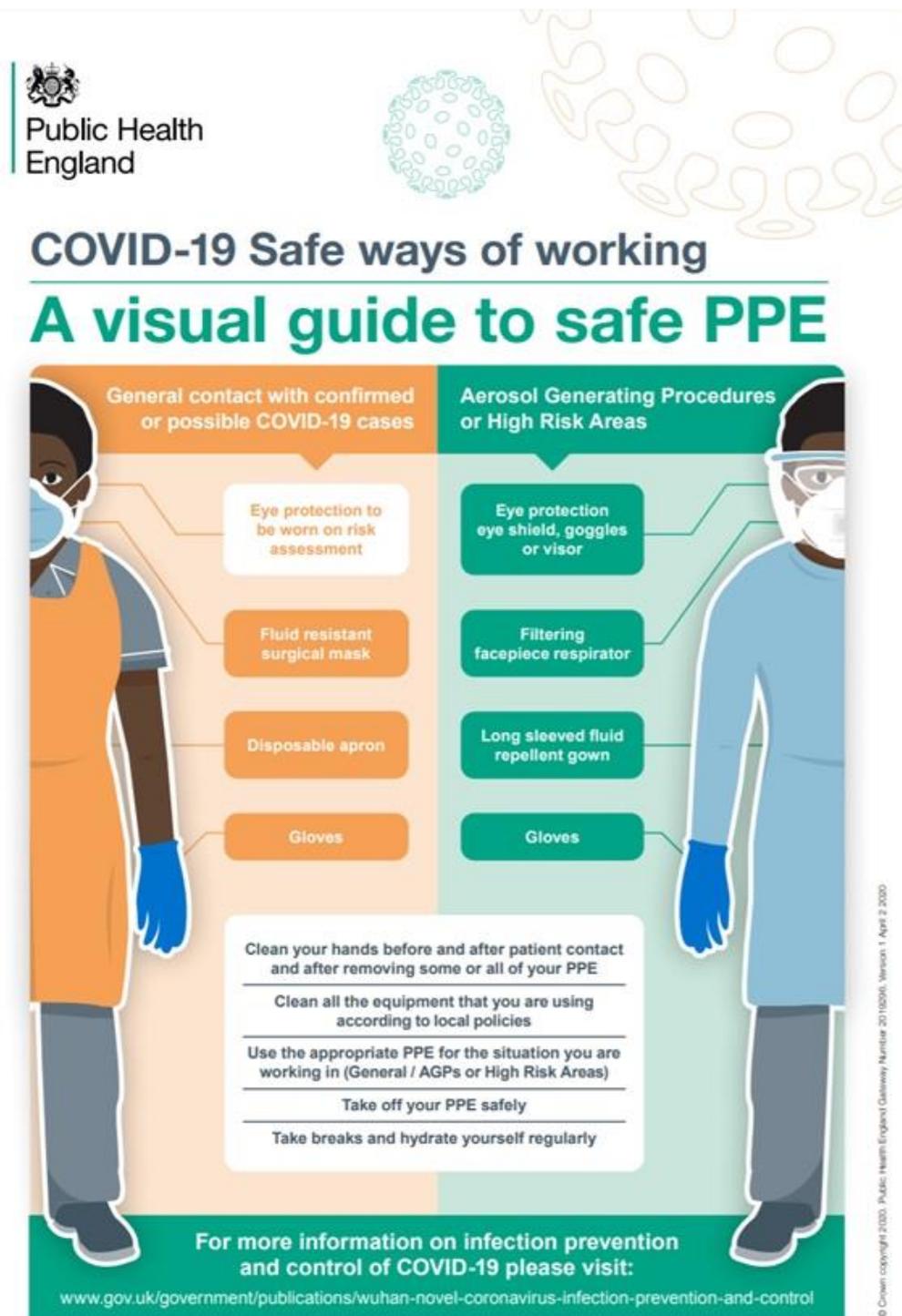


**Triaging of Respiratory Protective Equipment on the assumed risk of SARS-CoV-2 aerosol exposure in patient-facing healthcare workers delivering secondary care: a rapid review**

