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Gender and ethnicity biases in respiratory protective equipment for healthcare workers in the COVID-19 pandemic

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Gender and ethnicity biases in respiratory protective equipment for healthcare workers in the Covid-19 pandemic

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Dr Clarissa Carvalho was the study lead, lead researcher and writer of this article. Dr Jan Schumacher, Dr Paul Greig and Dr Kariem El-Boghdadly contributed to the design of the study, the results interpretation and the writing and review of the manuscript. Dr Danny Wong and Dr Paul Greig reviewed the results and conducted the statistical analysis. Dr Danny Wong also contributed to the interpretation of the results and the writing of the manuscript.

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The lead author, Dr Clarissa Carvalho, affirms that the manuscript is an honest, accurate and transparent account of the study reported. No important aspects of the study have been omitted and there were no discrepancies from the study as planned.

Ethical Approval: This study was assessed by the Research & Development Lead and the Clinical Governance Lead and was deemed exempt from ethical review as it met the criteria for a service evaluation. It was registered as a service evaluation with Guy's and St Thomas' NHS Foundation Trust (ID 10918).

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Sponsor: The study sponsor was responsible for the management and progression of the study

Statement of Independence of Researchers from funders: Each researcher worked independently of funding. No funding was required for this study.

Patient and Public Involvement: No patient or public involvement in this study.

Abstract

Objective:

To describe success rates of respiratory protective equipment (RPE) fit testing and factors associated with achieving suitable fit.

Design:

Prospective observational study of RPE fit testing according to health and safety, and occupational health requirements.

Setting:

A large tertiary referral UK healthcare facility.

Population:

1182 healthcare workers undergoing quantitative fit testing.

Main outcome measures:

Quantitative fit test success (pass/fail), and the count of tests each participant required before successful fit.

Results:

Healthcare workers were fit tested a median (interquartile range [IQR]) 2 (1–3) times before successful fit was obtained. Males were tested a median 1 (1–2) times, while females were tested a median 2 (1–2) times before a successful fit was found. This difference was statistically significant ($p < 0.001$). Modelling each fit test as its own independent trial ($n = 2359$) using multivariable logistic regression, male healthcare workers were significantly more likely to find a well-fitting respirator and achieve a successful fit on first attempt in comparison to females, after adjusting for other factors (adjusted odds ratio [OR] = 2.07, 95% confidence interval [CI]: 1.66–2.60, $p < 0.001$). Staff who described their ethnicity as White were also more likely to achieve a successful fit compared to staff who described their ethnicity as Asian (OR = 0.47, 95% CI: 0.38–0.58, $p < 0.001$), Black (OR = 0.54, 95% CI: 0.41–0.71, $p < 0.001$), Mixed (OR = 0.50, 95% CI: 0.31–0.80, $p = 0.004$), or Other (OR = 0.53, 95% CI: 0.29–0.99, $p = 0.043$).

Conclusions

Male and white ethnicity healthcare workers are more likely to achieve RPE fit test success. This has broad operational implications to healthcare services with a large female and Black, Asian and minority ethnic groups population. Fit-testing is imperative in ensuring RPE effectiveness in protecting healthcare workers during the Covid-19 pandemic and beyond.

Article Summary

This is a prospective observational study looking at fit testing of respiratory protective equipment (RPE) as per Health & Safety and Occupational Health requirements at a large tertiary referral teaching hospital in Central London.

1182 healthcare workers underwent fit testing. Our data demonstrates that male and white ethnicity healthcare workers were significantly more likely to achieve a successful fit and required fewer fit tests.

This data is important as the demographic of the healthcare workforce does not predominantly consist of white male workers. The NHS as a whole consists of 77% female healthcare workers and up to 40% of the workforce identify as Black, Asian or Minority Ethnic (BAME) in London. As many healthcare facilities fail to formally fit test their workforce this leaves a large proportion of staff vulnerable to inadvertent exposure to Covid-19. This proportion of staff will be mainly female and from BAME backgrounds. Unfortunately the review of healthcare worker deaths has shown that a disproportionately high number were from BAME backgrounds. A number of reasons have been postulated but inadequate RPE fit was not one of them until now. The design of RPE has not changed much since the 1960s when it was based on face panels created using volunteers from the US Air Force in 1967-68. The Certification and assessment of new RPE is also based on the anthropometric data collected from these volunteers. As the US Air Force consisted predominantly of white men of a certain height and stature it is clear to see why these masks would fail to fit the average female healthcare worker, particularly those of BAME backgrounds. Fit-testing is imperative in ensuring healthcare worker safety when

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3 facing the Covid-19 pandemic. Future work on RPE designs must take in to BAME
4 and female Healthcare staff.
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8 **Strengths & Weaknesses**

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- 11 • Single centre study
 - 12 • Demographics of the workforce observed in our study accurately reflects
13 those of the NHS workforce in London, UK. But may not reflect the rest of the
14 country.
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 - 16 • A large number of fit tests and participants were observed
 - 17 • Each individual did not test on every model of face mask
 - 18 • Anthropometric measurements were not collected
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Gender and ethnicity biases in respiratory protective equipment for healthcare workers in the Covid-19 pandemic

Carvalho CYM, Schumacher J, Greig P, Wong DJN, El-Boghdadly K

Introduction

The Covid-19 pandemic has dramatically affected the delivery of healthcare. Many routine procedures that produce potentially infectious aerosols were previously conducted regularly without protective face coverings, but this is no longer appropriate during the pandemic. Preventing aerosolised spread of infection from patients to healthcare workers relies on effective use of respiratory protective equipment (RPE), including tight-fitting filtering facepiece (FFP) respirators.[1-3] Protection of healthcare workers with suitable RPE must be prioritised as their exposure places them at high risk of contracting infection with Covid-19.[4-5] Critical shortages in the availability of adequate RPE have been highlighted, with healthcare workers from Black, Asian and minority ethnic (BAME) groups being disproportionately affected.[6]

The effectiveness of a respirator depends on a good fit on the healthcare workers' face.[7-9] Although respirators are designed to fit the majority of individuals, no single respirator can provide a universal fit.[8-11] The fit of RPE has been suggested to be unsuitable for women and BAME healthcare workers, however there remains insufficient objective data demonstrating this disparity. There is therefore a need to assess the ethnodemographic impact on suitability of respirators provided by employers. The purpose of this observational study is therefore to determine if

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3 ethnicity and gender are factors in the suitability of respirators in healthcare workers
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5 exposed to patients with Covid-19.
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11 12 **Methods**

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16 We conducted a prospective observational study examining fit testing results by
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18 ethnicity and gender from staff in a central London teaching hospital and designated
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20 Covid-19 centre. This study was deemed exempt from ethical review as it met the
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22 criteria for a service evaluation and was registered as a service evaluation with Guy's
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24 and St Thomas' NHS Foundation Trust (ID 10918). No patients or members of the
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26 public were included in this study. All members of the workforce in patient-facing roles
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28 were eligible to attend the fit testing clinic. We included healthcare workers who
29
30 were eligible to attend the fit testing clinic. We included healthcare workers who
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32 underwent quantitative fit tests (QNFT) only. Exclusion criteria were healthcare
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34 workers who were not in patient-facing roles, those unable to undertake the fit testing
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36 procedure (e.g. unable to remove head wear, remove facial hair, or unable to perform
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38 the procedure), those that underwent only qualitative fit testing, or those unwilling to
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40 participate in fit testing.
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46 Fit testing data were collected between 3rd February and 3rd July 2020 and included
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48 the participant's self-described gender and ethnicity in free-text. For the purposes of
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50 this study the free-text responses were mapped to the Office of National Statistics
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52 categories for ethnicity as used in the UK census.[15]
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57 Fit testing was conducted by certified fit testers. Participants had to refrain from
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59 smoking one hour prior to the test, had to be clean shaven and could not wear any
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3 head wear. The QNFT involved the use of a TSI Portacount 8030 (TSI UK, High
4 Wycombe) using the standard Health and Safety Executive fit testing procedure.[15]
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10 QNFT fit test scores were dichotomised as pass or fail based on achieving an overall
11 fit factor >100. We report the overall numbers and proportions of staff who passed
12 their first fit test and grouped by self-reported gender and ethnicity. The likelihood of
13 passing the first fit test for male and female genders, and White and BAME groups
14 were compared using Pearson's Chi-squared test (without Yate's Continuity, as all cell
15 frequencies were greater than 10). Logistic regression modelling was performed using
16 each fit test as a separate observation, with the binary outcome variable defined as fit
17 test success (pass/fail), and using the following explanatory variables: gender,
18 ethnicity and mask design (disposable vs reusable). We first modelled the bivariate
19 association between the outcome variable and each explanatory variable separately,
20 and then in a multivariable model including all explanatory variables to obtain adjusted
21 odds ratio (OR) estimates. Mask designs were specified in our models as categorical
22 variables and were compared against a reference design A, which was our most
23 widely-tested disposable mask design. All analyses were performed in Microsoft Excel
24 (Microsoft Corporation, Redmond, WA, USA) and R version 3.5.2 (R Foundation for
25 Statistical Computing, Vienna, Austria). Only records with complete data for the
26 variables modelled (gender, ethnicity, mask design, outcome of fit test) were analysed.
27 Continuous variables are reported as mean (standard deviation [SD]) for normally- or
28 uniformly-distributed data, or median (interquartile range [IQR]) for data with skewed
29 distributions. For discrete variables, numbers and proportions are reported. Non-
30 parametric data were compared with the Mann-Whitney U test, and the students t test
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was used for parametric data. A p value of <0.05 was considered statistically significant.

Results

A total of 1443 healthcare workers underwent fit testing during the study period. After exclusions were applied, a total of 1182 records were available for analysis. The gender and ethnicity breakdowns for the staff members are described in Table 1.

Table 1: Gender and Ethnicity of the staff that underwent quantitative fit testing

	<i>n (%)</i> <i>(n = 1182)</i>
Gender	
Male	365 (30.9%)
Female	817 (69.1%)
Ethnicity	
White	557 (47.1%)
Asian	383 (32.4%)
Black	175 (14.8%)
Mixed	39 (3.3%)
Other	28 (2.4%)

Each staff member was fit tested a median (IQR) 2 (1–3) times before a successful fit was found. Males were tested a 1 (1–2) times and females 2 (1–2) times before a successful fit was found (p <0.001).

There were 2359 independent quantitative fit tests modelled using logistic regression (Table 2).

Table 2: Logistic regression models. (D) = disposable mask; (R) = reusable mask.

Dependent outcome: Successful fit		Fail n (%)	Pass n (%)	OR (univariable)	OR (multivariable)
Gender	Female	709 (80.8)	1007 (67.9)	-	-
	Male	168 (19.2)	475 (32.1)	1.99 (1.63-2.44, p<0.001)	2.07 (1.66-2.60, p<0.001)
Ethnicity	White	301 (34.3)	721 (48.7)	-	-
	Asian	357 (40.7)	478 (32.3)	0.56 (0.46-0.68, p<0.001)	0.47 (0.38-0.58, p<0.001)
	Black	154 (17.6)	198 (13.4)	0.54 (0.42-0.69, p<0.001)	0.54 (0.41-0.71, p<0.001)
	Mixed	42 (4.8)	51 (3.4)	0.51 (0.33-0.78, p=0.002)	0.50 (0.31-0.80, p=0.004)
	Other	23 (2.6)	34 (2.3)	0.62 (0.36-1.08, p=0.083)	0.53 (0.29-0.99, p=0.043)
RPE mask model	Design A (D)	63 (7.2)	307 (20.7)	-	-
	Design B (D)	9 (1.0)	5 (0.3)	0.11 (0.03-0.34, p<0.001)	0.11 (0.03-0.35, p<0.001)
	Design C (D)	159 (18.1)	84 (5.7)	0.11 (0.07-0.16, p<0.001)	0.09 (0.06-0.14, p<0.001)
	Design D (D)	38 (4.3)	33 (2.2)	0.18 (0.10-0.30, p<0.001)	0.16 (0.09-0.27, p<0.001)
	Design E (D)	87 (9.9)	45 (3.0)	0.11 (0.07-0.17, p<0.001)	0.10 (0.06-0.16, p<0.001)
	Design F (D)	47 (5.4)	43 (2.9)	0.19 (0.11-0.31, p<0.001)	0.18 (0.11-0.30, p<0.001)
	Design G (R)	3 (0.3)	6 (0.4)	0.41 (0.11-1.98, p=0.216)	0.47 (0.12-2.33, p=0.305)
	Design H (R)	2 (0.2)	7 (0.5)	0.72 (0.17-4.90, p=0.684)	0.64 (0.14-4.50, p=0.592)
	Design I (R)	14 (1.6)	103 (7.0)	1.51 (0.83-2.91, p=0.193)	1.70 (0.93-3.31, p=0.096)
	Design J (R)	214 (24.4)	233 (15.7)	0.22 (0.16-0.31, p<0.001)	0.24 (0.17-0.34, p<0.001)
	Design K (R)	86 (9.8)	394 (26.6)	0.94 (0.66-1.34, p=0.735)	0.97 (0.67-1.39, p=0.863)
	Design L (R)	152 (17.3)	218 (14.7)	0.29 (0.21-0.41, p<0.001)	0.29 (0.21-0.41, p<0.001)
	Others	3 (0.3)	4 (0.3)	0.27 (0.06-1.42, p=0.095)	0.29 (0.06-1.51, p=0.112)

Table 3: Conditional probabilities of successful first attempt fit by gender and ethnicity.

