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

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Contributorship Statement

Dr Clarissa Carvalho was the study lead,lead researcher and writer of this article. Dr Jan Schumacher, Dr Paul Greig and Dr Kariem El-Bogdadhly 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.

Short title: Gender, ethnicity and fit testing

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

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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.

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 facing the Covid-19 pandemic. Future work on RPE designs must take in to BAME and female Healthcare staff.

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

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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 ethnicity and gender are factors in the suitability of respirators in healthcare workers exposed to patients with Covid-19.

Methods

We conducted a prospective observational study examining fit testing results by ethnicity and gender from staff in a central London teaching hospital and designated Covid-19 centre. This study was deemed exempt from ethical review as it met the criteria for a service evaluation and was registered as a service evaluation with Guy's and St Thomas' NHS Foundation Trust (ID 10918). No patients or members of the public were included in this study. All members of the workforce in patient-facing roles were eligible to attend the fit testing clinic. We included healthcare workers who underwent quantitative fit tests (QNFT) only. Exclusion criteria were healthcare workers who were not in patient-facing roles, those unable to undertake the fit testing procedure (e.g. unable to remove head wear, remove facial hair, or unable to perform the procedure), those that underwent only qualitative fit testing, or those unwilling to participate in fit testing.

Fit testing data were collected between 3rd February and 3rd July 2020 and included the participant's self-described gender and ethnicity in free-text. For the purposes of this study the free-text responses were mapped to the Office of National Statistics categories for ethnicity as used in the UK census.[15]

Fit testing was conducted by certified fit testers. Participants had to refrain from smoking one hour prior to the test, had to be clean shaven and could not wear any head wear. The QNFT involved the use of a TSI Portacount 8030 (TSI UK, High Wycombe) using the standard Health and Safety Executive fit testing procedure.[15]

QNFT fit test scores were dichotomised as pass or fail based on achieving an overall fit factor >100. We report the overall numbers and proportions of staff who passed their first fit test and grouped by self-reported gender and ethnicity. The likelihood of passing the first fit test for male and female genders, and White and BAME groups were compared using Pearson's Chi-squared test (without Yate's Continuity, as all cell frequencies were greater than 10). Logistic regression modelling was performed using each fit test as a separate observation, with the binary outcome variable defined as fit test success (pass/fail), and using the following explanatory variables: gender, ethnicity and mask design (disposable vs reusable). We first modelled the bivariate association between the outcome variable and each explanatory variable separately, and then in a multivariable model including all explanatory variables to obtain adjusted odds ratio (OR) estimates. Mask designs were specified in our models as categorical variables and were compared against a reference design A, which was our most widely-tested disposable mask design. 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.

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

	n (%) ***(n = 1182)***
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			
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

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 designs. Mask designs demonstrated variable performance in terms of obtaining a successful fit (Table 2).

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.[13] Failure of RPE to protect BAME healthcare workers affects a significant proportion of the NHS workforce.

Our data suggests 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.[10,12] 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.[12]

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. [6,12,13]

Recognising that the standard fit panels may no longer be appropriate, the National Institute for Occupational Safety and Health (NIOSH) conducted a new survey of the US work force in 2001.[17] 4026 subjects from 41 different sites in, eight states were recruited, and new fit moulding panels were proposed based on the anthropometric data collected.[17] However, the ethnic groups described in this study differ from the UK. The demographics of the workforce describes one third of the population as Hispanic and specifically categorises the ethnicities as White, African American, Hispanic and Other.[12,17] However, the largest ethnic group after White British in England and Wales is "White other", followed by Asian – Indian, Asian – Pakistani, Black – African and Asian other.[16] Although NIOSH suggest their data can be used as a starting point for design and certification as the US population is ethnically diverse, the US data may not map accurately to the ethnic makeup of the UK healthcare workforce. Every individual has different features which vary by gender, ethnicity and even occupational role.[14] Face length is a key feature in respirator fit and this has been shown to vary significantly across ethnic and gender groups.[14] For example, anthropometric data shows statistically significant differences in width and face and lip length between African Americans and White Americans.[14] A sample of African Americans and Hispanic individuals in the US workforce were found to have up to face lengths 2.7 and 2.8 mm longer than White Americans.[14] Prior to Covid-19 most respirators were used in industrial applications such as construction. Construction workers are more likely to be male than healthcare staff, and have different facial features, including longer noses.[14] Gender has also been shown to be a major determinant in facial differences and measurements. Nine out of 10 facial measurements vary by gender with the female face being significantly smaller than the male face.[14] This is of relevance to respirator fit in healthcare workers as 77% of the NHS workforce is female.

Future respirator design should consider the facial characteristics of the demographic of the workforce. Face panels consisting of a true representation of female and BAME healthcare workers could help improve respirator design and improve safety when caring for Covid-19 patients. Out-dated fit panels used in the design and certification of the respirators demonstrate the institutional gender and racial biases in respirator fit and must be addressed in order to protect BAME and female staff.

Use of facial anthropometric data representing the current demographics of the workforce is not only important in the design of RPE, it can be used to guide procurement strategies for the ongoing pandemic. For example, females have on average smaller faces so looking at the different proportions of female versus male healthcare workers can guide what proportion of the procured respirators should be smaller versus large.

Examining the shape and measurements of the respirator in comparison to a face panel representing the workforce could help decision making in procurement. These techniques using facial anthropometric data representative of the workforce and observing the success or fail rate of different respirator designs in each ethnic or gender group could help with the decision-making process of which respirators to stock. Guiding procurement processes can prevent excesses of poorly sized respirators and shortages of the correct sizes.

