RPE. Several studies have demonstrated that the efficiency of surgical masks against inert airborne particles is greatly reduced compared to FFP respirators (Derrick & Gomersall, 2005; Derrick *et al.*, 2006; Lawrence *et al.*, 2006; Tuomi, 1985). This difference in performance appears to be due to the fact that surgical masks are not sealed to the wearer's face as artificially sealing them can increase their efficiency (Derrick *et al.*, 2006; Weber *et al.*, 1993).

Little work has been done to evaluate the level of protection afforded by surgical masks against bioaerosols (reviewed by Rengasamy *et al.*, 2004). The physical characteristics of inert aerosols and bioaerosols are generally considered to be comparable. However, extrapolation of these observations to infectious bioaerosols is complicated by many factors, including infectious dose, the amount of the organism present and its viability in particles of different sizes. Furthermore, most studies using bioaerosols where the performance of RPE and/or surgical masks has been compared have concentrated on the filtration efficiency of the material against aerosolised bacteria, rather than the overall protection afforded to the wearer (for example, Chen *et al.*, 1994; McCullough *et al.*, 1997; Qian *et al.*, 1998). The filtration efficiency of surgical masks was also tested using a surrogate virus, MS2 bacteriophage (Balazy *et al.*, 2006). Filtration efficiencies of up to 97% for bacteria and up to 85% for MS2 bacteriophage are observed but these results might be misleading, as they do no account for facial seal leakage. A good facial seal appears to be key to the overall performance of a mask (Qian *et al.*, 1998, Yassi *et al.*, 2005), a feature not inherent to surgical masks.

Dreller *et al* measured the performance of a range of surgical masks against both an inert sodium chloride aerosol as specified in BS EN 149:2001, and against *Staphylococcus aureus*. The authors concluded that the filter efficiencies of the materials used in the construction of the surgical masks and the face seal performance against a sub-micron particle challenge were significantly lower than the requirements for FFP1. The filtration efficiencies were also significantly lower than that claimed by the surgical masks' manufacturers. The authors also concluded that a minimum of 40% reduction in exposure to *S. aureus* was measured on surgical masks (Dreller *et al.*, 2006). This might equate to a reduction factor of 2.2, although the report does not state whether the masks were sealed to the test head or not.

Some work was done by HSL a number of years ago to test the effectiveness of some RPE and surgical masks against a bacterial aerosol challenge (Crook B, Brown RC, Wake D, Redmayne AC. Final Report; Efficiency of respiratory protective equipment against microbiological aerosols; IR/L/M/96/05). This demonstrated the poor performance of some surgical masks against bioaerosols. Despite this, there is a lack of scientific evidence in regard to the protective effect of surgical masks against infectious aerosols (with reference to worker safety) to support HSE's pandemic planning activities. The following study aims to provide further scientific evidence using a combination of challenge studies to measure the efficiency of disposable FFP respirators and surgical masks to inert airborne particles. This is related to similar evaluations using a live influenza virus challenge to surgical masks.

2 MATERIALS AND METHODS

2.1 INERT PARTICLE TESTS ON TEST SUBJECT

2.1.1 General

The performance of a range of respirators and surgical masks against an inert aerosol was measured. The inert particle challenge was designed to simulate the particle size range and particle number found in a cough/sneeze-generated aerosol of saliva.

The original plan was to test the performance of the respirators and surgical masks when fitted to a 'Sheffield' dummy test head attached to a breathing simulator. This dummy head is described in BS EN 136:1998 and is employed in testing of various types of RPE. However, the initial tests showed that it was impossible to achieve a fit comparable with that obtained by an actual wearer on the dummy head. Alternative test heads were investigated, but improved fits were still not possible. When performing tests in accordance with British RPE Standards, it is permitted to aid the sealing of the mask on the dummy head with sealing tape, putty etc. For this study, sealing of the mask to the test head was not practicable, as this would have prevented the measurement of leakage around the mask. It was decided that, instead of using a test head and a breathing simulator, a volunteer test subject would be used.

The pulsed spray was synchronised with the inhalation breath of the test subject. The test subject was asked to remain still during the test. A sample of the air inside the mask was taken from a position between the mouth and nose using a sample probe as recommended in the HSE guidance on fit testing (OC 282/28).

2.1.2 Inert aerosol generation

The aerosol was generated by a simple pulsed compressed air atomiser, fed with a solution of artificial saliva, manufactured according to the recipe in BS 7115:1988 Part 2. This particular recipe was chosen as it was an innocuous mix and therefore suitable for use with a human volunteer. The atomiser generated a poly-dispersed aerosol covering a size range <1μm to >200μm with approximately 50% of the particle number distribution <20μm and 10% >100μm. This compares well with the particle size distribution of a cough calculated by Nicas *et al* (Nicas *et al*., 2005), where approximately 50% of the particles were <20μm and 25%>100μm.

The duration of the pulse was approximately 0.5 second. The number of particles generated by this method was >250,000 particles per ml (measured for the range <10μm). However, the number of particles within the size range of the instrumentation employed in the inert aerosol tests (0.02μm to approx. 1.2μm) was approximately 100,000.

2.1.3 Performance measurement

2.1.3.1 TSI Portacount

A TSI Portacount Plus ambient particle-counting device was employed to measure the effectiveness of the respirators and surgical masks against the generated aerosol. This device is used extensively in the UK and the USA for fit testing of tight-fitting facepieces (filtering

facepieces, half and full face masks). The Portacount determines the degree of fit by comparing the particle concentration on the outside of the facepiece to the particle concentration inside the facepiece. The Portacount operates within the size range 0.02μm to approx. 1.2μm. Therefore, only this size fraction of the generated aerosol ('sneeze') is measured and the inert particle challenge results are based upon this.

In order to determine a measure of face fit only (i.e. the measure of leakage around the facial seal) penetration of particles through the filtering media of the facepiece and within the size range of the Portacount has to be eliminated. When testing high efficiency filtering facepieces (FFP3), the particle penetration through the filter media is negligible and the output of a Portacount fit test is therefore a measure of the face fit. However, when fit testing masks of lower particle filtering efficiency such as FFP2, FFP1 and surgical masks, the particle penetration through the filter media is not negligible and in order to eliminate these particles a device referred to as an 'N95 Companion' is used in conjunction with the Portacount. The 'N95 Companion' is a particle classifier that removes from the particles sampled by the Portacount, the particle size range that is assumed to penetrate lower efficiency filter media. The resulting particle size range that is measured is approximately 0.03μm – 0.06μm. Therefore by employing both the Portacount and the Portacount together with the N95 Companion, a measure of both the face fit and the face fit plus filter penetration can determined.

Therefore in summary:

- Tests performed using the Portacount only – measures face fit and filter penetration. The results from these tests are reported as *reduction factors*.
- Tests performed using the Portacount and the N95 Companion – measures face fit only. The results from these tests are reported as *fit factors*.

2.1.3.2 Test procedure

A test subject fitted the respirator or surgical mask to be tested in accordance with the manufacturer's instructions. Adjustments were made in order to obtain the best fit possible. For the respirators the target was to achieve, during normal breathing, at least a fit factor of 100 for FFP3 with the Portacount, and 100 for FFP2 and FFP1 with the Portacount with the N95 Companion fitted. A fit factor of 100 was chosen as this is deemed to represent an adequate fit and is the pass criteria for FFPs published in HSE guidance OC282/28 (HSE 2004) Where the respirator was judged not to fit, the best-fit possible was obtained and the fact noted. Another respirator was not chosen, as the purpose of the tests was to test a sample of the products available from the NHS Logistics.

The volunteer was positioned at a distance of 1m away from the aerosol generator, such that the aerosol sprayed over the face of the volunteer.

The following tests and measurements were undertaken:

- With the test subject sat still, the performance of the respirator or surgical mask was measured using the naturally occurring ambient airborne particles only as the challenge
- With the test subject sat still, the performance of the respirator or surgical mask was measured using an aerosol spray as the challenge. The spray was synchronised with the test subject's inhalation breath. The test subject was exposed to at least five sprays

For both the above conditions the test was performed with the Portacount only and then with the Portacount with the N95 Companion fitted to give a measure of face fit and then a measure of face fit plus filter penetration; the latter is referred to as the *Reduction Factor*. The test sequence was randomised to reduce system bias.

Following a complete test the respirator or surgical mask was removed. The test was repeated twice to give three measurements. As surgical masks are not designed for reuse, a new mask was used for each test.

A schematic diagram of the test arrangement is shown in Figure 2.1.