		Failed first fit attempt	Passed first fit attempt	Probability of passing first fit attempt (%)
Gender	Ethnicity			
	White	206	163	44.2
	Asian	164	97	37.2
	F Black	78	65	45.5
	Mixed	23	9	28.1
	Other	7	5	58.3
M	White	80	108	57.4
	Asian	66	56	45.9
	Black	15	17	53.1
	Mixed	3	4	57.1
	Other	9	7	43.8

Male healthcare workers were significantly more likely to pass a fit test and achieve a successful fit test on first attempt compared with females. Staff who describe their ethnicity as White were also more likely to achieve a successful fit test compared to staff who describe their ethnicity as Asian, Black, mixed, or Other. There was wide variation in the likelihood of achieving successful mask fit between the different mask

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3 designs. Mask designs demonstrated variable performance in terms of obtaining a
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5 successful fit (Table 2).
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10 11 **Discussion**

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15 We investigated the suitability of respirators worn by healthcare workers and report
16
17 new evidence that indicates lower RPE fit testing success rates among BAME and
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19 female healthcare workers.[3,4] This may indicate that certain groups may be at
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21 particular risk from Covid-19 infection in the workplace due to unsuitable respiratory
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23 protection.
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29 The demographic diversity in our data may differ to the NHS England workforce.
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31 However, it is not dissimilar to the demographics expected of a healthcare facility in
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33 central London and so it is representative of London healthcare workers. BAME
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35 healthcare workers may account for 19.8% of the NHS workforce in England but ethnic
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37 minority healthcare workers demonstrate a higher representation in London (44.9%)
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39 with 1.7% identifying as having a mixed ethnic background.[13] Failure of RPE to
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41 protect BAME healthcare workers affects a significant proportion of the NHS
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43 workforce.
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50 Our data suggests that there could be biases in design and certification of respirators.
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52 Respirator design has historically focused on the fit for individuals from the US Air
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54 Force in the 1967-68.[10,12] However, it is unclear if the anthropometric data
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56 collected was even representative of the workforce in the 1960s and 70s as the US
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58 Air Force had clear height and weight restrictions, and consisted mainly of men.[12]
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3 Population demographics have changed drastically in the UK and US since the 1960s,
4 with increased numbers of women and people from ethnic minorities in all workplaces.
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6 This historical data is therefore unlikely to reflect current workforce demographics.
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13 Recognising that the standard fit panels may no longer be appropriate, the National
14 Institute for Occupational Safety and Health (NIOSH) conducted a new survey of the
15 US work force in 2001.[17] 4026 subjects from 41 different sites in, eight states were
16 recruited, and new fit moulding panels were proposed based on the anthropometric
17 data collected.[17] However, the ethnic groups described in this study differ from the
18 UK. The demographics of the workforce describes one third of the population as
19 Hispanic and specifically categorises the ethnicities as White, African American,
20 Hispanic and Other.[12,17] However, the largest ethnic group after White British in
21 England and Wales is “White other”, followed by Asian – Indian, Asian – Pakistani,
22 Black – African and Asian other.[16] Although NIOSH suggest their data can be used
23 as a starting point for design and certification as the US population is ethnically
24 diverse, the US data may not map accurately to the ethnic makeup of the UK
25 healthcare workforce. Every individual has different features which vary by gender,
26 ethnicity and even occupational role.[14] Face length is a key feature in respirator fit
27 and this has been shown to vary significantly across ethnic and gender groups.[14]
28 For example, anthropometric data shows statistically significant differences in width
29 and face and lip length between African Americans and White Americans.[14] A
30 sample of African Americans and Hispanic individuals in the US workforce were found
31 to have up to face lengths 2.7 and 2.8 mm longer than White Americans.[14] Prior to
32 Covid-19 most respirators were used in industrial applications such as construction.
33 Construction workers are more likely to be male than healthcare staff, and have
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3 different facial features, including longer noses.[14] Gender has also been shown to
4 be a major determinant in facial differences and measurements. Nine out of 10 facial
5 measurements vary by gender with the female face being significantly smaller than
6 the male face.[14] This is of relevance to respirator fit in healthcare workers as 77%
7 of the NHS workforce is female.
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17 Future respirator design should consider the facial characteristics of the demographic
18 of the workforce. Face panels consisting of a true representation of female and BAME
19 healthcare workers could help improve respirator design and improve safety when
20 caring for Covid-19 patients. Out-dated fit panels used in the design and certification
21 of the respirators demonstrate the institutional gender and racial biases in respirator
22 fit and must be addressed in order to protect BAME and female staff.
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33 Use of facial anthropometric data representing the current demographics of the
34 workforce is not only important in the design of RPE, it can be used to guide
35 procurement strategies for the ongoing pandemic. For example, females have on
36 average smaller faces so looking at the different proportions of female versus male
37 healthcare workers can guide what proportion of the procured respirators should be
38 smaller versus large.
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49 Examining the shape and measurements of the respirator in comparison to a face
50 panel representing the workforce could help decision making in procurement. These
51 techniques using facial anthropometric data representative of the workforce and
52 observing the success or fail rate of different respirator designs in each ethnic or
53 gender group could help with the decision-making process of which respirators to
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3 stock. Guiding procurement processes can prevent excesses of poorly sized
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5 respirators and shortages of the correct sizes.
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10 However, even if the correct respirator for the demographic of the workforce was
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12 sourced, supply and demand issues of RPE early in the Covid-19 pandemic meant
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14 healthcare facilities could not rely upon a steady supply of any single preferred
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16 respirator. Every respirator has a different design and fit, therefore individuals should
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18 be fit tested on the respirator model they don prior to patient interactions.[8,15] The
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20 multiple changes in respirator models mean healthcare workers must be repeatedly fit
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22 tested on the new models as supplies change. As healthcare facilities were
23
24 overwhelmed with the need to fit test staff repeatedly on different masks many adopted
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26 an approach to fit check only.[9] Our data demonstrates that respirators have a
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28 variable success rate on initial fit test. For example, Design J did not suitably fit 24.4%
29
30 of our staff. Some studies have demonstrated a fail rate as high as 78% when a
31
32 respirator is used without fit testing.[10] Failure to fit test may leave a significant
33
34 proportion of staff inadequately protected against Covid-19 and according to our data
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36 it is mixed ethnicity and Asian female healthcare workers who are at greatest risk.
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43 **Limitations**

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46 This was a single centre, single city study. The demographics of our data is
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48 representative of healthcare facilities in the London however further data should be
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50 collected to extrapolate the results to other areas.
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53 A large number of respirators were observed in this study and each individual did not
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55 test on every model. Increased data is required to evaluate the efficacy of each
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57 model.
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Conclusion

Respirator design and certification may be biased towards fitting a demographic that is not reflective of the current healthcare workforce. This could leave many healthcare workers vulnerable as they struggle to fit into a mask not designed for their faces. Lack of design consideration and supply issues could be a dangerous combination for healthcare staff as they rely upon the protection of a properly fitted respirator to reduce the risk of infection transmission whilst caring for patients with Covid-19.

Further research into the design and fit of respiratory protective equipment must consider the demographic of the healthcare workforce as we cannot rely on anthropometric data that represents only one section of the workforce. Creating new fit panels that accurately represent female workers and the ethnically diverse healthcare workforce is an essential first step towards designing well-fitting respirators. In the meantime, it is important to recognise that no one mask will fit all staff. [8-11,15] Therefore the focus should be on employers stocking a suite of RPE, so that a diverse workforce has the best chance of finding a respirator of appropriate fit.

Ensuring fit-testing and keeping adequate stock of a variety of respirator models can help maintain the safety of the whole workforce but future research should focus on the design of respirators for BAME and female healthcare workers.





References

1. Livingston E, Desai A, Berkwits M. Sourcing Personal Protective Equipment During the COVID-19 pandemic. *JAMA* 2020; 323:1912-1914
2. Public Health England. Guidance - Covid-19 Personal Protective Equipment 2020 <https://www.gov.uk/government/publications/wuhan-novel-coronavirus-infection-prevention-and-control/covid-19-personal-protective-equipment-ppe>
3. The Lancet. Editorial - COVID-19: Protecting health-care workers. March 2020.
<http://www.sciencedirect.com/science/article/pii/S0140673620306449>
4. El-Boghdadly K, Wong DJN, Owen R, et al. Risks to healthcare workers following tracheal intubation of patients with COVID-19: a prospective international multicentre cohort study. *Anaesthesia* June 2020; 75: 1437-1447
5. Cook T, Kursumovic E, Lennane S. Exclusive: Deaths of NHS Staff from COVID-19 analysed. April 2020 <https://www.hsj.co.uk/exclusive-deaths-of-nhs-staff-from-covid-19-analysed/7027471.article>

- 1
2
3 6. Amnesty International. UK among the highest COVID-19 healthcare
4 worker deaths in the world 2020. [https://www.amnesty.org.uk/press-](https://www.amnesty.org.uk/press-releases/uk-among-highest-covid-19-health-worker-deaths-world)
5
6 releases/uk-among-highest-covid-19-health-worker-deaths-world
7
8
9
- 10
11
12 7. British Medical Association. BMA survey reveals almost half of doctors
13 have relied upon donated or self-bought PPE and two thirds still don't feel
14 fully protected 2020. [https://www.bma.org.uk/bma-media-centre/bma-](https://www.bma.org.uk/bma-media-centre/bma-survey-reveals-almost-half-of-doctors-have-relied-upon-donated-or-self-bought-ppe-and-two-thirds-still-don-t-feel-fully-protected)
15 survey-reveals-almost-half-of-doctors-have-relied-upon-donated-or-self-
16 bought-ppe-and-two-thirds-still-don-t-feel-fully-protected
17
18
19
20
21
22
23
- 24
25
26 8. Health and Safety Executive. Fit Testing Face Masks to Avoid
27 Transmission during the coronavirus outbreak. 2020.
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
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51
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53
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55
56
57
58
59
60
60
[https://www.hse.gov.uk/coronavirus/ppe-face-masks/face-mask-ppe-](https://www.hse.gov.uk/coronavirus/ppe-face-masks/face-mask-ppe-rpe.htm)
rpe.htm
9. The Guardian. Hospitals Accused of Risking Staff Lives by Abandoning
PPE Fit Tests. March 2020.
[https://www.theguardian.com/world/2020/apr/14/nhs-hospitals-accused-](https://www.theguardian.com/world/2020/apr/14/nhs-hospitals-accused-of-risking-staff-lives-by-abandoning-ppe-fit-tests-coronavirus)
of-risking-staff-lives-by-abandoning-ppe-fit-tests-coronavirus
10. Manganyi J, Wilson K, Rees D. Quantitative respirator fit, face sizes and
determinants of fit in South African diagnostic laboratory respirator users.
Annals of Work Exposures and Health Nov 2017; 61;9:1154-1162

- 1
2
3 11. Oestenstad R, Elliot L, Beasley T. The effect of gender and respirator
4 brand on the association of respirator fit with facial dimensions. Journal of
5 Occupational and Environmental Hygiene Dec 2007;4 923-930
6
7
8
9
10
11
12 12. Bailar J, Meyer E, Pool R. Institute of Medicine: Assessment of the
13 NIOSH head-and-face anthropometric survey of US respirator users.
14 2007 pp1-108
15
16
17
18
19
20
21 13. NHS England. NHS Workforce Race and Equality Standard Report 2019.
22 [https://www.england.nhs.uk/wp-content/uploads/2020/01/wre-2019-data-](https://www.england.nhs.uk/wp-content/uploads/2020/01/wre-2019-data-report.pdf)
23 [report.pdf](https://www.england.nhs.uk/wp-content/uploads/2020/01/wre-2019-data-report.pdf)
24
25
26
27
28
29
30
31 14. Zhuang Z, Landsittel D, Benson S et al. Facial Anthropometric
32 differences among gender, ethnicity and age groups. Annals of
33 Occupational Hygiene Jun 2010; 54(4):391-402
34
35
36
37
38
39
40 15. Health and Safety Executive. Guidance on respiratory protective
41 equipment (RPE) fit testing 2019. [https://www.hse.gov.uk/respiratory-](https://www.hse.gov.uk/respiratory-protective-equipment/)
42 [protective-equipment/](https://www.hse.gov.uk/respiratory-protective-equipment/)
43
44
45
46
47
48
49 16. UK Census 2011. Ethnicity Facts and Figures [https://www.ethnicity-facts-](https://www.ethnicity-facts-figures.service.gov.uk/)
50 [figures.service.gov.uk/](https://www.ethnicity-facts-figures.service.gov.uk/)
51
52
53
54
55
56 17. American Industrial Hygiene Association. Respirator Fit Testing Methods
57 2010 ISBN 978-1-935082-24-8
58
59
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**Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0)
September 15, 2015**

Text Section and Item Name	Section or Item Description
Notes to authors	<ul style="list-style-type: none"> • The SQUIRE guidelines provide a framework for reporting new knowledge about how to improve healthcare • The SQUIRE guidelines are intended for reports that describe system level work to improve the quality, safety, and value of healthcare, and used methods to establish that observed outcomes were due to the intervention(s). • A range of approaches exists for improving healthcare. SQUIRE may be adapted for reporting any of these. • Authors should consider every SQUIRE item, but it may be inappropriate or unnecessary to include every SQUIRE element in a particular manuscript. • The SQUIRE Glossary contains definitions of many of the key words in SQUIRE. • The Explanation and Elaboration document provides specific examples of well-written SQUIRE items, and an in-depth explanation of each item. • Please cite SQUIRE when it is used to write a manuscript.
Title and Abstract	
1. Title	Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patient-centeredness, timeliness, cost, efficiency, and equity of healthcare) 
2. Abstract	<ol style="list-style-type: none"> a. Provide adequate information to aid in searching and indexing b. Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions 
Introduction	<i>Why did you start?</i>
3. Problem Description	Nature and significance of the local problem 
4. Available knowledge	Summary of what is currently known about the problem , including relevant previous studies 

5. <u>Rationale</u>	Informal or formal frameworks, models, concepts, and/or theories used to explain the problem , any reasons or assumptions that were used to develop the intervention(s) , and reasons why the intervention(s) was expected to work
6. Specific aims	Purpose of the project and of this report
Methods	<i>What did you do?</i>
7. <u>Context</u>	Contextual elements considered important at the outset of introducing the intervention(s)
8. <u>Intervention(s)</u>	a. Description of the intervention(s) in sufficient detail that others could reproduce it b. Specifics of the team involved in the work
9. Study of the Intervention(s)	a. Approach chosen for assessing the impact of the intervention(s) b. Approach used to establish whether the observed outcomes were due to the intervention(s)
10. Measures	a. Measures chosen for studying processes and outcomes of the intervention(s) , including rationale for choosing them, their operational definitions, and their validity and reliability b. Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency, and cost c. Methods employed for assessing completeness and accuracy of data
11. Analysis	a. Qualitative and quantitative methods used to draw inferences from the data b. Methods for understanding variation within the data, including the effects of time as a variable
12. Ethical Considerations	Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest
Results	<i>What did you find?</i>
13. Results	a. Initial steps of the intervention(s) and their evolution over time (e.g., time-line diagram, flow chart, or table), including modifications made to the intervention during the project b. Details of the process measures and outcome c. Contextual elements that interacted with the intervention(s) d. Observed associations between outcomes, interventions, and relevant contextual elements e. Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s) . f. Details about missing data
Discussion	<i>What does it mean?</i>
14. Summary	a. Key findings, including relevance to the rationale and specific aims b. Particular strengths of the project

<p>15. Interpretation</p>	<p>a. Nature of the association between the intervention(s) and the outcomes</p> <p>b. Comparison of results with findings from other publications</p> <p>c. Impact of the project on people and systems</p> <p>d. Reasons for any differences between observed and anticipated outcomes, including the influence of context</p> <p>e. Costs and strategic trade-offs, including opportunity costs</p>
<p>16. Limitations</p>	<p>a. Limits to the generalizability of the work</p> <p>b. Factors that might have limited internal validity such as confounding, bias, or imprecision in the design, methods, measurement, or analysis</p> <p>c. Efforts made to minimize and adjust for limitations</p>
<p>17. Conclusions</p>	<p>a. Usefulness of the work</p> <p>b. Sustainability</p> <p>c. Potential for spread to other contexts</p> <p>d. Implications for practice and for further study in the field</p> <p>e. Suggested next steps</p>
<p>Other information</p>	
<p>18. Funding</p>	<p>Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation, interpretation, and reporting</p>

Table 2. Glossary of key terms used in SQUIRE 2.0. This Glossary provides the intended meaning of selected words and phrases as they are used in the SQUIRE 2.0 Guidelines. They may, and often do, have different meanings in other disciplines, situations, and settings.

Assumptions

Reasons for choosing the activities and tools used to bring about changes in healthcare services at the [system](#) level.

Context

Physical and sociocultural makeup of the local environment (for example, external environmental factors, organizational dynamics, collaboration, resources, leadership, and the like), and the interpretation of these factors (‘sense-making’) by the healthcare delivery professionals, patients, and caregivers that can affect the effectiveness and [generalizability](#) of [intervention\(s\)](#).

Ethical aspects

The value of [system](#)-level [initiatives](#) relative to their potential for harm, burden, and cost to the stakeholders. Potential harms particularly associated with efforts to improve the quality, safety, and value of healthcare services include [opportunity costs](#), invasion of privacy, and staff distress resulting from disclosure of poor performance.

Generalizability

The likelihood that the [intervention\(s\)](#) in a particular report would produce similar results in other settings, situations, or environments (also referred to as external validity).

Healthcare improvement

Any systematic effort intended to raise the quality, safety, and value of healthcare services, usually done at the [system](#) level. We encourage the use of this phrase rather than “quality” which often refers to more narrowly defined approaches.

Inferences

The meaning of findings or data, as interpreted by the stakeholders in healthcare services – improvers, healthcare delivery professionals, and/or patients and families

Initiative

A broad term that can refer to organization-wide programs, narrowly focused projects, or the details of specific interventions (for example, planning, execution, and assessment)

Internal validity

Demonstrable, credible evidence for efficacy (meaningful impact or change) resulting from introduction of a specific intervention into a particular healthcare [system](#).