However, even if the correct respirator for the demographic of the workforce was sourced, supply and demand issues of RPE early in the Covid-19 pandemic meant healthcare facilities could not rely upon a steady supply of any single preferred respirator. Every respirator has a different design and fit, therefore individuals should be fit tested on the respirator model they don prior to patient interactions.[8,15] The multiple changes in respirator models mean healthcare workers must be repeatedly fit tested on the new models as supplies change. As healthcare facilities were overwhelmed with the need to fit test staff repeatedly on different masks many adopted an approach to fit check only.[9] Our data demonstrates that respirators have a variable success rate on initial fit test. For example, Design J did not suitably fit 24.4% of our staff. Some studies have demonstrated a fail rate as high as 78% when a respirator is used without fit testing.[10] Failure to fit test may leave a significant proportion of staff inadequately protected against Covid-19 and according to our data it is mixed ethnicity and Asian female healthcare workers who are at greatest risk.

Limitations

This was a single centre, single city study. The demographics of our data is representative of healthcare facilities in the London however further data should be collected to extrapolate the results to other areas.

A large number of respirators were observed in this study and each individual did not test on every model. Increased data is required to evaluate the efficacy of each model.

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.

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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	• 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	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	*Why did you start?*
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. 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
6. Specific aims	Purpose of the project and of this report
Methods	*What did you do?*
7. Context	Contextual elements considered important at the outset of introducing the intervention(s)
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
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	*What did you find?*
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	*What does it mean?*
14. Summary	a. Key findings, including relevance to the rationale and specific aims b. Particular strengths of the project

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

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 "qua 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's performance.

Opportunity costs

Loss of the ability to perform other tasks or meet other responsibilities resulting from the diversion of resources needed to introduce, test, or sustain a particular improvement initiative

Problem
Meaningful disruption, failure, inadequacy, distress, confusion or other dysfunction in a healthcare service delivery system that adversely affects patients, staff, or the system as a whole, or that prevents care from reaching its full potential

Process
The routines and other activities through which healthcare services are delivered

Rationale
Explanation of why particular intervention(s) were chosen and why it was expected to work, be sustainable, and be replicable elsewhere.

Systems
The interrelated structures, people, processes, and activities that together create healthcare services for and with individual patients and populations. For example, systems exist from the personal self-care system of a patient, to the individual provider-patient dyad system, to the microsystem, to the macrosystem, and all the way to the market/social/insurance system. These levels are nested within each other.

Theory or theories
Any “-rgeiavsionrg” account that asserts causal rela
that makes sense of an otherwise obscure process or situation (explanatory theory). Theories come in many forms, and serve different purposes in the phases of improvement work. It is important to 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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Manuscripts

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-Bogdadhly 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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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.

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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-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 ethnicity and gender are factors in the suitability of respirators in healthcare workers exposed to patients with Covid-19.

Methods

We conducted a prospective observational study examining fit testing results by ethnicity and gender from staff in a central London teaching hospital and designated Covid-19 centre. This study was deemed exempt from ethical review as it met the criteria for a service evaluation and was registered with Guy's and St Thomas' NHS Foundation Trust (ID 10918) as a service evaluation. No patients or members of the public were included in this study. All members of the workforce in patient-facing roles were eligible to attend the fit testing clinic. We included healthcare workers who underwent quantitative fit tests (QNFT) only. Exclusion criteria were healthcare workers who were not in patient-facing roles, those unable to undertake the fit testing procedure (e.g. unable to remove head wear, remove facial hair, or unable to perform the procedure), those that underwent only qualitative fit testing, or those unwilling to participate in fit testing.

Fit testing data were collected between 3rd February and 3rd July 2020 and included the participant's self-described gender and ethnicity in free-text. The free-text responses were mapped to the Office of National Statistics categories for ethnicity as used in the UK census.[12]

Fit testing was conducted by certified fit testers. Participants had to refrain from smoking one hour prior to the test, had to be clean shaven and could not wear any head wear. The QNFT involved the use of a TSI Portacount 8030 (TSI UK, High Wycombe) using the standard Health and Safety Executive fit testing procedure.[13]

QNFT fit test scores were dichotomised as pass or fail based on achieving an overall fit factor >100. We report the overall numbers and proportions of staff who passed their first fit test and grouped by self-reported gender and ethnicity. The likelihood of passing the first fit test for male and female genders, and White and BAME groups were compared using Pearson's Chi-squared test (without Yate's Continuity, as all cell frequencies were greater than 10). Logistic regression modelling was performed using each fit test as a separate observation, with the binary outcome variable defined as fit test success (pass/fail), and using the following explanatory variables: gender, ethnicity and mask design (disposable vs reusable). We first modelled the bivariate association between the outcome variable and each explanatory variable separately, and then in a multivariable model including all explanatory variables to obtain adjusted odds ratio (OR) estimates. Mask designs were specified in our models as categorical variables and were compared against a reference design A, which was our most widely-tested disposable mask design. The following *post hoc* analyses were performed to assess the possibility that healthcare workers could learn to game the fit testing process and repeated testing of the same healthcare workers using different masks could render the tests not independent of each other: First we fitted mixed effects logistic regression models with random-intercepts for healthcare workers, assuming that tests were nested within healthcare workers; Second we repeated the original fixed-effects only logistic regression modelling with a subset of our dataset, 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

	n (%) ***(n = 1182)***
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.