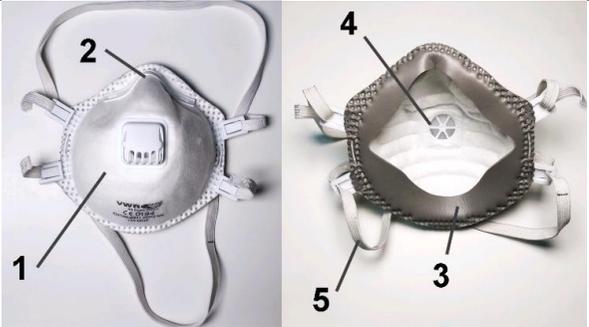
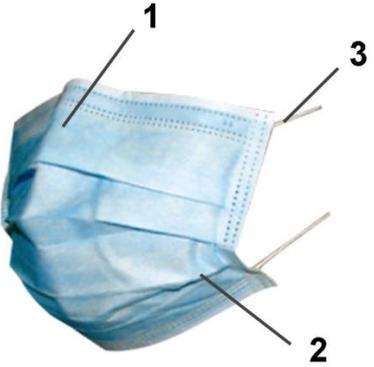
P Ramaraj, JT Super, R Doyle, C Aylwin, S Hettiaratchy. 2020.

**Appendices**

**Appendix 1 – HMG’s PPE Guidance as at 17<sup>th</sup> April 2020**



## Appendix 2 – An explanation of international nomenclature and testing standards surrounding respirators and surgical facemasks

Key Features							
	<p>(1) Dense polymer material (usually melt blown polypropylene) with sub-micron pores</p> <p>(2) Moulded, countered shaping or metal nose clip for close fit with face</p> <p>(3) Polymer lip creating airtight seal with skin</p> <p>(4) Exhaust valve (optional) to reduce exhalation pressure</p> <p>(5) Adjustable straps for close face fit</p>		<p>(1) Dense polymer material (usually melt blown polypropylene) with micron sized pores</p> <p>(2) Pleated, expandable form for loose coverage of all face shapes</p> <p>(3) Non-adjustable elastic straps/ fabric straps for user to tie to desired length</p>				
Relevant European standards	EN 149:2001		EN 14683:2019, ISO 22609:2004, ISO 10993				
Specific models +	European	FFP1,	FFP2	FFP3	Type I	Type II	Type IIR
	USA	N95	N99	N100	Level 1	Level 2	Level 3
Aerosol leakage	Requires seal with skin and a total inward leakage of air of <5%		No seal with skin and protection against leakage				
Particle filter efficiency*	99% of 0.6 um mean diameter particles <b>to wearer</b>		98% of 3 um mean diameter particles <b>through filter material.</b> <b>No testing for wearer exposure.</b>				

\*Highlighted are most relevant for this review as the models supplied by the NHS for HCW protection

\*Efforts have been made to harmonize difference test methods to compare filter efficiency

### **Appendix 3 – PICO Strategy and PubMed/MEDLINE Search Strand**

Population: patient-facing healthcare workers in secondary inpatient care.

Intervention: surgical masks (including international nomenclature: medical mask, fluid-repellent surgical mask).

Comparison: respirators (defined as FFP3, FFP2, FFP1, N95, N99 or N100 to include international nomenclature during a global crisis and variation of legal testing standards internationally).

Outcomes: SARS-CoV-2 protection (this ensured a broad outcome in terms of parameters used to define “protection” but maintained a SARS-CoV-2 specific search).

PubMed search strand:

*("respirator" AND/OR "surgical mask" AND/OR mask AND/OR FFP\* AND/OR "FFP3" AND/OR PPE AND/OR "personal protective equipment") AND ("viral" AND/OR "infection" AND/OR "respiratory" AND/OR "COVID" AND/OR "COVID-19" AND/OR "coronavirus" AND/OR "SARS-CoV-2")*

