Briefing Note for Safer Healthcare Biosafety Network

Formation of a 'Pandemic RPE Expert Group'

At end of the SHBN meeting on 22 March, the Chair kindly allowed me to say a few words about a new initiative that is getting underway. The purpose of this note is to provide members with further information.

1) Background

Members who watched the recent ITV drama, *Breathtaking* will have seen the central character, Dr Abbey Henderson, failing a 'face fit test' when using a FFP3 respirator during the Covid pandemic.

The explanation by the person carrying out the test was "*...**these FFP3s are made for wider jaws***" and Dr Henderson's comment in return "*...**life-saving for men!!***". She recognised that with a respirator which didn't fit tightly to her face she was endangered by the virus being able to enter the respirator and infect her. Despite this she bravely continued her work.

The reality is that this short clip in a TV drama, repeated hundreds of times over in real life, exposed a major failing in the provision of this type of Respiratory Protective Equipment (RPE) for healthcare workers (HCW) during the pandemic – it requires a good tight fit to the face in order to avoid leakage.

2) The issue

FFP3 (Filtering Face Piece) respirators provide an excellent level of respiratory protection and are recommended by HSE as providing a suitable level of protection against airborne microbiological risks in their guidance (appendix 6). HSE do not recommend surgical masks (of any type) for this purpose.

The material from which these respirators are made provides an efficient physical filter for very small particles and aerosols. In addition, the application of an electrostatic charge during the manufacturing process significantly enhances their ability to trap these airborne contaminants. As such, FFP3 respirators are a far cry from fluid resistant surgical masks which do not protect the wearer against inhalation of airborne contaminants but merely give the wearer a false sense of security which, in its own right, is a danger.

FFP3 respirators are widely used in other working environments such as the manufacturing, chemical and engineering sectors. However, in line with HSE's guidance, they are typically used to protect workers undertaking activities which involve relatively short periods of time. HSE do not recommend their use for extended periods and suggest an hour as a suitable maximum wear-time.

Although FFP3s do have a valuable place in the healthcare sector for relatively short, ad-hoc exposures to infectious patients, they are not appropriate for staff who have to spend much of their time in close contact with suspected or confirmed infectious patients. A step change in mindset is required when planning for future pandemics or even for local outbreaks of communicable diseases.

However, over and above the 'equality' issues alluded to above, there are a number of other factors which suggest that FFP3 respirators should not be considered the RPE of choice where needed to be worn for lengthy periods of time:

i) Discomfort to the wearer (possible reluctance to wear, or loosening by the wearer);
ii) PPE-Related Occupational Dermatoses (e.g. acne, itch/rash, abrasion/pressure sores, urticaria, hyperpigmentation);
iii) Respiratory distress;
iv) Headaches;
v) Failure of components (particularly the seal) whilst in use, due to age-related degradation of materials†;
vi) Reduction of efficiency due to dissipation of electrostatic charge‡;
vii) Pain arising from pressure on the skin;
viii) Communication with the patient is impaired;
ix) Facial recognition difficulties.

† Such degradation is unlikely to happen provided that the respirators are stored and used in accordance with manufacturers' instructions and used within the manufacturers' expiration date. Otherwise, after donning and passing the initial 'user fit check', users would not necessarily become aware of any inward leakage caused by seal deterioration during the session of use and unwittingly inhale virus.

‡ Dissipation of electrostatic charge occurs more rapidly with increased temperature and humidity (as occurs when breathing), particularly when respirators are worn for a long period of time. Wearers would not be aware of decreased filter efficiency through dissipation of electrostatic charge and this may lead to an increase in inhalation of virus.

I suspect that many front-line HCWs who were lucky enough to be provided with life-saving FFP3 respirators would agree that they are far from ideal when it comes to prolonged close-quarter care of patients and would welcome an alternative device which provides equivalent or better protection. As discussed in section 7 below, it is for this reason that the Pandemic RPE Expert Group is being formed.

3) Equality issues / Conformity with safety standards

FFP3 respirators must be tested and certified to conform to the standard BS EN 149:2001. This requires the FFP3 to be mounted on a 'Sheffield Dummy Head' so that various measurements can be taken. This represents the facial features of a **white male**. The same dummy head is also used for BS EN 140:1999 which is the standard for a reusable type of tight-fitting RPE such as elastomeric half-masks. The use of this device for testing and certifying RPE dates back over 30 years.