		Failed first fit attempt (n)	***Passed first fit attempt (n)***	***Probability of passing first fit attempt (%)***
Gender	Ethnicity			
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]

Recognising that the standard fit panels may no longer be appropriate, the National Institute for Occupational Safety and Health (NIOSH) conducted a new survey of the US work force in 2001.[16] 4026 subjects from 41 different sites in, eight states were recruited, and new fit moulding panels were proposed based on the anthropometric data collected.[16] However, the ethnic groups described in this study differ from the UK. The demographics of the workforce describes one third of the population as Hispanic and specifically categorises the ethnicities as White, African American, Hispanic and Other.[15,16] However, the largest ethnic group after White British in England and Wales is "White other", followed by Asian – Indian, Asian – Pakistani, Black – African and Asian other.[12] Although NIOSH suggest their data can be used as a starting point for design and certification as the US population is ethnically diverse, the US data may not map accurately to the ethnic makeup of the UK healthcare workforce. Every individual has different features which vary by gender, ethnicity and even occupational role.[17] Face length is a key feature in respirator fit and this has been shown to vary significantly across ethnic and gender groups.[17] For example, anthropometric data shows statistically significant differences in width and face and lip length between African Americans and White Americans.[17] A sample of African Americans and Hispanic individuals in the US workforce were found to have up to face lengths 2.7 and 2.8 mm longer than White Americans.[17] Prior to Covid-19 most respirators were used in industrial applications such as construction. Construction workers are more likely to be male than healthcare staff, and have different facial features, including longer noses.[17] Gender has also been shown to be a major determinant in facial differences and measurements. Nine out of 10 facial measurements vary by gender with the female face being significantly smaller than the male face.[17] This is of relevance to respirator fit in healthcare workers as 77% of the NHS workforce is female.

Future respirator design should consider the facial characteristics of the demographic of the workforce. Face panels consisting of a true representation of female and BAME healthcare workers could help improve respirator design and improve safety when caring for Covid-19 patients. Out-dated fit panels used in the design and certification of the respirators demonstrate the institutional gender and racial biases in respirator fit and must be addressed in order to protect BAME and female staff.

Use of facial anthropometric data representing the current demographics of the workforce is not only important in the design of RPE, it can be used to guide procurement strategies for the ongoing pandemic. For example, females have on average smaller faces so looking at the different proportions of female versus male healthcare workers can guide what proportion of the procured respirators should be smaller versus large.

Examining the shape and measurements of the respirator in comparison to a face panel representing the workforce could help decision making in procurement. These techniques using facial anthropometric data representative of the workforce and observing the success or fail rate of different respirator designs in each ethnic or gender group could help with the decision-making process of which respirators to stock. Guiding procurement processes can prevent excesses of poorly sized respirators and shortages of the correct sizes.

However, even if the correct respirator for the demographic of the workforce was sourced, supply and demand issues of RPE early in the Covid-19 pandemic meant healthcare facilities could not rely upon a steady supply of any single preferred respirator. Every respirator has a different design and fit, therefore individuals should be fit tested on the respirator model they don prior to patient interactions.[8,13] The multiple changes in respirator models mean healthcare workers must be repeatedly fit tested on the new models as supplies change. As healthcare facilities were overwhelmed with the need to fit test staff repeatedly on different masks many adopted an approach to fit check only.[9] Our data demonstrates that respirators have a variable success rate on initial fit test. For example, Design J did not suitably fit 24.4% of our staff. Some studies have demonstrated a fail rate as high as 78% when a respirator is used without fit testing.[10] Failure to fit test may leave a significant proportion of staff inadequately protected against Covid-19 and according to our data it is mixed ethnicity and Asian female healthcare workers who are at greatest risk.

Limitations

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

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.

