Evaluating the national PPE guidance for NHS healthcare workers during the COVID-19 pandemic

Authors: John P Thomas,^A Anand Srinivasan,^B Chandu S Wickramarachchi,^C Parveen K Dhesi,^D Yat MA Hung^D and Ajay V Kamath^E

ABSTRACT

Tragically, many of the infections and deaths recorded in the global coronavirus disease 2019 (COVID-19) pandemic have occurred in healthcare workers. Some have attributed this to inadequate provision of personal protective equipment (PPE). In the UK, several organisations have voiced their concerns that the national PPE guidance issued by Public Health England is inadequate. Despite recent revisions to these guidelines, concerns remain that they offer insufficient protection to frontline NHS healthcare workers. In this report, we evaluate whether these concerns are merited, through critical appraisal of the available evidence, review of international PPE guidance, and consideration of the ethical implications.

KEYWORDS: COVID-19, personal protective equipment, pandemic, NHS, SARS-CoV-2

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Introduction

The coronavirus disease 2019 (COVID-19) pandemic has indiscriminately thrown healthcare systems across the globe into turmoil. The public health strategy adopted by the UK Government will ultimately determine the outcome of the battle against COVID-19 on our own shores. Protected by modern healthcare, it is reasonable to assume we will eventually win this battle – but at what cost?

Tragically, many of the infections and deaths recorded in this global outbreak have occurred in healthcare workers (HCWs). HCWs account for 9% and 13% of the total confirmed COVID-19 cases in Italy and Spain respectively.^{1–3} On 17 April 2020, the

Authors: ^ANational Institute for Health Research academic clinical fellow, Norfolk and Norwich University Hospital, Norwich, UK; ^Bfoundation trainee, Oxford University Hospitals NHS Foundation Trust, Oxford, UK;^csenior house officer, Havering and Redbridge University Hospitals NHS Trust, Romford, UK; ^Dsenior house officer, Norfolk and Norwich University Hospital, Norwich, UK; ^Econsultant respiratory physician, Norfolk and Norwich University Hospital, Norwich, UK Italian National Institute of Health announced that nearly 17,000 HCWs in Italy had contracted the illness.⁴ Shortly afterwards, the Italian Federation of Medical Associations (FNOMCeO) reported that 139 Italian doctors had so far died of the disease.⁵ In the UK, as of 28 April 2020, the Government have verified 49 deaths among NHS HCWs due to COVID-19 during the pandemic, although other organisations report that the actual figure may have surpassed 100 deaths.⁶

Frontline NHS HCWs and organisations such as the British Medical Association (BMA) and Doctors' Association UK (DAUK) have consistently voiced their fears that the national personal protective equipment (PPE) guidelines issued by Public Health England (PHE)⁷ are inadequate to offer sufficient protection – both in terms of quantity and quality. Despite several revisions to the PPE guidance by PHE since the early stages of the pandemic, there are still concerns that the recommendations remain sub-optimal.^{8–10} In this report, we evaluate whether these concerns are justified through comparison of global PPE guidance, evaluation of the scientific basis of PPE, and consideration of the ethical implications.

Global PPE guidance vs Public Health England PPE guidance

Since the first reports of the outbreak, multiple governing bodies have published recommendations for institutions under their jurisdiction, both to protect the health of the caring workforce and mitigate COVID-19 propagation through the healthcare environment. There has been a remarkable degree of congruence between these various recommendations in secondary care settings (shown in Table 1). It appears that even following several revisions, the PHE guidance (as of 24 April 2020) falls short of its counterparts in many clinical scenarios (Table 1).⁷ Although the guidance now recommends respirator masks, disposable surgical gowns and eye/ face protection when performing selected 'aerosol-generating procedures (AGPs)' or working in specific 'higher risk acute care areas' with possible/confirmed cases, in other clinical settings such protective measures are deemed unnecessary. For instance, the PHE guidelines still translate clinically to frontline HCWs caring for suspected and confirmed COVID-19 patients in most inpatient wards (which are considered not to be 'higher risk acute care areas') with the protection of a surgical facemask, disposable gloves, plastic apron, and face shield/goggles subject to risk-assessment and proximity to the patient. Furthermore, the guidance suggests that surgical facemasks and plastic aprons are sufficient for those