Intervention(s)

The specific activities and tools introduced into a healthcare [system](#) with the aim of changing its performance for the better. Complete description of an intervention includes its inputs, internal activities, and outputs (in the form of a logic model, for example), and the mechanism(s) by which these components are expected to produce changes in a [system](#) performance.

Opportunity costs

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3 Loss of the ability to perform other tasks or meet other responsibilities resulting from the diversion
4 of resources needed to introduce, test, or sustain a particular [improvement](#) initiative
5
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7 **Problem**

8 Meaningful disruption, failure, inadequacy, distress, confusion or other dysfunction in a healthcare
9 service delivery [system](#) that adversely affects patients, staff, or the [system](#) as a whole, or that
10 prevents care from reaching its full potential
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12 **Process**

13 The routines and other activities through which healthcare services are delivered
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16 **Rationale**

17 Explanation of why particular [intervention\(s\)](#) were chosen and why it was expected to work, be
18 sustainable, and be replicable elsewhere.
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20 **Systems**

21 The interrelated structures, people, [processes](#), and activities that together create healthcare services
22 for and with individual patients and populations. For example, systems exist from the personal self-
23 care system of a patient, to the individual provider-patient dyad system, to the microsystem, to the
24 macrosystem, and all the way to the market/social/insurance system. These levels are nested within
25 each other.
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28 **Theory or theories**

29 Any “-ig ei a s i o n i g ” a c c o u n t t h a t a s s e r t s c a u s a l r e l a
30 that makes sense of an otherwise obscure [process](#) or situation (explanatory theory). Theories come
31 in many forms, and serve different purposes in the phases of [improvement](#) work. It is important to
32 be explicit and well-founded about any informal and formal theory (or theories) that are used.
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BMJ Open

A Prospective Observational Study of Gender and ethnicity biases in respiratory protective equipment for healthcare workers in the Covid-19 pandemic

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Prospective observational study of gender and ethnicity biases in respiratory protective equipment for healthcare workers in the Covid-19 pandemic

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Dr Clarissa Carvalho was the study lead, lead researcher and writer of this article.

Dr Jan Schumacher, Dr Paul Greig and Dr Kariem El-Boghdadly contributed to the design of the study, the results interpretation and the writing and review of the manuscript. Dr Danny Wong and Dr Paul Greig reviewed the results and conducted the statistical analysis. Dr Danny Wong also contributed to the interpretation of the results and the writing of the manuscript.

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Short title: Gender, ethnicity and fit testing

Keywords: COVID-19, PPE, RPE, fit testing, infection, ethnicity, gender

Competing Interests:

No Competing Interests. All authors have completed the Unified Competing Interest form and declare: no support from any organisation for the submitted; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work

Transparency Declaration:

The lead author, Dr Clarissa Carvalho, affirms that the manuscript is an honest, accurate and transparent account of the study reported. No important aspects of the study have been omitted and there were no discrepancies from the study as planned.

Ethical Approval: This study was assessed by the Research & Development Lead and the Clinical Governance Lead and was deemed exempt from ethical review as it met the criteria for a service evaluation. It was registered as a service evaluation with Guy's and St Thomas' NHS Foundation Trust (ID 10918).

Funding: No funding was required and no funding was provided.

Sponsor: The study sponsor was responsible for the management and progression of the study

Statement of Independence of Researchers from funders: Each researcher worked independently of funding. No funding was required for this study.

Abstract

Objective:

To describe success rates of respiratory protective equipment (RPE) fit testing and factors associated with achieving suitable fit.

Design:

Prospective observational study of RPE fit testing according to health and safety, and occupational health requirements.

Setting:

A large tertiary referral UK healthcare facility.

Population:

1443 healthcare workers undergoing quantitative fit testing.

Main outcome measures:

Quantitative fit test success (pass/fail), and the count of tests each participant required before successful fit.

Results:

Healthcare workers were fit tested a median (interquartile range [IQR]) 2 (1–3) times before successful fit was obtained. Males were tested a median 1 (1–2) times, while females were tested a median 2 (1–2) times before a successful fit was found. This difference was statistically significant ($p < 0.001$). Modelling each fit test as its own independent trial ($n = 2359$) using multivariable logistic regression, male healthcare workers were significantly more likely to find a well-fitting respirator and achieve a successful fit on first attempt in comparison to females, after adjusting for other factors (adjusted odds ratio [OR] = 2.07, 95% confidence interval [CI]: 1.66–2.60, $p < 0.001$). Staff who described their ethnicity as White were also more likely to achieve a successful fit compared to staff who described their ethnicity as Asian (OR = 0.47, 95% CI: 0.38–0.58, $p < 0.001$), Black (OR = 0.54, 95% CI: 0.41–0.71, $p < 0.001$), Mixed (OR = 0.50, 95% CI: 0.31–0.80, $p = 0.004$), or Other (OR = 0.53, 95% CI: 0.29–0.99, $p = 0.043$).

Conclusions

Male and white ethnicity healthcare workers are more likely to achieve RPE fit test success. This has broad operational implications to healthcare services with a large female and Black, Asian and minority ethnic groups population. Fit-testing is imperative in ensuring RPE effectiveness in protecting healthcare workers during the Covid-19 pandemic and beyond.

Strengths & Weaknesses

- Single centre study
- Demographics of the workforce observed in our study accurately reflects those of the NHS workforce in London, UK. But may not reflect the rest of the country.
- A large number of fit tests and participants were observed
- Each individual did not test on every model of face mask
- Anthropometric measurements were not collected
- Other factors affecting the fit testing were not investigated or adjusted for

Prospective observational study of gender and ethnicity biases in respiratory protective equipment for healthcare workers in the Covid-19 pandemic

Carvalho CYM, Schumacher J, Greig P, Wong DJN, El-Boghdady K

Introduction

The Covid-19 pandemic has dramatically affected the delivery of healthcare. Many routine procedures that produce potentially infectious aerosols were previously conducted regularly without protective face coverings, but this is no longer appropriate during the pandemic. Preventing aerosolised spread of infection from patients to healthcare workers relies on effective use of respiratory protective equipment (RPE), including tight-fitting filtering facepiece (FFP) respirators.[1-3] Protection of healthcare workers with suitable RPE must be prioritised as their exposure places them at high risk of contracting infection with Covid-19.[4-5] Critical shortages in the availability of adequate RPE have been highlighted, with healthcare workers from Black, Asian and minority ethnic (BAME) groups being disproportionately affected.[6]

The effectiveness of a respirator depends on a good fit on the healthcare workers' face.[7-9] Although respirators are designed to fit the majority of individuals, no single respirator can provide a universal fit.[8-11] The fit of RPE has been suggested to be unsuitable for women and BAME healthcare workers, however there remains insufficient objective data demonstrating this disparity. There is therefore a need to assess the ethnodemographic impact on suitability of respirators provided by

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3 employers. The purpose of this observational study is therefore to determine if
4 ethnicity and gender are factors in the suitability of respirators in healthcare workers
5 exposed to patients with Covid-19.
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14 **Methods**

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18 We conducted a prospective observational study examining fit testing results by
19 ethnicity and gender from staff in a central London teaching hospital and designated
20 Covid-19 centre. This study was deemed exempt from ethical review as it met the
21 criteria for a service evaluation and was registered with Guy's and St Thomas' NHS
22 Foundation Trust (ID 10918) as a service evaluation. No patients or members of the
23 public were included in this study. All members of the workforce in patient-facing roles
24 were eligible to attend the fit testing clinic. We included healthcare workers who
25 underwent quantitative fit tests (QNFT) only. Exclusion criteria were healthcare
26 workers who were not in patient-facing roles, those unable to undertake the fit testing
27 procedure (e.g. unable to remove head wear, remove facial hair, or unable to perform
28 the procedure), those that underwent only qualitative fit testing, or those unwilling to
29 participate in fit testing.
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48 Fit testing data were collected between 3rd February and 3rd July 2020 and included
49 the participant's self-described gender and ethnicity in free-text. The free-text
50 responses were mapped to the Office of National Statistics categories for ethnicity as
51 used in the UK census.[12]
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3 Fit testing was conducted by certified fit testers. Participants had to refrain from
4 smoking one hour prior to the test, had to be clean shaven and could not wear any
5 head wear. The QNFT involved the use of a TSI Portacount 8030 (TSI UK, High
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8 Wycombe) using the standard Health and Safety Executive fit testing procedure.[13]
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14 QNFT fit test scores were dichotomised as pass or fail based on achieving an overall
15 fit factor >100. We report the overall numbers and proportions of staff who passed
16 their first fit test and grouped by self-reported gender and ethnicity. The likelihood of
17 passing the first fit test for male and female genders, and White and BAME groups
18 were compared using Pearson's Chi-squared test (without Yate's Continuity, as all cell
19 frequencies were greater than 10). Logistic regression modelling was performed using
20 each fit test as a separate observation, with the binary outcome variable defined as fit
21 test success (pass/fail), and using the following explanatory variables: gender,
22 ethnicity and mask design (disposable vs reusable). We first modelled the bivariate
23 association between the outcome variable and each explanatory variable separately,
24 and then in a multivariable model including all explanatory variables to obtain adjusted
25 odds ratio (OR) estimates. Mask designs were specified in our models as categorical
26 variables and were compared against a reference design A, which was our most
27 widely-tested disposable mask design. The following *post hoc* analyses were
28 performed to assess the possibility that healthcare workers could learn to game the fit
29 testing process and repeated testing of the same healthcare workers using different
30 masks could render the tests not independent of each other: First we fitted mixed
31 effects logistic regression models with random-intercepts for healthcare workers,
32 assuming that tests were nested within healthcare workers; Second we repeated the
33 original fixed-effects only logistic regression modelling with a subset of our dataset,
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only including data from first attempt fit tests. The results of the *post hoc* analyses were compared with our original findings and reported within the Supplementary Material. All analyses were performed in Microsoft Excel (Microsoft Corporation, Redmond, WA, USA) and R version 3.5.2 (R Foundation for Statistical Computing, Vienna, Austria). Only records with complete data for the variables modelled (gender, ethnicity, mask design, outcome of fit test) were analysed. Continuous variables are reported as mean (standard deviation [SD]) for normally- or uniformly-distributed data, or median (interquartile range [IQR]) for data with skewed distributions. For discrete variables, numbers and proportions are reported. Non-parametric data were compared with the Mann-Whitney U test, and the students t test was used for parametric data. A p value of <0.05 was considered statistically significant.

Patient and Public Involvement: There was no patient or public involvement in this study.

Results

A total of 1443 healthcare workers underwent fit testing during the study period. After exclusions were applied, a total of 1182 records were available for analysis. The gender and ethnicity breakdowns for the staff members are described in Table 1.

Table 1: Gender and ethnicity of the staff that underwent quantitative fit testing

	<i>n (%)</i> <i>(n = 1182)</i>
Gender	
Male	365 (30.9%)
Female	817 (69.1%)
Ethnicity	
White	557 (47.1%)
Asian	383 (32.4%)
Black	175 (14.8%)
Mixed	39 (3.3%)
Other	28 (2.4%)

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5 Each staff member was fit tested a median (IQR) 2 (1–3) times before a successful fit
6 was found. Males were tested a 1 (1–2) times and females 2 (1–2) times before a
7 successful fit was found ($p < 0.001$).
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14 There were 2359 independent quantitative fit tests modelled using logistic regression
15 (Table 2). Values are number (proportion) or odds ratio (95%CI). To assess the
16 possibility of non-independence between tests performed on the same healthcare
17 worker, an additional *post hoc* mixed-effects model fitted with random-intercepts for
18 healthcare workers did not materially change our findings (Supplementary Material,
19 Figure A). Similarly, a post hoc fixed-effects only model fitted using only data from first
20 fit test attempts also did not materially change our findings (Supplementary Material,
21 Figure B).
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35 Male healthcare workers were significantly more likely to pass a fit test compared with
36 females. Staff who describe their ethnicity as White were also more likely to achieve
37 a successful fit test compared to staff who describe their ethnicity as Asian, Black,
38 mixed, or Other (Table 3). There was wide variation in the likelihood of achieving
39 successful mask fit between the different mask designs. The different mask designs
40 were all N99 or FFP3 filtration, were CE marked and approved according to the
41 European Norm EN149:2001 (Supplementary table). Mask designs demonstrated
42 variable performance in terms of obtaining a successful fit (Table 2). Investigating the
43 conditional probability of successful fit a first attempt by gender and ethnicity, males
44 were generally more likely to achieve success than females ($p < 0.001$, Table 3).
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Table 2: Logistic regression models. (D) = disposable mask; (R) = reusable mask.

Dependent outcome: Successful fit		Fail n (%)	Pass n (%)	OR (univariable)	OR (multivariable)
Gender	Female	709 (80.8%)	1007 (67.9%)	-	-
	Male	168 (19.2%)	475 (32.1%)	1.99 (1.63-2.44, p<0.001)	2.07 (1.66-2.60, p<0.001)
Ethnicity	White	301 (34.3%)	721 (48.7%)	-	-
	Asian	357 (40.7%)	478 (32.3%)	0.56 (0.46-0.68, p<0.001)	0.47 (0.38-0.58, p<0.001)
	Black	154 (17.6%)	198 (13.4%)	0.54 (0.42-0.69, p<0.001)	0.54 (0.41-0.71, p<0.001)
	Mixed	42 (4.8%)	51 (3.4%)	0.51 (0.33-0.78, p=0.002)	0.50 (0.31-0.80, p=0.004)
	Other	23 (2.6%)	34 (2.3%)	0.62 (0.36-1.08, p=0.083)	0.53 (0.29-0.99, p=0.043)
RPE mask model	Design A (D)	63 (7.2%)	307 (20.7%)	-	-
	Design B (D)	9 (1.0%)	5 (0.3%)	0.11 (0.03-0.34, p<0.001)	0.11 (0.03-0.35, p<0.001)
	Design C (D)	159 (18.1%)	84 (5.7%)	0.11 (0.07-0.16, p<0.001)	0.09 (0.06-0.14, p<0.001)
	Design D (D)	38 (4.3%)	33 (2.2%)	0.18 (0.10-0.30, p<0.001)	0.16 (0.09-0.27, p<0.001)
	Design E (D)	87 (9.9%)	45 (3.0%)	0.11 (0.07-0.17, p<0.001)	0.10 (0.06-0.16, p<0.001)
	Design F (D)	47 (5.4%)	43 (2.9%)	0.19 (0.11-0.31, p<0.001)	0.18 (0.11-0.30, p<0.001)
	Design G (R)	3 (0.3%)	6 (0.4%)	0.41 (0.11-1.98, p=0.216)	0.47 (0.12-2.33, p=0.305)
	Design H (R)	2 (0.2%)	7 (0.5%)	0.72 (0.17-4.90, p=0.684)	0.64 (0.14-4.50, p=0.592)
	Design I (R)	14 (1.6%)	103 (7.0%)	1.51 (0.83-2.91, p=0.193)	1.70 (0.93-3.31, p=0.096)
	Design J (R)	214 (24.4%)	233 (15.7%)	0.22 (0.16-0.31, p<0.001)	0.24 (0.17-0.34, p<0.001)
	Design K (R)	86 (9.8%)	394 (26.6%)	0.94 (0.66-1.34, p=0.735)	0.97 (0.67-1.39, p=0.863)
	Design L (R)	152 (17.3%)	218 (14.7%)	0.29 (0.21-0.41, p<0.001)	0.29 (0.21-0.41, p<0.001)
	Others	3 (0.3%)	4 (0.3%)	0.27 (0.06-1.42, p=0.095)	0.29 (0.06-1.51, p=0.112)

Table 3: Conditional probabilities of successful first attempt fit by gender and ethnicity. Values are number or proportion.