## Appendix 4 – Full appraisal of all included studies using the appropriate CASP checklist

## Laboratory studies

Author	Study Design	Question	Mask/Respirator	Pathogen/Particle	Findings	Appraisal
Lee SA., et al. 2016. <sup>21</sup>	Human (N = 30)	Do respirators with higher filtration efficiencies provide greater protection when human subjects don the respirators?	1x FFP2, 1x FFP3 with 3x FRSM	NaCl	<ol style="list-style-type: none"> <li>The respirators provided between 11.5 to 15.9 times the protection of the FRSMs, suggesting that FRSMs are not a good substitute for respirators when concerns exist about airborne transmission of bacterial and viral pathogens.</li> <li>18.3% of the tested FFP2 respirators had PFs &lt;10, and 41.7% of the tested FFP3 respirators had PFs<sup>1</sup> &lt;20, indicating that the European standard for APF of 10 for FFP2 respirators and 20 for FFP3 respirators may overestimate the actual protection offered by these respirators against particles in the size range of 0.093–1.61 µm.</li> </ol>	<ul style="list-style-type: none"> <li>+ Standardised and peer reviewed method of testing.</li> <li>+ Controlled for age, sex, facial anatomy and hair, fit testing, smoking, previous respiratory use, allergies, cardiovascular/respiratory illness, and drinking within 30 mins of testing.</li> <li>+ Standardised for loss of particles into the sampling devices' lines prior to detection.</li> <li>- No mention of randomisation or blinding.</li> <li>- Small study population (N = 30), narrow age range (18 – 24 year olds), all of Taiwanese origin, respirators from only two companies. Difficult to generalise to wider global population and respirators produced by other companies.</li> </ul>

<sup>1</sup> Protection Factor: a ratio of the test particle/pathogen per unit volume on the outside of the test mask/respirator compared to that on the inside, over a standardised time frame with standardised temperature, humidity, and windspeed.<sup>21</sup>

					<p>3. The protection factors of respirators against particles in the size range of 0.093–1.61 µm were not size dependent. The size ranges of viral and bacterial particles fall into this size range, and they are expected to have similar PFs.</p> <p>4. Correct fit is an important consideration.</p>	
Health Safety Laboratory. 2008. <sup>6</sup>	Dummy & Human	What is the contribution of surgical masks in the protection against any residual aerosol risk of airborne particles generated from a simulated sneeze (including those that contain live, infectious influenza virus)?	<p>11x FFP (2x FFP1) (4x FFP2) (5x FFP3)</p> <p>8x FRSM (5x Tie) (3x Strap)</p>	NaCl & Live <i>Influenza A</i>	<p>1. There is a lack of scientific evidence regarding the protective effect of surgical masks against infectious aerosols (with reference to worker safety) to support HSE's pandemic planning activities.</p> <p>2. Surgical masks will achieve a mean reduction factor<sup>2</sup> of 2 against a</p>	<p>+ Controlled for <i>Influenza A</i> in bioaerosol challenge by calculating reduction factor.</p> <p>+ Standardisation of inert aerosol generation with particle size of human cough.</p> <p>+ Standardisation of fit factors for FFP respirators</p> <p>- No mention of blinding.</p> <p>- Unable to fit FFP respirators to the Sheffield dummy, therefore FFP respirators not tested with live viable <i>Influenza A</i>.</p> <p>- Inert testing on one human does not control for different face anatomy</p>

$$^2 \text{Reduction Factor} = \frac{\text{Particle concentration outside the facepiece}}{\text{Particle concentration inside the facepiece}}$$