Table 1. Global comparison of personal protective equipment (PPE) for healthcare workers in secondary care settings when providing care for patients with suspected/confirmed COVID-19

	World Health Organization ²⁴	China ⁶⁹	ECDC (Italy, Spain, France, Germany) ⁷⁰	CDC (USA) ⁷¹	Australia ⁷²	PHE (UK) ⁷
Respiratory protection	Medical facemask*	N95/FFP2 respirator mask	FFP2/FFP3 respirator mask ⁺	N95 respirator mask	N95 respirator mask	Fluid-repellent surgical mask*
Body protection	Long-sleeved gown	Long-sleeved medical protective uniform Shoe cover Hat	Long-sleeved water-resistant gown	Gown	Long-sleeved gown	Plastic apron [‡] Bare below the elbows
Eye protection (face shield or goggles)	Yes	Yes	Yes	Yes	Yes	Dependent on clinical setting, proximity to patient and/or risk assessment [§]
Hand protection (gloves)	Yes	Yes	Yes	Yes	Yes	Yes

*Respirator masks are only recommended if performing selected aerosol-generating procedures (AGPs) or also in the UK if working in higher risk acute care areas (defined by PHE as: 'ICU/HDUs; ED resuscitation areas; wards with non-invasive ventilation; operating theatres; endoscopy units for upper respiratory, ENT or upper GI endoscopy; and other clinical areas where AGPs are regularly performed').

⁺In the absence of FFP2/3 respirator masks, healthcare workers should use masks with the highest available filter level. Respirator masks can be used for up to 4 hours for multiple patients without removing them, unless the respirator is damaged, soiled or contaminated, for example a symptomatic suspected case coughing on them.

*Disposable fluid-resistant gowns or coveralls to be only worn if performing selected AGPs or working in higher-risk acute care areas or in operating theatre/labour ward area with possible or confirmed case.

⁵Eye/face protection should be worn if working in a higher risk acute care area/labour ward/operating theatre with possible or confirmed case or when performing selected AGPs or if in close proximity (ie <2 metres) to a possible or confirmed case in an acute assessment/inpatient/maternity/radiology area. In other instances, eye/face protection should be worn if following an individual risk assessment there is thought to be an anticipated/likely risk of contamination to the eyes from splashes, droplets of blood or body fluids.

CDC = Centers for Disease Control and Prevention; ECDC = European Centre for Disease Prevention and Control; FFP = filtering face piece; PHE = Public Health England

undertaking procedures which do not fall within the criteria of 'potentially infectious AGPs for COVID-19' – notable examples within this excluded category include collection of nasal/nasopharyngeal swabs, cardiopulmonary resuscitation and administration of highflow humidified oxygen.¹¹ As demonstrated, the PHE PPE guidance appears complex and convoluted in comparison to its counterparts which have adopted far more uniform, simplified yet enhanced PPE measures across secondary care settings.

Scientific basis of PPE

Transmission

Current evidence indicates that SARS-CoV-2, as with SARS-CoV-1, may be spread by four major routes: direct or fomite contact; respiratory droplets generated during coughing or sneezing; faeco-oral; and airborne via aerosols.^{12,13} Airborne and faeco-oral transmission have the potential to result in super-spreading events – particularly in nosocomial settings.^{12,14–17}