Gender	Ethnicity	Failed first fit attempt (n)	Passed first fit attempt (n)	Probability of passing first fit attempt (%)
F	White	206	163	44.2%
	Asian	164	97	37.2%
	Black	78	65	45.5%
	Mixed	23	9	28.1%
	Other	7	5	58.3%
M	White	80	108	57.4%
	Asian	66	56	45.9%
	Black	15	17	53.1%
	Mixed	3	4	57.1%
	Other	9	7	43.8%

Discussion

We investigated the suitability of respirators worn by healthcare workers and report new evidence that indicates lower RPE fit testing success rates among BAME and female healthcare workers.[3,4] This may indicate that certain groups may be at particular risk from Covid-19 infection in the workplace due to unsuitable respiratory protection.

The demographic diversity in our data may differ to the NHS England workforce. However, it is not dissimilar to the demographics expected of a healthcare facility in central London and so it is representative of London healthcare workers. BAME healthcare workers may account for 19.8% of the NHS workforce in England but ethnic minority healthcare workers demonstrate a higher representation in London (44.9%) with 1.7% identifying as having a mixed ethnic background.[14] Failure of RPE to protect BAME healthcare workers affects a significant proportion of the NHS workforce.

Our data suggest that there could be biases in design and certification of respirators. Respirator design has historically focused on the fit for individuals from the US Air Force in the 1967-68.[10,15] However, it is unclear if the anthropometric data collected was even representative of the workforce in the 1960s and 70s as the US Air Force had clear height and weight restrictions, and consisted mainly of men.[15] Population demographics have changed drastically in the UK and US since the 1960s, with increased numbers of women and people from ethnic minorities in all workplaces. This historical data is therefore unlikely to reflect current workforce demographics. [6,15,14]

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4 Recognising that the standard fit panels may no longer be appropriate, the National
5 Institute for Occupational Safety and Health (NIOSH) conducted a new survey of the
6 US work force in 2001.[16] 4026 subjects from 41 different sites in, eight states were
7 recruited, and new fit moulding panels were proposed based on the anthropometric
8 data collected.[16] However, the ethnic groups described in this study differ from the
9 UK. The demographics of the workforce describes one third of the population as
10 Hispanic and specifically categorises the ethnicities as White, African American,
11 Hispanic and Other.[15,16] However, the largest ethnic group after White British in
12 England and Wales is “White other”, followed by Asian – Indian, Asian – Pakistani,
13 Black – African and Asian other.[12] Although NIOSH suggest their data can be used
14 as a starting point for design and certification as the US population is ethnically
15 diverse, the US data may not map accurately to the ethnic makeup of the UK
16 healthcare workforce. Every individual has different features which vary by gender,
17 ethnicity and even occupational role.[17] Face length is a key feature in respirator fit
18 and this has been shown to vary significantly across ethnic and gender groups.[17]
19 For example, anthropometric data shows statistically significant differences in width
20 and face and lip length between African Americans and White Americans.[17] A
21 sample of African Americans and Hispanic individuals in the US workforce were found
22 to have up to face lengths 2.7 and 2.8 mm longer than White Americans.[17] Prior to
23 Covid-19 most respirators were used in industrial applications such as construction.
24 Construction workers are more likely to be male than healthcare staff, and have
25 different facial features, including longer noses.[17] Gender has also been shown to
26 be a major determinant in facial differences and measurements. Nine out of 10 facial
27 measurements vary by gender with the female face being significantly smaller than
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3 the male face.[17] This is of relevance to respirator fit in healthcare workers as 77%
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5 of the NHS workforce is female.
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10 Future respirator design should consider the facial characteristics of the demographic
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12 of the workforce. Face panels consisting of a true representation of female and BAME
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14 healthcare workers could help improve respirator design and improve safety when
15
16 caring for Covid-19 patients. Out-dated fit panels used in the design and certification
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18 of the respirators demonstrate the institutional gender and racial biases in respirator
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20 fit and must be addressed in order to protect BAME and female staff.
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26 Use of facial anthropometric data representing the current demographics of the
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28 workforce is not only important in the design of RPE, it can be used to guide
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30 procurement strategies for the ongoing pandemic. For example, females have on
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32 average smaller faces so looking at the different proportions of female versus male
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34 healthcare workers can guide what proportion of the procured respirators should be
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36 smaller versus large.
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42 Examining the shape and measurements of the respirator in comparison to a face
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44 panel representing the workforce could help decision making in procurement. These
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46 techniques using facial anthropometric data representative of the workforce and
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48 observing the success or fail rate of different respirator designs in each ethnic or
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50 gender group could help with the decision-making process of which respirators to
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52 stock. Guiding procurement processes can prevent excesses of poorly sized
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54 respirators and shortages of the correct sizes.
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3 However, even if the correct respirator for the demographic of the workforce was
4 sourced, supply and demand issues of RPE early in the Covid-19 pandemic meant
5 healthcare facilities could not rely upon a steady supply of any single preferred
6 respirator. Every respirator has a different design and fit, therefore individuals should
7 be fit tested on the respirator model they don prior to patient interactions.[8,13] The
8 multiple changes in respirator models mean healthcare workers must be repeatedly fit
9 tested on the new models as supplies change. As healthcare facilities were
10 overwhelmed with the need to fit test staff repeatedly on different masks many adopted
11 an approach to fit check only.[9] Our data demonstrates that respirators have a
12 variable success rate on initial fit test. For example, Design J did not suitably fit 24.4%
13 of our staff. Some studies have demonstrated a fail rate as high as 78% when a
14 respirator is used without fit testing.[10] Failure to fit test may leave a significant
15 proportion of staff inadequately protected against Covid-19 and according to our data
16 it is mixed ethnicity and Asian female healthcare workers who are at greatest risk.

36 **Limitations**

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39 This was a single centre study. The demographics of our data is representative of
40 healthcare facilities in the London however further data should be collected to
41 extrapolate the results to other areas. A large number of respirators were observed
42 in this study and each individual did not test on every model. More data are required
43 to evaluate the efficacy of each model. Finally, previous experience with fit-testing
44 was not accounted for, although quantitative fit-testing is objective and independent
45 of experience, and the use of respirators was generally poor prior to the pandemic so
46 we assumed a homogeneous lack of experience in our cohort.
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Conclusion

Respirator design and certification may be biased towards fitting a demographic that is not reflective of the current healthcare workforce. This could leave many healthcare workers vulnerable as they struggle to fit into a mask not designed for their faces. Lack of design consideration and supply issues could be a dangerous combination for healthcare staff as they rely upon the protection of a properly fitted respirator to reduce the risk of infection transmission whilst caring for patients with Covid-19.

Further research into the design and fit of respiratory protective equipment must consider the demographic of the healthcare workforce as we cannot rely on anthropometric data that represents only one section of the workforce. Creating new fit panels that accurately represent female workers and the ethnically diverse healthcare workforce is an essential first step towards designing well-fitting respirators. In the meantime, it is important to recognise that no one mask will fit all staff. [8-11,13] Therefore the focus should be on employers stocking a suite of RPE, so that a diverse workforce has the best chance of finding a respirator of appropriate fit.

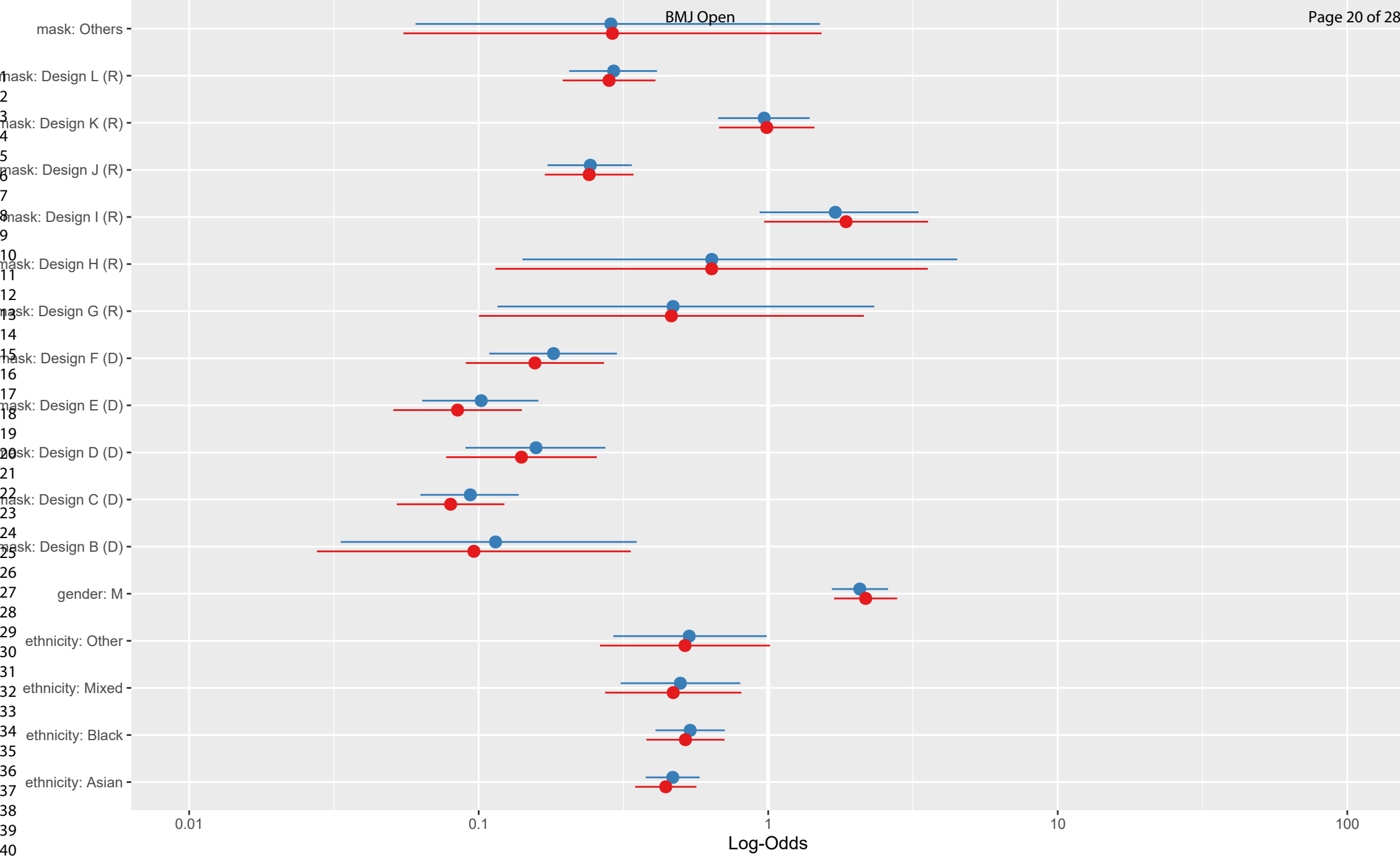
Ensuring fit-testing and keeping adequate stock of a variety of respirator models can help maintain the safety of the whole workforce but future research should focus on the design of respirators for BAME and female healthcare workers.

References

1. Livingston E, Desai A, Berkwits M. Sourcing Personal Protective Equipment During the COVID-19 pandemic. *JAMA* 2020; 323:1912-1914
2. Public Health England. Guidance - Covid-19 Personal Protective Equipment 2020 <https://www.gov.uk/government/publications/wuhan-novel-coronavirus-infection-prevention-and-control/covid-19-personal-protective-equipment-ppe>
3. The Lancet. Editorial - COVID-19: Protecting health-care workers. March 2020.
<http://www.sciencedirect.com/science/article/pii/S0140673620306449>
4. El-Boghdadly K, Wong DJN, Owen R, et al. Risks to healthcare workers following tracheal intubation of patients with COVID-19: a prospective international multicentre cohort study. *Anaesthesia* June 2020; 75: 1437-1447
5. Cook T, Kursumovic E, Lennane S. Exclusive: Deaths of NHS Staff from COVID-19 analysed. April 2020 <https://www.hsj.co.uk/exclusive-deaths-of-nhs-staff-from-covid-19-analysed/7027471.article>

- 1
2
3 6. Amnesty International. UK among the highest COVID-19 healthcare
4
5 worker deaths in the world 2020. [https://www.amnesty.org.uk/press-](https://www.amnesty.org.uk/press-releases/uk-among-highest-covid-19-health-worker-deaths-world)
6
7 releases/uk-among-highest-covid-19-health-worker-deaths-world
8
9
- 10
11
12 7. British Medical Association. BMA survey reveals almost half of doctors
13
14 have relied upon donated or self-bought PPE and two thirds still don't feel
15
16 fully protected 2020. [https://www.bma.org.uk/bma-media-centre/bma-](https://www.bma.org.uk/bma-media-centre/bma-survey-reveals-almost-half-of-doctors-have-relied-upon-donated-or-self-bought-ppe-and-two-thirds-still-don-t-feel-fully-protected)
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18 survey-reveals-almost-half-of-doctors-have-relied-upon-donated-or-self-
19
20 bought-ppe-and-two-thirds-still-don-t-feel-fully-protected
21
22
- 23
24
25 8. Health and Safety Executive. Fit Testing Face Masks to Avoid
26
27 Transmission during the coronavirus outbreak. 2020.
28
29 [https://www.hse.gov.uk/coronavirus/ppe-face-masks/face-mask-ppe-](https://www.hse.gov.uk/coronavirus/ppe-face-masks/face-mask-ppe-rpe.htm)
30
31 rpe.htm
32
33
- 34
35
36 9. The Guardian. Hospitals Accused of Risking Staff Lives by Abandoning
37
38 PPE Fit Tests. March 2020.
39
40 [https://www.theguardian.com/world/2020/apr/14/nhs-hospitals-accused-](https://www.theguardian.com/world/2020/apr/14/nhs-hospitals-accused-of-risking-staff-lives-by-abandoning-ppe-fit-tests-coronavirus)
41
42 of-risking-staff-lives-by-abandoning-ppe-fit-tests-coronavirus
43
44
45
46
47
48
49
- 50
51 10. Manganyi J, Wilson K, Rees D. Quantitative respirator fit, face sizes and
52
53 determinants of fit in South African diagnostic laboratory respirator users.
54
55 *Annals of Work Exposures and Health* Nov 2017; 61;9:1154-1162
56
57
58
59
60

- 1
2
3 11. Oestenstad R, Elliot L, Beasley T. The effect of gender and respirator
4 brand on the association of respirator fit with facial dimensions. Journal of
5 Occupational and Environmental Hygiene Dec 2007;4 923-930
6
7
8
9
10
11
12 12. UK Census 2011. Ethnicity Facts and Figures [https://www.ethnicity-facts-](https://www.ethnicity-facts-figures.service.gov.uk/)
13 [figures.service.gov.uk/](https://www.ethnicity-facts-figures.service.gov.uk/)
14
15
16
17
18
19 13. Health and Safety Executive. Guidance on respiratory protective
20 equipment (RPE) fit testing 2019. [https://www.hse.gov.uk/respiratory-](https://www.hse.gov.uk/respiratory-protective-equipment/)
21 [protective-equipment/](https://www.hse.gov.uk/respiratory-protective-equipment/)
22
23
24
25
26
27
28 14. NHS England. NHS Workforce Race and Equality Standard Report 2019.
29 [https://www.england.nhs.uk/wp-content/uploads/2020/01/wre-2019-data-](https://www.england.nhs.uk/wp-content/uploads/2020/01/wre-2019-data-report.pdf)
30 [report.pdf](https://www.england.nhs.uk/wp-content/uploads/2020/01/wre-2019-data-report.pdf)
31
32
33
34
35
36
37 15. Bailar J, Meyer E, Pool R. Institute of Medicine: Assessment of the
38 NIOSH head-and-face anthropometric survey of US respirator users.
39 2007 pp1-108
40
41
42
43
44
45
46
47 16. American Industrial Hygiene Association. Respirator Fit Testing Methods
48 2010 ISBN 978-1-935082-24-8
49
50
51
52
53
54
55 17. Zhuang Z, Landsittel D, Benson S et al. Facial Anthropometric
56 differences among gender, ethnicity and age groups. Annals of
57 Occupational Hygiene Jun 2010; 54(4):391-402
58
59
60



