University College London Hospitals
NHS Foundation Trust

SARS-CoV-2 Acquisition in Frontline Health Care Workers – Evaluation to Inform Response - PLUS (SAFER-PLUS)

Participant Information Sheet

WHY are we doing this?

Healthcare Workers (HCWs) who work during the COVID-19 pandemic are at risk in two ways: catching the infection from their patients, and carrying the infection during work and passing it to their patients.

This study investigates your continued risk while working in your hospital of catching the novel coronavirus SARS-CoV-2 which causes COVID-19.

We also know from research during the first wave of COVID-19 that some people have SARS-CoV-2, and are asymptomatic but they can still pass this infection on to others.

We also want to answer key questions around:

- The risk of re-infection by SARS-CoV-2, and how the presence of antibodies you may have produced from previous infections can alter this risk.
- The impact of other respiratory viruses and seasonal co-infections.
- The severity and duration of COVID-19 infection.
- Clinical outcomes in Black, Asian and Minority Ethnic (BAME) HCWs.
- HCWs perceptions of risk, personal protective behaviours, and vaccination against COVID-19.
- Patterns of HCW movement, contact and interactions to identify where virus transmission occurs in the hospital
- Other initiatives in HCW COVID-19 research by collaborations such as that with the national SIREN study.

All of this information would allow us to better inform staff of risks from working during a viral pandemic and potentially how best to protect themselves. Additionally, we hope it will help to identify ways of reducing the risk of transmission of coronavirus to inpatients.

WHO can get involved?

HCW staff aged 16 and above, at University College London Hospitals (UCLH), and Camden and Islington NHS Trust Highgate Mental Health Centre (C&I Highgate MHC), including on site contractors.

You can still participate if you have previously tested positive for COVID-19, have antibodies against COVID-19 infection, or have received a vaccine against COVID-19

WHAT do I need to do?

- Read the full patient information sheet on the following pages.
- If you are interested in taking part then please email uclh.saferstudy@nhs.net and / or follow this link to complete the online informed consent form.
- After signing the consent form you will be provided with further links to complete online questionnaires.
- You will then be asked to provide different types of samples (swab, oral, blood) at intervals over the study duration, as detailed in the 'you and your samples section' below.
- Participation in SAFER-PLUS will be from 6 to 12 months, depending on the date when you were enrolled into the study.
- You will also be provided with links to information about other studies within SAFER-PLUS, and external collaborations.
- Participation is voluntary, and strictly confidential.

FURTHER DETAILS OF THE STUDY ARE BELOW

Invitation to take part in a research study

You are being invited to take part in a Health Care Workers (HCWs) COVID-19 research study during the subsequent waves of the pandemic.

This Participant Information Sheet (PIS) will explain the purpose of the study (SAFER–PLUS) and what your involvement will be. Please read this information sheet before you decide to participate. You may want to discuss with colleagues, who may also have been invited to participate, before taking part. Please ask us anything that requires further explanation or anything that is not clear. Take time to decide whether or not to participate. Participation is entirely voluntary.

What is the purpose of the study?

The SAFER study evaluated whether 200 HCWs working at UCLH during the first wave of COVID-19 were at risk of catching SARS-CoV-2 at work. Samples and symptoms were collected from these HCWs for 12 weeks and the first month of results reported high rates (44%) of SARS-CoV-2 infection, and 38% of infections were asymptomatic.

With SAFER-PLUS we have the opportunity to continue the study of transmission in the hospital setting for up to 12 months, investigate how long infections can last, and if antibody

levels following an infection drop over time increasing the risk of re-infection, especially important in the healthcare setting where SARS-CoV-2 exposures can happen often.

In addition to UCLH SAFER participants we are also able to expand our recruitment to include participants from the UCLH staff testing programme (through Occupational Health / enhanced surveillance). SAFER-PLUS will also include other clinical work settings such as the Camden and Islington NHS Trust, that includes Highgate Mental Health Centre, and a number of care homes.

This expansion of recruitment will also help to answer questions on clinical outcomes in Black, Asian and Minority Ethnic (BAME) HCWs, and assess what makes COVID-19 more severe in some people.

In addition to SARS-CoV-2 the study will assess the impact of other respiratory viruses and co-infections like RSV, influenza and seasonal coronaviruses.

SAFER-PLUS will also include behavioural studies that explore front-facing HCWs perceptions of risk, personal protective behaviours and vaccination against COVID-19. Participants will also be invited to join a movement / tracking programme which aims to determine patterns of movement, contact and working practices to identify the locations and conditions under which virus transmission occurs.