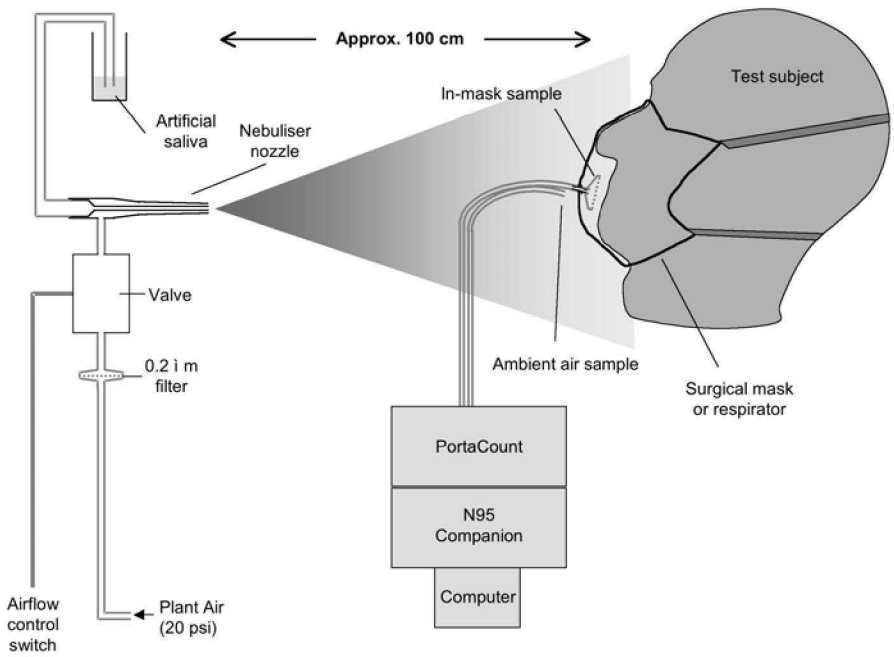

Figure 2.1. Schematic diagram of the inert aerosol test arrangement

2.2 RESPIRATORS AND SURGICAL MASKS EMPLOYED IN THE STUDY

A selection of respirators of class FFP1, FFP2 and FFP3 and a selection of surgical masks from the NHS list of products available via NHS Logistics were tested. The products chosen were those that had the highest sales for the year 2005-2006. In addition to the highest selling products others were selected in order to cover a representative sample of the range of masks available. A copy of the list of products available via NHS Logistics for the year 2005-2006 and the revised list updated 2006 are appended to this report (Sections 7.1 and 7.2). The range of filtering facepieces available is somewhat limited, and therefore in addition to those chosen from the NHS lists, other FFP3, FFP2 and FFP1 that are popular 'industrial' type respirators were selected for comparison purposes and to increase the range of products tested.

The surgical masks can be crudely subdivided into two main types – those with tie-fastenings, and those with elastic straps (either single or double). A diagram of the different mask designs included in the test is shown in Figure 2.2.

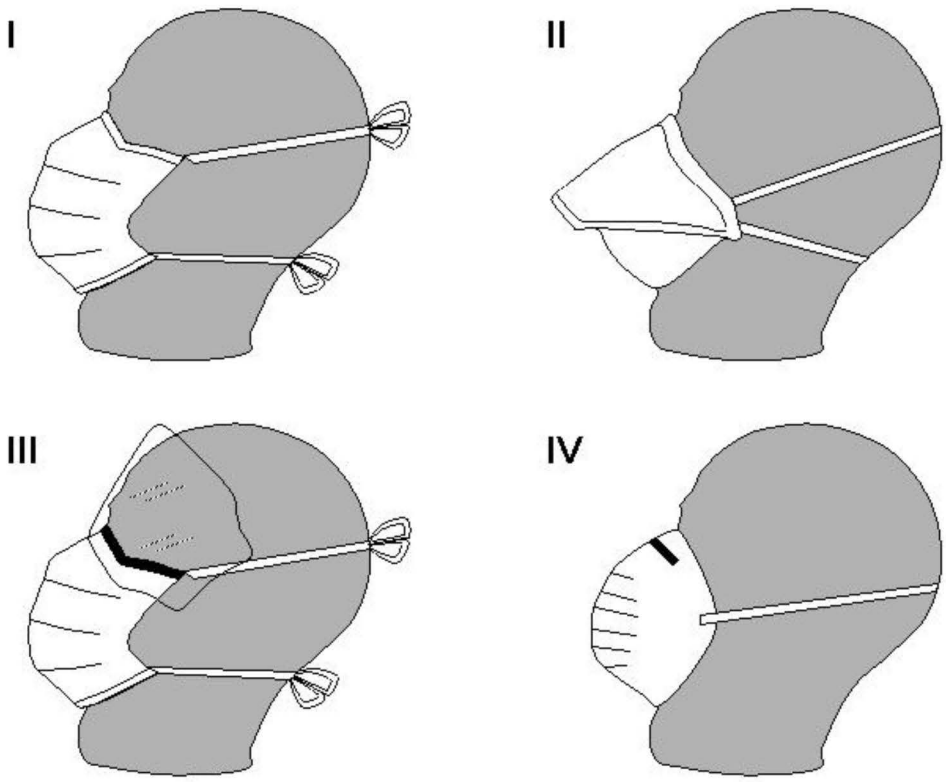

Figure 2.2. A diagrammatic representation of those surgical mask designs included in the tests; I: Typical tie mask (Tie A, B, D and E). II: 'Duckbill' strap mask (Strap A and B). III: Tie mask with integral splash visor (Tie C). IV: Moulded strap mask (Strap C).

2.3 INFLUENZA BIOAEROSOL TESTS

2.3.1 Virus Culture and Processing

A variant of Influenza virus A/PR/8/34 that was adapted for growth on Madin-Darby Canine Kidney (MDCK) cells was obtained from the American Type Culture Collection (LGC Promochem Ltd UK). MDCK cells were obtained from the European Collection of Cell Cultures (ECACC) and cultured as directed by the supplier. High titre stocks of virus were grown on cultured MDCK cells essentially as described elsewhere (Gaush & Smith, 1968). Briefly, cells were inoculated with a 1:500 dilution of virus in serum-free Virus Infection Medium. After allowing virus to adsorb for 1 hour at 35°C in a humidified 5% CO_2 incubator, the inoculum was removed and cells were maintained in Virus Infection Medium at 35°C. Virus titre in the supernatant was monitored by Haemagglutination (HA) assay as described (Cann(Ed), 1999) using chicken red blood cells (TCS Biosciences). When the HA titre was at a maximum (usually day 3 or 4 post infection) cellular debris was removed from the crude virus

preparation by centrifugation at 1000 x*g*. This clarified viral preparation was subsequently stored at -80°C.

Prior to use in surgical mask challenge studies, influenza virus was concentrated from the crude preparation by ultracentrifugation at 100,000 x*g* for 2.5 hours at 4°C. The supernatant was aspirated and the viral pellet resuspended in Phosphate Buffered Saline (PBS) + 0.2% Fraction V Bovine Serum Albumin (BSA) overnight at 4°C. Virus collected from approximately 36ml of crude preparation was resuspended in 6ml PBS + 0.2% BSA. The presence of virus and a crude titre was confirmed using HA assay.

2.3.2 Inert aerosol sampling

Prior to the live influenza bioaerosol exposure tests and for each surgical mask tested, a measure of the reduction factor against the inert aerosol generated using PBS + 0.2% BSA solution (in which influenza virus was to be suspended) was obtained. The purpose of this test was to provide a link between the inert aerosol tests on the human volunteer and the live bioaerosol tests on the dummy head.

The dummy head was positioned within a 1200mm Class II Microbiological Safety Cabinet immediately opposite a pulsed compressed air atomiser. A diagram of the testing rig is shown in Figure 2.3. The sampling distance from the atomiser to the front of the dummy head was approximately 70cm (this is a slightly shorted distance to that employed in earlier tests due to the size restrictions of the cabinet). A surgical mask was fitted to the dummy head, taking care to achieve the best representative fit possible. The cabinet airflow was switched off and the breathing simulator was activated, allowing the head to inhale/exhale at 40 litres per minute (stroke volume of 2.0 litres x 20 cycles per minute). This breathing rate represents a medium-low work rate. A 0.5s pulsed spray of PBS + 0.2% BSA was synchronised with the inhalation breath and air was sampled from both inside and outside the mask using a TSI Portacount ambient particle counting device to measure the effectiveness of the mask against the inert aerosol generated. Only the Portacount and not the Portacount plus the N95 Companion was employed because the measurement of interest in these particular tests was the overall protection (reduction factor) afforded by the masks and not just the quality of the face fit.

Because the solution in which the influenza virus was suspended was a different solution to that used in the inert aerosol tests on the human volunteer, the size distribution was re-measured. The particle size distribution ranged from <1μm to >200μm with approximately 50% of the particle number distribution <60μm and 15%>100μm. This size distribution of this spray covers the same range but contains a slightly higher proportion of larger particles than that used in the tests on the human volunteer.

2.3.3 Live influenza bioaerosol sampling

The cabinet airflow was switched on to enable safe manipulation of the influenza test suspension. The PBS + 0.2% BSA drained from the atomiser, which was then charged with concentrated influenza test suspension. Air was sampled directly into virus infection medium in separate collecting devices concurrently from both immediately in front and immediately behind each surgical mask. These were connected to a vacuum pump and calibrated to a flow rate of 1 litre per minute *in situ* using a rotameter.

With the airflow switched off, three separate external and internal samples from the air were taken for each mask. External and internal negative control air samples were then taken in the

absence of a spray of influenza test suspension after bioaerosol sampling (this would also reveal any cross contamination problems arising during manipulations between samples).

2.3.4 Sample processing

The titre of influenza virus present in the air samples was determined by plaque dilution assay (Cann(Ed), 1999; Gaush & Smith, 1968). 1/10 and 1/100 dilutions of each sample were prepared in virus infection medium. Monolayers of MDCK cells grown in 6-well dishes were inoculated with 250µl of neat sample, or diluted samples. Internal and external sample pairs were assayed using separate wells of the same dishes. The titre of the influenza test suspension was also determined using the same assay, except with serial 10-fold dilutions of each sample were prepared in virus infection medium down to $1x10^{-15}$.

Following adsorption for one hour at 35°C, a molten agarose overlay was prepared which was a 1:1 mix of 3% low gelling temperature agarose and 2x Minimal Essential Medium (see section 7.3 for full constituents). The inoculum was removed and the cells washed in PBS before the addition of 2ml of molten agarose overlay to the cells. The prepared assay dishes were incubated at 35°C for 72 hours.

The overlay prevents the diffusion of viral particles through the medium, allowing the formation of discrete viral foci of infection, or plaques. After this incubation, viral plaques were counted in the wells where clearly separate foci could be distinguished and enumerated. The influenza virus titre could then be expressed as plaque-forming units (PFU) per ml of inoculum.