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Model 1 (fixed effects only) Model 2 (mixed effects with random intercept for HCW)

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mask: Others

mask: Design L (R)

mask: Design K (R)

mask: Design J (R)

mask: Design I (R)

mask: Design H (R)

mask: Design G (R)

mask: Design F (D)

mask: Design E (D)

mask: Design D (D)

mask: Design C (D)

mask: Design B (D)

gender: M

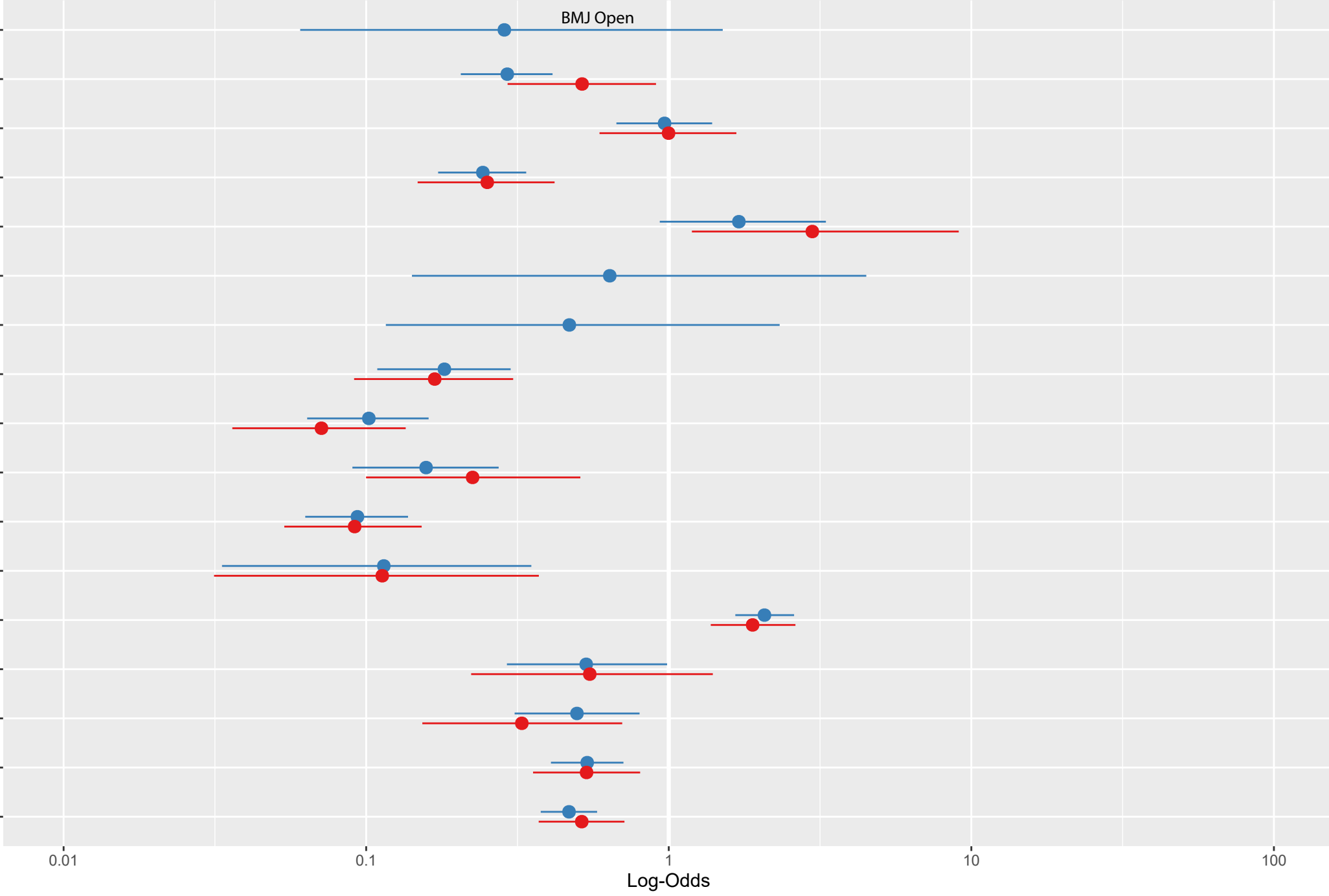
ethnicity: Other

ethnicity: Mixed

ethnicity: Black

ethnicity: Asian

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Supplementary Material

Supplementary Table: Description of Different Masks Used

Mask Design	Manufacturer	Model	Shape	Expiratory Filter Y/N	Reusable (R) / Disposable (D)	Grade of mask
A	Full Support Group	Easimask FSM18	Cup	N	D	FFP3 / N99 equivalent
B	Full Support Group	Easimask FSM16	Duckbill	N	D	FFP3 / N99 equivalent
C	3M	1863	Fold out 3 Panel	N	D	FFP3 / N99 equivalent
D	3M	8833	Cup	Y	D	FFP3 / N99 equivalent
E	3M	1873	Fold out 3 Panel	Y	D	FFP3 / N99 equivalent
F	3M	Aura 1863+	Fold out 3 Panel	N	D	FFP3 / N99 equivalent
G	3M	6500 +P3 Filter	Half mask	Y	R	FFP3 / N99 equivalent
H	3M	7500 +P3 Filter	Half mask	Y	R	FFP3 / N99 equivalent
I	Scott Safety	Aviva 50 +P3 Filter	Half mask	Y	R	FFP3 / N99 equivalent
J	JSP Safety	Force 8 +P3 Filter	Half mask	Y	R	FFP3 / N99 equivalent
K	Sundstrom	SR100 +P3 Filter	Half mask	Y	R	FFP3 / N99 equivalent
L	PureFlo	PF1000 +P3 Filter	Half mask	Y	R	FFP3 / N99 equivalent

Figure A

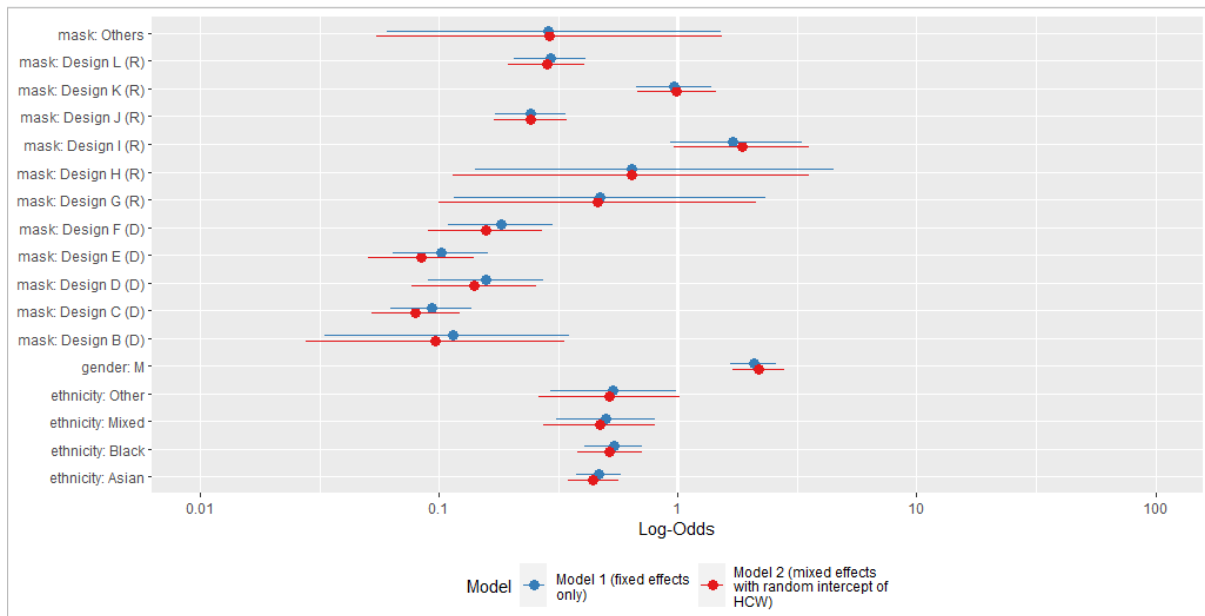


Figure A: Forest plot comparing the fixed effects point estimates and 95% confidence intervals the original model in the manuscript (Model 1) compared to a revised model fitted using mixed effects logistic regression with a random intercept for HCW (Model 2).

Figure B

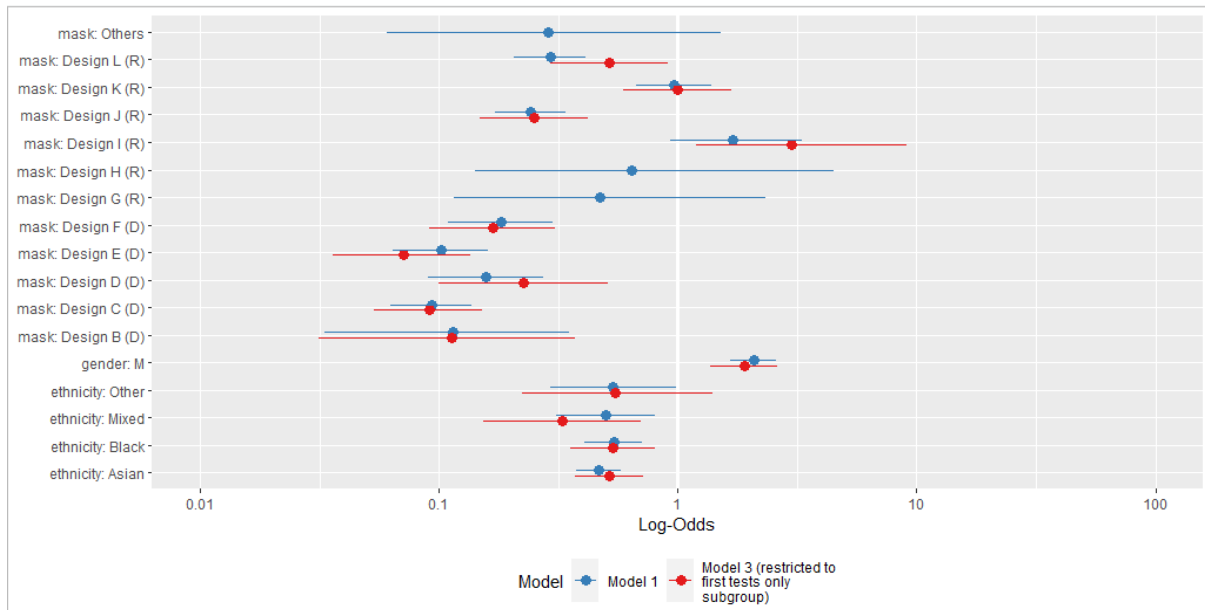


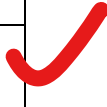
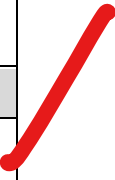


Figure B: Forest plot comparing the fixed effects point estimates and 95% confidence intervals the original model in the manuscript (Model 1) compared to a revised model fitted using only subgroup data from first fit

**Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0)
September 15, 2015**

Text Section and Item Name	Section or Item Description
Notes to authors	<ul style="list-style-type: none"> • The SQUIRE guidelines provide a framework for reporting new knowledge about how to improve healthcare • The SQUIRE guidelines are intended for reports that describe system level work to improve the quality, safety, and value of healthcare, and used methods to establish that observed outcomes were due to the intervention(s). • A range of approaches exists for improving healthcare. SQUIRE may be adapted for reporting any of these. • Authors should consider every SQUIRE item, but it may be inappropriate or unnecessary to include every SQUIRE element in a particular manuscript. • The SQUIRE Glossary contains definitions of many of the key words in SQUIRE. • The Explanation and Elaboration document provides specific examples of well-written SQUIRE items, and an in-depth explanation of each item. • Please cite SQUIRE when it is used to write a manuscript.
Title and Abstract	
1. Title	Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patient-centeredness, timeliness, cost, efficiency, and equity of healthcare) ✓
2. Abstract	<ol style="list-style-type: none"> a. Provide adequate information to aid in searching and indexing b. Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions
Introduction	<i>Why did you start?</i>
3. Problem Description	Nature and significance of the local problem ✓
4. Available knowledge	Summary of what is currently known about the problem , including relevant previous studies ✓

5. <u>Rationale</u>	Informal or formal frameworks, models, concepts, and/or theories used to explain the problem , any reasons or assumptions that were used to develop the intervention(s) , and reasons why the intervention(s) was expected to work	✓
6. Specific aims	Purpose of the project and of this report	✓
Methods	<i>What did you do?</i>	
7. <u>Context</u>	Contextual elements considered important at the outset of introducing the intervention(s)	✓
8. <u>Intervention(s)</u>	a. Description of the intervention(s) in sufficient detail that others could reproduce it b. Specifics of the team involved in the work	
9. Study of the Intervention(s)	a. Approach chosen for assessing the impact of the intervention(s) b. Approach used to establish whether the observed outcomes were due to the intervention(s)	
10. Measures	a. Measures chosen for studying processes and outcomes of the intervention(s) , including rationale for choosing them, their operational definitions, and their validity and reliability b. Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency, and cost c. Methods employed for assessing completeness and accuracy of data	✓
11. Analysis	a. Qualitative and quantitative methods used to draw inferences from the data b. Methods for understanding variation within the data, including the effects of time as a variable	✓
12. Ethical Considerations	Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest	✓
Results	<i>What did you find?</i>	
13. Results	a. Initial steps of the intervention(s) and their evolution over time (e.g., time-line diagram, flow chart, or table), including modifications made to the intervention during the project b. Details of the process measures and outcome c. Contextual elements that interacted with the intervention(s) d. Observed associations between outcomes, interventions, and relevant contextual elements e. Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s) . f. Details about missing data	✓
Discussion	<i>What does it mean?</i>	
14. Summary	a. Key findings, including relevance to the rationale and specific aims b. Particular strengths of the project	✓

<p>1</p> <p>2</p> <p>3</p> <p>4</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>15. Interpretation</p>	<p>a. Nature of the association between the intervention(s) and the outcomes</p> <p>b. Comparison of results with findings from other publications</p> <p>c. Impact of the project on people and systems</p> <p>d. Reasons for any differences between observed and anticipated outcomes, including the influence of context</p> <p>e. Costs and strategic trade-offs, including opportunity costs</p> 
<p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>16. Limitations</p>	<p>a. Limits to the generalizability of the work</p> <p>b. Factors that might have limited internal validity such as confounding, bias, or imprecision in the design, methods, measurement, or analysis</p> <p>c. Efforts made to minimize and adjust for limitations</p> 
<p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>17. Conclusions</p>	<p>a. Usefulness of the work</p> <p>b. Sustainability</p> <p>c. Potential for spread to other contexts</p> <p>d. Implications for practice and for further study in the field</p> <p>e. Suggested next steps</p> 
<p>23</p> <p>24</p> <p>Other information</p>	
<p>25</p> <p>26</p> <p>27</p> <p>18. Funding</p>	<p>Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation, interpretation, and reporting</p> 

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3 **Table 2. Glossary of key terms used in SQUIRE 2.0. This Glossary provides the intended**
4 **meaning of selected words and phrases as they are used in the SQUIRE 2.0 Guidelines. They**
5 **may, and often do, have different meanings in other disciplines, situations, and settings.**
6

7 **Assumptions**

8 Reasons for choosing the activities and tools used to bring about changes in healthcare services at
9 the [system](#) level.
10
11