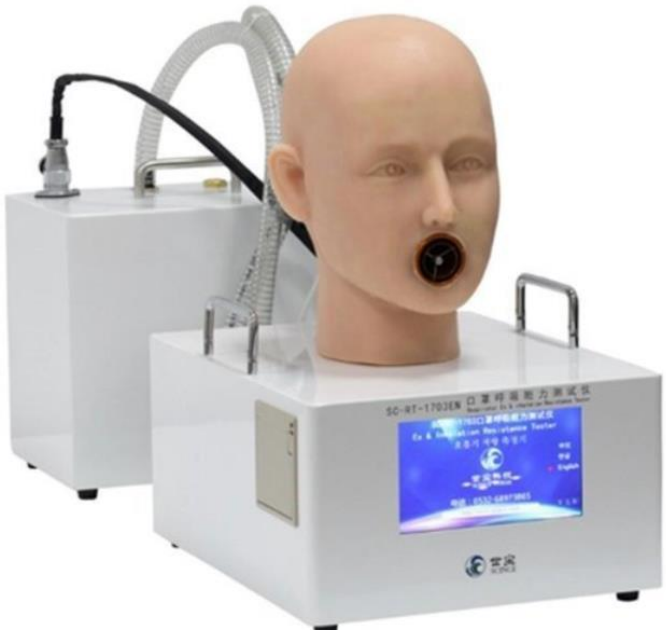

Fig 1: The 'Sheffield Dummy Head' Source: Scince Purge Technology

It is illegal for suppliers to sell RPE in the UK which does not conform to these standards or is otherwise approved by the Health and Safety Executive.

No provision was made during the pandemic planning process to cater for the respiratory protection needs of other ethnic groups or females who have different facial characteristics (morphology). In a diverse working community such as the NHS this was a major omission.

There was also a failure to consider men of certain faiths who are required to have beards and other faiths where they choose to do so as a symbol of religious piety or devotion. Tight-fitting masks simply do not provide an effective seal to the face when the wearer has facial hair. Similarly, the practical issues arising from the wearing of religious attire such as turbans and hijabs were not considered.

In future pandemic planning we must keep the provisions of the Equality Act 2010 firmly in mind, since omission to provide effective RPE protection for **all** workers regardless of gender, faith or ethnicity would contravene this legislation.

4) Healthcare Worker Response to a Future Pandemic – Willingness to serve?

At the previous SHBN meeting (Nov 2023), there was an excellent talk by NHS Resolution who presented their 'Being Fair 2' initiative. This addressed issues relating to 'workplace culture', the way that some staff in the NHS are treated (incivility, endemic bullying etc) and how this might be overcome.

In the Q&A I commented that during my work over the past 3 years I had come across so many NHS staff who had been severely harmed by the disease, were suffering from post-COVID syndrome so badly that they can no longer work, without support packages and facing financial and emotional ruin.

I posed the question as to whether, having witnessed the impact on colleagues in terms of disease and death and the uncompassionate way that survivors were being treated, this may have irreversibly compromised their trust in the organisation's ability to keep them safe when confronted with any future pandemic. The concern being as to whether this might give rise to a widespread 'refusal to treat' in the event of a future pandemic – with all the mayhem and civil disorder that would most likely ensue.

The response from our colleague in NHS Resolution was that the majority of HCWs are incredibly dedicated and will go "above and beyond". Indeed that is absolutely true and this has been manifestly evident during the darkest days of the pandemic. We all salute them all for their selfless dedication.

However, my contention is that HCWs should not be forced into a position where "going above and beyond" presents a very real danger to their life and to that of their families at home. To prepare for a future pandemic with this expectation in mind would represent a serious breach of Article 2 of the EU Charter of Fundamental Rights (i.e. 'Right to Life').