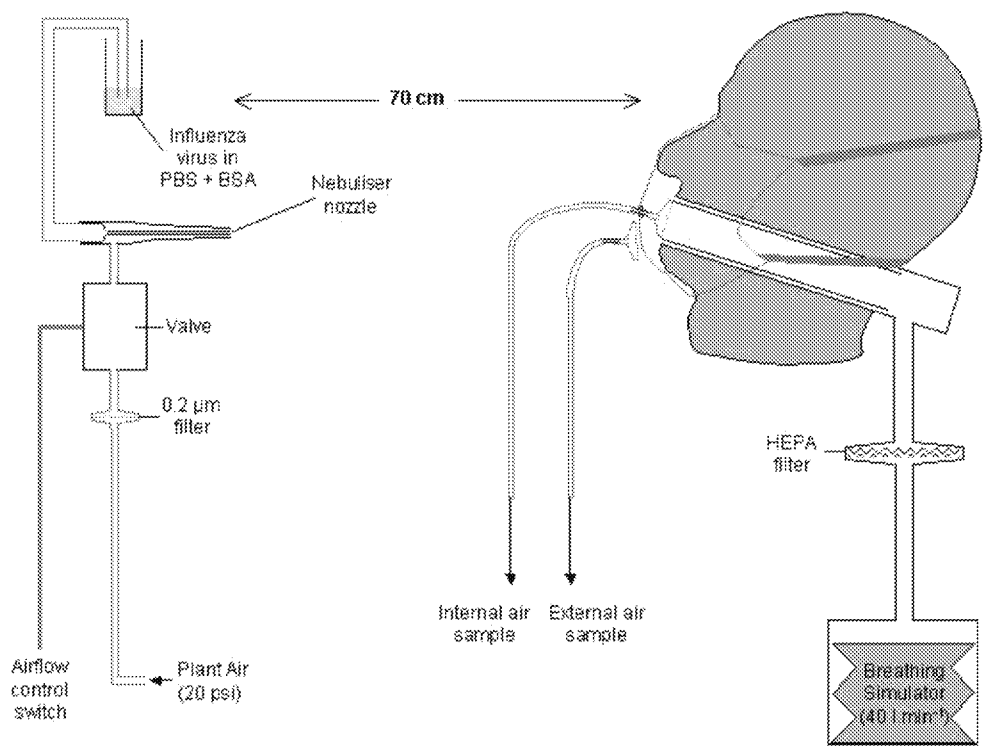

Figure 2.3. Diagrammatic representation of the influenza bioaerosol testing rig

3 RESULTS

3.1 INERT PARTICLE EXPOSURE TESTS ON TEST SUBJECT

3.1.1 Calculation of the reduction factor and fit factors

The performance of the respirators and surgical masks was determined by calculating the ratio of the particle concentration inside and outside the facepiece as shown below:

$$\text{Reduction factor} = \frac{\text{Particle concentration outside the facepiece (Co)}}{\text{Particle concentration inside the facepiece (Ci)}}$$

The fit factors, i.e. the measure of the leakage around the facial seal, is similarly calculated as shown above, for tests where the N95 Companion was employed.

For the ambient challenge tests, the mean particle count inside and outside of the facepiece over a sample period of 1 minute was calculated and used to determine the reduction factor. For the simulated sneeze, the mean of the peak particle count both inside and outside of the facepiece for each spray was calculated and used to determine the reduction factor. Figure 3.1 shows an example of the particle count trace during the test.

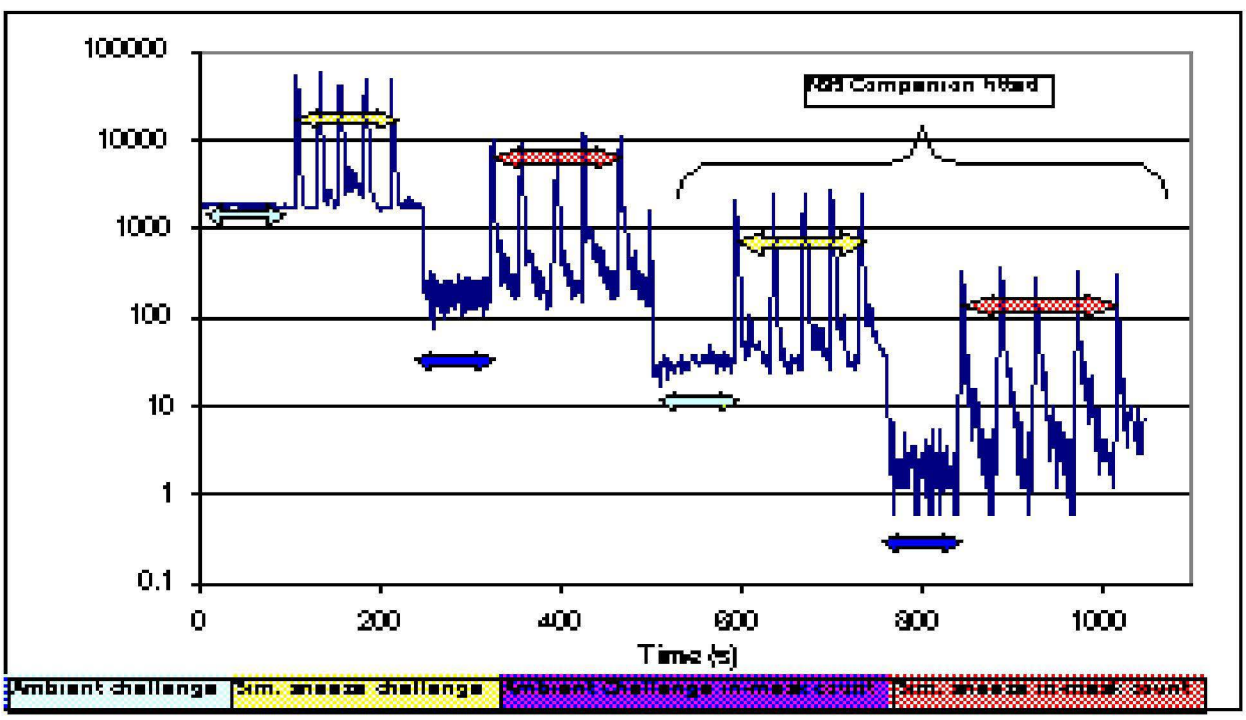

Figure 3.1. Example of challenge and in-mask particle concentration during testing of a surgical mask

Each of the respirators and surgical masks were tested three times using three separate fittings. The means of the three tests were calculated and the results for the Reduction Factors are presented in the Table 2, Figure 3.2 and Figure 3.3. The results for the Fit Factors are presented in Table 2 and Figures 3.3 and Figure 3.4. Furthermore the results of the mean of the filtering facepiece classes and of the surgical masks, separated by design i.e. straps or tie, were calculated and are presented in Table 3 and Figure 3.6.

Table 2. Reduction factors and fit factor results for the range of filtering facepieces and surgical masks tested

Mask Type	Reduction Factor		Fit Factor	
	Ambient Particles	Simulated Sneeze	Ambient Particles	Simulated Sneeze
FFP3 A	12166	1493	7068	3809
FFP3 B	280	130	800	253
FFP3 C	1559	1480	5520	2941
FFP3 D	91	90	2496	522
FFP3 E	151	70	220	43
FFP2 A	57	26	98	23
FFP2 B	88	85	1925	444
FFP2 C	382	183	1070	84
FFP2 D	282	122	493	187
FFP1 A	94	94	2195	214
FFP1 B	17	27	1513	766
Tie A	3	2	3	2
Tie B	7	4	7	3
Tie C	7	2	12	4
Tie D	2	1	2	1
Tie E	6	3	7	3
Strap A	17	17	1754	358
Strap B	7	4	273	172
Strap C	2	1	3	1

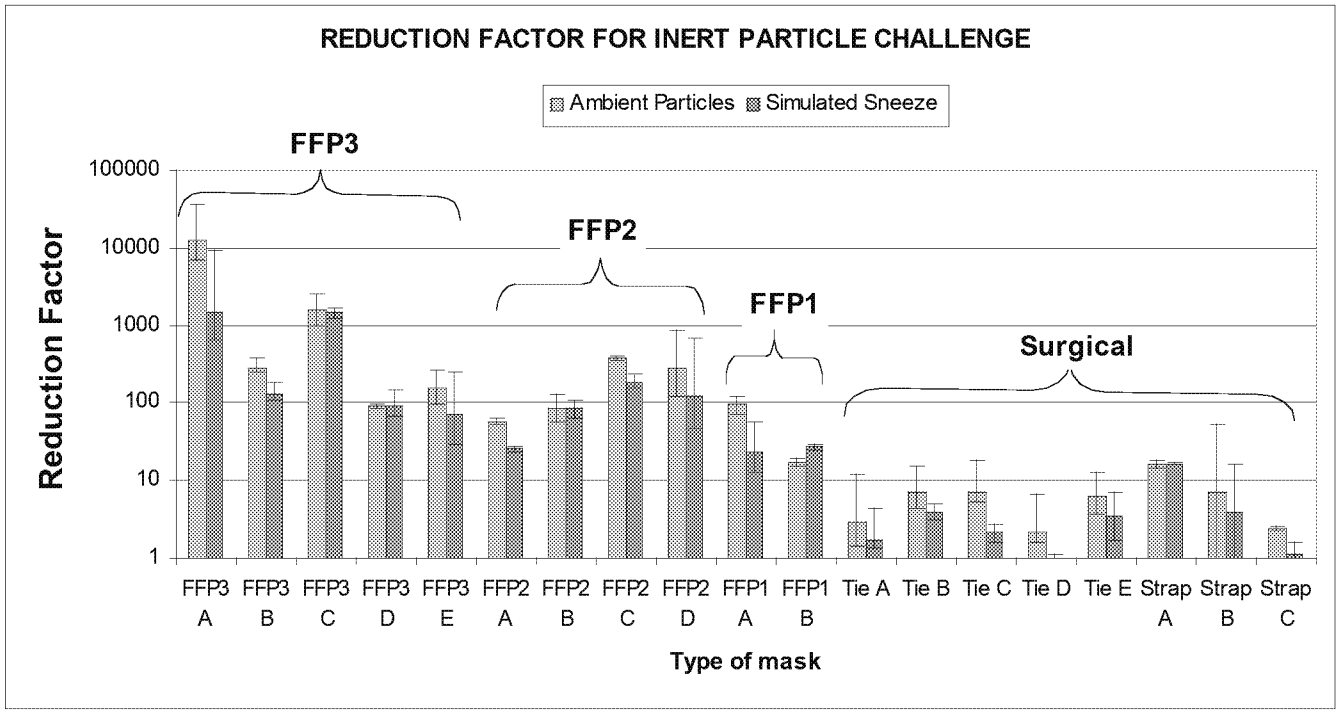

Figure 3.2. Inert particle reduction factors for all filtering facepieces and surgical masks tested. Error bars show the spread of results measured