Aerosols

While respiratory droplets (>5 μ m) tend to fall to the ground rapidly within one metre from the source, aerosols (<5 μ m), by

virtue of their size, remain suspended in the air for prolonged periods.^{15,18,19} Coughing and sneezing, two common clinical symptoms of COVID-19, can produce both droplets and aerosols, with particles varying in size from <1 to >2000 µm, but mostly in the <20 µm range.¹⁹⁻²¹ Speech was recently shown to generate respiratory droplets ranging from 20–500 µm in size using a laser light-scattering approach.¹⁹ A recent model of respiratory emissions suggests that droplets and aerosols carrying pathogens may actually spread up to eight metres as a turbulent gas cloud.²²

Based on a 2013 systematic review, the World Health Organization (WHO) identifies certain clinical tasks, such as tracheal intubation, suctioning and cardiopulmonary resuscitation, as AGPs.^{23,24} But recent studies report activities including oxygen mask adjustment, physical examination, and intravenous access are similarly aerosol-generating.²⁵ Influenza viral shedding has also been observed even during normal breathing in the community setting.²⁶ A more recent study showed that viral RNA could be found in respiratory droplets and aerosols generated during exhaled breaths from influenza, coronavirus and rhinovirusinfected patients.²⁷ Another study found that there was influenza RNA concentration surpassing the infectious dose in all sampled clinical areas providing routine care in a tertiary hospital.²⁸ HCWs were exposed to mainly small influenza virus particles (diameter ${<}4.7~\mu\text{m})$ even at distances of 1.829 m from patients.^{28}

SARS-CoV-2 has been shown to remain viable as bio-aerosols for at least 3 hours, and on other surfaces (such as cardboard, plastic and metals) for longer.²⁹ Evidence from surface and air sampling from early studies demonstrate widespread environmental contamination in patient care areas by viral RNA, indicating significant aerosol-mediated viral shedding.^{12,30,31}

Thus with current evidence yet to conclusively elucidate the nature and degree of airborne spread of SARS-CoV-2,³² PPE guidance that risk-stratifies based on the aerosol-generating potential of a clinical activity at specific clinical locations or proximity to a patient may be greatly underestimating the risk. For instance, even in 'low' or 'intermediate' risk clinical settings, such as general medical wards, HCWs may receive significant viral exposure as they encounter multiple COVID-19 patients shedding unpredictable viral loads generated through breathing, speaking or coughing.

Respiratory protection

The major mask manufacturer 3M states that surgical facemasks are inadequate to protect the wearer from inhaling particles smaller than 100 μ m, which includes aerosols and most droplet particles generated through sneezing or coughing.³³ Instead, 3M recommends at least an N95 respirator mask to protect against inhaling particles of this size.³³ N95 respirator masks have at least a 95% efficiency of filtering particles 0.3 μ m in size.³³ N95 is an American standard and is roughly equivalent to the European mask standard of filtering face piece 2 (FFP2) as detailed in Table 2.

Concordantly, in surrogate viral exposure studies with comparison to surgical masks, respirator masks were associated with as much as 15-fold less filter penetration and aerosol transmission under laboratory experimental conditions.^{21,34–36} Concerningly, live viruses could be detected in the air behind all surgical masks tested.²¹

The few clinical trials comparing respirator masks and surgical facemasks, in the setting of respiratory viral infections, have generally suffered from low power and confounding factors.³⁷ A meta-analysis of randomised controlled trials (RCTs) concluded that there were no statistically significant differences in preventing laboratory-confirmed influenza infections (n=8,444 participants from five RCTs) and respiratory viral infections (n=3,264 participants from four RCTs) when comparing N95 respirator masks with surgical facemasks.³⁷ However, a subgroup analysis of 2,818 participants in three of the four included trials indicated a statistically significant 39% risk-reduction in respiratory viral infections when using N95 respirator masks in comparison to surgical facemasks.³⁷ In the case of SARS-CoV-1, a meta-analysis of seven case-control studies revealed that surgical facemasks

	Table 2. Respirator mask standards ⁷³				
Respirator standard		Filter efficiency			
	FFP1	At least 80%			
	FFP2	At least 94%			
	N95	At least 95%			
	N99 & FFP3	At least 99%			
	N100	At least 99.97%			
	EED = filtering face piece: N = 'pet resistant to pil'				