The study will also be collaborating with other initiatives in HCW research, offering SAFER-PLUS participants the opportunity to participate in high-quality studies, including:

- Contributing participants re-infection rate data to the National PHE SIREN HCW study*
- COVID-19 related loss of taste and smell
- The study of HCWs pets in the household transmission of SARS-CoV-2
- Mental health impact and wellbeing
- Providing residual samples to the Francis Crick COVID-19 Consortium LEGACY cohort

*Further details of the SIREN study (SARS-CoV-2 Immunity & Reinfection Evaluation) can be found at: https://snapsurvey.phe.org.uk/siren/ however participation would be through SAFER-PLUS and no additional activity or samples will be required in addition to that already being done for SAFER-PLUS.

Who can take part in the study?

We aim to include every member of staff aged 16 years or older at UCLH and Camden and Islington NHS Trust Highgate Mental Health Centre in order to have sufficient samples and data for SAFER PLUS. We aim to recruit at least 1000 staff members who already have antibodies to COVID-19 infection, and 500 from the symptomatic group. It is a requirement that contractors on site who wish to take part in the study, but are not employed by UCLH or Camden and Islington NHS Trust inform their employer.

You can still participate if you have previously tested positive for COVID-19, have antibodies against COVID-19 infection, or have received a vaccine against COVID-19

Do I have to take part in the study?

No. The decision on whether you take part in the study or not is entirely yours. You can also participate in the wider SAFER-PLUS study without taking part in the behavioural, tracking or collaborative studies, if you so wish. If you do decide to take part, you are still free to withdraw at any time and without giving a reason. Your line managers and/or colleagues will not be notified of your decision of whether or not you take part.

What will happen if I do take part in the study?

If you decide to take part in the study, you will be asked to complete and sign an electronic consent form and be emailed a copy of this, in addition to this information sheet to keep. Once you have signed the consent form, the researcher will ask you to complete study questionnaires as detailed below.

Since we know staff are busy when at work and require undisturbed break times, we will either recruit from staff already enrolled in the staff testing programs, or provide swabs which can be used at a convenient time. We will also text you (if you consent to this option) or come onto the ward frequently to remind staff to participate and offer swabs and attend phlebotomy. Each interaction should take 1-2 minutes.

For blood draws, we will take up to 10mls blood for serology assays and up to 18mls blood to store cells. Full details for all samples taken are given below.

Study Questionnaires

Baseline questionnaire: After informed consent, participants will be invited to complete an online baseline (enrolment) questionnaire, providing information about yourself, your role in the hospital and baseline health status. If you prefer not to share health data, you will be able to indicate that on the form. This should take about 5 minutes to complete.

Behavioural questionnaires: The behavioural questionnaire (survey) has previously been approved as part of the original SAFER study. Participants in SAFER-PLUS will be asked to complete it at approximately 3-monthly intervals to capture changes in perceptions of risk and use of protective behaviours over the course of the pandemic. The online questionnaire takes approximately 20 minutes to complete.

Symptom questionnaires: Participants will be asked to complete a brief online questionnaire if they do a swab test while exhibiting symptoms**.**

Behavioural Interviews

This is interview is to discuss in depth, your experiences of working during the COVID-19 pandemic. Participation in the interview is an additional voluntary option and you will be asked to enter your contact details at the end of the behavioural survey if you would like to receive further information (PIS) about this option. These interviews will require an additional consent form to be completed.

Movement / tracking

If you gave consent to be contacted about the movement / tracking study, you will be sent a separate PIS and invitation to join, which will require an additional consent form to be completed. Participation is voluntary and there is no obligation to take part. If you agree to participate in the movement tracking study, you will be asked to download an app which will use Bluetooth to track your location around the hospital. The app will not track your movement anywhere outside of the hospital environment. Your staff identifier will be used to match up your records from the SAFER-PLUS to routinely collected hospital data such as staff rota records and door card access logs. This study will investigate the movements and interactions of HCWs with staff and patients around the hospital, with the aim to identify risk factors associated with the transmission of the virus.

You and Your Samples

The SAFER-PLUS study will test for the SARS-CoV-2 virus in the nose and throat, which in most cases will be part of the existing staff testing programs. It will also collect saliva, oral swabs (crevicular fluid) and blood samples to see if there are antibodies in these specimens to the virus. If you are participating in the pet virus transmission study you may be asked to collect a faecal sample from your pet to post to the study team, for which kits will be provided.

Laboratory assays to test your samples will take place at the UCLH Advanced Pathogen Diagnostics Unit (APDU) at UCLH Health Service Laboratories (HSL), at University College London (UCL), and the Francis Crick Institute.

During the study, samples will be stored in fridges and freezers in the Virology Department of UCLH, APDU UCLH, UCL or the Francis Crick Institute. Sample testing that is in addition to the current staff testing programs will be arranged by the research team at the host institutions. Your samples will also be used to expand COVID-19 diagnostics and develop assays at the end of the study will also become part of the Francis Crick-UCLH LEGACY cohort.