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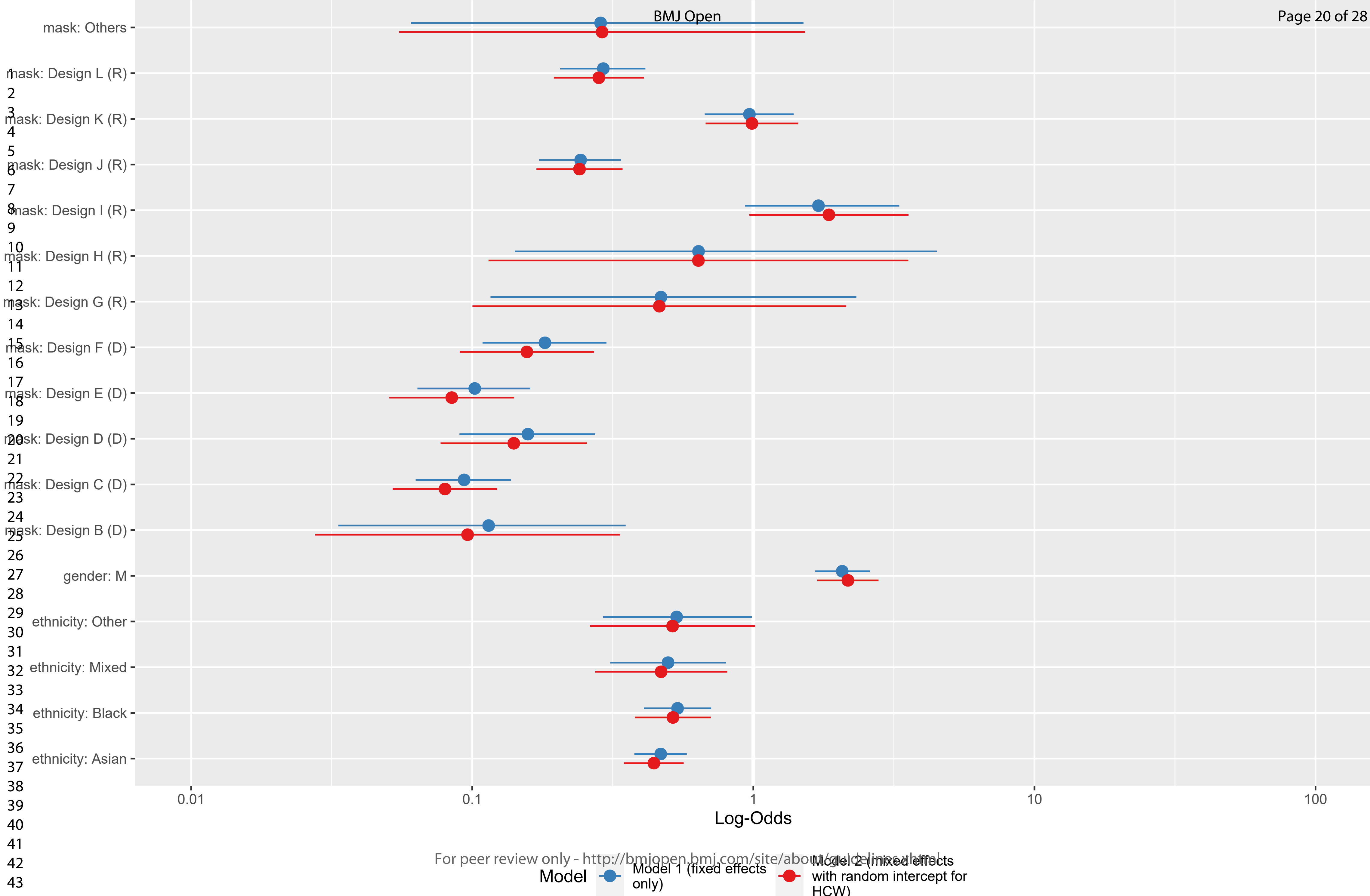
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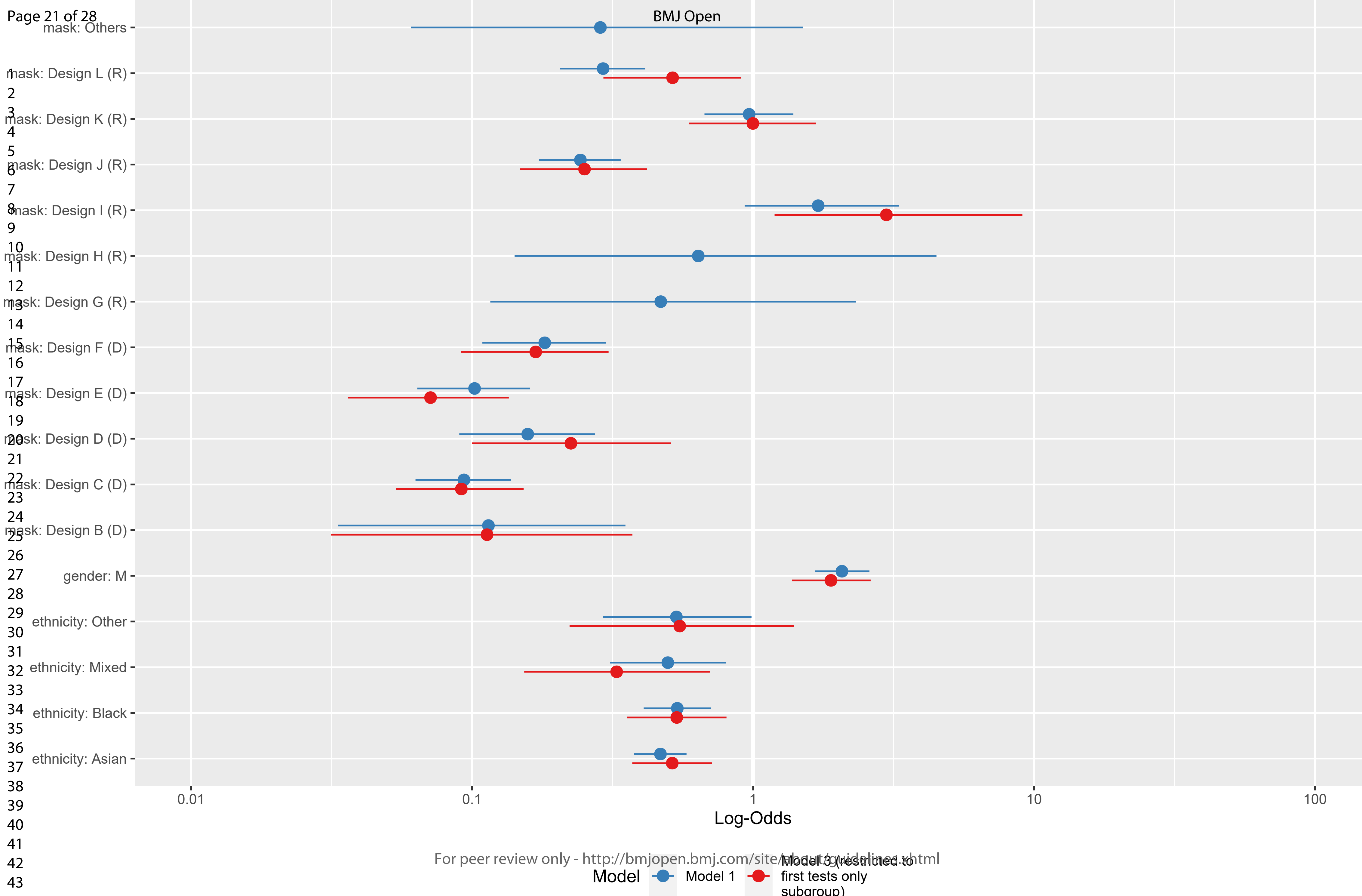
mask: Design H (R)
mask: Design G (R)
mask: Design F (D)
mask: Design E (D)
mask: Design D (D)
mask: Design C (D)
mask: Design B (D)
gender: M
ethnicity: Other
ethnicity: Mixed
ethnicity: Black
ethnicity: Asian
0.01
0.1
1
10
100
Log-Odds
Model
Model 1 (fixed effects only)
Model 2 (mixed effects with random intercept for HCW)