					<p>simulated sneeze of inert airborne particles.</p> <p>3. The efficiency of FRSMs against inert airborne particles is greatly reduced compared to respirators.</p> <p>4. 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.</p> <p>5. Surgical masks provide a 6-fold reduction in exposure to live, infectious <i>Influenza A</i> virus. By contrast, properly fitted respirators provide at least a 100-fold reduction.</p>	<p>- Bioaerosol challenge from only one distance (70cm).</p> <p>- Does not account for environmental factors on <i>Influenza A</i> transmission such as humidity, temperature, ventilation.</p>
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He X., et al. 2014. <sup>22</sup>	Dummy	How does breathing frequency affect N95 and FRSM performance against viral and other submicron particles?	1x N95, 1x FRSM	NaCl	<ol style="list-style-type: none"> <li>1. The N95 filtered 13.4 times more particles than the FRSM at the highest Mean Inspiratory Flow (MIF) and 108.2 times more particles at the lowest MIF. (N95 <math>P_{\text{filter}} = 0.72\%</math> at 85 L/min (MIF); <math>0.05\%</math> at 15 L/min (<math>p &lt; 0.0001</math>). FRSM: <math>P_{\text{filter}} = 9.65\%</math>; MIF = 85 L/min; <math>P_{\text{filter}} = 5.41\%</math>, MIF = 15 L/min, (<math>p &lt; 0.0001</math>)).</li> <li>2. The FRSM allowed the Total Inspiratory Leakage (TIL) of 18.9 times more particles at 10 breaths/minute and 14.9 times more at 30 breaths/min than the N95. N95: (10 breaths/min, mean TIL = 1.22%; 30 breaths/min, mean TIL = 1.73% (<math>p &gt; 0.0025</math>)). FRSM: (10 breaths/min, mean TIL = 23.1%; 30 breaths/min, mean TIL = 25.7%) (<math>p &lt; 0.0025</math>)).</li> </ol>	<ul style="list-style-type: none"> <li>+ measurements controlled for NaCl concentrations higher than environmental concentrations of virus.</li> <li>+ utilised reliable and reproducible parameters.</li> <li>+ controlled for temperature and humidity.</li> <li>+ randomised independent variables to reduce risk of bias.</li> <li>- Only one model of respirator and one mask.</li> <li>- RPE removed after 20 tests, so later tests will be impacted by NaCl loading/"clogging".</li> <li>- RPE taped to mannequin for <math>P_{\text{filter}}</math> testing.</li> <li>- Unclear exactly how many tests were performed.</li> </ul>
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## Clinical trials

Author	Setting	Participants	Interventions	Findings	Appraisal
Radonovich, et al. 2019. <sup>23</sup>	7 US medical centres; outpatient setting	2862 randomized participants	N95 vs FRSM	1. N95 respirators vs FRSM as worn by participants in this trial resulted in no significant difference in the incidence of laboratory-confirmed influenza	<p>Randomised Control Trial.</p> <ol style="list-style-type: none"> <li>1. Adherence to infection control was evaluated throughout the study.</li> <li>2. Exposure to patients, co-workers and others with respiratory illness was self-reported in a diary.</li> <li>3. Participants were recruited from the outpatient setting</li> <li>4. Testing methodology - only tested using RT-PCR when symptomatic thus may have missed asymptomatic individuals, as well as 2 random swabs during the study.</li> <li>5. Only assumed that 65% participants were vaccinated against the influenza virus (they did not collect this data) yet they were measuring infection by influenza.</li> <li>6. No protective equipment was worn outside the workplace.</li> <li>7. Only N95 and FRSM masks were tested so authors warn against making generalisations about effectiveness.</li> </ol>

Loeb, et al. 2009. <sup>24</sup>	8 hospitals in Ontario, Canada: EDs, AMUs and Paediatric units	446 nurses	N95 vs FRSM	<p>There were no significant differences between the FRSM and N95 respirator groups in respiratory syncytial virus type B, metapneumovirus, parainfluenza 3, rhinovirus-enterovirus, or coronaviruses.</p> <p>Only 12% of lab confirmed viral infections had fever.</p> <p>No difference between FRSM and targeted N95 use.</p>	<ol style="list-style-type: none"> <li>1. The study was abandoned at the start of the 2009 influenza pandemic when all nurses were advised to wear N95.</li> <li>2. Self-reporting of data during 2x weekly questionnaires.</li> <li>3. Only tested if self-reported as symptomatic and sent a test to perform themselves.</li> <li>4. No mention of vaccination history.</li> <li>5. Audits conducted were done via telephone to assess whether patients were admitted to the wards with febrile respiratory illness/influenza. If so, an auditor went into the hospital to observe the use of the protective equipment.</li> <li>6. Only one room entry was recorded per observation.</li> <li>7. Emergency departments were not audited.</li> <li>8. Co-workers and families were not surveyed as a source of infection.</li> <li>9. Hand hygiene, use of gloves and gowns was not monitored.</li> </ol>
MacIntyre, et al. 2013. <sup>25</sup>	19 hospitals in Beijing, China: EDs	1,669 hospital-based workers: nurses, doctors, or ward clerks	Targeted N95 use Vs Continuous N95 use vs FRMS	Rate of CRI (2 or more respiratory symptoms or one respiratory symptom and a systemic symptom) was highest in medical mask (17%) vs targeted N95 (11.8%) and lowest in the continuous N95 arm (7.2%) (P < 0.05).	<p>Randomised Control Trial.</p> <ol style="list-style-type: none"> <li>1. Asymptomatic patients were not tested.</li> <li>2. Vaccination status was assessed.</li> <li>3. The study was only carried out for 4 weeks, followed by one week of non-mask wearing to allow for incubation periods.</li> </ol>