12 **Context**

13 Physical and sociocultural makeup of the local environment (for example, external environmental
14 factors, organizational dynamics, collaboration, resources, leadership, and the like), and the
15 interpretation of these factors (“sense-making”) by the healthcare delivery professionals, patients,
16 and caregivers that can affect the effectiveness and [generalizability](#) of [intervention\(s\)](#).
17
18

19 **Ethical aspects**

20 The value of [system](#)-level [initiatives](#) relative to their potential for harm, burden, and cost to the
21 stakeholders. Potential harms particularly associated with efforts to improve the quality, safety, and
22 value of healthcare services include [opportunity costs](#), invasion of privacy, and staff distress
23 resulting from disclosure of poor performance.
24
25

26 **Generalizability**

27 The likelihood that the [intervention\(s\)](#) in a particular report would produce similar results in other
28 settings, situations, or environments (also referred to as external validity).
29
30

31 **Healthcare improvement**

32 Any systematic effort intended to raise the quality, safety, and value of healthcare services, usually
33 done at the [system](#) level. We encourage the use of this phrase rather than “quality improvement,”
34 which often refers to more narrowly defined approaches.
35
36

37 **Inferences**

38 The meaning of findings or data, as interpreted by the stakeholders in healthcare services –
39 improvers, healthcare delivery professionals, and/or patients and families
40
41

42 **Initiative**

43 A broad term that can refer to organization-wide programs, narrowly focused projects, or the details
44 of specific interventions (for example, planning, execution, and assessment)
45
46

47 **Internal validity**

48 Demonstrable, credible evidence for efficacy (meaningful impact or change) resulting from
49 introduction of a specific intervention into a particular healthcare [system](#).
50
51

52 **Intervention(s)**

53 The specific activities and tools introduced into a healthcare [system](#) with the aim of changing its
54 performance for the better. Complete description of an intervention includes its inputs, internal
55 activities, and outputs (in the form of a logic model, for example), and the mechanism(s) by which
56 these components are expected to produce changes in a [system's](#) performance.
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59 **Opportunity costs**

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3 Loss of the ability to perform other tasks or meet other responsibilities resulting from the diversion
4 of resources needed to introduce, test, or sustain a particular [improvement](#) initiative
5
6

7 **Problem**

8 Meaningful disruption, failure, inadequacy, distress, confusion or other dysfunction in a healthcare
9 service delivery [system](#) that adversely affects patients, staff, or the [system](#) as a whole, or that
10 prevents care from reaching its full potential
11

12 **Process**

13 The routines and other activities through which healthcare services are delivered
14
15

16 **Rationale**

17 Explanation of why particular [intervention\(s\)](#) were chosen and why it was expected to work, be
18 sustainable, and be replicable elsewhere.
19

20 **Systems**

21 The interrelated structures, people, [processes](#), and activities that together create healthcare services
22 for and with individual patients and populations. For example, systems exist from the personal self-
23 care system of a patient, to the individual provider-patient dyad system, to the microsystem, to the
24 macrosystem, and all the way to the market/social/insurance system. These levels are nested within
25 each other.
26
27

28 **Theory or theories**

29 Any “reason-giving” account that asserts causal relationships between variables (causal theory) or
30 that makes sense of an otherwise obscure [process](#) or situation (explanatory theory). Theories come
31 in many forms, and serve different purposes in the phases of [improvement](#) work. It is important to
32 be explicit and well-founded about any informal and formal theory (or theories) that are used.
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A prospective observational study of gender and ethnicity biases in respiratory protective equipment for healthcare workers in the Covid-19 pandemic

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42 tables)
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51 **Contributorship Statement**

52 Dr Clarissa Carvalho was the study lead, lead researcher and writer of this article.

53 Dr Jan Schumacher, Dr Paul Greig and Dr Kariem El-Boghdadly contributed to the
54 design of the study, the results interpretation and the writing and review of the

55 manuscript. Dr Danny Wong and Dr Paul Greig reviewed the results and conducted
56 the statistical analysis. Dr Danny Wong also contributed to the interpretation of the
57 results and the writing of the manuscript.
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Keywords: COVID-19, PPE, RPE, fit testing, infection, ethnicity, gender

Competing Interests:

No Competing Interests. All authors have completed the Unified Competing Interest form and declare: no support from any organisation for the submitted; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work

Transparency Declaration:

The lead author, Dr Clarissa Carvalho, affirms that the manuscript is an honest, accurate and transparent account of the study reported. No important aspects of the study have been omitted and there were no discrepancies from the study as planned.

Ethical Approval: This study was assessed by the Research & Development Lead and the Clinical Governance Lead and was deemed exempt from ethical review as it met the criteria for a service evaluation. It was registered as a service evaluation with Guy's and St Thomas' NHS Foundation Trust (ID 10918).

Funding: No funding was required and no funding was provided.

Sponsor: The study sponsor was responsible for the management and progression of the study

Statement of Independence of Researchers from funders: Each researcher worked independently of funding. No funding was required for this study.

Data Availability: No additional data available

Abstract

Objective:

To describe success rates of respiratory protective equipment (RPE) fit testing and factors associated with achieving suitable fit.

Design:

Prospective observational study of RPE fit testing according to health and safety, and occupational health requirements.

Setting:

A large tertiary referral UK healthcare facility.

Population:

1443 healthcare workers undergoing quantitative fit testing.

Main outcome measures:

Quantitative fit test success (pass/fail), and the count of tests each participant required before successful fit.

Results:

Healthcare workers were fit tested a median (interquartile range [IQR]) 2 (1–3) times before successful fit was obtained. Males were tested a median 1 (1–2) times, while females were tested a median 2 (1–2) times before a successful fit was found. This difference was statistically significant ($p < 0.001$). Modelling each fit test as its own independent trial ($n = 2359$) using multivariable logistic regression, male healthcare workers were significantly more likely to find a well-fitting respirator and achieve a successful fit on first attempt in comparison to females, after adjusting for other factors (adjusted odds ratio [OR] = 2.07, 95% confidence interval [CI]: 1.66–2.60, $p < 0.001$). Staff who described their ethnicity as White were also more likely to achieve a successful fit compared to staff who described their ethnicity as Asian (OR = 0.47, 95% CI: 0.38–0.58, $p < 0.001$), Black (OR = 0.54, 95% CI: 0.41–0.71, $p < 0.001$), Mixed (OR = 0.50, 95% CI: 0.31–0.80, $p = 0.004$), or Other (OR = 0.53, 95% CI: 0.29–0.99, $p = 0.043$).

Conclusions

Male and white ethnicity healthcare workers are more likely to achieve RPE fit test success. This has broad operational implications to healthcare services with a large female and Black, Asian and minority ethnic group population. Fit-testing is imperative in ensuring RPE effectiveness in protecting healthcare workers during the Covid-19 pandemic and beyond.

Strengths & Weaknesses

- This was a single centre study.
- Although the demographics of the workforce observed in our study accurately reflects those of the NHS workforce in London (UK) they may not be reflective of the rest of the country.
- A large number of fit tests and participants were observed.
- Each individual did not test on every model of face mask.
- Other factors affecting the fit testing were not investigated or adjusted for.

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4 **A prospective observational study of gender and ethnicity biases in**
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19 **Introduction**
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23 The Covid-19 pandemic has dramatically affected the delivery of healthcare. Many
24 routine procedures that produce potentially infectious aerosols were previously
25 conducted regularly without protective face coverings, but this is no longer appropriate
26 during the pandemic. Preventing aerosolised spread of infection from patients to
27 healthcare workers relies on effective use of respiratory protective equipment (RPE),
28 including tight-fitting filtering facepiece (FFP) respirators.[1-3] Protection of healthcare
29 workers with suitable RPE must be prioritised as their exposure places them at high
30 risk of contracting infection with Covid-19.[4-5] Critical shortages in the availability of
31 adequate RPE have been highlighted, with healthcare workers from Black, Asian and
32 minority ethnic (BAME) groups being disproportionately affected.[6]
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49 The effectiveness of a respirator depends on a good fit on the healthcare workers'
50 face.[7-9] Although respirators are designed to fit the majority of individuals, no single
51 respirator can provide a universal fit.[8-11] The fit of RPE has been suggested to be
52 unsuitable for women and BAME healthcare workers, however there remains
53 insufficient objective data demonstrating this disparity. There is therefore a need to
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3 assess the ethnodemographic impact on suitability of respirators provided by
4 employers. The purpose of this observational study is therefore to determine if
5 ethnicity and gender are factors in the suitability of respirators in healthcare workers
6 exposed to patients with Covid-19.
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17 **Methods**

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20 We conducted a prospective observational study examining fit testing results by
21 ethnicity and gender from staff in a central London teaching hospital and designated
22 Covid-19 centre. This study was deemed exempt from ethical review as it met the
23 criteria for a service evaluation and was registered with Guy's and St Thomas' NHS
24 Foundation Trust (ID 10918) as a service evaluation. No patients or members of the
25 public were included in this study. All members of the workforce in patient-facing roles
26 were eligible to attend the fit testing clinic. We included healthcare workers who
27 underwent quantitative fit tests (QNFT) only. Exclusion criteria were healthcare
28 workers who were not in patient-facing roles, those unable to undertake the fit testing
29 procedure (e.g. unable to remove head wear, remove facial hair, or unable to perform
30 the procedure), those that underwent only qualitative fit testing, or those unwilling to
31 participate in fit testing.
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50 Fit testing data were collected between 3rd February and 3rd July 2020 and included
51 the participant's self-described gender and ethnicity in free-text. The free-text
52 responses were mapped to the Office of National Statistics categories for ethnicity as
53 used in the UK census.[12]
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3 Fit testing was conducted by certified fit testers. Participants had to refrain from
4 smoking one hour prior to the test, had to be clean shaven and could not wear any
5 head wear. The QNFT involved the use of a TSI Portacount 8030 (TSI UK, High
6 Wycombe) using the standard Health and Safety Executive fit testing procedure.^[13]
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14 QNFT fit test scores were dichotomised as pass or fail based on achieving an overall
15 fit factor >100. We report the overall numbers and proportions of staff who passed
16 their first fit test and grouped by self-reported gender and ethnicity. The likelihood of
17 passing the first fit test for male and female genders, and White and BAME groups
18 were compared using Pearson's Chi-squared test (without Yate's Continuity, as all cell
19 frequencies were greater than 10). Logistic regression modelling was performed using
20 each fit test as a separate observation, with the binary outcome variable defined as fit
21 test success (pass/fail), and using the following explanatory variables: gender,
22 ethnicity and mask design (disposable vs reusable). We first modelled the bivariate
23 association between the outcome variable and each explanatory variable separately,
24 and then in a multivariable model including all explanatory variables to obtain adjusted
25 odds ratio (OR) estimates. Mask designs were specified in our models as categorical
26 variables and were compared against a reference design A, which was our most
27 widely-tested disposable mask design. The following *post hoc* analyses were
28 performed to assess the possibility that healthcare workers could learn to game the fit
29 testing process and repeated testing of the same healthcare workers using different
30 masks could render the tests not independent of each other: First we fitted mixed
31 effects logistic regression models with random-intercepts for healthcare workers,
32 assuming that tests were nested within healthcare workers; Second we repeated the
33 original fixed-effects only logistic regression modelling with a subset of our dataset,
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only including data from first attempt fit tests. The results of the *post hoc* analyses were compared with our original findings and reported within the Supplementary Material Figure A and Figure B. All analyses were performed in Microsoft Excel (Microsoft Corporation, Redmond, WA, USA) and R version 3.5.2 (R Foundation for Statistical Computing, Vienna, Austria). Only records with complete data for the variables modelled (gender, ethnicity, mask design, outcome of fit test) were analysed. Continuous variables are reported as mean (standard deviation [SD]) for normally- or uniformly-distributed data, or median (interquartile range [IQR]) for data with skewed distributions. For discrete variables, numbers and proportions are reported. Non-parametric data were compared with the Mann-Whitney U test, and the students t test was used for parametric data. A p value of <0.05 was considered statistically significant.

Patient and Public Involvement: There was no patient or public involvement in this study.

Results

A total of 1443 healthcare workers underwent fit testing during the study period. After exclusions were applied, a total of 1182 records were available for analysis. The gender and ethnicity breakdowns for the staff members are described in Table 1.

Table 1: Gender and ethnicity of the staff that underwent quantitative fit testing

	<i>n (%)</i> <i>(n = 1182)</i>
Gender	
Male	365 (30.9%)
Female	817 (69.1%)
Ethnicity	
White	557 (47.1%)
Asian	383 (32.4%)
Black	175 (14.8%)

Mixed	39 (3.3%)
Other	28 (2.4%)

Each staff member was fit tested a median (IQR) 2 (1–3) times before a successful fit was found. Males were tested a 1 (1–2) times and females 2 (1–2) times before a successful fit was found ($p < 0.001$).

There were 2359 independent quantitative fit tests modelled using logistic regression (Table 2). Values are number (proportion) or odds ratio (95%CI). To assess the possibility of non-independence between tests performed on the same healthcare worker, an additional *post hoc* mixed-effects model fitted with random-intercepts for healthcare workers did not materially change our findings (Supplementary Material, Figure A). Similarly, a *post hoc* fixed-effects only model fitted using only data from first fit test attempts also did not materially change our findings (Supplementary Material, Figure B).

Male healthcare workers were significantly more likely to pass a fit test compared with females. Staff who describe their ethnicity as White were also more likely to achieve a successful fit test compared to staff who describe their ethnicity as Asian, Black, mixed, or Other (Table 3). There was wide variation in the likelihood of achieving successful mask fit between the different mask designs. The different mask designs were all N99 or FFP3 filtration, were CE marked and approved according to the European Norm EN149:2001 (Supplementary table). Mask designs demonstrated variable performance in terms of obtaining a successful fit (Table 2). Investigating the conditional probability of successful fit a first attempt by gender and ethnicity, males were generally more likely to achieve success than females ($p < 0.001$, Table 3).

Table 2: Logistic regression models. (D) = disposable mask; (R) = reusable mask.

Dependent outcome: Successful fit		Fail n (%)	Pass n (%)	OR (univariable)	OR (multivariable)
Gender	Female	709 (80.8%)	1007 (67.9%)	-	-
	Male	168 (19.2%)	475 (32.1%)	1.99 (1.63-2.44, p<0.001)	2.07 (1.66-2.60, p<0.001)
Ethnicity	White	301 (34.3%)	721 (48.7%)	-	-
	Asian	357 (40.7%)	478 (32.3%)	0.56 (0.46-0.68, p<0.001)	0.47 (0.38-0.58, p<0.001)
	Black	154 (17.6%)	198 (13.4%)	0.54 (0.42-0.69, p<0.001)	0.54 (0.41-0.71, p<0.001)
	Mixed	42 (4.8%)	51 (3.4%)	0.51 (0.33-0.78, p=0.002)	0.50 (0.31-0.80, p=0.004)
	Other	23 (2.6%)	34 (2.3%)	0.62 (0.36-1.08, p=0.083)	0.53 (0.29-0.99, p=0.043)
RPE mask model	Design A (D)	63 (7.2%)	307 (20.7%)	-	-
	Design B (D)	9 (1.0%)	5 (0.3%)	0.11 (0.03-0.34, p<0.001)	0.11 (0.03-0.35, p<0.001)
	Design C (D)	159 (18.1%)	84 (5.7%)	0.11 (0.07-0.16, p<0.001)	0.09 (0.06-0.14, p<0.001)
	Design D (D)	38 (4.3%)	33 (2.2%)	0.18 (0.10-0.30, p<0.001)	0.16 (0.09-0.27, p<0.001)
	Design E (D)	87 (9.9%)	45 (3.0%)	0.11 (0.07-0.17, p<0.001)	0.10 (0.06-0.16, p<0.001)
	Design F (D)	47 (5.4%)	43 (2.9%)	0.19 (0.11-0.31, p<0.001)	0.18 (0.11-0.30, p<0.001)
	Design G (R)	3 (0.3%)	6 (0.4%)	0.41 (0.11-1.98, p=0.216)	0.47 (0.12-2.33, p=0.305)
	Design H (R)	2 (0.2%)	7 (0.5%)	0.72 (0.17-4.90, p=0.684)	0.64 (0.14-4.50, p=0.592)
	Design I (R)	14 (1.6%)	103 (7.0%)	1.51 (0.83-2.91, p=0.193)	1.70 (0.93-3.31, p=0.096)
	Design J (R)	214 (24.4%)	233 (15.7%)	0.22 (0.16-0.31, p<0.001)	0.24 (0.17-0.34, p<0.001)
	Design K (R)	86 (9.8%)	394 (26.6%)	0.94 (0.66-1.34, p=0.735)	0.97 (0.67-1.39, p=0.863)
	Design L (R)	152 (17.3%)	218 (14.7%)	0.29 (0.21-0.41, p<0.001)	0.29 (0.21-0.41, p<0.001)
	Others	3 (0.3%)	4 (0.3%)	0.27 (0.06-1.42, p=0.095)	0.29 (0.06-1.51, p=0.112)

Table 3: Conditional probabilities of successful first attempt fit by gender and ethnicity. Values are number or proportion.