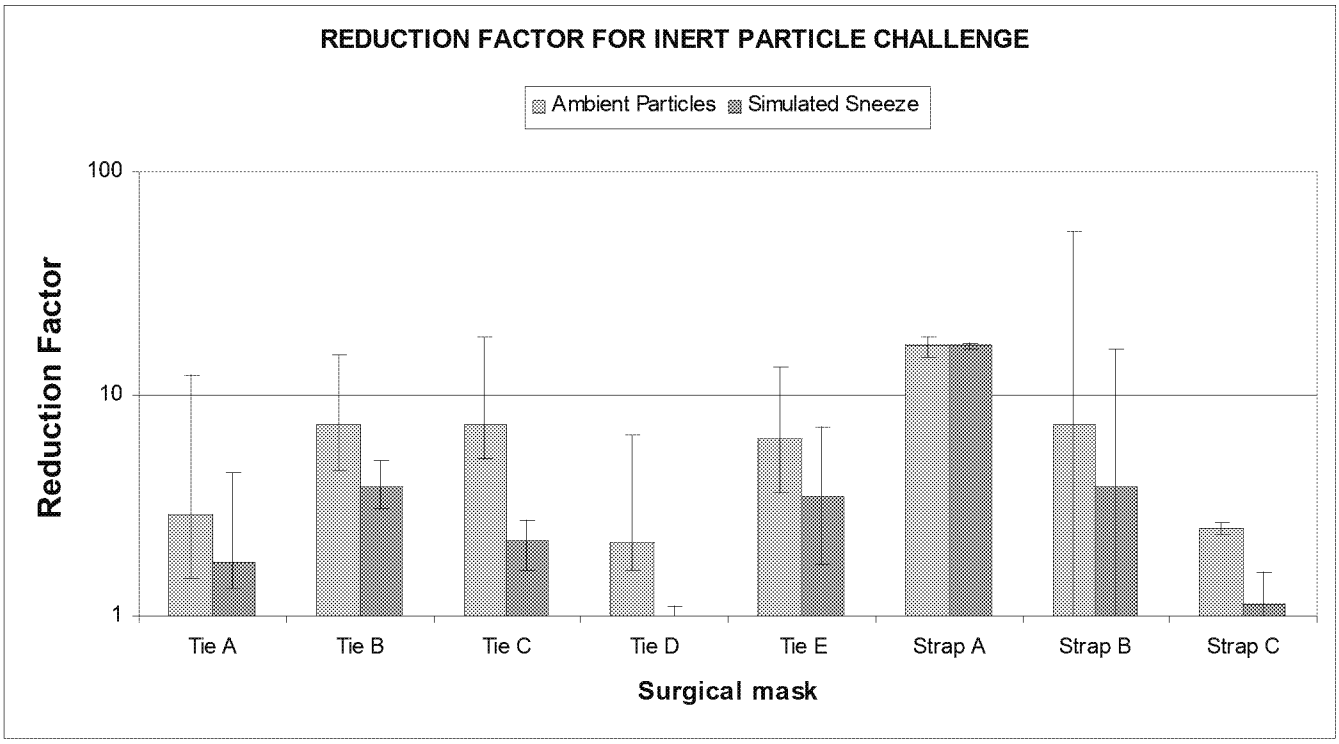

Figure 3.3. Inert particle reduction factors for all the surgical masks tested. Error bars show the spread of results measured

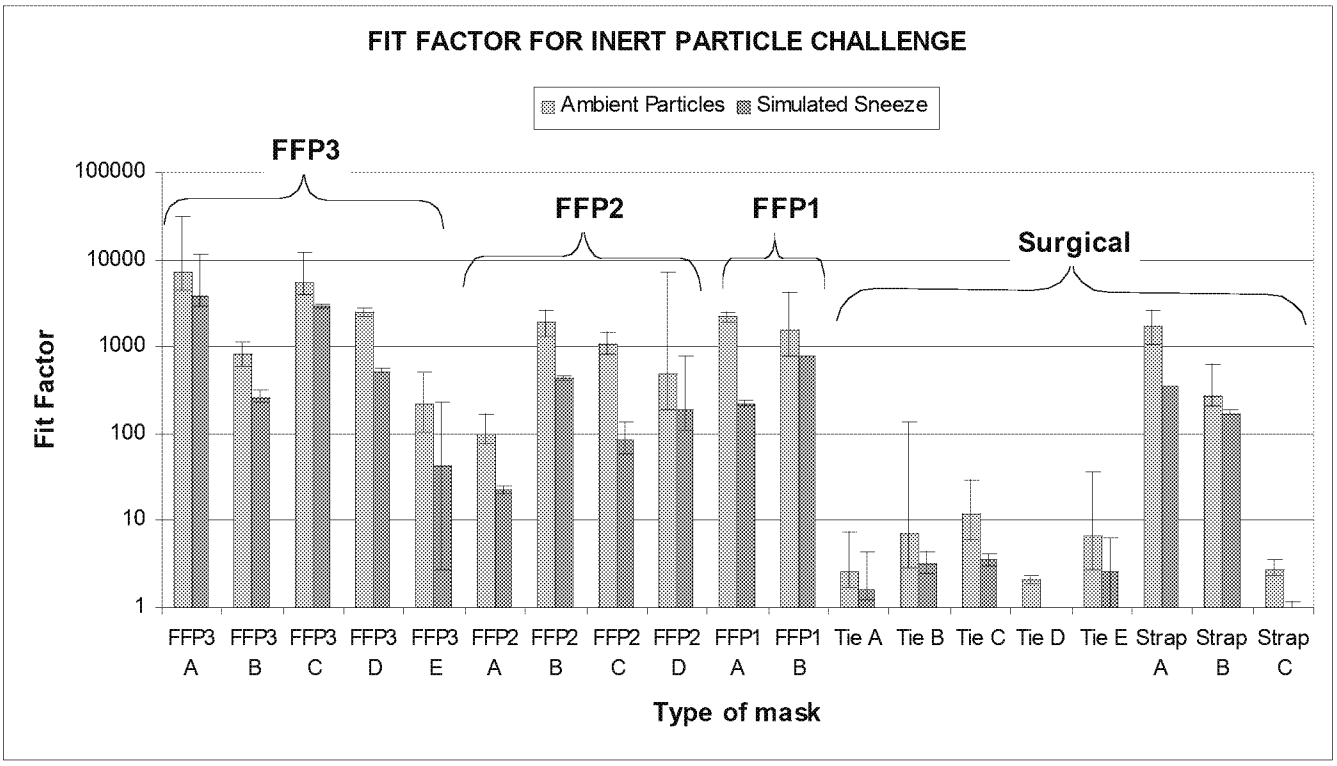

Figure 3.4. Fit factors for all filtering facepieces and surgical masks tested. Error bars show the spread of results measured