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
0.01
0.1
1
10
100
Log-Odds
Model
Model 1
Model 3 (restricted to first tests only subgroup)

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

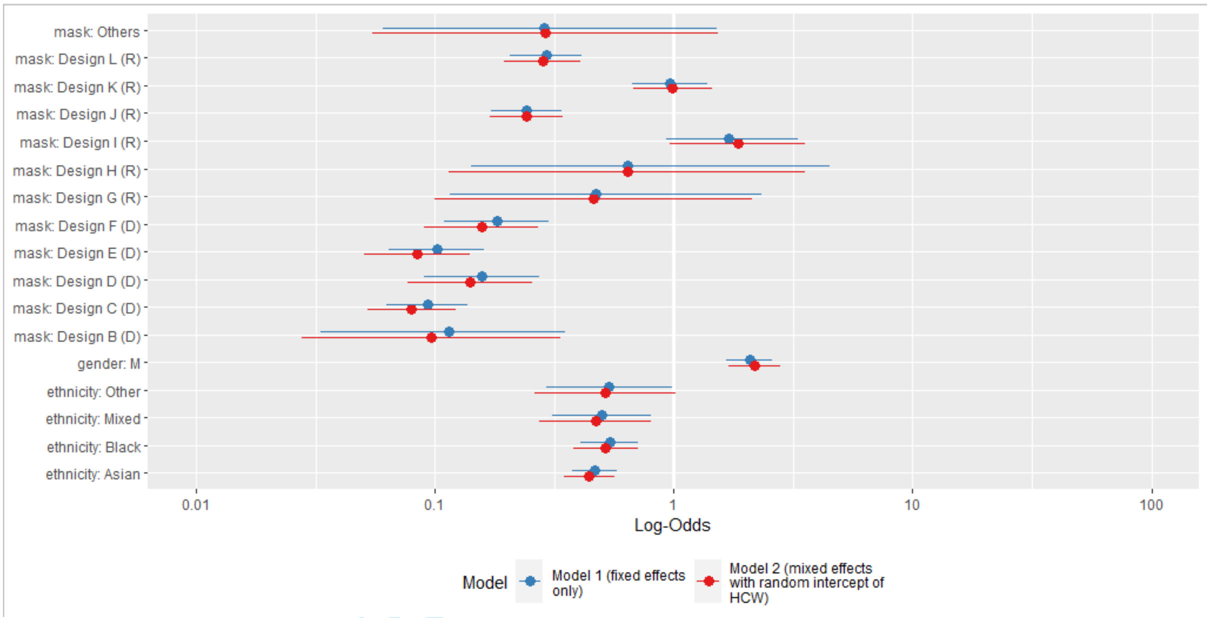


Figure A: Forest plot comparing the fixed effects point estimates and 95% confidence intervals the original model in the manuscript (Model 1) compared to a revised model fitted using mixed effects logistic regression with a random intercept for HCW (Model 2).

Figure B

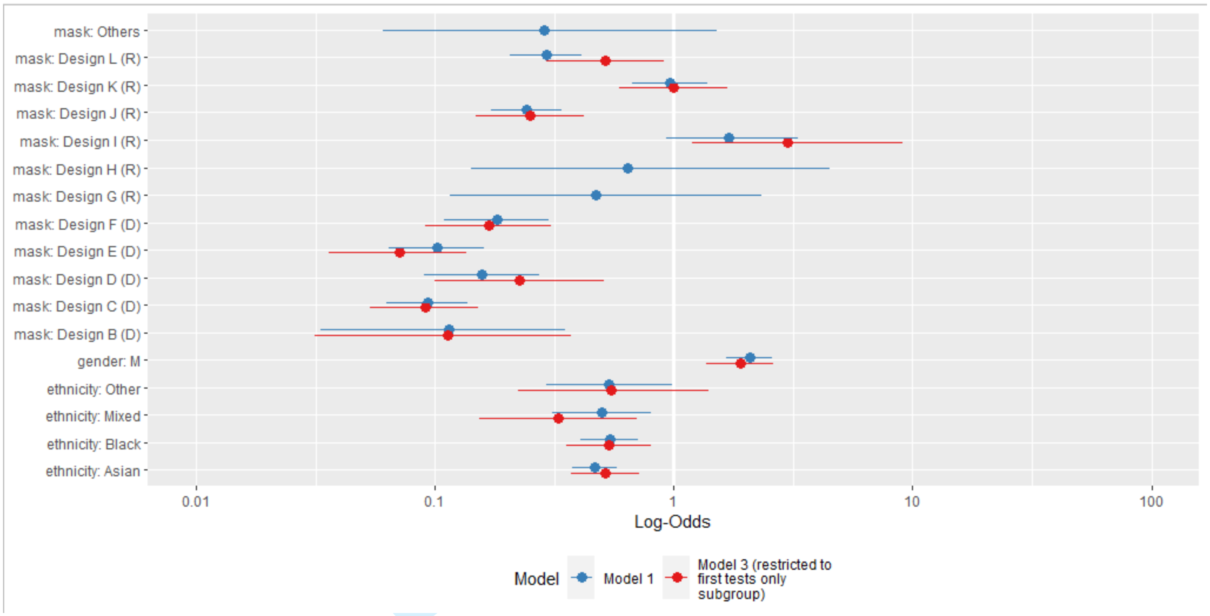


Figure B: Forest plot comparing the fixed effects point estimates and 95% confidence intervals the original model in the manuscript (Model 1) compared to a revised model fitted using only subgroup data from first fit

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	• 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	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	*Why did you start?*
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. 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
6. Specific aims	Purpose of the project and of this report
Methods	*What did you do?*
7. Context	Contextual elements considered important at the outset of introducing the intervention(s)
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
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	*What did you find?*
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	*What does it mean?*
14. Summary	a. Key findings, including relevance to the rationale and specific aims b. Particular strengths of the project

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

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 improvement," 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's performance.

