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UK-REACH: United Kingdom research study into ethnicity and COVID-19 outcomes in healthcare workers

Submission date
19/11/2020

Registration date
23/11/2020

Last Edited
13/03/2024

Recruitment status
No longer recruiting

Overall study status
Ongoing

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
People from ethnic minority communities may be at higher risk of getting COVID-19 and of having a more severe illness than those of White ethnicity. Healthcare workers may also be at higher risk of COVID-19. This study aims to look at the risk of COVID-19 in ethnic minority healthcare workers and try to understand the reasons why ethnicity may impact on COVID-19 outcomes over the next 25 years.
Alongside the main study, three sub studies will also investigate closely related issues in smaller groups of healthcare workers and stakeholders:
1. The ethical, legal and acceptability issues that large studies involving personal and health data have to consider.
2. A qualitative study with the aim of understanding HCWs experiences of COVID-19, especially things like their views of the pandemic, challenges they have faced, or things that they think have put them or others at risk.
3. A stakeholder group of members from organisations representing different health care professions in the UK will provide feedback on the data coming out of the other work packages of UK-REACH.

Who can participate?
The main study will look at health records of over 1.5 million people from ethnic minority backgrounds including healthcare workers from the UK.
The sub studies will also recruit healthcare workers who have experienced working in a healthcare setting during the COVID-19 pandemic and members of NHS collaborating organisations.

What does the study involve?
Information from NHS human resource records will be linked with medical records containing information relevant to COVID-19. This linkage and the storage of data will occur in a “trusted research environment” which provides the best possible security for this information.
Healthcare workers will be asked to fill out an online questionnaire containing questions on topics including their job, their interaction with COVID-19 patients, their physical and mental

health and their social and living circumstances.
The sub studies will involve interviews and focus group discussions to gather qualitative data.

What are the possible benefits and risks of participating?
There are no risks associated with participating. The only benefit to participating is helping with the research and allowing us to advise on how to make things safer for ethnic minority healthcare workers.

Where is the study run from?
The University of Leicester (UK)

When is the study starting and how long is it expected to run for?
The main study will run from August 2020 to August 2045.
The sub studies will run from August 2020 to July 2021.

Who is funding the study?
1. UK research and Innovation
2. National Institute for Health Research (NIHR) (UK)

Who is the main contact?
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Study website
https://www.uk-reach.org

Contact information

Type(s)
Scientific

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
288316

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 288316, Sponsor Reference 0801

Study information

Scientific Title
United Kingdom Research Study into Ethnicity And COVID-19 outcomes in Healthcare workers

Acronym
UK-REACH

Study objectives
Ethnic minority healthcare workers may be at increased risk of acquisition of, and adverse outcome from, coronavirus disease 2019 (COVID-19) compared to their White colleagues. However, the quality of data relating to COVID-19 outcomes in HCWs remains poor, with no large dataset analysis of the risk of COVID-19 in clinical or ancillary staff stratified by ethnicity or occupation type, or controlling for potential confounders.

UK-REACH aims to investigate:
1. The relationship between ethnicity and COVID-19 diagnosis and clinical outcomes in HCWs through expedited linkage and analysis of anonymised NHS human resource, Professional registration and NHS datasets within a Trusted Research Environment (SAIL databank)
2. The changes in health outcomes, social circumstances and professional roles of ethnic minority HCWs (White ethnic group as comparator) over the course of forthcoming pandemic waves and beyond, through a novel longitudinal cohort study of ethnic minority HCWs

facilitating understanding of absolute risk and generalisability of the findings
3. The ethical and legal implications of linking professionals' registration data to healthcare data through a comprehensive policy analysis and interviews with key stakeholders and cohort participants
4. Risk perceptions, support and coping mechanisms relevant to COVID-19 through qualitative research with ethnic minority HCWs
5. Key priorities and recommendations for addressing ethnic disparities in COVID-19 outcomes through sustained joint working with a multi-professional, national stakeholder group represented by the GMC/NMC, Royal Colleges, ethnic minority Professionals’ Associations, and HCWs

