Cv-19 NHS

OCCUPATIONAL RISKS OF COVID-19 IN NHS STAFF; AN ANALYSIS OF SICKNESS ABSENCE BY ETHNICITY, PROFESSIONAL ROLE, AGE, SEX AND ANTIGEN/ANTIBODY TEST RESULTS.

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This protocol describes the Occupational Risks of COVID-19 in NHS staff study and provides information about procedures for entering participants. Every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the study. Problems relating to this study should be referred, in the first instance, to the Chief Investigator.

This study will adhere to the principles outlined in the UK Policy Framework for Health and Social Care Research. It will be conducted in compliance with the protocol, the Data Protection Act and other regulatory requirements as appropriate.

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GLOSSARY OF ABBREVIATIONS

BME	Black and minority ethnic
ESR	Electronic staff record
NHS	National Health Service
PHE	Public Health England
PPE	Personal protective equipment
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2

KEYWORDS
Covid-19, sickness absence, ethnicity

STUDY SUMMARY

TITLE Occupational risks of COVID-19 in NHS staff: an analysis of sickness absence by ethnicity, professional role, age, sex and antigen/antibody test results.

DESIGN Retrospective cohort study

AIMS To explore the risk of sickness absence ascribed to suspected Covid-19 according to sex, age, ethnicity, occupation and department and in relation to available data on antigen or antibody test results.

OUTCOME MEASURES Rates of sickness absences due to Covid-19 infection

POPULATION NHS staff

ELIGIBILITY All members of staff who were continuously employed at one of the participating Trusts and in all other NHS Trusts from 1 January 2019 to the date when data abstraction begins.

DURATION Project duration six months

1. INTRODUCTION

1.1 BACKGROUND

So long as a substantial proportion of the general population lacks specific immunity to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), there will be a continuing threat of outbreaks of Covid-19. A particular concern when such outbreaks occur is the risk to healthcare staff whose work entails close proximity to patients carrying the disease or handling of material contaminated by the virus. High levels of exposure may increase not only the likelihood of contracting infection, but also the severity of disease that ensues (1). Risks may be mitigated by use of personal protective equipment (PPE), but there have been problems in its provision, and its practical effectiveness in hospital settings is currently uncertain.

Another concern is that members of staff from certain ethnic groups may be more vulnerable to severe disease than their white counterparts (2). In the UK, there have been suggestions that people from black and minority ethnic (BME) backgrounds are disproportionately represented among healthcare workers who have died from Covid-19 (3). However, the extent of any increased risk is not yet established.

To optimise strategies for risk-management, better information is needed on the extent to which different types of work in healthcare increase the risk of contracting Covid-19 infection and its severity, and whether staff from BME backgrounds are more vulnerable to severe disease. This would help to inform the design of occupational tasks, use of control measures and protective equipment, and also decisions on whether there are some types of work that should be avoided by people who would be unusually vulnerable to severe outcomes should they develop Covid-19.

A challenge in assessing relative risks of acquiring Covid-19 by occupation is the requirement to ascertain the occurrence of infection with similar completeness and accuracy across the occupational roles that are to be compared. Ideally, cases would be ascertained systematically through regular, frequent testing for viral antigen, but that would be costly to implement on a large scale; similarly, antibody testing is as yet of uncertain validity as an indicator of past infection and is yet to be rolled out universally. A more practicable option is to use reports of symptomatic illness as a proxy measure, albeit imperfect, for the occurrence of infection. In the UK, workers who developed symptoms indicative of Covid-19 infection (e.g. cough and fever) were instructed to remain at home, and not go to work, for at least seven days. Thus records of sickness absence attributed to suspected Covid-19 infection offer a way of monitoring the occurrence of such illness systematically across different occupations, especially within the same organisation.

National Health Service (NHS) Trusts in England collect data on sickness absence in an electronic staff record (ESR), which since early in the Covid-19 epidemic has used a code specifically for absence because of symptoms suggestive of Covid-19. The ESR also holds information on each staff member's sex, date of birth, ethnicity, occupation and department, as well as on absence for other reasons; and, more recently, the option to append the results of any antigen or antibody test results.

