Royal Cornwall Hospitals NHS
NHS Trust

FULL TITLE OF THE STUDY
How has the increased use of FFP3 style respirators during the COVID-19 Pandemic affected hospital doctor's facial hair? Implications for staff safety and welfare.

SHORT STUDY TITLE / ACRONYM

Facial Hair, PPE and COVID-19

RESEARCH REFERENCE NUMBERS

IRAS Number:	**283609**
SPONSORS Number:	TBC
FUNDERS Number:	N/A

This protocol has regard for the HRA guidance and order of content

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KEY STUDY CONTACTS

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STUDY SUMMARY

Study Title	How has the increased use of FFP3 style respirators during the COVID-19 Pandemic affected hospital doctor's facial hair? Implications for staff safety and welfare.
Internal ref. no. (or short title	Facial Hair, PPE and COVID-19
Study Design	A single site, cross-sectional questionnaire
Study Participants	Trust staff with facial hair required to use PPE due to COVID-19
Planned Size of Sample (if applicable)	N/A
Follow up duration (if applicable)	N/A
Planned Study Period	1 Month
Research Question/Aim(s)	To assess how the increased use of FFP3 style respirators during the COVID-19 Pandemic has affected hospital doctor's facial hair?

STUDY PROTOCOL

How has the increased use of FFP3 style respirators during the COVID-19 Pandemic affected hospital doctor's facial hair? Implications for staff safety and welfare.

1 BACKGROUND

The importance of effective personal protective equipment (PPE) has been highlighted during the COVID-19 global pandemic. Part of this equipment has been the use of filtering facepieces class 3 (FFP3) masks, which are particularly important to those staff undertaking “aerosol generating procedures” (AGP) such as chest compressions, intubation or endoscopy.[1] However, for effective use, these need to be “fit tested” to the individual, which involves using a test aerosol to assess the efficacy of the mask. It is widely accepted that facial hair affects the effectiveness of these masks,[2,3] and there is clear guidance from Public Health England regarding which facial hair styles are likely to pass and fail fit testing.[1] However, there is little data reporting the adherence of this guidance, especially for hospital doctors for whom this guidance is relevant.

The research question is to assess whether these guidelines are being followed during this global pandemic, and if not, explore the reasons this may be the case. This has implications as FFP3 masks are not the only form of PPE for the face, and this study may highlight a need for employers to diversify which PPE they supply to their employees, such as full hoods.[4]

We will be targeting hospital doctors, as they are front line staff whom the FFP3 guidance directly affects. There may be implications from this research regarding the forms of PPE that are being supplied to employees, especially if there are particular reasons that employees have for maintaining their facial hair. The implications also include provision of alternative PPE for those who have failed fit testing.

2 RATIONALE

COVID-19 is a highly contagious virus which has caused a global pandemic. There have been significant health consequences for healthcare workers, which may be related to the provision of personal protective equipment (PPE). Following PPE guidance is a significant health and safety concern, under which facial hair guidance for tight fitting masks falls.

This has implications as FFP3 masks are not the only form of PPE for the face, and this study may highlight a need for employers to diversify which PPE they supply to their employees, such as full hoods if staff need to maintain facial hair for cultural or religious reasons.

3 RESEARCH QUESTION/AIM(S)

How has the increased use of FFP3 style respirators during the COVID-19 Pandemic affected hospital doctor's facial hair?

Is there a difference between the prevalence of altered facial hair among those expected to perform aerosol generating procedures when compared to those who are not?

Are there doctors at RCHT who report religious or cultural reasons to changing their facial hair?

Have alternative forms of PPE been offered to those who do not achieve an adequate fit with FFP3 respirators?

3.1 Objectives

To understand if the current PPE FFP3 guidance is suitable for everyone it is intended for. Anyone with facial hair and in particular, the effects on those whose ethnic or religious beliefs prevent them from removing any facial hair.

3.2 Outcome

To see if having facial hair in any context affected appropriate use of the FFP3. Consideration will also be given to if the current guidance is broad enough to offer an equal and diverse option of PPE FFP3 to all, in particular those with specific cultural, personal and ethnic needs and if not, what options can be taken to ensure that all staff needs are supported. Secondly, we will be looking to measure the personal impact on individuals having to remove facial hair because of the guidance and advice currently offering only one source of protection.