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/10/2020, London-Brighton & Sussex Research Ethics Committee (Ground Floor, Skipton House, 80 London Road, London, SE1 6LH; +44 (0)207 104 8241; brightonandsussex.rec@hra.nhs.uk), ref: 20/HRA/4718

Study design
Work package 1 - UK-wide retrospective data-linkage cohort study of a minimum 7 months duration
Work package 2 - Multicentre longitudinal cohort study of 25 years duration
Work package 3 - Qualitative study utilising in-depth semi-structured interviews
Work package 4 - Qualitative study utilising in-depth semi-structured interviews and focus groups.
Work package 5 - Separate patient and public involvement, engagement and participation work package to inform and support the work of the other work packages

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Impact of ethnicity on COVID-19 outcomes in healthcare workers

Interventions
Work package 1
Investigators will undertake expedited linkage and analysis of anonymised data on COVID-19

outcomes among clinical and ancillary NHS healthcare workers, including NHS human resource (Electronic Staff Record), professional registration, and NHS datasets, including primary care data, hospital episode statistics, Intensive Care National Audit and Research Centre data, mortality data, Public Health England COVID-19 results, and COVID-19 Symptom Tracker data within a Trusted Research Environment (SAIL databank) to understand the impact of ethnicity (as per ONS classification) on COVID-19 outcomes. Researchers will compute crude/adjusted incidence rate ratios to compare ethnicity (White, Asian, Black, Other) in terms of COVID-19 diagnosis and outcomes (diagnosis, hospitalisation, ITU admission and death) and will adjust for core predictors including age, sex, deprivation and comorbidities, including cardiometabolic conditions. Work package 1 will assess risk across occupations and by setting (hospital, community etc), assessing interactions with ethnicity.

Work package 2
Work package 2 aims to recruit at least 30,000 staff (clinical and ancillary Staff) (66% of whom will be from minority ethnic groups). Researchers will invite healthcare workers to participate via healthcare regulators and NHS organisations. Following an online consent process, participants will be asked to complete a baseline questionnaire with questions relating to demographics, healthcare role (type, setting and redeployment), location of work/residence, interaction with COVID-19 patients, levels of sickness/PPE, social circumstances and physical/mental health. Participants will be asked to provide consent to follow their health by extracting information from their past and future NHS healthcare records (including NHS number), any COVID-19 related records, and from “Zoe COVID-19 symptom tracker” websites or apps if they use them.

Work packages 3, 4 and 5
The proposed qualitative research component in UK-REACH will utilise semi-structured interviews (both WP3 and 4) and focus groups (WP 4 only) to explore the experiences and perceptions of staff in healthcare settings, including both clinical and ancillary staff from ethnic minority communities, around risk, support, and coping mechanisms. WP3 will have a particular focus on ethico-legal aspects, specifically looking at the ethical and legal implications of large dataset analyses/cohort studies, such as risks of re-identification and identifying core principles of information governance in the context of sensitive data and healthcare worker datasets.
The rich diversity of the project will be complemented by a robust Public Involvement and Engagement (PIE) strategy which has been in-built into the project (WP5) and conforms to the principles of (i) being receptive of public views and opinions, (ii) collaborating and co-creating with the public and (iii) involving the public in the wider dissemination of results.

Intervention Type
Other

Primary outcome measure
Work package 1
1. Suspected (based on self report or symptoms) or confirmed (positive molecular test for SARS-CoV-2) COVID-19 diagnosis
2. Hospitalisations, which includes all hospitalisations (any hospital admission recorded during the study period in secondary care or CHESS data) during the study period and COVID-19 related hospitalisations (any hospitalisation where COVID specific ICD-10 codes are recorded or the is record of a positive SARS-CoV-2 test during or within 28 days prior to a hospital admission)
3. ITU admission - admissions to ITU recorded during the study period in those with a COVID-19 hospitalisation using secondary care or CHESS data or with an ITU admission and confirmed COVID-19 notification recorded in ICNARC
4. Mortality, both all cause mortality (any death registration recorded during the study period in

ONS mortality data). and mortality due to COVID-19 (any death registration with COVID-19 specific ICD-10 codes recorded for the primary or secondary cause of death during the study period in ONS mortality data.)