1.2 RATIONALE FOR CURRENT STUDY

A retrospective epidemiological study using ESR data from all NHS Trusts in England supplemented by additional information from a sample of collaborating English NHS Trusts, to explore the risk of sickness absence ascribed to suspected Covid-19 according to sex, age, ethnicity, occupation and department and in relation to available antigen/antibody test results.

The study will also be used to explore possible impacts of the Covid-19 epidemic on patterns of sickness absence among NHS staff for other reasons, and particularly that ascribed to mental illness. In recent years, mental illness has become one of the two main reasons for sickness absence in the UK working population (4). In theory, the emergence of Covid-19 might impact on such absence in the NHS in two ways. Greater pressures at work (because of the need to treat large numbers of cases and higher absence rates among staff), coupled in some cases with redeployment to unfamiliar tasks and teams, may have increased the occurrence or severity of mental illness in staff. On the other hand, heightened perceptions of duty during the emergency may have raised thresholds for taking absence for some types of illness, including mental health disorders. The Academy of Medical Sciences has highlighted an urgent need for high quality data on the effect of the Covid-19 pandemic on the mental health of workers (5), and our study will help to address that need.

2. STUDY OBJECTIVE

To explore the risk of sickness absence ascribed to suspected Covid-19 according to sex, age, ethnicity, occupation and department. The study will answer the following three questions:

Among staff employed by NHS Trusts:

1) how have rates of sickness absence ascribed to suspected Covid-19 infection varied according to ethnicity, age, sex, and potential for occupational contact with Covid-19 as indicated by occupation and department? How are these related to available data on antigen/antibody test results?

2) how have rates of *prolonged* sickness absence ascribed to suspected Covid-19 infection varied according to ethnicity, age, sex, and potential for occupational contact with Covid-19 as indicated by occupation and department?

3) how have rates of sickness absence ascribed to mental illness and other causes unrelated to Covid-19, varied over the course of the epidemic as compared with 12 months earlier, and have changes differed by ethnicity, occupation and department?

3. STUDY DESIGN

Type of study: retrospective cohort study

Duration: Six months

Type of subjects: NHS staff

3.1 METHODS

Study population: All NHS organisations in England

In addition, the study will collect localised Covid-19 data from the occupational health departments at the following 11 NHS hospital Trusts in England:

- Cambridge University Hospitals NHS Foundation Trust
- University Hospitals Southampton NHS Foundation Trust
- Stockport NHS Foundation Trust
- University Hospitals Morecambe Bay NHS Foundation Trust
- Bolton NHS Foundation Trust
- Newcastle upon Tyne Hospitals NHS Foundation Trust
- East Suffolk and North Essex NHS Foundation Trust
- Norfolk and Norwich University Hospital NHS Foundation Trust
- Royal Berkshire NHS Foundation Trust
- University Hospitals of Leicester NHS Trust
- Guy's and St Thomas' NHS Foundation Trust

The study population will comprise all members of staff who were continuously employed at one of the participating Trusts from 1 January 2019 to the date when data abstraction begins.

3.2 DATA COLLECTION, DATA TRANSFER AND DATA STORAGE

Two methods will be used for data collection.

Method 1: Sickness absence and antibody and antigen data recorded on national ESR database

In consultation with our collaborator at the ESR Central Team, a specially developed algorithm will be used for data extraction. To safeguard privacy, once the extract has been downloaded from the ESR Data Warehouse the ESR Central Team will ensure that the NHS Employee Numbers identifiers are replaced with unique study identifiers prior to data sharing. In addition, to further minimise any risk (actual or perceived) of staff identification, sickness absence data extracted will be further aggregated into two job role categories:

> Category 1: Major staffing groups (eight in total) for all NHS staff as per National Workforce Dataset coding (using standard categories e.g. medical/dental, nursing, allied health professional, admin/clerical)
> Category 2: Eight 'exposure' categories which are currently being developed by the study team).

In addition, we will group 'age' into five year bandings e.g. 16-20, 21-25 etc

To further enhance the pseudonymisation and privacy protection of the data at the point of data extraction, our collaborator at the ESR Central Team will run the extract with the low-level occupation codes included (e.g. A4A) and then will use the mapping provided by the study team to convert the occupation code to an exposure level using a VLOOKUP to the mapping table. Once the mapping is complete, the ESR Central Team will remove the low-level, detailed occupation code from the extract before sending to the study team.

