Letter to the Editor

Respiratory Protective Equipment and Covid-19

Dear Sir,

On the British Broadcasting Corporation television news of 31st March 2020, it was commented that in Spain and Italy 13% and 9% respectively of all covid-19 deaths had occurred in medical personnel.

In any pandemic situation there are two basic requirements for RPE: to prevent infected persons passing their infection onto others who are not infected and to prevent uninfected persons becoming infected by inhaling air contaminated with the viruses or bacteria of concern.

In the UK guidance from bodies such as Public Health Scotland (2020) recommend the use of FFP3 respirators in Critical Care situations and fluid resistant surgical face masks in all other health and social care situations.

In normal situations the type of RPE used by medical staff in the UK are surgical masks.

Surgical masks are intended to prevent medical staff from passing infection to patients in situations where the major mechanism of transfer is in liquid droplets from the medical staffs' respiratory systems. That is, surgical masks are not intended to protect medical staff and are not Certified as such under the PPE Use Directive, EU (1996), as amended. In the RPE field surgical masks are considered to be low performance devices and are not addressed in HSE Guidance Note HSG53, HSE (2013).

Most surgical masks consist of flat sheets of filter media that are stitched together and fitted with a deformable wire around the top edge of the mask so that it can be adjusted to fit around the nose and two elastic cords; the lower of which fits around the neck and the upper one fits above the ears. In some masks the elastic cords are looped behind the ears.

From observation of the current television news programmes many of the surgical masks being worn have not had the wire correctly deformed to fit around the nose; gaps around the nostrils being clearly visible, and in many cases the sides of the mask are puckered; therefore, the masks are often not sealing against the face. Such gaps permit both inward and outward leakage.

The literature on the protective performance of Surgical Masks has been consistent for many years in that the reported protective performance of such masks is poor.

For example, McCullough et al (1997) commented that "surgical masks were the least efficient of all filters tests; these were not certified by NIOSH". These authors tested the filtration efficiency of devices against a polystyrene latex aerosol of 0.55 um. Three models of surgical masks were tested and exhibited penetrations between about 65 and 75%. Revoir and Ching-Tsen (1991) cited data indicating that the aerosol penetration of 0.3 um diameter particles through the filter of a flat surgical mask was about 65% at a flow rate of 100 l/min, i.e. the peak inhalation rate for a minute volume of about 30 litres. Lee et al (2008) noted that 29% of N95 respirators and ~100% of surgical masks had protection factors <10, that the protection factors of N95 devices were 8-12 times higher than from surgical masks and concluded that "N95 filtering facepiece respirators may not achieve the expected protection level against bacteria and viruses". Skaria and Smaldone (2014) commented that "Studies have shown that there is substantial leakage through the mask-nasal bridge interface to the upward direction and some downward leakage

through the lower edges when wearing a surgical mask". Goa et al (2016) concluded that "Surgical Masks do not provide measurable protection against surgical smoke" and also commented that "Since surgical masks have a comparatively poor fit, faceseal leakage represents a prominent penetration pathway. This is especially true for small particles, e.g. those in the size range of influenza A virons, as well as causing Human Papilloma (HPV), Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS)." Goa et al (2016) also commented that "although N95 filtering facepiece respirators are more efficient than surgical masks … allow no more than 5% penetration … penetration of ultrafine particles (<100 nm) may exceed this threshold."

From my reading I am led to the conclusion that surgical masks provide inadequate protection for either medical staff or patients against free viral "particles" in terms of mask penetration, inadequate in terms of leakage of mucous droplets out of or into the masks and that the protection provided by N95 masks may be questionable: particularly so for "free" viruses.

In the UK the Assigned Protection Factor (APF) for FFP3 devices is 20, HSE (2013).

When BS 4275 was drafted in 1996 most of the workplace studies on which the APF were based had been carried out in the USA. US studies used, and still use, shallow in-mask sampling techniques that simply measure penetration of the filter media when testing filtering facepiece devices rather than total inward leakage. Such in-mask sampling can therefore underestimate the in-mask concentrations by factors of 2-6, Bostock (1988), or by up to a factor of 20, Bostock et al (2002).

The workplace data for filtering facepiece and half-mask devices were very low once attempt had been made to correct the US results to those assumed likely to have been collected using EN 136 or EN 149 large diameter, deep probe style in-mask sampling. There was extremely strong resistance from the manufacturers' representatives on the BSI committee to set the APF for all filtering facepiece and half-mask devices to in the region of about 2 (for FFP1 or P1 devices) to about 5 (for FFP3 or half-mask P3 devices).

To get agreement to set the APF for the "high" performance devices (i.e. full facemasks and powered full-face mask devices) at the figure of 40, based on UK studies such as Tannahill (1991) and Howie et al (1996), down from 2,000, it was agreed to set the APF for filtering facepiece and half-mask devices to 4, 10 and 20 for FFP1, FFP2 and FFP3, and equivalent half-mask, devices respectively. This was "justified" on the basis of the assumption that the lower performance devices would never be worn in life-threatening situations and "occasionally" lower short-term performance would not be significant in terms of long-term exposures.

In addition, as the in-mask sampler in all of the published WPF studies operated throughout the breathing cycle the measured concentration assumed to have been inhaled by the respirator wearers was underestimated by a further factor of about 2; as during exhalation only that proportion of the inhaled aerosol that had not been retained in the wearers' bodies was exhaled: so, diluting the in-mask aerosol concentration. All reported WPF, and thus APF, should therefore be about halved.

If it were assumed that the danger of developing covid-19 could depend on the short-term viral load inhaled, I suspect that for medical staff inhaling about 5-20% of any ambient concentration of such viruses in high risk, or unknown risk, situations could be dangerous: particularly if it occurred on a day-to-day basis over periods of weeks to months.

In "high risk" situations, such as Covid-19 treatment hubs, and para-medics and ambulance staff taking infected patients to and from such hubs, all personnel should be issued with power assisted full face mask respirators certified to Standard EN 12942:1999. However, it should be appreciated that because these devices are fitted with exhaust valves no protection will be provided to patients or the immediate environment from any contamination released by the wearers. In such conditions patients should be fitted

with unvalved FFP2 or FFP3 devices. The provision of such devices to patients will also minimise the risk of the patients contaminating ambulances, their equipment or staff.

I understand that RPE fit testing is to be introduced into National Health Service situations.

It must be stressed that fit testing identifies “gross misfits only” between wearers and RPE combinations, e.g. see BSI (1997). “Passing” a fit test does not indicate that the wearer-mask combination is suitable.

In the Howie et al (1996) study it was observed that the investigators, all of whom had achieved at least Fit Factors of 10,000 in the laboratory and who wore the same types of respirators as the workmen, obtained the same 95%ile WPF of about 40 as the workmen: none of whom had had Fit Testing or any additional fitting instruction during the study. Offeddu et al (2017) found no difference in performance between those provided with Fit Testing and those not provided with Fit Testing.

Current HSE guidance on fit testing states that such tests are able to identify the correct wearer-mask combination. However, even after about 20 years of asking, HSE has failed/refused to publish any data supporting such assertion.

Fit testing is an excellent training aid and can illustrate the consequence of not fitting head straps correctly, not deforming the nose seal, if present, or, the deleterious effect of facial hair.

In the longer term it would be useful to provide surgeries and reception areas with room ventilators, such as used in Negative Pressure Units for asbestos removal operations and that are fitted with high efficiency particulate filters giving performance equivalent to P3 performance as specified in Standard EN 143, BSEN (2000), to both capture and dilute any contamination released in the protected rooms.

Robin Howie,
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