Work package 2
1. COVID-19 outcomes (infection, hospitalisation, mortality) by linkage to healthcare records (as for work package 1 above)
2. Mental health outcomes by the inclusion of validated screening tools in the questionnaire
3. Sociodemographic, occupational and health differences between ethnic groups that may impact on COVID-19 outcomes, through the inclusion of questionnaire items relating to changes in professional roles/practice, social circumstances and physical/mental well-being

Work package 3 and 4
The proposed qualitative research component in UK-REACH will utilise semi-structured interviews (both WP3 and 4) and focus groups (WP 4 only) to explore the experiences and perceptions of staff in healthcare settings, including both clinical and ancillary staff from ethnic minority communities, around risk, support, and coping mechanisms. WP3 will have a particular focus on ethico-legal aspects, specifically looking at the ethical and legal implications of large dataset analyses/cohort studies, such as risks of re-identification and identifying core principles of information governance in the context of sensitive data and healthcare worker datasets.

Work package 5
Work package 5 is a Public Involvement and Engagement (PIE) strategy. The primary outcome of which will be to complement the other work packages through designing, delivering and disseminating all aspects of the project, including monthly reports with recommendations to inform policy and practice.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/08/2020

Completion date
01/08/2045

Eligibility

Key inclusion criteria
Work package 1
1. Adult (aged 16 or over)
2. Healthcare worker - as identified by HR records or professional registers

Work package 2
1. Adult (aged 16 or over)
2. Lives and works in the UK
3. Healthcare worker or ancillary worker in a healthcare setting
4. Willing and able to provide informed consent

Work package 3 and 4
1. Adult (aged 16 or over)

2. Willing and able to provide informed consent
3. Has experience of working in a healthcare setting during the COVID-19 pandemic

Work package 5
1. Adult (aged 16 or over)
2. Member of a collaborating organisation and/or has experience of working in a healthcare setting during the COVID-19 pandemic

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
Work package 1 - approximately 1.5 million, Work package 2 - 30,000, Work package 3 - 30, Work package 4 - 150, Work package 5 - N/A

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/11/2020

Date of final enrolment
01/04/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leicester Royal Infirmary
University Hospitals of Leicester NHS Trust
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Sponsor information

Organisation
University of Leicester

Sponsor details
Research Ethics
Governance and Integrity Office
Research and Enterprise Division
University Road
Leicester
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United Kingdom
LE1 7RH
+44 (0)116 2584867
RGOsponsor@le.ac.uk

Sponsor type
University/education

Website
http://www.le.ac.uk/

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Research council

Funder Name
UK Research and Innovation

Alternative Name(s)
UKRI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journals. There will be a number of publications throughout the study.

Intention to publish date
01/11/2045

Individual participant data (IPD) sharing plan
Work package 1 & 2 datasets will be stored in an anonymised format at the SAIL databank. Anonymised data from work packages 1 and 2 may be made available to facilitate other research projects. For work package 2 we will have obtained consent for this, however, work package 1 is a data linkage study and therefore consent from individual participants will not be sought. Access to study data may be granted after discussion with the chief investigator and data access committee (to be set up).

In work packages 3, 4 & 5 datasets will be kept on secure University servers. Access to these datasets may be granted after discussion with the chief investigator and data access committee (to be set up).

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Preprint results	non-peer-reviewed protocol in preprint	25/02/2021	17/03/2021	No	No
Preprint results	non-peer-reviewed results in preprint	03/03/2021	17/03/2021	No	No
Protocol article		17/09/2021	21/09/2021	Yes	No

Results article	Risk factors associated with SARS-CoV-2 infection	26/05/2022	27/05/2022	Yes	No
Results article	Cross-sectional analysis	10/10/2022	10/10/2022	Yes	No
HRA research summary			28/06/2023	No	No