Due to the study design and outcomes of interest, it would not be possible to restrict the data set further to a minimum number in specific groups. While we acknowledge the issue with regard to the potential to identify (we suspect very few) individuals from very small sub-groups, that concern equally applies to many pseudonymised datasets. Furthermore, we are content that this would be a negligible risk when one factors in the data security arrangements of Imperial College London (sponsor) where the data will be held.

For each member of the study population, we will abstract the following anonymised data from his/her electronic staff record:

- name of Trust
- a coded individual identifier
- sex
- year of birth (grouped)
- ethnicity
- occupation (at the finest level commensurate with data protection - see above)
- number of episodes of absence since 1 January 2019 and the start of data acquisition. These will include spells of absence that began before 2019 and continued into that year, and spells that began before the state of data acquisition and had not ended by that date.
- for each of those spells of absence, we will abstract
    - date started
    - date finished
    - reason for absence (classified according to standard national codes, which distinguish sickness absence from annual and compassionate leave, and include categories for sickness because of: Covid-19 symptomatic; anxiety/stress/depression/other psychiatric illnesses; and cold/cough/flu; as well as new codes for paid special leave because of self-isolation; and as a carer).
- Covid-19 antigen and antibody test results (including date of testing) where recorded on the ESR.

Method 2: Localised Covid-19 data from 11 collaborating sites:

- weekly hospital admissions for Covid-19 infections from January 2020 to the date of data extraction
- information on the extent and timing of temporary redeployment of staff during the pandemic period
- availability and utilisation of PPE during the pandemic
- antibody (Ab) and antigen (Ag) testing results for staff during the pandemic (see Note below)

  Note: to obtain anonymised testing data from the 11 participating sites, we will send a case report form (in the form of a spreadsheet) to our local OH site collaborators which will contain a full list of unique study identifiers for each staff member as generated by our collaborator at the ESR Central Team. The collaborator at the ESR Central Team will separately email the local OH site collaborators a simple Excel formula (instructions) on how to convert the unique study identifiers back to the individual NHS employee numbers. Once these are matched, antibody (Ab) and antigen (Ag) testing data (test date and results) will then be recorded onto the case report file by the collaborating OH department. Once complete, the NHS Employee Number column will be deleted so only the unique study identifiers are shown prior to sending back the complete case report form to the central study team.

We will provide our local site collaborators with case report forms to record data on weekly hospital admissions and redeployment. In addition, we will undertake semi-structured telephone interviews with local site collaborators for the purpose of collecting qualitative data on their perceptions and feedback on the availability, quality and utilisation of PPE during the pandemic period.

The transfer of pseudonymised study data between partner organisations will occur via email correspondence. Spreadsheet attachments will be password protected and password details communicated in a separate email. Upon receipt, study data will be downloaded and saved on local computer drivers at Imperial College where access to email systems and local computer drives are further password protected. To safeguard privacy, once the extract has been downloaded from the ESR Data Warehouse the ESR Central Team will ensure that the NHS Employee Numbers are replaced with unique study identifiers prior to data sharing. The same approach will be used by our local OH site collaborators to pseudonymise the antibody and antigen testing result data prior to data transfer to the study team.

We plan possible extensions to this study as follows.

1. With appropriate permissions and (further) ethical approval it may be possible to approach a subset of BAME and non BAME staff members (cases of absence for Covid-19 symptoms and appropriately matched controls) to obtain more detailed information on duties, use of PPE, and other possible risk factors for infection in the period immediately before the case's illness episode.
2. Using data from our linked study on sickness absence in other employment sectors (separate proposal), we may be able to compare age and sex-adjusted rates of sickness absence for suspected Covid-19 infection in healthcare workers with those among BAME and non-BAME workers in other occupations. This would further enrich the evidence upon which to base the risk assessment for BAME workers in other at-risk occupations.

4. PARTICIPANT ENTRY

4.1 INCLUSION CRITERIA

All NHS staff who were continuously employed at all NHS organisations in England from 1 January 2019 to the date when data abstraction begins.

4.2 EXCLUSION CRITERIA

All NHS staff who were not continuously employed at an NHS organisation in England from 1 January 2019 to the date when data abstraction begins. In addition, agency staff, contractors, students.