Opportunity costs

Loss of the ability to perform other tasks or meet other responsibilities resulting from the diversion of resources needed to introduce, test, or sustain a particular improvement initiative

Problem
Meaningful disruption, failure, inadequacy, distress, confusion or other dysfunction in a healthcare service delivery system that adversely affects patients, staff, or the system as a whole, or that prevents care from reaching its full potential

Process
The routines and other activities through which healthcare services are delivered

Rationale
Explanation of why particular intervention(s) were chosen and why it was expected to work, be sustainable, and be replicable elsewhere.

Systems
The interrelated structures, people, processes, and activities that together create healthcare services for and with individual patients and populations. For example, systems exist from the personal self-care system of a patient, to the individual provider-patient dyad system, to the microsystem, to the macrosystem, and all the way to the market/social/insurance system. These levels are nested within each other.

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

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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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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Contributorship Statement

Dr Clarissa Carvalho was the study lead, lead researcher and writer of this article. Dr Jan Schumacher, Dr Paul Greig and Dr Kariem El-Bogdadhly 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.

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.

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.

A 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-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 ethnicity and gender are factors in the suitability of respirators in healthcare workers exposed to patients with Covid-19.

Methods

We conducted a prospective observational study examining fit testing results by ethnicity and gender from staff in a central London teaching hospital and designated Covid-19 centre. This study was deemed exempt from ethical review as it met the criteria for a service evaluation and was registered with Guy's and St Thomas' NHS Foundation Trust (ID 10918) as a service evaluation. No patients or members of the public were included in this study. All members of the workforce in patient-facing roles were eligible to attend the fit testing clinic. We included healthcare workers who underwent quantitative fit tests (QNFT) only. Exclusion criteria were healthcare workers who were not in patient-facing roles, those unable to undertake the fit testing procedure (e.g. unable to remove head wear, remove facial hair, or unable to perform the procedure), those that underwent only qualitative fit testing, or those unwilling to participate in fit testing.

Fit testing data were collected between 3rd February and 3rd July 2020 and included the participant's self-described gender and ethnicity in free-text. The free-text responses were mapped to the Office of National Statistics categories for ethnicity as used in the UK census.[12]

Fit testing was conducted by certified fit testers. Participants had to refrain from smoking one hour prior to the test, had to be clean shaven and could not wear any head wear. The QNFT involved the use of a TSI Portacount 8030 (TSI UK, High Wycombe) using the standard Health and Safety Executive fit testing procedure.[13]

QNFT fit test scores were dichotomised as pass or fail based on achieving an overall fit factor >100. We report the overall numbers and proportions of staff who passed their first fit test and grouped by self-reported gender and ethnicity. The likelihood of passing the first fit test for male and female genders, and White and BAME groups were compared using Pearson's Chi-squared test (without Yate's Continuity, as all cell frequencies were greater than 10). Logistic regression modelling was performed using each fit test as a separate observation, with the binary outcome variable defined as fit test success (pass/fail), and using the following explanatory variables: gender, ethnicity and mask design (disposable vs reusable). We first modelled the bivariate association between the outcome variable and each explanatory variable separately, and then in a multivariable model including all explanatory variables to obtain adjusted odds ratio (OR) estimates. Mask designs were specified in our models as categorical variables and were compared against a reference design A, which was our most widely-tested disposable mask design. The following *post hoc* analyses were performed to assess the possibility that healthcare workers could learn to game the fit testing process and repeated testing of the same healthcare workers using different masks could render the tests not independent of each other: First we fitted mixed effects logistic regression models with random-intercepts for healthcare workers, assuming that tests were nested within healthcare workers; Second we repeated the original fixed-effects only logistic regression modelling with a subset of our dataset, 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

	n (%) *(n = 1182)*
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.

		Failed first fit attempt (n)	***Passed first fit attempt (n)***	***Probability of passing first fit attempt (%)***
Gender	Ethnicity			
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]

Recognising that the standard fit panels may no longer be appropriate, the National Institute for Occupational Safety and Health (NIOSH) conducted a new survey of the US work force in 2001.[16] 4026 subjects from 41 different sites in, eight states were recruited, and new fit moulding panels were proposed based on the anthropometric data collected.[16] However, the ethnic groups described in this study differ from the UK. The demographics of the workforce describes one third of the population as Hispanic and specifically categorises the ethnicities as White, African American, Hispanic and Other.[15,16] However, the largest ethnic group after White British in England and Wales is "White other", followed by Asian – Indian, Asian – Pakistani, Black – African and Asian other.[12] Although NIOSH suggest their data can be used as a starting point for design and certification as the US population is ethnically diverse, the US data may not map accurately to the ethnic makeup of the UK healthcare workforce. Every individual has different features which vary by gender, ethnicity and even occupational role.[17] Face length is a key feature in respirator fit and this has been shown to vary significantly across ethnic and gender groups.[17] For example, anthropometric data shows statistically significant differences in width and face and lip length between African Americans and White Americans.[17] A sample of African Americans and Hispanic individuals in the US workforce were found to have up to face lengths 2.7 and 2.8 mm longer than White Americans.[17] Prior to Covid-19 most respirators were used in industrial applications such as construction. Construction workers are more likely to be male than healthcare staff, and have different facial features, including longer noses.[17] Gender has also been shown to be a major determinant in facial differences and measurements. Nine out of 10 facial measurements vary by gender with the female face being significantly smaller than the male face.[17] This is of relevance to respirator fit in healthcare workers as 77% of the NHS workforce is female.