4 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

The study design will be a cross sectional study in the form of a single survey.

The population of interest are all hospital doctors at a Royal Cornwall hospital. A list of these doctors will be provided by the postgraduate centre, and an email, detailing the purpose of the research and an information sheet, will be circulated to these doctors, informing them that their participation is voluntary. In this email, there will be a link to a questionnaire which will take approximately 5 minutes to complete. The participants will not be required to input any identifiable information, so data will be anonymous to the researchers. Participants will be asked demographic questions such as age, gender, grade, department and whether they have the potential to be involved in aerosol generating procedures (AGP). They will also be asked if they passed fit testing, the most common level of PPE they wear at work,and whether they have been offered an alternative to a FFP3 mask.The participants will then be asked if they are able to grow facial hair, and if so they will be asked to select from a chart (taken with permission from Public Health England guidance) the styles which most resembled their facial hair before and after the first cases of COVID-19 were treated in our hospital. Participants will then be asked if their facial hair was influenced by FFP3 guidance, if they are happy with their current style, if they have any religious or culture reasons for maintaining their style, and whether there have been any religious, emotional or wellbeing effects to changing facial hair style. They will then be asked to select from a separate chart their favourite facial hair style, followed by any optional free text responses. The study will only be asking about FFP3 style respirator face protector PPE, and not any other form of protective equipment which may affect patient's hair.

We have deliberately included all genders as not everybody identifies as either male or female, and the ability to grow facial hair is not limited to men. We have considered that we may offend female members of staff, however the email is generic to all doctors and not targeted to specific people. We also ask the question as such, "Do you grow facial hair which you can stylise? (This includes facial hair that you regularly shave, but does not include vellus or downy hair)". Our aim is to be as inclusive as possible, but to also not offend an already marginalised group of society (i.e. those who do not identify as either male or female). We suspect most of our responses will be from those identifying as male, but did not want to limit our population responses to this.

Data will be imported into Microsoft Excel, and statistical analysis will be performed using the R and R studio software packages. The odds ratio and relative risk will be calculated of a self-reported change in facial hair style in those who wore an FFP3 appropriate facial hair style prior to the COVID-19 pandemic versus those who did not, among the responders to the survey who reported they were able

to grow facial hair. Researchers will also calculate the odds ratio of a reported facial hair change in those expected to perform aerosol generating procedures versus those who were not. Confidence intervals will be calculated at the 95% confidence level. All statistical analysis will be performed by the researchers.

Once the study has ended and the final analysis of the project has concluded, the study documents will be archived for a minimum of 5 years in line with the Trust archiving Standard Operating Procedure RD&I SOP-07.

5 SAMPLE AND RECRUITMENT

5.1 Eligibility Criteria

5.1.1 Inclusion criteria

All hospital doctors at RCHT are included in the study population. This includes all genders and ethnicities. However, those unable to grow facial hair will be excluded from parts of the statistical analysis.

5.1.2 Exclusion criteria

The principle exclusion criteria are those who do not work at Royal Cornwall Hospital. Also, while not forming part of the exclusion criteria, those who are unable to grow facial hair will be excluded from the statistical analyses that involve reported odds and risks of change in facial hair.

5.2.1 Size of sample

A total of 1025 Doctors work at Royal Cornwall hospital, the questionnaire will be distributed to all Doctors. The sample will be the entire population of the hospital doctors at Royal Cornwall Hospital. We do acknowledge that there will be some drop out as people may not fill the questionnaire or fit the inclusion criteria, so at a 20% completion and inclusion rate, we suspect our sample will be around 205.

5.3 Recruitment

Recruitment will be via an anonymised online survey sent out to all Royal Cornwall Hospital doctors. Participants will be asked to complete consent and demographic data prior click to moving on to the survey questions. The questionnaire will automatically only show participants questions for which they meet inclusion criteria based on demographic details.

5.3.1 Sample identification

A list of doctors and their emails will be provided by the Royal Cornwall hospital postgraduate centre. The NHS mail is a secure means of communicating between healthcare staff.

Participation consent will be confirmed by those that have completed the online survey. They will be approached via NHS email. The online survey will be completely anonymised and no personal or identifiable information will be included or contained within the survey.

There will be no payments for participation in the study.