FFP = filtering face piece; N = 'not resistant to oil'

significantly reduced the risk of infection in comparison to no mask (odds ratio [OR] 0.32), while N95 respirator masks were even more effective based on three studies (OR 0.17).³⁸

Thus, based on manufacturer advice, experimental data and clinical studies, there is insufficient evidence to conclude that surgical facemasks offer adequate protection against SARS-CoV-2. Furthermore, focusing on the efficacy of respirator masks in reducing symptomatic infections should not preclude their potential for reducing the risk of HCWs from becoming asymptomatic carriers/transmitters of COVID-19.^{39,40} Given the higher virulence associated with SARS-CoV-2 in comparison to influenza and other respiratory viruses,⁴¹ and the current lack of evidence to rule out its airborne transmission, it would be prudent to err on the side of caution while awaiting more definitive studies.

Body, hand and eye protection

A systematic review of PPE measures for SARS-CoV-138 reported favourable evidence for eye protection (OR 0.10), gloves (OR 0.32), gowns (OR 0.33) and handwashing (OR 0.54). A combination of these methods with respiratory protection was even more effective (OR 0.09).³⁸ These approaches have also been proven to be efficacious in the setting of respiratory syncytial virus and influenza.^{38,42} A re-analysis of a simulated exposure study using fluorescent stain found that gowns are superior to aprons in reducing contamination caused by simulated splashes.^{43,44} Similar comparisons have also favoured superiority of sealed suits over traditional gown and gloves (OR 0.68).^{44,45} In the UK, where HCWs follow the 'bare below the elbow' policy, unlike their international counterparts whose uniforms cover the forearms, gowns are likely to provide more skin coverage than apron alone and minimise contamination by respiratory secretions and fomites.

In one study, 62% of COVID-19 cases had a history of hand–eye contact and 4.68% presented with conjunctival congestion.⁴⁶ While eye protection has primarily been shown to be effective in the context of respiratory syncytial virus, it has typically been studied when used alongside other PPE.⁴⁷ Of note, published studies do not differentiate between different activities for the risk of transmission via conjunctiva. Face-shields can potentially simultaneously offer eye and respiratory protection,⁴⁸ but provide insufficient protection against aerosols and droplet contamination if used on their own.^{48,49}

Cost-effectiveness

Cost-effectiveness modelling has revealed that utilising enhanced PPE (respirators, gowns and goggles) for all patients would be costeffective in the setting of a pandemic⁵⁰ or a highly virulent disease such as severe acute respiratory syndrome (SARS)⁵¹ when taking into account the costs associated with medical staff absenteeism and illness due to inadequate PPE. But as real-world studies on this subject are limited,⁵² data from this ongoing crisis should be evaluated to inform future policies on preparation and stockpiling.

Ethical considerations

To secure ourselves against defeat lies in our own hands, but the opportunity of defeating the enemy is provided by the enemy himself.⁵³

In our battle against COVID-19, many factors may lie beyond our control and we recognise that risk cannot be completely mitigated. However, as Sun Tzu posits, our security through defence remains

our choice, while the breakthrough in overcoming this pandemic might be provided by gaining further insights into the SARS-CoV-2 virus itself. As previously mentioned, prudence in the face of scientific uncertainty would dictate that we favour caution over convenience, which is encapsulated by the 'precautionary principle'.⁵⁴ Furthermore, Beauchamp and Childress' ethical framework encourages us to counterbalance beneficence with non-maleficence.⁵⁵ When acting for the former, ie providing acute healthcare during this pandemic, we must actively safeguard the latter – avoiding both harm to the public when our frontlines become viral vectors, and tragic loss when those staff succumb to illness.