Future respirator design should consider the facial characteristics of the demographic of the workforce. Face panels consisting of a true representation of female and BAME healthcare workers could help improve respirator design and improve safety when caring for Covid-19 patients. Out-dated fit panels used in the design and certification of the respirators demonstrate the institutional gender and racial biases in respirator fit and must be addressed in order to protect BAME and female staff.

Use of facial anthropometric data representing the current demographics of the workforce is not only important in the design of RPE, it can be used to guide procurement strategies for the ongoing pandemic. For example, females have on average smaller faces so looking at the different proportions of female versus male healthcare workers can guide what proportion of the procured respirators should be smaller versus large.

Examining the shape and measurements of the respirator in comparison to a face panel representing the workforce could help decision making in procurement. These techniques using facial anthropometric data representative of the workforce and observing the success or fail rate of different respirator designs in each ethnic or gender group could help with the decision-making process of which respirators to stock. Guiding procurement processes can prevent excesses of poorly sized respirators and shortages of the correct sizes.

However, even if the correct respirator for the demographic of the workforce was sourced, supply and demand issues of RPE early in the Covid-19 pandemic meant healthcare facilities could not rely upon a steady supply of any single preferred respirator. Every respirator has a different design and fit, therefore individuals should be fit tested on the respirator model they don prior to patient interactions.[8,13] The multiple changes in respirator models mean healthcare workers must be repeatedly fit tested on the new models as supplies change. As healthcare facilities were overwhelmed with the need to fit test staff repeatedly on different masks many adopted an approach to fit check only.[9] Our data demonstrates that respirators have a variable success rate on initial fit test. For example, Design J did not suitably fit 24.4% of our staff. Some studies have demonstrated a fail rate as high as 78% when a respirator is used without fit testing.[10] Failure to fit test may leave a significant proportion of staff inadequately protected against Covid-19 and according to our data it is mixed ethnicity and Asian female healthcare workers who are at greatest risk.

Limitations

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

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.

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Figure A

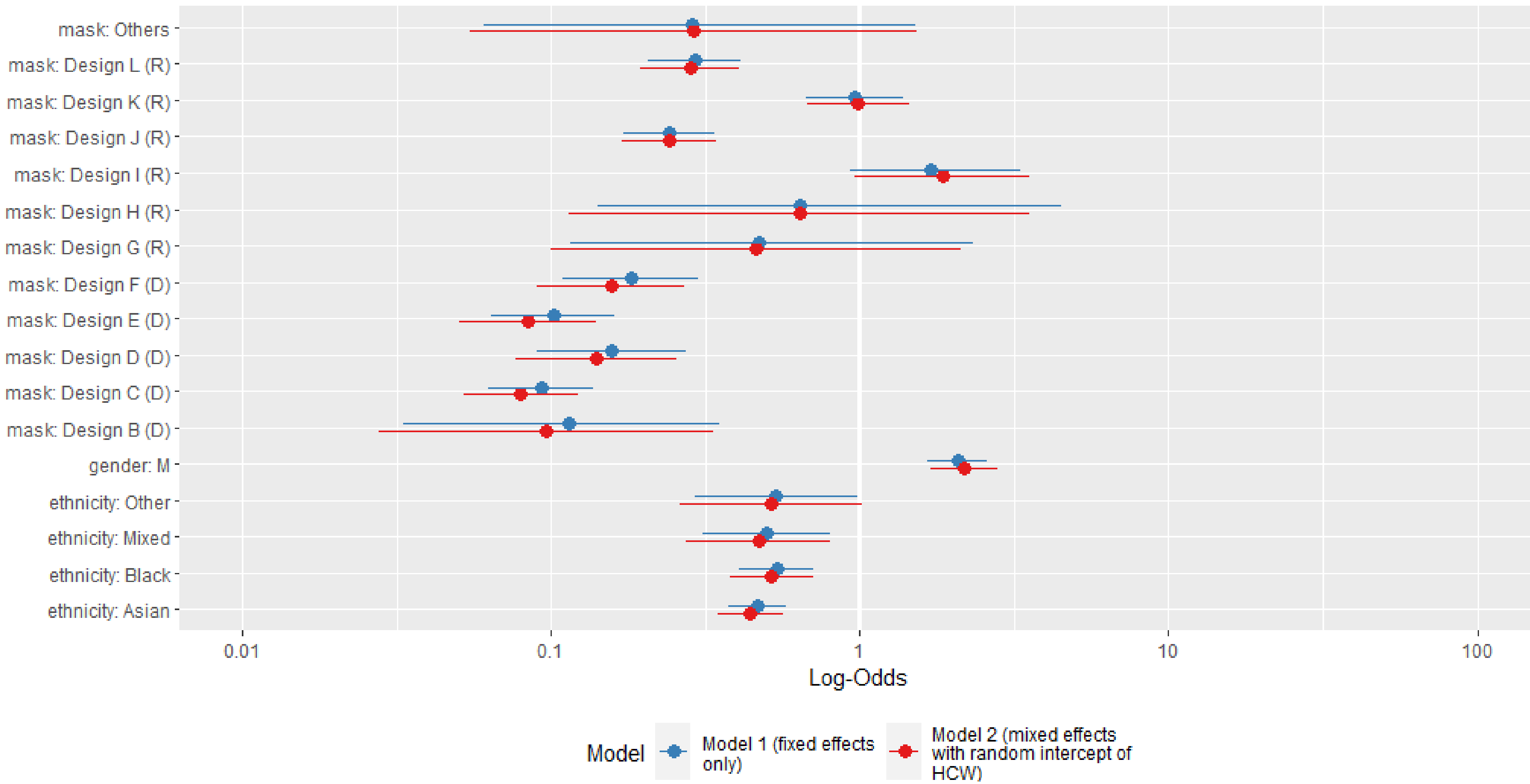

Figure A: Forest plot comparing the fixed effects point estimates and 95% confidence intervals the original model in the manuscript (Model 1) compared to a revised model fitted using mixed effects logistic regression with a random intercept for HCW (Model 2).