5.3.2 Consent

As the study requires the participants to complete an online questionnaire, the opening page will explain what the study is about, why the project is being undertaken and will then lead onto advise that completion of the form will constitute as consent to participate in the study (See Appendix 1).

The email will contain an information sheet for participants. Participants wishing to take part will then click on a link on their email which will take them to the Questionnaire. The first question on the questionnaire will ask participants if they consent to participating in the research and subsequently their anonymised data being used for research purposes, analysis and any future publications which may arise as a result of this data.

6 ETHICAL AND REGULATORY CONSIDERATIONS

This study will only include staff currently working with the Royal Cornwall Hospitals NHS Trust and will not include any personal or identifiable information. The survey will be carried out by Survey Monkey and ethical approval will be sought by the appropriate governing bodies.

6.1 Research Ethics Committee (REC) and other Regulatory review & reports

Before the study is stared, a favourable opinion will be sought from the relevant ethics committee for the protocol. The project will not being until the relevant approvals are in place and the 'green light' is given by the study Sponsor to confirm that recruitment can begin. This study will undertaken in accordance with the UK policy on health and social care research (2017).

Should there be a need for any substantial amendments, we will ensure that they are submitted for the relevant review.

All correspondence with the REC will be retained including annual reports and the end of study declaration when the project is completed.

Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

6.2 Regulatory Review & Compliance

Before the site enrols anyone into the study, the Chief Investigator or designee will ensure that appropriate approvals from the participating organisations are in place.

6.3 Amendments

If there is a need for a substantial amendment, the sponsor will submit a valid notice of amendment to the REC for consideration and will await the relevant response regarding the amendment within 35 days of receipt of the notice. It is the sponsor's responsibility to decide whether an amendment is substantial or non-substantial for the purposes of submission to the REC.

A copy of the relevant amended documentation both clean and with tracked changes will be submitted with the amendment application.

Once the amendment has been agreed, the Sponsor will send out a copy of the amendment notice along with the updated documents and a new version control to everyone involved in the study.

7 DATA PROTECTION AND PATIENT CONFIDENTIALITY

All investigators and staff involved in the study will comply with the requirements of the Data Protection Act (2018) with reference to the collection, storage, processing and disclosure of personal information and they will uphold the Act's core principles. All study personnel are aware of the importance of maintaining confidentiality and adhering to the GDPR regulations

Archiving will be authorised by the Sponsor following submission of the end of study report and in accordance with the RD&I SOP 07 archiving procedure. The Sponsor will be responsible for archiving any original study data in a secure location for a minimum period of 5 years after the end of the trial.

7.1 Indemnity

This is an NHS-sponsored research study and as such, any legal liability arising from the research will be covered by the NHS indemnity insurance.

8 DISSEMINATION

8.1 Dissemination policy

Once the study has been completed and the report / publication drafted, the author will send a copy to the Sponsor for review and final approval. Once the document has been approved by the Sponsor, it will then presented for publication in relevant peer reviewed scientific journals.

9.2 Authorship eligibility guidelines and any intended use of professional writers

Authorship of the final report will be granted to the Chief Investigator. Any peer reviewed publication arising from the data collect in the study will be authored in line with individual journal policies. Authors will always include the Chief Investigator and may include members of the supervisory and contributing team.

10 REFERENCES

1. Public Health England (2020) COVID-19: Infection Prevention and Control Guidance. Public Health England Gateway Number: 2019302. V2. 09-04-2020. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/881489/COVID-19_Infection_prevention_and_control_guidance_complete.pdf

2. Terrence J. Stobbe, Robert A. Daroza & Margo A. Watkins (1988) Facial Hair and Respirator Fit: A Review of the Literature, American Industrial Hygiene Association Journal, 49:4, 199-204, DOI: 10.1080/15298668891379594.

3. Frost S. Harding A. Health and Safety Laboratory (2015) The effect of wearer stubble on the protection given by Filtering Facepieces Class 3 (FFP3) and Half Masks. Available at: https://www.hse.gov.uk/research/rrpdf/rr1052.pdf

4. NHS employers (2020) Infection control. Available at: www.nhsemployers.org/covid19/health-safety-and-wellbeing/infection-control.

11. APPENDICES

11.1 Appendix 1- Required documentation

1. Questionnaire
2. Participant Information Sheet
3. Email to be sent to participants