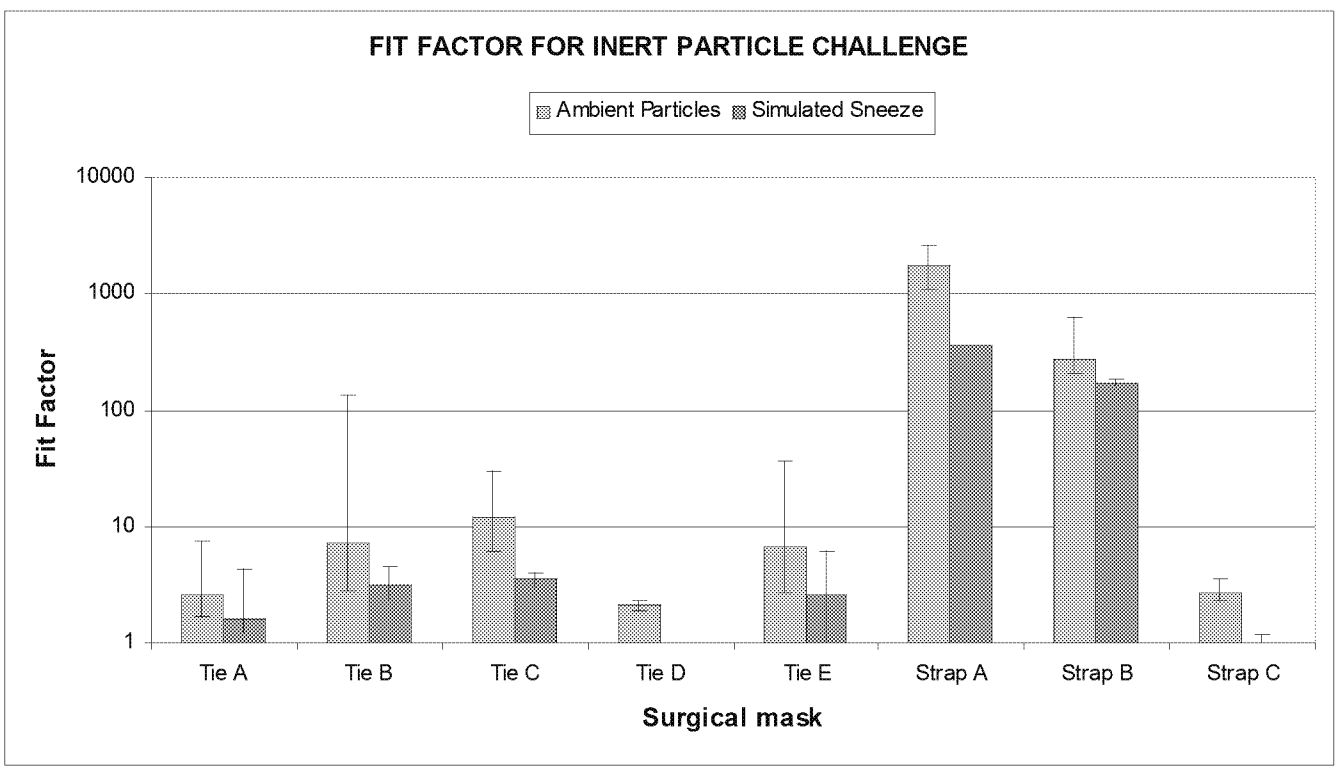

Figure 3.5. Fit factors for all the surgical masks tested. Error bars show the spread of results measured

Table 3. Harmonic mean values of the reduction factors and fit factor results for the grouped range of filtering facepieces and surgical masks tested

Mask Type	Reduction Factor		Fit Factor	
	Ambient Particles	Simulated Sneeze	Ambient Particles	Simulated Sneeze
FFP3	228	145	766	167
FFP2	95	54	258	52
FFP1	29	42	1791	335
Surgical mask - tie	4	2	4	2
Surgical mask - strap	5	2	9	2
Surgical mask - all	4	2	5	2

Note: When calculating the 'mean' of a series of fit factors or reduction factors, the correct method is to calculate the harmonic mean, which is the reciprocal of the arithmetic mean of the reciprocals of the data series.

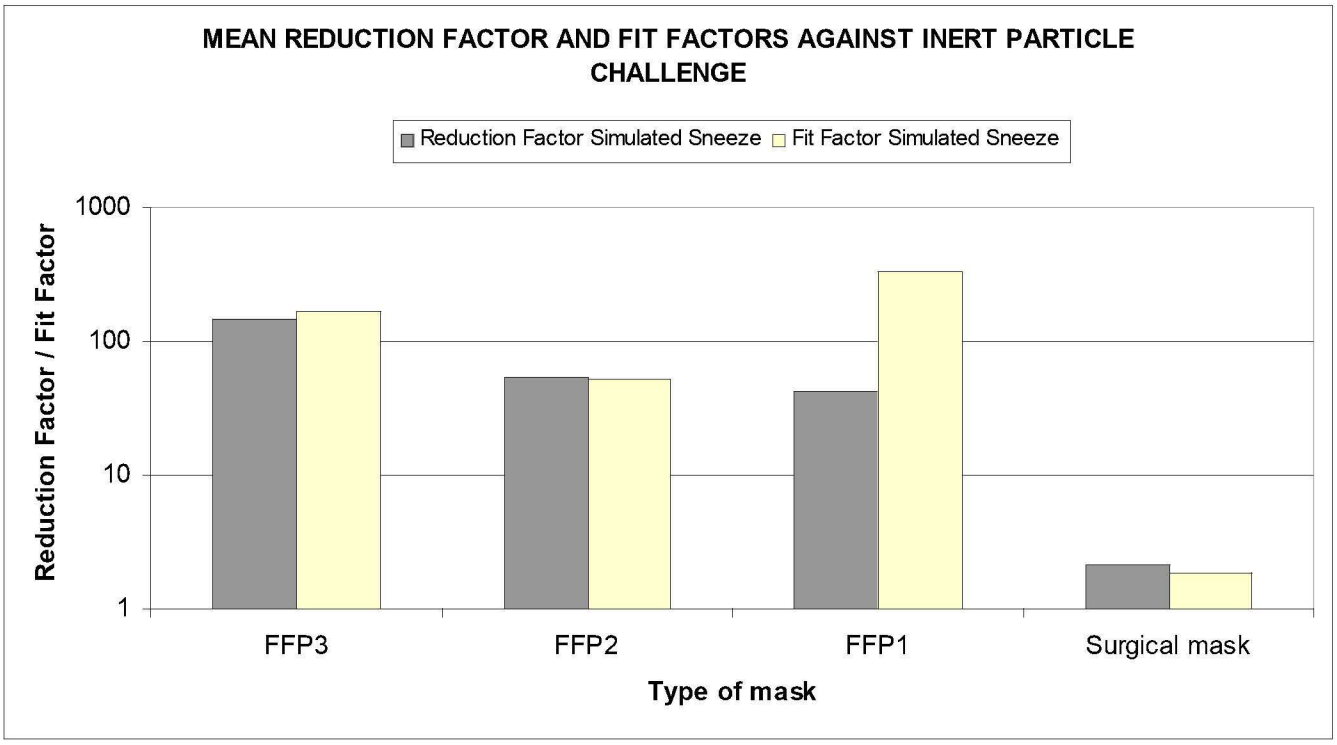

Figure 3.6 Mean values of the reduction factors and fit factor results for the grouped range of filtering facepieces and surgical masks tested against the inert simulated sneeze

3.1.1.1 *Reduction factors during exposure to the simulated sneeze*

As expected, the performance provided by the filtering facepieces increased progressively from FFP1 to FFP3. The reduction factors for the filtering facepieces when exposed to the simulated sneeze ranged from 25 to >4000.

The performance provided by all the seven surgical masks tested against the simulated sneeze were significantly lower than the minimum requirement for a class FFP1 filtering facepiece. The reduction factors achieved with each mask when exposed to the simulated sneeze ranged from 1.0 to 16.5. A reduction factor of 1 represents zero protection. All surgical masks with ties returned a reduction factor <10. One out the three surgical masks fitted with elasticated straps achieved a reduction factor >10.

3.1.1.2 *Fit factors during exposure to the simulated sneeze*

The fit factors for the filtering facepieces ranged from 25 to >3000; a fit factor >100 is deemed a satisfactory fit (OC282/28). During the tests, when only the ambient airborne particles were challenging the filtering facepieces, only one facepiece returned a fit factor <100. This moulded-cup shaped facepiece was deemed by the test subject to 'not fit', and therefore would have been rejected when selecting suitable RPE. This type was not on the NHS Logistics list of products. When subjected to the simulated sneeze (i.e. a particle challenge concentration 10 fold that of the ambient particle challenge concentration) two further filtering facepieces returned a fit factor <100.

The fit factors measured on the five surgical masks with ties were significantly lower than 100. The maximum fit factor measured against the ambient particle challenge was 12 and the lowest was 2.0. The fit factors against the simulated sneeze were lower at a maximum of 4 and a minimum of 1.0. The surgical masks with straps fared better with two out of the three tested returning fit factors >100 under ambient and simulated sneeze conditions. The fit of the surgical mask 'Strap-C' fitted with only one elasticated strap was extremely poor, returning a fit factor of 1.0.

3.2 INFLUENZA BIOAEROSOL TESTS

Quantitative demonstrations of the relative levels of protection afforded by surgical masks against live aerosolised influenza virus in a simulated sneeze were conducted. The range of seven surgical masks used in the inert particle tests was evaluated.

All masks were tested in accordance with the procedure set out in Section 2.3.3. The testing rig is shown in Figure 2.3. The performance of the surgical masks with respect to the influenza bioaerosol was determined by calculating the ratio of live virus sampled from the air outside versus that sampled from inside the mask, using a plaque assay. This ratio was termed the "influenza plaque reduction factor" i.e:

$$\text{Influenza plaque reduction factor} = \frac{\text{Influenza virus titre of external air sample}}{\text{Influenza virus titre of internal air sample}}$$

Therefore, the influenza plaque reduction factor is broadly equivalent to the reduction factor measured for the inert particle tests calculated using the Portacount equipment (except that for the inert particle tests, only the particle sizes within the Portacount's range were measured). The inert particle reduction factor is an estimate of the level of fit and filter penetration achieved on the dummy head in the experimental setting.

The results for all surgical masks tested are shown in Figure 3.7. The inert particle reduction factors achieved with each mask varied greatly, ranging from 1.3 to 20. Likewise, the influenza plaque reduction factor varied between masks, ranging between 1.1 and 55. The performance of the surgical masks in the inert particle challenges was related to the performance against influenza virus bioaerosols – i.e. a higher performance in inert particle tests was associated with better performance in the bioaerosol assays. Apart from two notable exceptions (masks "Tie C" and "Strap A", which perform better in these tests), all the masks demonstrated that they would reduce the exposure to infectious influenza virus present in a direct challenge by around 10-fold or less (i.e. a 1 log reduction or below). The calculated harmonic mean influenza plaque reduction factor for all bioaerosol challenge tests was 6.