It is reasonably foreseeable that in the event of a future pandemic basic human instincts of self-preservation will hold sway. If staff again walk onto a ward only to be told "these surgical masks will keep you safe" and "we have to follow national guidance", many will turn round and walk straight back out again. The greater the Case Fatality Ratio (CFR) of an emerging pandemic, the more likely this is to happen. With COVID-19 the CFR was fortunately relatively low (an estimated 2.5 to 3% at the outset), whereas with other foreseeable pandemics such as SARS(1), MERS and Avian Flu H5N1 (where limited human-to-human transmission has already occurred) the CFR would be 5 to 10 times higher, if not more.

However, rebuilding HCW trust is neither impossible nor insurmountable. They need to see a genuine acceptance that where mistakes were made they will never be made again. More importantly HCWs, and their elected safety representatives in Trade Unions, need to see actual positive action and investment in the provision of better control of airborne risk. This should include improvements in ventilation and air-purification in places where contact with infectious patients is anticipated. However, there also needs to be a recognition that this alone will not keep workers safe when delivering close contact care. As one of the attendees at the meeting astutely observed during the Q&A, Respiratory Protective Equipment will always be needed as a part of 'airborne precautions' to protect against the close-range aerosol plume emanating from infectious patients.

5) Powered Air Purifying Respirators (PAPRs)

As discussed above, there are many reasons why FFP3 respirators should not be the RPE of choice. This is echoed in HSE's guidance on RPE (HSG53) "*where RPE is required to be worn continuously for long periods, powered respirators … with a loose-fitting facepiece such as a hood or helmet are better options*"

An example of an NHS Trust which recognised the airborne nature of COVID-19 early in the pandemic and managed HCW protection in a proactive and responsible manner was University Hospital Southampton. Facing the acute shortage of RPE they, together with the university, developed a powered respirator which they named the PeRSo (**Pe**rsonal **R**espirator **So**uthampton). The development work was carried out at pace, using such components as were readily available to them, an account of which may be seen in this BBC news report (Jan 2021).

A fan pumps air through a high-grade HEPA filter worn on the belt and pipes it to the hood, providing a flow of purified, cooling air over the face. These devices are suitable for everyone regardless of gender, race or religion and, because they are not tight-fitting, wearers do not have to undergo a 'face-fit test'. They also aid better communication with the patient compared with the FFP3 respirators or surgical masks as patients can see the HCW smile, lip-read, etc.

The PeRSo product was eagerly accepted by staff and COVID infection rates greatly reduced. Following feedback from users, the style of the hood was refined as seen in figure 2 below.

Fig 2: The PeRSo Respirator Images: Ric Gillams Photography

6) 'Source Control' – IPC Considerations

Some IPC practitioners may be concerned that PAPRs do not provide 'source control', meaning that an infected HCW could present a risk to patients. This is an important point which needs to be properly addressed:

6.1 Prevention: Clearly the first consideration is to stop HCWs becoming a 'source' in the first place by preventing them from contracting the disease from their patients. This is particularly important when providing close-contact care where the patient's and HCW's breathing zones intermingle. General room ventilation does not create sufficient air velocity to disperse the aerosol plume before the HCW inhales the patient's expiration.

Therefore, where the disease may to any extent (i.e. 'wholly' or 'partially') be transmitted by the airborne route†, then RPE {within the meaning of COSHH Regulation 7(9)(b)} must be provided. This does not include surgical masks of any type.

It is entirely logical that we protect HCWs in the best possible way. Apart from it being a moral and ethical imperative, it is also a basic requirement of UK legislation. In planning for any future pandemic it is essential that the provisions of health & safety legislation and the "duty of care" owed to healthcare workers must be the planners' foremost concern (as well as those who allocate budgets). Besides, from a pragmatic point of view, the country needs them at their posts to help us in our hour of need.

† "Airborne transmission" is taken to mean the process whereby aerosolised infectious respiratory particles are inhaled (as per the recent WHO definition "Indoor airborne risk assessment in the context of SARS-CoV-2"). It should be assumed that wherever "direct deposition" occurs (WHO's new term for "droplet transmission"), then aerosolised infectious respiratory particles will also be expelled, thereby mandating the use of RPE – the only difference being that the RPE must also have fluid resistant properties (a requirement which the visors of PAPRs satisfy).

6.2 Detection: Despite best endeavours to protect HCWs from occupational exposure to the disease, they may contract the disease in the community or elsewhere in the workplace. The risk of cross-infection to patients needs to be controlled as far as is reasonably practicable. This may be achieved by implementing a rigorous testing regime and scrutiny for symptoms, then removing them from front-line service. Elimination of the hazard represents the ultimate in "source control".