				Rates of laboratory-confirmed respiratory virus infections were low and not significant between the groups.	4. Self-reported data using pocket diary (previously validated method of reporting). 5. Only conducted for 4 weeks - limitation due to seasonality of different respiratory pathogens.
MacIntyre, et al. 2014. <sup>26</sup>	Healthcare workers based in hospitals in Beijing, China	1441 nurses or doctors, working full time in the emergency department or respiratory wards.	N95 vs FRSM	N95 respirators were significantly protective ( $p < 0.05$ ) against bacterial colonization, co-colonization and viral-bacterial co-infection, compared with FRSM users and the control group.  Dual respiratory virus or bacterial-viral co-infections can be reduced by the use of N95 respirators.  FRSMs had no significant efficacy against any outcome compared to control.	Randomised Control Trial. 1. Participants only tested if symptomatic. 2. Participants self-reporting symptoms, hours worked, and masks worn. 3. The study was only conducted for 4 weeks. 4. No information regarding vaccination history is mentioned. 5. Information about potential infection outside of working from co-workers or family was not considered.

Ng, et al. 2020. <sup>27</sup>	Inpatient HCWs	41 HCWs exposed to a COVID-19 positive patient	FRSM vs N95	<p>None of the health care workers tested positive (PCR) for COVID-19 or experienced any symptoms.</p> <p>85% of the staff were exposed to AGPs whilst wearing FRSM. The other 15% wore N95.</p> <p>There is no evidence that N95 is superior to FRSM.</p>	<p>Case report.</p> <ol style="list-style-type: none"> <li>1. All patients were swabbed on the same day, ranging from 1-5 days after last exposure to the patient.</li> <li>2. Methodology is poorly reported. Retrospective study design. Small study - only 41 participants with exposure to one single COVID-19 patient. No power calculation.</li> <li>3. Definition of 'exposure' was an AGP of at least 10 minutes, within 2 metres of the patient.</li> <li>6. Conclusion is not based on the results- no evidence to suggest N95 superior to surgical mask does not infer that a N95 and FRSM have the same efficacy.</li> </ol>
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Loeb, et al. 2004. <sup>28</sup>	2 hospitals in Ontario: coronary care units and ICUs with SARS patients	43 nurses	Surgical masks vs N95	<p>Either droplet or limited aerosol generation are the means of transmission to healthcare workers (SARS).</p> <p>Almost 80% reduction in risk for infection for nurses who consistently wore masks (either surgical or N95).</p> <p>When we compared use of N95 to use of surgical masks, the relative SARS risk associated with the N95 mask was half that for the surgical mask; however, because of the small sample size, the result was not statistically significant.</p> <p>Our data suggest that the N95 mask offers more protection than a surgical mask.</p>	<p>Retrospective cohort.</p> <ol style="list-style-type: none"> <li>1. Use of PPE determined by reviewing documentation and retrospective interviews, may be inaccurate/recall bias.</li> <li>2. No power calculation.</li> <li>3. Subjective measurements of exposure.</li> <li>4. No comment on blinding outcome assessors to exposure (ie did the interviewers know whether the nurse had been SARS +ve?).</li> <li>5. Confounders- any other possible exposure of nurses? Bank shifts at other hospitals? Contact in the break room/canteen?</li> <li>6. Precision of some results questionable- large CIs and p-values (eg in manual ventilation RR).</li> </ol>
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