Gender	Ethnicity	Failed first fit attempt (n)	Passed first fit attempt (n)	Probability of passing first fit attempt (%)
F	White	206	163	44.2%
	Asian	164	97	37.2%
	Black	78	65	45.5%
	Mixed	23	9	28.1%
	Other	7	5	58.3%
M	White	80	108	57.4%
	Asian	66	56	45.9%
	Black	15	17	53.1%
	Mixed	3	4	57.1%
	Other	9	7	43.8%

Discussion

We investigated the suitability of respirators worn by healthcare workers and report new evidence that indicates lower RPE fit testing success rates among BAME and female healthcare workers.[3,4] This may indicate that certain groups may be at particular risk from Covid-19 infection in the workplace due to unsuitable respiratory protection.

The demographic diversity in our data may differ to the NHS England workforce. However, it is not dissimilar to the demographics expected of a healthcare facility in central London and so it is representative of London healthcare workers. BAME healthcare workers may account for 19.8% of the NHS workforce in England but ethnic minority healthcare workers demonstrate a higher representation in London (44.9%) with 1.7% identifying as having a mixed ethnic background.[14] Failure of RPE to protect BAME healthcare workers affects a significant proportion of the NHS workforce.

Our data suggest that there could be biases in design and certification of respirators. Respirator design has historically focused on the fit for individuals from the US Air Force in the 1967-68.[10,15] However, it is unclear if the anthropometric data collected was even representative of the workforce in the 1960s and 70s as the US Air Force had clear height and weight restrictions, and consisted mainly of men.[15] Population demographics have changed drastically in the UK and US since the 1960s, with increased numbers of women and people from ethnic minorities in all workplaces. This historical data is therefore unlikely to reflect current workforce demographics. [6,15,14]

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4 Recognising that the standard fit panels may no longer be appropriate, the National
5 Institute for Occupational Safety and Health (NIOSH) conducted a new survey of the
6 US work force in 2001.[16] 4026 subjects from 41 different sites in, eight states were
7 recruited, and new fit moulding panels were proposed based on the anthropometric
8 data collected.[16] However, the ethnic groups described in this study differ from the
9 UK. The demographics of the workforce describes one third of the population as
10 Hispanic and specifically categorises the ethnicities as White, African American,
11 Hispanic and Other.[15,16] However, the largest ethnic group after White British in
12 England and Wales is “White other”, followed by Asian – Indian, Asian – Pakistani,
13 Black – African and Asian other.[12] Although NIOSH suggest their data can be used
14 as a starting point for design and certification as the US population is ethnically
15 diverse, the US data may not map accurately to the ethnic makeup of the UK
16 healthcare workforce. Every individual has different features which vary by gender,
17 ethnicity and even occupational role.[17] Face length is a key feature in respirator fit
18 and this has been shown to vary significantly across ethnic and gender groups.[17]
19 For example, anthropometric data shows statistically significant differences in width
20 and face and lip length between African Americans and White Americans.[17] A
21 sample of African Americans and Hispanic individuals in the US workforce were found
22 to have up to face lengths 2.7 and 2.8 mm longer than White Americans.[17] Prior to
23 Covid-19 most respirators were used in industrial applications such as construction.
24 Construction workers are more likely to be male than healthcare staff, and have
25 different facial features, including longer noses.[17] Gender has also been shown to
26 be a major determinant in facial differences and measurements. Nine out of 10 facial
27 measurements vary by gender with the female face being significantly smaller than
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3 the male face.[17] This is of relevance to respirator fit in healthcare workers as 77%
4
5 of the NHS workforce is female.
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10 Future respirator design should consider the facial characteristics of the demographic
11
12 of the workforce. Face panels consisting of a true representation of female and BAME
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14 healthcare workers could help improve respirator design and improve safety when
15
16 caring for Covid-19 patients. Out-dated fit panels used in the design and certification
17
18 of the respirators demonstrate the institutional gender and racial biases in respirator
19
20 fit and must be addressed in order to protect BAME and female staff.
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26 Use of facial anthropometric data representing the current demographics of the
27
28 workforce is not only important in the design of RPE, it can be used to guide
29
30 procurement strategies for the ongoing pandemic. For example, females have on
31
32 average smaller faces so looking at the different proportions of female versus male
33
34 healthcare workers can guide what proportion of the procured respirators should be
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36 smaller versus large.
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42 Examining the shape and measurements of the respirator in comparison to a face
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44 panel representing the workforce could help decision making in procurement. These
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46 techniques using facial anthropometric data representative of the workforce and
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48 observing the success or fail rate of different respirator designs in each ethnic or
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50 gender group could help with the decision-making process of which respirators to
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52 stock. Guiding procurement processes can prevent excesses of poorly sized
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54 respirators and shortages of the correct sizes.
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3 However, even if the correct respirator for the demographic of the workforce was
4 sourced, supply and demand issues of RPE early in the Covid-19 pandemic meant
5 healthcare facilities could not rely upon a steady supply of any single preferred
6 respirator. Every respirator has a different design and fit, therefore individuals should
7 be fit tested on the respirator model they don prior to patient interactions.[8,13] The
8 multiple changes in respirator models mean healthcare workers must be repeatedly fit
9 tested on the new models as supplies change. As healthcare facilities were
10 overwhelmed with the need to fit test staff repeatedly on different masks many adopted
11 an approach to fit check only.[9] Our data demonstrates that respirators have a
12 variable success rate on initial fit test. For example, Design J did not suitably fit 24.4%
13 of our staff. Some studies have demonstrated a fail rate as high as 78% when a
14 respirator is used without fit testing.[10] Failure to fit test may leave a significant
15 proportion of staff inadequately protected against Covid-19 and according to our data
16 it is mixed ethnicity and Asian female healthcare workers who are at greatest risk.

36 **Limitations**

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39 This was a single centre study. The demographics of our data is representative of
40 healthcare facilities in the London however further data should be collected to
41 extrapolate the results to other areas. A large number of respirators were observed
42 in this study and each individual did not test on every model. More data are required
43 to evaluate the efficacy of each model. Finally, previous experience with fit-testing
44 was not accounted for, although quantitative fit-testing is objective and independent
45 of experience, and the use of respirators was generally poor prior to the pandemic so
46 we assumed a homogeneous lack of experience in our cohort.
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Conclusion

Respirator design and certification may be biased towards fitting a demographic that is not reflective of the current healthcare workforce. This could leave many healthcare workers vulnerable as they struggle to fit into a mask not designed for their faces. Lack of design consideration and supply issues could be a dangerous combination for healthcare staff as they rely upon the protection of a properly fitted respirator to reduce the risk of infection transmission whilst caring for patients with Covid-19.

Further research into the design and fit of respiratory protective equipment must consider the demographic of the healthcare workforce as we cannot rely on anthropometric data that represents only one section of the workforce. Creating new fit panels that accurately represent female workers and the ethnically diverse healthcare workforce is an essential first step towards designing well-fitting respirators. In the meantime, it is important to recognise that no one mask will fit all staff. [8-11,13] Therefore the focus should be on employers stocking a suite of RPE, so that a diverse workforce has the best chance of finding a respirator of appropriate fit.

Ensuring fit-testing and keeping adequate stock of a variety of respirator models can help maintain the safety of the whole workforce but future research should focus on the design of respirators for BAME and female healthcare workers.

Acknowledgements

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References

1. Livingston E, Desai A, Berkwits M. Sourcing Personal Protective Equipment During the COVID-19 pandemic. *JAMA* 2020; 323:1912-1914
2. Public Health England. Guidance - Covid-19 Personal Protective Equipment 2020 <https://www.gov.uk/government/publications/wuhan-novel-coronavirus-infection-prevention-and-control/covid-19-personal-protective-equipment-ppe>
3. The Lancet. Editorial - COVID-19: Protecting health-care workers. March 2020.
<http://www.sciencedirect.com/science/article/pii/S0140673620306449>
4. El-Boghdadly K, Wong DJN, Owen R, et al. Risks to healthcare workers following tracheal intubation of patients with COVID-19: a prospective international multicentre cohort study. *Anaesthesia* June 2020; 75: 1437-1447
5. Cook T, Kursumovic E, Lennane S. Exclusive: Deaths of NHS Staff from COVID-19 analysed. April 2020 <https://www.hsj.co.uk/exclusive-deaths-of-nhs-staff-from-covid-19-analysed/7027471.article>

- 1
2
3 6. Amnesty International. UK among the highest COVID-19 healthcare
4 worker deaths in the world 2020. [https://www.amnesty.org.uk/press-](https://www.amnesty.org.uk/press-releases/uk-among-highest-covid-19-health-worker-deaths-world)
5
6 releases/uk-among-highest-covid-19-health-worker-deaths-world
7
8
9
- 10
11
12 7. British Medical Association. BMA survey reveals almost half of doctors
13 have relied upon donated or self-bought PPE and two thirds still don't feel
14 fully protected 2020. [https://www.bma.org.uk/bma-media-centre/bma-](https://www.bma.org.uk/bma-media-centre/bma-survey-reveals-almost-half-of-doctors-have-relied-upon-donated-or-self-bought-ppe-and-two-thirds-still-don-t-feel-fully-protected)
15 survey-reveals-almost-half-of-doctors-have-relied-upon-donated-or-self-
16 bought-ppe-and-two-thirds-still-don-t-feel-fully-protected
17
18
19
20
21
22
23
- 24
25
26 8. Health and Safety Executive. Fit Testing Face Masks to Avoid
27 Transmission during the coronavirus outbreak. 2020.
28
29
30
31 [https://www.hse.gov.uk/coronavirus/ppe-face-masks/face-mask-ppe-](https://www.hse.gov.uk/coronavirus/ppe-face-masks/face-mask-ppe-rpe.htm)
32 rpe.htm
33
34
35
36
37
- 38 9. The Guardian. Hospitals Accused of Risking Staff Lives by Abandoning
39 PPE Fit Tests. March 2020.
40
41
42 [https://www.theguardian.com/world/2020/apr/14/nhs-hospitals-accused-](https://www.theguardian.com/world/2020/apr/14/nhs-hospitals-accused-of-risking-staff-lives-by-abandoning-ppe-fit-tests-coronavirus)
43 of-risking-staff-lives-by-abandoning-ppe-fit-tests-coronavirus
44
45
46
47
48
49
50
- 51 10. Manganyi J, Wilson K, Rees D. Quantitative respirator fit, face sizes and
52 determinants of fit in South African diagnostic laboratory respirator users.
53
54 Annals of Work Exposures and Health Nov 2017; 61;9:1154-1162
55
56
57
58
59
60

- 1
2
3 11. Oestenstad R, Elliot L, Beasley T. The effect of gender and respirator
4 brand on the association of respirator fit with facial dimensions. Journal of
5 Occupational and Environmental Hygiene Dec 2007;4 923-930
6
7
8
9
10
11
12 12. UK Census 2011. Ethnicity Facts and Figures [https://www.ethnicity-facts-](https://www.ethnicity-facts-figures.service.gov.uk/)
13 [figures.service.gov.uk/](https://www.ethnicity-facts-figures.service.gov.uk/)
14
15
16
17
18
19 13. Health and Safety Executive. Guidance on respiratory protective
20 equipment (RPE) fit testing 2019. [https://www.hse.gov.uk/respiratory-](https://www.hse.gov.uk/respiratory-protective-equipment/)
21 [protective-equipment/](https://www.hse.gov.uk/respiratory-protective-equipment/)
22
23
24
25
26
27
28 14. NHS England. NHS Workforce Race and Equality Standard Report 2019.
29 [https://www.england.nhs.uk/wp-content/uploads/2020/01/wre-2019-data-](https://www.england.nhs.uk/wp-content/uploads/2020/01/wre-2019-data-report.pdf)
30 [report.pdf](https://www.england.nhs.uk/wp-content/uploads/2020/01/wre-2019-data-report.pdf)
31
32
33
34
35
36
37 15. Bailar J, Meyer E, Pool R. Institute of Medicine: Assessment of the
38 NIOSH head-and-face anthropometric survey of US respirator users.
39 2007 pp1-108
40
41
42
43
44
45
46
47 16. American Industrial Hygiene Association. Respirator Fit Testing Methods
48 2010 ISBN 978-1-935082-24-8
49
50
51
52
53
54
55 17. Zhuang Z, Landsittel D, Benson S et al. Facial Anthropometric
56 differences among gender, ethnicity and age groups. Annals of
57 Occupational Hygiene Jun 2010; 54(4):391-402
58
59
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Figure A

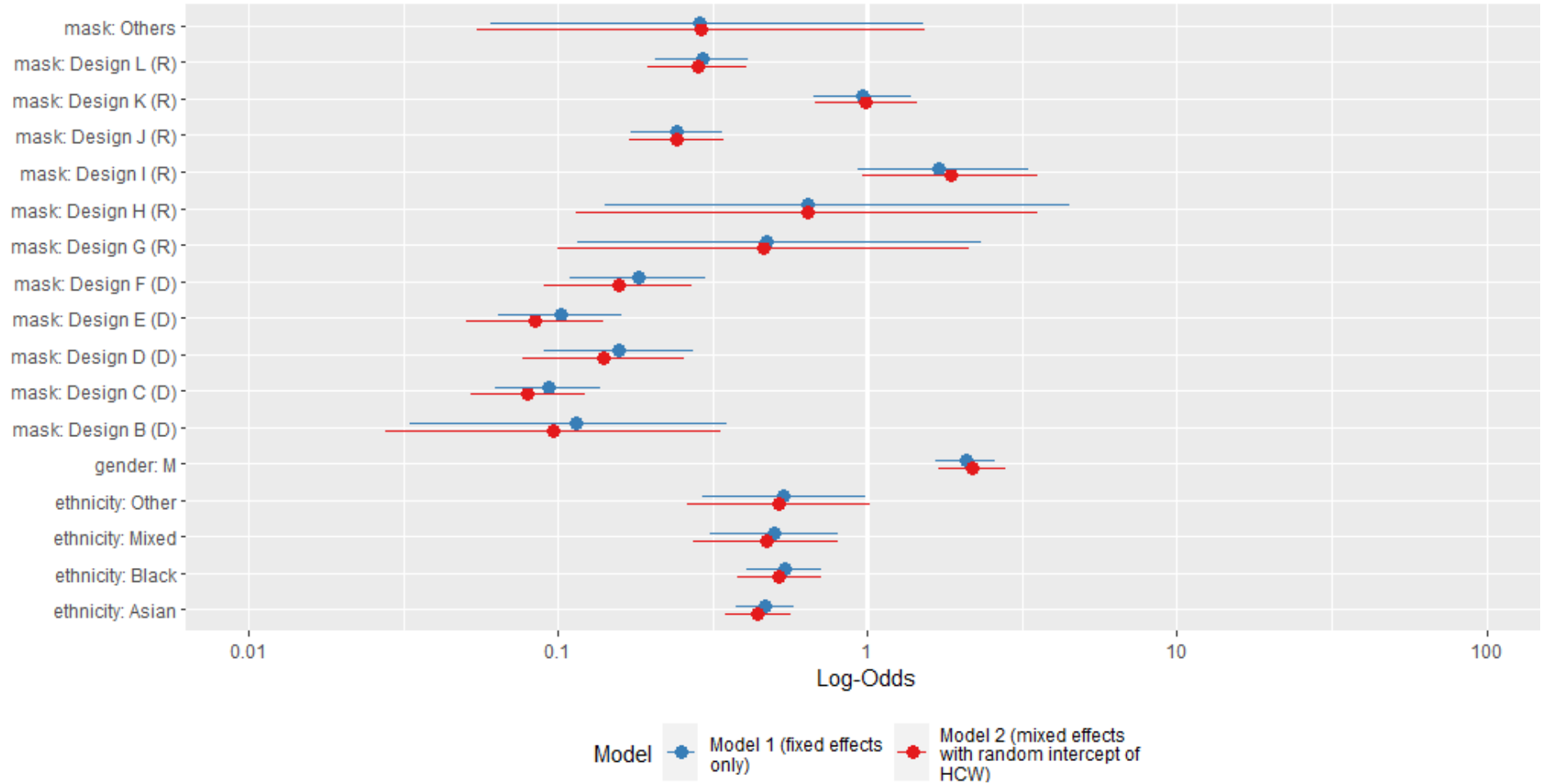


Figure A: Forest plot comparing the fixed effects point estimates and 95% confidence intervals the original model in the manuscript (Model 1) compared to a revised model fitted using mixed effects logistic regression with a random intercept for HCW (Model 2).