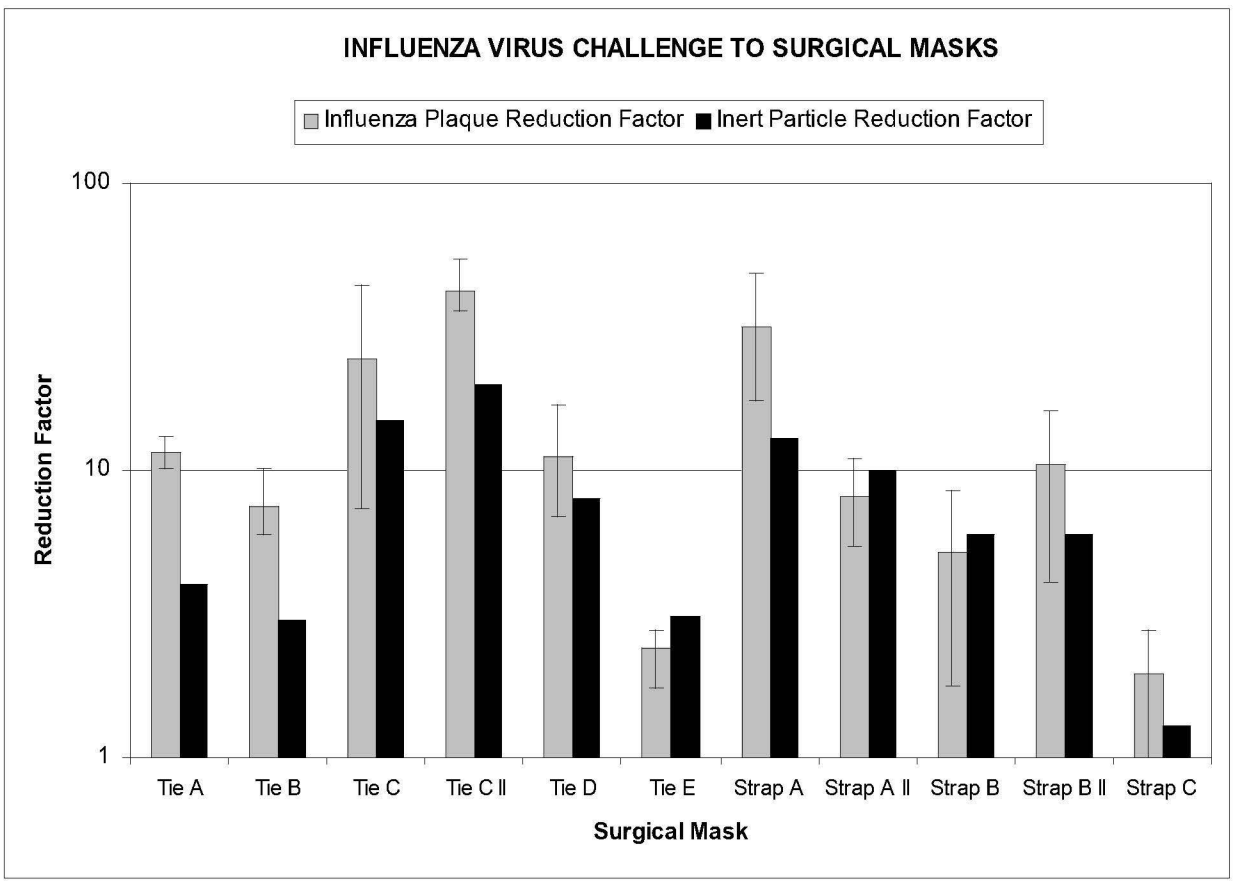

Figure 3.7. Mean (harmonic) influenza plaque reduction factors and associated inert particle reduction factors for all surgical masks tested. Error bars show spread of the calculated data

4 DISCUSSION

The aim of this study was to evaluate the ability of surgical masks to provide respiratory protection against an influenza virus bioaerosol and compare this to the performance of FFP respirators. A combination of challenge studies was used to assess the performance of surgical masks and FFP respirators to non-biological airborne particles and surgical masks to an aerosol of influenza virus.

4.1 FITTED FACEPIECE RESPIRATORS

As can be seen from the fit factor results shown in Figure 3.4, measures of fit achieved for FFP2 and FFP1 were sometimes better than that measured for FFP3. There are two possible reasons for this:

- Firstly, the particular design (size & shape) of the FFP1/2 may be more suitable to the test subject, for example FFP2-D which has two separate elasticated straps, together with a longer nose seal did fit the test subject much better than the FFP3-E facepiece, which has a short nose strip and a single looped elasticated strap.

- Secondly, the breathing resistance increases as more filtering layers are added to the facepiece in order to achieve higher efficiencies. The higher the breathing resistance the higher the possible face seal leakage. If a face seal leakage is present, then the proportion of leakage via this route increases proportional to the breathing resistance. For example Fit Factors for FFP1-A, FFP2-C and FFP3-B, decreased in ascending order of class (i.e. FFP1-A>FFP2-C>FFP3-B) as increasing layers of filter media are used.

In most cases, FFP3 facepieces have additional sealing aids over that of lower classes of filtering facepieces, such as a rubber/foam face seal around the facepiece. FFP3s that have such sealing aids (e.g. FFP3-A and FFP3-C) tend to perform better than FFP2s. This was also evident in this study. Neither of these filtering facepieces is on the list of products provided via NHS Logistics.

4.2 SURGICAL MASKS

The model scenario was a viral bioaerosol generated by a cough or a sneeze from a potentially infectious patient. The respiratory protection provided by the surgical masks against an inert challenge was significantly lower than that provided by the FFPs. The reduction factors and fit factors measured for the surgical masks with ties failed to achieve a reduction factor of 10. Whilst the surgical masks with two elasticated straps (Strap A and Strap B) fitted better than the surgical masks with ties and achieved an order of fit that would be acceptable as a FFP (i.e. >100; see Figure 3.4), the filtration efficiency was still very low and considerably lower than the results obtained for the FFP1 (see Figure 3.1).

Whilst the physical characteristics of inert aerosols and bioaerosols are generally considered to be comparable, direct extrapolation of these observations to infectious bioaerosols would not necessarily be accurate. For example, the ability of an organism to remain viable in an aerosol is an important consideration. If the organism cannot survive in an aerosol long enough, the effectiveness of a surgical mask against influenza virus might be higher than that indicated by

inert particle challenges. Therefore we have undertaken both inert particle tests alongside similar analyses using a live, representative microbiological challenge.

Influenza virus was the chosen agent for this study. This is particularly relevant as the UK makes preparations for a potential pandemic of influenza. An A-type influenza virus (strain A/PR/8/34, subtype H1N1) was used, which is expected to have similar biophysical properties to those that have caused previous pandemic outbreaks, as well as the current H5N1 candidate strain.

A dummy head, attached to a breathing simulator and wearing a surgical mask, was subjected to a direct challenge with an aerosol containing live, infectious influenza virus. The distance from the point at which the aerosol was generated to the outside of the surgical mask was 70cm (i.e. within one metre). Air was sampled concurrently, but separately, from immediately in front of the mask and immediately behind the mask over a short period (1 minute). The quantitative assay performed on the sampled air only measured levels of *viable virus*. Thus an evaluation of the protective effect of surgical masks against a direct challenge with an influenza bioaerosol was possible. Furthermore, the data could be compared to that obtained using inert particle challenges, which model the physical characteristics of the scenario more closely.

The original intention was to test both surgical masks and FFP respirators but initial tests showed that it was difficult to achieve a good fit on the 'Sheffield' dummy head (see Section 2.1). Artificially sealing respirators or surgical masks to the test head was not considered representative of the model scenario. It was decided to limit this phase of the study to the analysis of surgical masks only, as the level of fit achieved on the dummy head was comparable to that achieved on the human test subject during inert particle challenge tests. Inert particle and bioaerosol tests were conducted in parallel on the surgical masks. Since the performance of the surgical masks in the inert particle challenges was related to that against bioaerosols, some extrapolation of the data is now possible.

These tests were performed in a closed microbiological safety cabinet. In reality, infectious bioaerosols would be generated in more open space, therefore diluting the infectious organism over time and reducing the likelihood of infection. Therefore, it was not possible to directly mimic this dilution effect. There are also environmental parameters that may affect the viability of the virus and the characteristics of the bioaerosol (e.g. temperature, humidity, ventilation etc) that were not accounted for in this study. However, air was only sampled for a short period (one minute) so the effects of dilution and environmental factors would not be expected to substantially impact upon the results obtained using these tests. Furthermore, the influenza bioaerosol interacts with the external sampler more directly. Therefore, if there is any bias in the sampling system, it would artificially increase the proportion of influenza virus recovered by the external sampler, resulting in a higher influenza plaque reduction factor and perceived protective effect.

Live, infectious virus was extracted in enumerable quantities from the air from behind all the surgical masks tested. This suggests that influenza virus can survive in aerosol particles and bypass/penetrate a surgical mask and that a residual infectious aerosol hazard may exist. Whether or not the surgical masks tested will offer adequate protection against infection will be dependent on the infectious dose of the virus, and its titre in secretions. The infectious dose for humans with respect to a potential pandemic virus is unknown and cannot be determined until the virus itself emerges. The 50% human infectious dose for another strain of influenza has been estimated at 0.6 to 3.0 50% tissue culture infectious doses ($TCID_{50}$; Alford *et al.*, 1966). If it is assumed that 1 $TCID_{50}$/ml equates to approximately 0.5 PFU/ml, then the PFU needed for human infection will be of similar order. The amount of infectious virus present in nasal secretions has been estimated to reach levels of 10^7 to 10^8 $TCID_{50}$/ml (Murphy *et al.*, 1973).