Nevertheless, despite all of the above, there will always be a need for "source control". For instance tests may not be available in the early stages of a pandemic, tests will usually return a proportion of "false negatives" etc. We therefore need to address the adequacy of PAPRs in comparison with surgical masks.

6.3 Efficacy as 'Source control': Whether or not one agrees with their "airborne/droplet dichotomy", WHO/Public Health/IPC have constantly reminded us throughout the pandemic, transmission of COVID-19 may occur through "droplets" and "aerosols". Considering these in turn:

- Droplets (i.e. "direct deposition"):
  - Surgical Masks:

    Surgical masks compliant with BS EN 14683:2019 are designed to prevent transmission of droplets which may leave the wearer's nose or mouth and there is no reason to doubt that they do this effectively.

  - PAPRs:

    A quick glance at the device in figure 2 above will soon reveal the impossibility of droplets escaping through the visor.
- Aerosols (i.e. "airborne infectious respiratory particles"):
  - Surgical Masks:

    Expert researchers in bioaerosol transmission have opined that:

    - "Surgical masks do work as source control albeit very imperfectly. They only cut out about 50% of fine particle aerosols";
    - "Surgical masks serve more as a deflector of aerosol emissions rather than as a filter"
  - PAPRs:

    Commercially available PAPRs do not filter aerosols from outbound breath.

So PAPRs and surgical masks both involve aerosol emission to a certain extent. However, it is understood that exhalation filters have been successfully trialled with a variant of the PeRSo respirator.

6.4 Precedent in IPC Guidance: It should be noted that at the outset of the pandemic, IPC guidance (issued 15 Jan 2020) allowed for the use of PAPRs (without expiration filters) as being a valid and perfectly acceptable form of RPE alongside FFP3s.

The 4-nations IPC guidance, from version 2 (April 2020) right through until it was withdrawn in 2022, recommended PAPRs as a valid and acceptable form of RPE. Thereafter the Scottish, English and Welsh National IPC Manuals have all continued to recommend PAPRs as a valid and acceptable form of RPE without any filtration of the expelled air.

6.5 Limitations: PAPRs are not to be used when undertaking a sterile procedure or directly over the surgical field. The decision as to which type of RPE should be used would be taken following risk assessment and clinical judgement. See CAS alert Ref NatPSA/2021/009/NHSPS for more information. The question of filtration of exhaled air from PAPRs is likely to be considered by the Expert Group (see below). It may also be appropriate to consider directing the emission of exhaled air to the rear of the wearer's head (away from the patient) and diffused (so as to prevent an expiratory jet). Factors such as air pressure and air flow through the system would need consideration.

7) Pandemic RPE Expert Group

Discussion with Prof Paul Elkington MBE (pictured in fig 2 above, wearing a PeRSo) has revealed that the development team encountered numerous hurdles with the regulatory framework. They would ideally like to see an even more lightweight, user-friendly version of the PeRSo developed. However, attaining compliance and certification with the required standard (BS EN 12942) has proved problematical and discouraged interest in pursuing such a development. It is beyond the scope of this note to expand upon the technical issues involved. Suffice it to say that the safety requirements of the standard are primarily aimed at respirators used in manufacturing, chemical and other industry sectors where the working environment is quite different from healthcare. We see the need for a new BS EN standard for powered respirators that are to be used specifically in the healthcare sector. Alternatively perhaps, there could be a derogation from some aspects of the design and testing requirements within the existing standard.

With this in mind an expert group is being assembled specifically to look into pandemic RPE for healthcare. A colleague, Professor Kevin Bampton, Chief Executive of the British Occupational Hygiene Society, the Chartered Society for Worker Health Protection is gathering together RPE experts from within his organisation, HSE and the British Standards Institute to get this off the ground. This expert group will focus on the technical, legal and regulatory aspects of the project. In parallel, it is intended to form a consultative user-group which we hope will include key organisations involved with worker safety such as the RCN, BMA TUC and health and safety practitioners from within the healthcare sector. Naturally there be also be consultation with other stakeholders such as NHS Supply Chain and IPC as the project advances.

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