4.3 WITHDRAWAL CRITERIA

Not applicable to this study

5. ADVERSE EVENTS

Not applicable to this study

6. ASSESSMENT AND FOLLOW-UP

Not applicable to this study

7. STATISTICS AND DATA ANALYSIS

Classification of non-outcome variables

Preliminary checks on data quality and reclassification of non-outcome variables will be carried out "blind" to all data on sickness absence for Covid-19. We will first check the completeness of the data abstracted from the ESR, and decide how best to handle missing information for each variable. Depending on the variable and the prevalence of missing

data, this could be by use of a category for "unknown", or by exclusion of the individual from further analysis.

Next, we will generate descriptive statistics for the non-outcome variables abstracted from the ESR, and decide how best to specify explanatory variables for analysis. Considerations in the specification of variables will include the distribution of the data (avoidance of categories too small for meaningful analysis) and prior expectations of relevance to sickness absence for Covid-19 infection. In particular, a bespoke job-exposure matrix will be applied to aggregated occupational categories according to their potential for exposure to SARS-CoV-2.

Classification of outcome variables

We will then explore the distribution of periods of absence ascribed to Covid-19 infection, and on that basis, we will determine a suitable cut-point by which to define prolonged absence for such infection.

Timing and magnitude of epidemic locally

We will explore hospital admissions data on admissions for Covid-19 in each of the 11 participating trust, to establish the approximate date from which the disease started to appear in the community served by that Trust, the date at which the weekly number of admissions reached its peak, and the total number of admissions over the study period.

Main analyses

To address the first two study questions, we will focus on two outcomes – sickness absence ascribed to Covid-19 symptoms, and *prolonged* sickness absence ascribed to Covid-19 symptoms.

We will calculate cumulative prevalence rates for each of these outcomes by sex, age and Trust, if necessary, adjusting the latter for the approximate date on which Covid-19 first started to appear in the community served by the Trust. We will examine spells of ascribed sickness absence in relation to available data on antigen or antibody tests.

Taking cumulative prevalence as an outcome measure, we will then use logistic regression (or Poisson regression if the cumulative prevalence of sickness absence for Covid-19 is >10%) to explore the associations of absence ascribed to Covid-19 and prolonged absence ascribed to Covid-19 with:

- sex
- age
- ethnicity
- occupation
- potential for workplace exposure to SARS-CoV-2, as inferred from occupation

- number of spells of sickness absence for cough/cold/flu in 2019
- number of spells of sickness absence for other reasons in 2019

Results will be summarised by cumulative prevalence odds ratios (or cumulative prevalence ratios) with 95% confidence intervals (CIs).

To address the third study question, we will calculate the cumulative prevalence, number of spells and total duration of sickness absence ascribed a) to all causes other than Covid-19 symptoms and b) specifically to anxiety/stress/depression/other psychiatric illness, during the period from onset of the Covid-19 epidemic locally to the date of data abstraction. These will be compared with equivalent data for the corresponding period 12 months earlier to derive estimates of percentage change with 95% confidence intervals. Subsidiary analyses will be restricted to specified occupations and departments.

Statistical power

Preliminary data from Guys and St Thomas's NHS Trust indicate that during March 2020, among a total of approximately 17,780 staff members, 1373 had spells of absence because of symptoms suggestive of Covid-19. To *illustrate* statistical power, we assume a total study sample of 100,000 in the 11 collaborating Trusts, of whom 6000 will have taken absence for Covid-19 symptoms, including 500 with at least one prolonged spell of such absence (these assumptions allow for the fact that Guys and St Thomas's is a relatively large Trust, that London has had higher rates of Covid-19 than some other parts of the country, and that absences will accumulate over longer than one month). With these numbers of cases, the table below shows odds ratios that would be detectable with 80% power and a 5% level of statistical significance, according to the prevalence of a risk factor in those with no absence for Covid-19 symptoms.

Prevalence (%) of risk factor among workers with no absence for Covid-19 symptoms	**Detectable odds ratio for any absence because of Covid-19 symptoms**	**Detectable odds ratio for any prolonged absence because of Covid-19 symptoms**
0.1	2.26	5.56
0.2	1.87	4.09
1	1.38	2.32
2	1.27	1.93
5	1.17	1.60
10	1.13	1.44
20	1.10	1.34
50	1.08	1.29

Note that the national data have the potential to include 1.2m staff records.