The concentration of influenza virus in the test samples was between 10^{14} and 10^{15} PFU/ml. Therefore, the levels of virus present in the bioaerosol challenge were probably considerably higher than those present in a natural cough or sneeze emanating from a pandemic influenza patient. These levels were required in order to recover sufficient virus to make meaningful quantitative assessments of surgical mask performance. At these levels, there may have been a protective effect on the stability of the virus. However, since these effects would be reflected in the amount of virus recovered in both the internal and external samplers, this would not be expected to affect the calculated reduction factors.

The performance of surgical mask Tie C was consistently better than other surgical masks in the bioaerosol challenge and the parallel inert particle tests undertaken using the dummy head. However this mask did not perform at this level when worn by the human test subject. This mask has an integral visor, which may have protected the major leakage areas (e.g. around the nose) and blocked the bioaerosol challenge sufficiently from reaching this area so as to improve overall protection. Similar masks, or the use of a splash visor in conjunction with a conventional surgical mask, could be employed to give added protection to the respiratory system in the event that FFP respirators are not available. The use of a visor would also protect the eyes from large droplets/splashes and would discourage manual inoculation of the eyes via direct contact. Further research is needed to evaluate the ability of a visor to enhance protective effect of a surgical mask.

Most of the surgical masks tested gave a reduction factor in aerosolised influenza of around 1 log, although some were considerably lower than this (the harmonic mean for all bioaerosol challenge tests was 6 fold). The data presented here demonstrate that, in order to afford a consistent protective effect above this level, an FFP respirator is required. This is highlighted by the results of strap mask B (an N95 class respirator) where a good level of fit can be achieved and performance is similar to FFP1/FFP2 respirators in the inert particle tests with a human wearer (see Figure 3.4 and Figure 3.5). However, a good level of fit cannot be achieved on the dummy head, and the mask performs less well in both inert particle and bioaerosol tests (see Figure 3.7).

The results of the inert particle challenge tests, which are also supported somewhat by the bioaerosol challenge tests, indicated that surgical masks with double elasticated straps performed better than the surgical masks with ties. The closer the design of the surgical mask to that of a FFP respirator (e.g. surgical mask Strap A) the better the fit and therefore the better the protection afforded. This highlights the fact that correct fitting of masks with a facial seal is required to achieve the required protection.

Other studies have measured the penetration of various inert and bioaerosols and have shown that the efficiency of the filter media employed in surgical masks is very variable ranging from 10 to >90% (Chen *et al.*, 1994; Dreller *et al.*, 2006; McCullough *et al.*, 1997; Weber *et al.*, 1993). Two of these studies investigated face fit of surgical masks and, like the findings of this study, found the fit factors to be low (Dreller *et al.*, 2006; Pippin *et al.*, 1987). Additional protection in inert particle challenges has also been demonstrated when the sides of surgical masks were taped to the face to minimise leakage (Derrick *et al.*, 2006).

Even if the mask is manufactured from high efficiency filtering media, a high proportion of particles challenging the surgical mask will enter the breathing zone via breaches in the face seal. Furthermore, a high efficiency filtration media and fluid-resistant layers are likely to increase breathing resistance. This, together with a poor face fit, will increase the degree of leakage around the face seal. This is of concern as fluid-repellent surgical masks (typically with poor face fit characteristics) are being recommended for work in proximity to patients infected

with pandemic influenza to protect against splashes and large droplets (HPA 2005; DH 2007a; NHS 2007).

As surgical masks cannot be fitted well to the face, their use may not be adequate for protection against a residual airborne infection hazard. Based upon the measurements obtained in this study, on average, a reduction factor of 10 or below can be anticipated. Whether or not that would negate the need for widespread use of FFP respirators will depend upon the nature of, and consequences of exposure to, the organism.

It is important that the distinction between the protection factors assigned (APF) to FFPs and the results obtained in this study is not overlooked. The APFs are derived from the 5th percentile point of ranked data obtained from workplace protection factor (WPF) studies following an accepted protocol and within an effective RPE management programme. APFs cannot be calculated from the tests performed in this study. However, if the data that has been obtained for surgical masks against the influenza virus challenge were from accepted workplace studies, the calculated 5th percentile would be 2.4 – this value for surgical masks would be significantly less than the harmonic mean of 6 quoted earlier in the report. Although FFP3 were not tested against the bioaerosol, if a similar relationship existed as for that for the surgical masks between the results for the inert and bioaerosol challenges, then the use of well fitting FFP3 respirators would potentially give a reduction factor of at least 100.

5 CONCLUSIONS

In principle, surgical masks provide adequate protection against large droplets, splashes and contact transmission. There is a common misperception that they will provide protection against aerosols. This study did not assess the protective capacity of surgical masks against large droplets, splashes and contact but rather focussed on their performance against a respiratory aerosol challenge. The results of this study confirm that surgical masks provide the lowest level of respiratory protection compared to FFP respirators. Furthermore, the level of protection afforded by surgical masks against inert aerosols is similar to the level of protection afforded against a live bioaerosol containing influenza virus. A reduction factor of around 6 can be anticipated, depending on the type of surgical mask used. Many surgical masks on the NHS logistics list tested here offer considerably less protection than this.

It is recognised that a pandemic of influenza will result in a sustained period of pressure on healthcare service providers, particularly at the point of patient care. Healthcare service delivery arrangements will be adapted to cope with the rise in demand at all levels, including patient management and the provision of treatment. These arrangements will involve organisational, environmental and procedural controls and will probably be based upon normal delivery mechanisms as far as is practicable. Central to these arrangements is the application of effective infection control procedures to prevent nosocomial spread of the virus within hospitals caring for those patients with severe symptoms that require treatment.

The national risk assessment should be able to demonstrate that there is no or negligible risk arising from naturally occurring respiratory aerosols. Even if the probability of infection is considered to be low, the consequences, both to the exposed healthcare worker, and to the ability of healthcare service providers to cope with sustained pressure during a pandemic, should be carefully considered. If there is a residual airborne risk of harm to health, respiratory protection may be required.

If it is decided that there is an additional need for respiratory protection, organisational and management controls may need to be reviewed to allow those healthcare workers required to be in proximity to infectious patients to be supplied with appropriate respirators. The use of FFP respirators would necessitate correct maintenance, correct storage, fit testing and use by trained personnel. Furthermore, tailoring supply of dedicated respirators to individuals may also represent an issue. These aspects, as well as respirator demand and increased costs, present planning challenges to the healthcare sector. The widespread use of respirators might be difficult to sustain during a pandemic unless provision is made for their use in advance.

Surgical masks may provide adequate protection against large droplets, splashes and contact transmission. They may also reduce any residual aerosol risk but it remains unclear whether this level of protection sufficiently reduces the likelihood of transmission via this route so as to minimise the risk of infection to as low as reasonably practicable. With this in mind, it is recommended that HSE draw the results of this research to the attention of DH/HPA so that it can be considered as part of the wider issue of modes of influenza transmission.

6 RECOMMENDATIONS FOR FUTURE WORK

This study has generated valuable data and further evidence as to the effectiveness of surgical masks against aerosols. The testing system developed is novel insofar as it models a direct challenge with live airborne influenza virus to a healthcare worker wearing a surgical mask more realistically than any previously published study. There were some limitations to the study, for example, filtering facepieces were not subjected to the influenza bioaerosol tests and the tests were carried out on only one human test subject or a dummy test head. No attempt was made to include a representative sample of facial shapes and sizes. Some of these limitations could be addressed in further studies using the bioaerosol testing system developed here, or by developing the system further.

6.1 TESTING A BROADER RANGE OF SURGICAL MASKS AND RESPIRATORS

The surgical mask designs employed in the study were representative of the variety of available surgical masks, but only a relatively small number of surgical masks were the tested. A broader range of masks could therefore be tested using the testing system developed here. Inert particle challenge tests could also be tested on a variety of facial shapes and sizes

6.2 MAXIMISING THE PROTECTIVE EFFECT OF SURGICAL MASKS AGAINST INFLUENZA BIOAEROSOLS

The results of the bioaerosol challenges indicated that a mask with a built-in splash visor offers better protection than a conventional surgical mask of similar design and construction but without the integral visor. This should be further explored by performing inert particle and influenza bioaerosol tests on masks with built-in fluid shield compared with their conventional surgical mask counterparts. Also, conventional masks in conjunction with a separate splash visor could be tested.

The level of added protection achieved by taping the sides of surgical masks to the face in order to reduce leakage could also be investigated.

6.3 ANALYSIS OF SURGICAL MASK PROTECTION AGAINST A MORE REPRESENTATIVE INFLUENZA BIOAEROSOL

The levels of virus present in the bioaerosol challenge used in this study were probably considerably higher than those present in a natural cough or a sneeze. The studies outlined here could be repeated using influenza virus at levels more representative of a real sneeze. This would probably not permit quantitative data to be obtained regarding the protection factor afforded by the masks. However, the ability to recover live, infectious virus from behind the mask following a lower-titre challenge could be tested.

6.4 TESTING OF THE SURVIVAL AND DISSEMINATION OF LIVE INFLUENZA BEYOND ONE METRE

A larger microbiological safety cabinet or bespoke isolator could be used to test the effectiveness of surgical masks to influenza bioaerosols at a distance greater than 70cm, or against an indirect bioaerosol challenge (i.e. an ambient bioaerosol challenge test). Alternatively, the HSL exposure chamber could be employed to conduct bioaerosol tests in a side-room mock-up. This would allow the analysis of surgical mask protection beyond a distance of one metre, as well as allowing for the dilution effect of a larger area. Furthermore, the ability of live influenza to travel distances of greater than one metre in an aerosol could be analysed.