Figure B

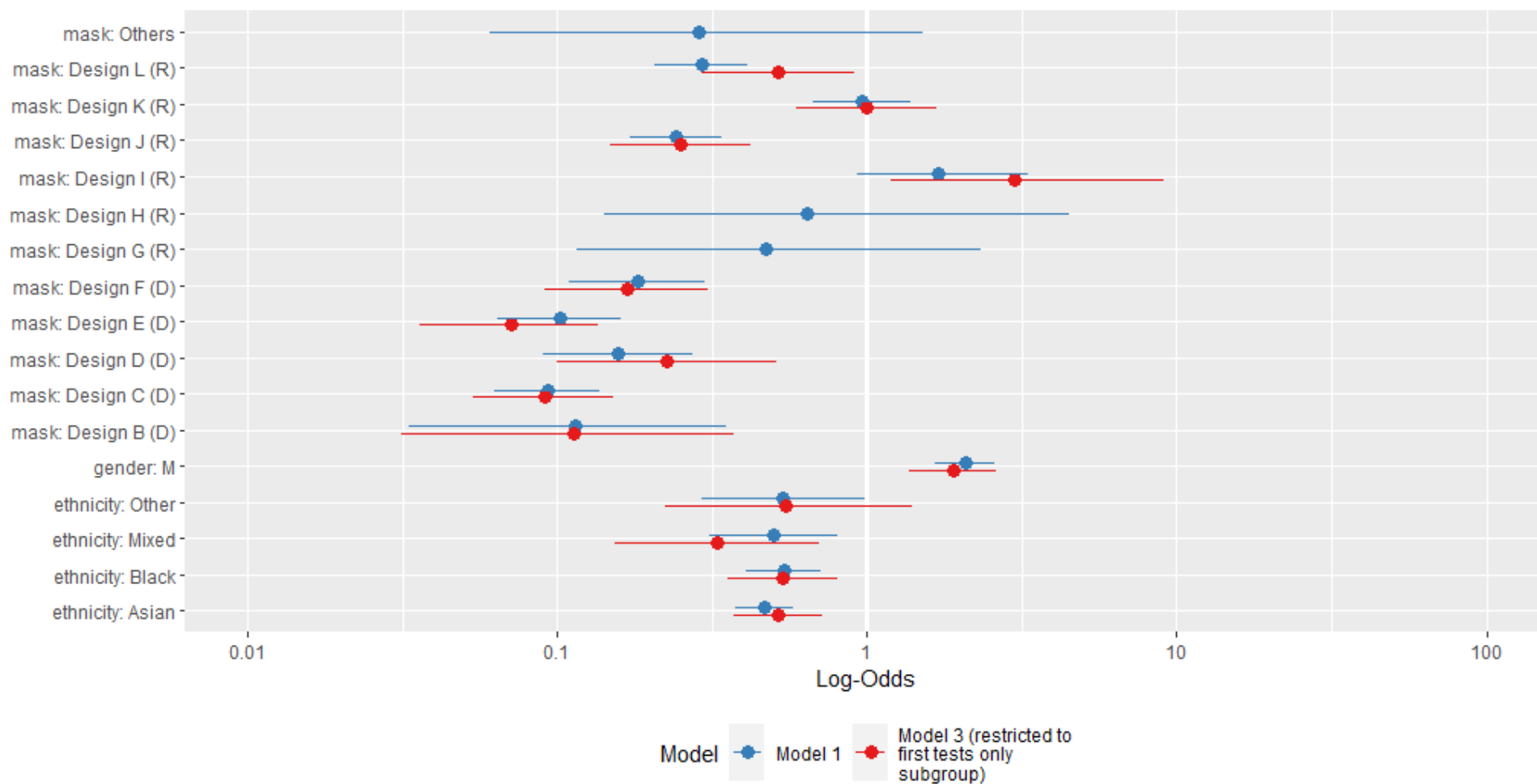


Figure A: Forest plot comparing the fixed effects point estimates and 95% confidence intervals the original model in the manuscript (Model 1) compared to a revised model fitted using only subgroup data from first fit test attempts (Model 3).

Supplementary Table

Supplementary Table: Description of Different Masks Used

Mask Design	Manufacturer	Model	Shape	Expiratory Filter Y/N	Reusable (R) / Disposable (D)	Grade of mask
A	Full Support Group	Easimask FSM18	Cup	N	D	FFP3 / N99 equivalent
B	Full Support Group	Easimask FSM16	Duckbill	N	D	FFP3 / N99 equivalent
C	3M	1863	Fold out 3 Panel	N	D	FFP3 / N99 equivalent
D	3M	8833	Cup	Y	D	FFP3 / N99 equivalent
E	3M	1873	Fold out 3 Panel	Y	D	FFP3 / N99 equivalent
F	3M	Aura 1863+	Fold out 3 Panel	N	D	FFP3 / N99 equivalent
G	3M	6500 +P3 Filter	Half mask	Y	R	FFP3 / N99 equivalent
H	3M	7500 +P3 Filter	Half mask	Y	R	FFP3 / N99 equivalent
I	Scott Safety	Aviva 50 +P3 Filter	Half mask	Y	R	FFP3 / N99 equivalent
J	JSP Safety	Force 8 +P3 Filter	Half mask	Y	R	FFP3 / N99 equivalent
K	Sundstrom	SR100 +P3 Filter	Half mask	Y	R	FFP3 / N99 equivalent
L	PureFlo	PF1000 +P3 Filter	Half mask	Y	R	FFP3 / N99 equivalent

**Revised Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0)
September 15, 2015**

Text Section and Item Name	Section or Item Description
Notes to authors	<ul style="list-style-type: none"> • The SQUIRE guidelines provide a framework for reporting new knowledge about how to improve healthcare • The SQUIRE guidelines are intended for reports that describe system level work to improve the quality, safety, and value of healthcare, and used methods to establish that observed outcomes were due to the intervention(s). • A range of approaches exists for improving healthcare. SQUIRE may be adapted for reporting any of these. • Authors should consider every SQUIRE item, but it may be inappropriate or unnecessary to include every SQUIRE element in a particular manuscript. • The SQUIRE Glossary contains definitions of many of the key words in SQUIRE. • The Explanation and Elaboration document provides specific examples of well-written SQUIRE items, and an in-depth explanation of each item. • Please cite SQUIRE when it is used to write a manuscript.
Title and Abstract	
1. Title	Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patient-centeredness, timeliness, cost, efficiency, and equity of healthcare)
2. Abstract	<ol style="list-style-type: none"> a. Provide adequate information to aid in searching and indexing b. Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions
Introduction	<i>Why did you start?</i>
3. Problem Description	Nature and significance of the local problem
4. Available knowledge	Summary of what is currently known about the problem , including relevant previous studies

Page 1

Page 3

Page 6

Page 13-14

5. Rationale	Informal or formal frameworks, models, concepts, and/or theories used to explain the problem , any reasons or assumptions that were used to develop the intervention(s) , and reasons why the intervention(s) was expected to work	Page 13-14 Page 15-16
6. Specific aims	Purpose of the project and of this report	Page 6,7, 13
Methods	<i>What did you do?</i>	
7. Context	Contextual elements considered important at the outset of introducing the intervention(s)	Page 7-8
8. Intervention(s)	a. Description of the intervention(s) in sufficient detail that others could reproduce it b. Specifics of the team involved in the work	Page 7-8
9. Study of the Intervention(s)	a. Approach chosen for assessing the impact of the intervention(s) b. Approach used to establish whether the observed outcomes were due to the intervention(s)	
10. Measures	a. Measures chosen for studying processes and outcomes of the intervention(s) , including rationale for choosing them, their operational definitions, and their validity and reliability b. Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency, and cost c. Methods employed for assessing completeness and accuracy of data	Page 9
11. Analysis	a. Qualitative and quantitative methods used to draw inferences from the data b. Methods for understanding variation within the data, including the effects of time as a variable	Page 9-12
12. Ethical Considerations	Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest	Page 13-16
Results	<i>What did you find?</i>	
13. Results	a. Initial steps of the intervention(s) and their evolution over time (e.g., time-line diagram, flow chart, or table), including modifications made to the intervention during the project b. Details of the process measures and outcome c. Contextual elements that interacted with the intervention(s) d. Observed associations between outcomes, interventions, and relevant contextual elements e. Unintended consequences such as unexpected benefits, problems, failures, or costs associated with the intervention(s) . f. Details about missing data	Page 9-12
Discussion	<i>What does it mean?</i>	
14. Summary	a. Key findings, including relevance to the rationale and specific aims b. Particular strengths of the project	Page 11 Page 13-16

<p>1 2 3 4 5 6 7 8 9 10 11</p> <p>15. Interpretation</p>	<p>a. Nature of the association between the intervention(s) and the outcomes</p> <p>b. Comparison of results with findings from other publications</p> <p>c. Impact of the project on people and systems</p> <p>d. Reasons for any differences between observed and anticipated outcomes, including the influence of context</p> <p>e. Costs and strategic trade-offs, including opportunity costs</p>	<p>page 9-11 Page 13-14</p>
<p>12 13 14 15 16</p> <p>16. Limitations</p>	<p>a. Limits to the generalizability of the work</p> <p>b. Factors that might have limited internal validity such as confounding, bias, or imprecision in the design, methods, measurement, or analysis</p> <p>c. Efforts made to minimize and adjust for limitations</p>	<p>Page 16</p>
<p>17 18 19 20 21 22</p> <p>17. Conclusions</p>	<p>a. Usefulness of the work</p> <p>b. Sustainability</p> <p>c. Potential for spread to other contexts</p> <p>d. Implications for practice and for further study in the field</p> <p>e. Suggested next steps</p>	<p>Page 15-17</p>
<p>23 24</p> <p>Other information</p>		
<p>25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60</p> <p>18. Funding</p>	<p>Sources of funding that supported this work. Role, if any, of the funding organization in the design, implementation, interpretation, and reporting</p>	<p>Page 2</p>

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3 **Table 2. Glossary of key terms used in SQUIRE 2.0. This Glossary provides the intended**
4 **meaning of selected words and phrases as they are used in the SQUIRE 2.0 Guidelines. They**
5 **may, and often do, have different meanings in other disciplines, situations, and settings.**
6

7 **Assumptions**

8 Reasons for choosing the activities and tools used to bring about changes in healthcare services at
9 the [system](#) level.
10
11

12 **Context**

13 Physical and sociocultural makeup of the local environment (for example, external environmental
14 factors, organizational dynamics, collaboration, resources, leadership, and the like), and the
15 interpretation of these factors (“sense-making”) by the healthcare delivery professionals, patients,
16 and caregivers that can affect the effectiveness and [generalizability](#) of [intervention\(s\)](#).
17
18

19 **Ethical aspects**

20 The value of [system](#)-level [initiatives](#) relative to their potential for harm, burden, and cost to the
21 stakeholders. Potential harms particularly associated with efforts to improve the quality, safety, and
22 value of healthcare services include [opportunity costs](#), invasion of privacy, and staff distress
23 resulting from disclosure of poor performance.
24
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26 **Generalizability**

27 The likelihood that the [intervention\(s\)](#) in a particular report would produce similar results in other
28 settings, situations, or environments (also referred to as external validity).
29
30

31 **Healthcare improvement**

32 Any systematic effort intended to raise the quality, safety, and value of healthcare services, usually
33 done at the [system](#) level. We encourage the use of this phrase rather than “quality improvement,”
34 which often refers to more narrowly defined approaches.
35
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37 **Inferences**

38 The meaning of findings or data, as interpreted by the stakeholders in healthcare services –
39 improvers, healthcare delivery professionals, and/or patients and families
40
41

42 **Initiative**

43 A broad term that can refer to organization-wide programs, narrowly focused projects, or the details
44 of specific interventions (for example, planning, execution, and assessment)
45
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47 **Internal validity**

48 Demonstrable, credible evidence for efficacy (meaningful impact or change) resulting from
49 introduction of a specific intervention into a particular healthcare [system](#).
50
51

52 **Intervention(s)**

53 The specific activities and tools introduced into a healthcare [system](#) with the aim of changing its
54 performance for the better. Complete description of an intervention includes its inputs, internal
55 activities, and outputs (in the form of a logic model, for example), and the mechanism(s) by which
56 these components are expected to produce changes in a [system's](#) performance.
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59 **Opportunity costs**

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3 Loss of the ability to perform other tasks or meet other responsibilities resulting from the diversion
4 of resources needed to introduce, test, or sustain a particular [improvement](#) initiative
5
6

7 **Problem**

8 Meaningful disruption, failure, inadequacy, distress, confusion or other dysfunction in a healthcare
9 service delivery [system](#) that adversely affects patients, staff, or the [system](#) as a whole, or that
10 prevents care from reaching its full potential
11

12 **Process**

13 The routines and other activities through which healthcare services are delivered
14
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16 **Rationale**

17 Explanation of why particular [intervention\(s\)](#) were chosen and why it was expected to work, be
18 sustainable, and be replicable elsewhere.
19

20 **Systems**

21 The interrelated structures, people, [processes](#), and activities that together create healthcare services
22 for and with individual patients and populations. For example, systems exist from the personal self-
23 care system of a patient, to the individual provider-patient dyad system, to the microsystem, to the
24 macrosystem, and all the way to the market/social/insurance system. These levels are nested within
25 each other.
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28 **Theory or theories**

29 Any “reason-giving” account that asserts causal relationships between variables (causal theory) or
30 that makes sense of an otherwise obscure [process](#) or situation (explanatory theory). Theories come
31 in many forms, and serve different purposes in the phases of [improvement](#) work. It is important to
32 be explicit and well-founded about any informal and formal theory (or theories) that are used.
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