Assuming an 1% cumulative prevalence of absence for mental illness during the first six months of 2019 (https://www.kingsfund.org.uk/blog/2019/10/nhs-sickness-absence) among a total study sample of 100,000, and a subset of 5000, 95% confidence intervals (CIs) about specified increases or reductions in the corresponding cumulative prevalence are as set out in the table below.

Cumulative prevalence (%) of absence for mental illness in first six months of 2020	**Difference in percentage from previous year**	**95% CI for difference in percentage in sample of 100,000**	**95% CI for difference in percentage in sample of 5000**
0.5	-0.5	(-0.58, -0.42)	(-0.84, -0.16)
0.8	-0.2	(-0.28, -0.12)	(-0.57, 0.17)
0.9	-0.1	(-0.19, -0.01)	(-0.48, 0.28)
1.1	0.1	(0.01, 0.19)	(-0.30, 0.50)
1.2	0.2	(0.11, 0.29)	(-0.21, 0.61)
1.5	0.5	(0.40, 0.60)	(0.06, 0.94)

Data and all appropriate documentation will be stored for a minimum of 10 years after the completion of the study, including the follow-up period.

8. INFORMATION GOVERNANCE AND DATA SHARING

This study is exempt from the requirement to obtain approval from the HRA Confidentiality Advisory Group (CAG) to access patient data. In response to the Covid-19 pandemic the Secretary of State for Health and Social Care issued NHS Digital with a Control of Patient Information Notice (COPI Notice) with regard to the release and processing of patient data relating to Covid-19. The study team sought confirmation from the NHS IG Policy Team (Senior Data Sharing & Privacy Manager) and NHSX Data Sharing team that NHS staff record data held in the Employee Staff Record is covered by the COPI Notice on the basis that NHS staff are patients of occupational health departments within their employing NHS organisation. The Caldicott Guardian and the Head of IG at Guy's and St Thomas NHS Foundation Trust each reviewed the protocol and were content with the collection and processing of this data for the purpose of this study.

A memorandum of understanding (MoU) and the IRAS Organisation Information Document which sets out the legal and statutory requirements of data protection and confidentiality with regard to this study will be signed between partner organisations and Imperial College (sponsor) prior to the commencement of this study. These documents stipulate the requirement that all parties must strictly adhere to relevant data protection

and information governance legislation (GDPR, NHS Code of Confidentiality and Imperial College policies). In addition, study team members and local collaborators have a contractual requirement to follow relevant organisational policies and guidance with regard to data protection and information governance.

As part of the research governance approval process, this study will be registered with Imperial's NHS IG team.

8.1 ETHICS APPROVAL

The Study Coordination Centre has obtained approval from the Health Research Authority (ref XX). The study will also receive confirmation of capacity and capability from each participating NHS Trust before any research activity is carried out. The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

8.2 CONSENT

Individual participant consent is not required to conduct this study on the basis that access to this data is covered by the COPI Notice which authorises the release and processing of patient data relating to CV-19. As per section 2.2.1 / 2.2.2, the COPI permits researchers to access specific health data (such as staff record data) in order to understand risks and trends of COVID-19.

8.3 CONFIDENTIALITY

The study team members will ensure they comply fully with GDPR and college requirements relating to confidentiality and data protection.

8.4 INDEMNITY

Imperial College London holds negligent harm and non-negligent harm insurance policies which apply to this study.

8.5 SPONSOR

Imperial College London will act as the main Sponsor for this study. Delegated responsibilities will be assigned to the NHS Trusts taking part in this study.

8.6 FUNDING

The COLT Foundation has agreed to fund this study. Participating NHS organisations will be paid up to £1,000 to cover data extraction costs.

8.7 AUDITS

The study may be subject to inspection and audit by Imperial College London under their remit as sponsor and other regulatory bodies to ensure adherence to GCP and the UK Policy Framework for Health and Social Care Research.

9. STUDY MANAGEMENT

The day-to-day management of the study will be co-ordinated through regular meetings between the Chief and co-investigators, the study analyst and the study manager.

10. PUBLICATION POLICY

The study team will produce a final report detailing the results and interpretations for each of three research questions. The report will also propose a series of policy and clinical recommendations to mitigate against future risk factors for Covid-19 infection for particular vulnerable worker groups should a similar pandemic arise in the future.

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