6.5 BIOAEROSOL CHALLENGE TO FFP RESPIRATORS

FFP respirators were not tested against bioaerosols in the current study because it was difficult to achieve a good fit on the dummy head (see Section 2.1). The data presented here enables us to extrapolate the influenza bioaerosol data from surgical masks to infer the level of protection likely from an FFP respirator. However, these respirators could be tested directly by artificially sealing them to the dummy head. This would enable definitive data to be obtained on the effectiveness of properly fitted FFP respirators against an influenza bioaerosol.

7 APPENDICES

7.1 DETAILS OF PRODUCTS AVAILABLE VIA NHS LOGISTICS (LIST RECEIVED AT HSL FEB MAY 2006)

Masks sales analysis by product

2005/2006 projected sales for financial year (based on 9 months sales)

NHS Purchasing and Supply Agency

NPC Code	Manufacturers product code	Brand	Supplier		Projected quantity purchased by pack size	Projected total number of individual units purchased
				FFP1 Respirators		
BTP030	42902	Barrier	Molnlycke	Mask face respirator EN149 Class FFP1 Case of 20	6	120
BTP009	1861	3M	3M	Mask face respirator Unvalved to EN149 class FFP1S Pack of 20	500	10,000
				FFP2 Respirators		
BTP003	1862	3M	3M	Mask face respirator Unvalved to EN149 class FFP2S Pack of 20	8,300	166,000
BTP010	1872V	3M	3M	Mask face respirator Valved to EN149 class FFP2S Pack of 10	1,780	17,800
BTP018	HM240001	Moldex	Universal	Mask face respirator Unvalved to EN149 class FFP2S Pack of 20	4	80
BTP031	42904	Barrier	Molnlycke	Mask face respirator EN149 Class FFP2 Case of 20	15	300
BTP021	UN62408	Tecnol	Universal	Mask face respirator Unvalved to EN149 class FFP2 and niosh standards (N95) for TB, pack of 50	15,030	751,500
				FFP3 Respirators		
BTP006	1863	3M	3M	Mask face respirator Unvalved to EN149 class FFP3S Pack of 20	1,010	20,200
BTP011	1873V	3M	3M	Mask face respirator Valved to EN149 class FFP3S Pack of 10	1,270	12,700
BTP017	HM250501	Moldex	Universal	Mask face respirator Valved to EN149 class FFP3S Pack of 20	50	1,000
				Surgical face mask, 4 ties		
BWM005	UN48100	Liteone	Universal	Mask face 4 ties with noseband non woven disposable Pleated Pack of 50	165,250	8,262,500
BWM006	42280	Barrier	Molnlycke	Mask face 4 ties with noseband non woven disposable Pleated Pack of 50	39,850	1,992,500
BWM014	UN48207	Tecnol	Universal	Mask face 4 ties with noseband non woven disposable Pleated with fluid membrane, pack of 50	3,770	188,500
BWM016	1818	3M	3M	Mask face 4 ties with noseband non woven disposable Blue pleated fluid resistant, pack of 50	2,680	134,000
BWM055	4233	Barrier	Molnlycke	Mask face 4 ties with noseband non woven disposable Pouched, pack of 50	280	14,000
BWM056	UN48247	Tecnol	Universal	Mask face 4 ties with noseband non woven disposable Pleated with plastic fluid shield, pack of 25	15,800	395,000
				Face masks, miscellaneous		
BWM022	1800	3M	3M	Mask face surgical aseptic, Blue moulded rigid fluid resistant elastic headloop, pack of 50	1,200	60,000
BWM205	6700	Robinson He	Robinson H	Mask face cestra muslin Sterile Pack of 36	120	4,320
BWM009	UN47700	Tecnol	Universal	Mask face particle free Duckbill double elasticated headband Pack of 50	2,000	100,000
				Total quantity sold	258915	12,130,520

7.2 DETAILS OF PRODUCTS AVAILABLE VIA NHS LOGISTICS (LIST RECEIVED AT HSL MAY 2006)

Respirators available via NHS Logistics

Supplier	Brand	MPC	NPC	Description	Qty Sold 2005/2006 (singles)
3M	3M	1861	BTP009	Mask face respirator class FFP1 unvalved	10,640
Medisavers	Bodyguards	FM3015B	BTP033	Mask face respirator class FFP2 unvalved (new)	new
Molnlycke	Barrier	42904	BTP031	Mask face respirator class FFP2 unvalved	1,820
Universal	**Tecnol**	**UN62408**	**BTP021**	**Mask face respirator class FFP2 unvalved and NIOSH standards (N95)**	**671,550**
3M	3M	1862	BTP003	Mask face respirator class FFP2 unvalved	178,580
Medisavers	Bodyguards	FM3016B	BTP034	Mask face respirator class FFP2 valved (new)	new
3M	3M	1872V	BTP010	Mask face respirator class FFP2 valved	19,770
Medisavers	Bodyguards	FM3017B	BTP035	Mask face respirator class FFP3 unvalved (new)	new
3M	3M	1863	BTP006	Mask face respirator class FFP3 unvalved	28,220
Universal	Tecnol	UN62360	BTP036	Mask face respirator class FFP3 valved (new)	new*
3M	3M	1873V	BTP011	Mask face respirator class FFP3 valved	20,690

* sales expected to be high

Surgical masks available via NHS Logistics

Supplier	Brand	MPC	NPC	Description	Qty Sold 2005/2006 (singles)
Molnlycke	Barrier	42280	BWM006	Mask face non woven disposable	1,972,600
Molnlycke	Barrier	4280	BWM031	Mask face non woven disposable pleated (new)	new
Universal	**Lite One**	**UN48100**	**BWM005**	**Mask face non woven disposable pleated**	**8,400,800**
3M	3M	1826	BWM025	Mask face non woven disposable pleated (new)	new
Cardinal	Cardinal	FS71050	BWM029	Mask face non woven disposable pleated (new)	new
Molnlycke	Barrier	4233	BWM055	Mask face non woven disposable pouched	60,050
Universal	Tecnol	UN47700	BWM009	Mask face particle free duckbill double elasticated headband	106,950
3M	3M	1838	BWM026	Mask face particle free duckbill with 4 ties (new)	new
3M	3M	1818	BWM016	Mask face non woven blue pleated fluid resistant	134,500
Molnlycke	Barrier	4234	BWM020	Mask face non woven disposable pleated fluid resistant (new)	new
Cardinal	Cardinal	AT74535	BWM028	Mask face non woven disposable pleated fluid resistant (new)	new
Universal	**Tecnol**	**UN48207**	**BWM014**	**Mask face non woven disposable pleated with fluid membrane**	**197,500**
3M	3M	1800+NL	BWM022	Mask face surgical blue moulded ridged fluid resistant elastic headloop latex free	63,850
3M	3M	1835FS	BWM021	Mask face non woven disposable pleated with fluid shield (new)	new
Cardinal	Cardinal	AT74635	BWM027	Mask face non woven disposable pleated with fluid shield (new)	new
Universal	**Tecnol**	**UN48247**	**BWM056**	**Mask face non woven disposable pleated with plastic fluid shield**	**1,121,900**
Molnlycke	Barrier	4232	BWM019	Mask face non woven disposable pleated with fluid shield (new)	new

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9 GLOSSARY

APF	Assigned protection factor: The level of protection that 95% of properly trained and supervised users of well maintained and correctly fitted RPE can expect to achieve or exceed in real use situations. APF is conventionally represented by the 5^{th} percentile of valid workplace or simulated workplace protection factor measurements. The APF is the correct value to use when selecting RPE which is capable of providing adequate levels of protection. See also NPF, PF and WPF.
FFP3	Filtering facepiece respirator achieving class 3 performance against airborne particles.
Fit Factor	A measure of the effectiveness of the faceseal of the respirator or surgical mask against a wearer's face.
Inert particle reduction factor	A measure of the inert particle concentration inside the respirator or surgical mask compared to the particle concentration challenging the facepiece.
Influenza plaque reduction factor	A measure of the influenza virus titre in air sampled inside the surgical mask compared to the corresponding titre in the air challenging the facepiece.
NPF	Nominal protection factor. The level of protection achieved in laboratory certification tests, assuming the maximum leakage permitted in the performance requirement applied. Being measured under ideal laboratory conditions, this level of protection is unlikely to be achieved in real-use situations, and should not be used in the selection of equipment. See also APF and WPF.
WPF	Workplace protection factor. The level of protection provided by an item of PPE or ensemble, measured in real use conditions using appropriate methodology. With a sufficient body of WPF data, the assigned protection factor (APF) is taken as the fifth percentile of ranked WPF data. For technical or ethical reasons, it may be impractical to measure WPF in real use situations. Simulation of realistic working activity with a suitable tracer challenge agent is considered to be an acceptable substitute for real WPF data.

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Evaluating the protection afforded by surgical masks against influenza bioaerosols

Gross protection of surgical masks compared to filtering facepiece respirators

The UK is preparing for a potential influenza pandemic. The main route of transmission of influenza is believed to be via direct contact with large droplets. The relative importance of aerosols in transmission is considered to be minor, but it cannot be ruled-out. The current UK Pandemic Influenza Infection Control Guidance recommends that workers who are in close contact with patients should wear surgical masks to reduce exposure to large droplets. However, surgical masks are not intended to provide protection against infectious aerosols. The guidance recommends that procedures that are likely to generate aerosols should be minimised, or where unavoidable, workers should wear appropriate respiratory protection. There is a common misperception amongst workers and employers that surgical masks will protect against aerosols. This study aims to evaluate the relative levels of protection provided by both surgical masks and respirators against aerosols.

This study focussed on the effectiveness of surgical masks against a range of airborne particles. Using separate tests to measure levels of inert particles and live aerosolised influenza virus, our findings show that surgical masks provide around a 6-fold reduction in exposure. Live viruses could be detected in the air behind all surgical masks tested. By contrast, properly fitted respirators could provide at least a 100-fold reduction.

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