Figure B

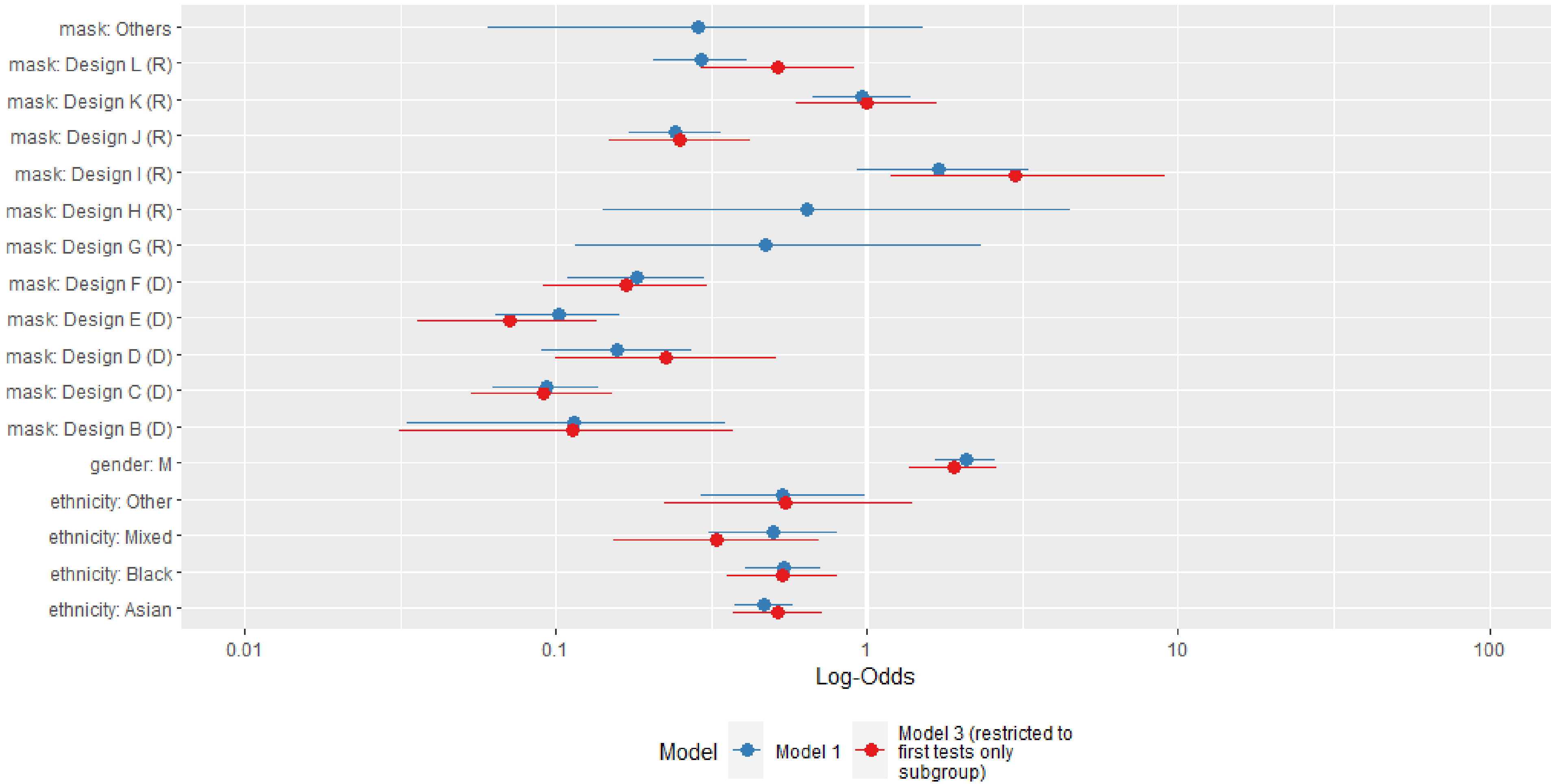

Figure A: Forest plot comparing the fixed effects point estimates and 95% confidence intervals the original model in the manuscript (Model 1) compared to a revised model fitted using only subgroup data from first fit test attempts (Model 3).

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	• 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)	Page 1
2. Abstract	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	Page 3
Introduction	*Why did you start?*	
3. Problem Description	Nature and significance of the local problem	Page 6
4. Available knowledge	Summary of what is currently known about the problem, including relevant previous studies	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	*What did you do?*	
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	*What did you find?*	
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	*What does it mean?*	
14. **Summary**	a. Key findings, including relevance to the rationale and specific aims b. Particular strengths of the project	Page 11 Page 13-16

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

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 improvement," 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's performance.

Opportunity costs

Loss of the ability to perform other tasks or meet other responsibilities resulting from the diversion of resources needed to introduce, test, or sustain a particular improvement initiative

Problem
Meaningful disruption, failure, inadequacy, distress, confusion or other dysfunction in a healthcare service delivery system that adversely affects patients, staff, or the system as a whole, or that prevents care from reaching its full potential

Process
The routines and other activities through which healthcare services are delivered

Rationale
Explanation of why particular intervention(s) were chosen and why it was expected to work, be sustainable, and be replicable elsewhere.

Systems
The interrelated structures, people, processes, and activities that together create healthcare services for and with individual patients and populations. For example, systems exist from the personal self-care system of a patient, to the individual provider-patient dyad system, to the microsystem, to the macrosystem, and all the way to the market/social/insurance system. These levels are nested within each other.

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