Additionally, if there is insufficient quantity or quality of PPE to protect the workforce, for whatever reason, then our leaders have a moral duty to be open and honest. It is imperative that all frontline HCWs are duly informed of their own personal risks when caring for COVID-19 patients. It is a reasonable expectation to hold our modern governments to the corresponding standards of our modern health professionals: specifically, transparency in decision-making and the duty of candour.^{56,57}

Recommendations

Based on our appraisal of PPE guidance of healthcare organisations across the globe and the available scientific evidence, we believe that there are still shortcomings to the current PHE PPE guidelines. In particular, there is insufficient evidence to suggest that PPE protection standards can be safely lowered when frontline HCWs are not working in specific 'higher risk acute care areas' or not performing certain AGPs as advised by PHE. Given the scientific uncertainty of novel SARS-CoV-2 transmission and pathogenesis, a more precautionary approach is ethically justified. Accordingly, we recommend that PHE urgently amends its PPE guidance to make it simplified, uniform, and enhanced across all secondary care settings/ scenarios – as seen in other healthcare systems across the globe.

We suggest that all NHS HCWs treating any suspected or confirmed case of COVID-19 in any clinical setting or scenario should wear the following PPE:

- > Respiratory protection: N95 or FFP2/3 respirator masks
- > Eye protection: Goggles or face shield
- > Body protection: Long-sleeved water-resistant gown
- > Hand protection: Gloves

Practical considerations

Given the global demand for PPE in this pandemic, we appreciate that it may not be easily feasible to source appropriate levels of stock and fully adhere to the above recommendations.⁵⁸ Nevertheless, guidelines should ideally reflect best practice based on the available scientific evidence rather than be driven by political or organisational factors, particularly when these measures relate to the health and safety of frontline HCWs.⁵² This is especially important in the emergency situation of a pandemic, where reliable national guidance is essential for an efficient and coordinated nationwide response. While local NHS trusts are not mandated to follow all national guidelines (particularly if deemed to be inadequate), trusts must be prepared to justify their actions, and to take into account the medico-legal consequences and ethical considerations of deviating from them.

To ease the demand for PPE and to ensure that it is utilised properly, we recommend that all staff are adequately trained in wearing PPE (for example, through fit-testing of respirator masks

and training of proper PPE donning/doffing technique). If sourcing stock proves to be truly challenging, the Government should actively encourage innovative approaches to producing and/or procuring PPE by liaising with research institutions and industry as a matter of urgency. We have already seen the potential of such resourcefulness with examples such as the production of medicalgrade ventilators by Dyson and the assembly of visors by Royal Mint.^{59,60} At the same time it is important to be cautious of homemade PPE which fails to meet medical-grade specifications. For instance, one trial found that cloth masks were significantly inferior to medical-arade masks in protectina HCWs from influenza-like illnesses.⁶¹ If adequate PPE is still unavailable, then we should consider measures to safely limit the contact of our frontline staff with confirmed COVID-19 patients. Such an approach for ward settings has been proposed by the British Thoracic Society and Royal College of Physicians, termed 'SPACES' (Sharing Patient Assessments Cuts Exposure for Staff).⁶² Additionally, in exceptional circumstances of stock shortages, extended use and reuse of PPE may be necessary, as outlined in recently published PHE PPE guidance which is based on CDC and WHO guidelines.⁶³ However, there is limited data on the efficacy of such measures, and existing evidence suggests they have the potential to increase the risk of self-inoculation through contact transmission or re-aerosolisation of contaminated PPE.^{29,64–68} Therefore, any guidance on extended use or limited re-use of PPE must be complemented by appropriate strategies for training staff to minimise self-contamination.

Conclusion

Through our appraisal of the available evidence and comparison of international PPE guidance, we conclude that the concerns regarding the current PHE COVID-19 PPE advice remain warranted. We recommend further urgent revision of these guidelines to ensure sufficient protection to the NHS workforce during this pandemic.

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Address for correspondence: Dr John P Thomas, Department of Respiratory Medicine, Norfolk and Norwich University Hospital, Colney Lane, Norwich NR4 7UY, UK. Email: drjohnpthomas@gmail.com