Participants that already have antibodies against SARS-CoV-2 (baseline seropositive individuals):

Staff employed at UCLH, or Camden and Islington NHS Trust Highgate Mental Health Centre that have antibodies to SARS-CoV-2 will be asked to:

- Complete electronic consent for access to prospective and retrospective SARS-CoV-2 PCR (swab) test and serology (antibody) results.

- provide serology samples (blood for serum every 1-2 months), saliva and oral swab (crevicular fluid) for up to 12 months (up to 13 of each samples in total), and blood to study immune cells twice.

Occupational health/enhanced surveillance participants:

This includes staff working in UCLH and Camden & Islington NHS Trust Highgate Mental Health Centre who:

- Attend for symptomatic SARS-CoV-2 PCR (swab) testing, arranged via the Occupational Health service.

AND/OR

- Work in a clinical area where staff undergo regular weekly swabs as routine surveillance whether symptomatic or not.

These participants will be asked to:

- Complete electronic consent for access to prospective and retrospective SARS-CoV-2 PCR (swab) test and serology (antibody) results.
- Provide nose and throat swab, oral swab (crevicular fluid) and saliva samples for SARS-CoV-2 tests in the event of testing positive (symptomatic or asymptomatic) every 48 hours for at least 7 days, or until testing negative on two occasions.
- Provide blood samples for serum (serology), and immune cells and to study certain host genetic associations influencing immune responses and serology 7-21 days after testing PCR positive for SARS-CoV-2 (symptomatic or asymptomatic).
- If this is your first infection your samples will be collected as above day 7-21 post positive SARS-CoV-2 test result.
- If you develop antibodies you will also be asked to provide serology samples as detailed for baseline seropositive participants.

Participants vaccinated against COVID-19:

- Complete electronic consent for access to prospective and retrospective SARS-CoV-2 PCR (swab) test and serology (antibody) results.
- Provide blood samples pre-vaccination (if feasible), and then 14-30 days after first vaccination dose, and 7-21 days after second vaccination dose, for serology (serum) and immune cells.
- If you develop antibodies you will also be asked to provide serology samples as detailed for baseline seropositive participants.
- If you are attending for symptomatic testing or routine enhanced surveillance testing, you will also be asked to follow the testing schedules as detailed above.

At the end of the study period, we would like to ask you if you are interested in being contacted about future follow up studies to further investigate COVID-19 in HCWs.

What are the possible risks of taking part in the study?

Potential harms or risks to participants:

The collection of nose and throat swabs, saliva and oral swabs (crevicular fluid), and blood samples is considered to be of minimum risk for participants. Potential harms:

Venepuncture: taking blood samples may cause some discomfort and occasionally result in a bruise.

Throat swab: participants may gag a little when the sample is taken**.**

Nose swab: this can tickle but is not painful.

Saliva and crevicular fluid: oral swabs can tickle but are not painful.

Self-isolation

As real-time swab testing is available to participants, you are expected to be provided with your results within 48hrs. This will enable you to self-isolate promptly and prevent onward transmission of the infection, if you do test positive for SARS-CoV-2. All participants are recommended to follow National and Trust guidance on self-isolation, assessment of your symptoms and testing for COVID-19, and your test results. If you become ill with symptoms of COVID-19 and self-isolate, swabs may be collected from your home / and / or posted to you.

What are the possible benefits of taking part in the study?

The SAFER study helped to establish the risk to staff of acquiring SARS-CoV-2 whilst working on a COVID-19 cohort ward or a general medical ward during the first wave of the pandemic. SAFER-PLUS will continue to add and contribute research data during the subsequent waves of the pandemic, and winter respiratory virus season when hospitals are already over-burdened, and the months following.

Overall the data will help strengthen infection control, pandemic response and preparedness, and importantly, give us detailed information on how to protect the most vulnerable from acquiring SARS-CoV-2 and other infections from those working to care for them, and also to reduce transmission risk for the HCW.

Will taking part in the study be kept confidential?

Yes, all the information that is collected about you during the study will be kept strictly confidential and secure in line with the law as set out in the General Data Protection Regulation (GDPR). We will only use information that we need for the research study and will also follow all privacy rules, and we will make sure no-one can work out who you are from the reports we write.

How will we use information about you?

In this research study we will collect and use information from you which will include your:

- Initials
- Name

- Date of birth
- Sex
- Contact details
- NHS number (optional).

Those working on this study will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number (study code) instead so that you remain anonymous. Your name and phone number may be used to process laboratory tests and contact you with results, if you agree to this.

Results of nose and throat swabs, and serology for SARS-CoV-2 will be acquired from the EPIC system at UCLH, which participants use to submit their surveillance swabs, and occupational health use to perform testing for symptomatic staff. Participants will input data and respond to questionnaires directly using a personalised link to the UCL online REDCap research database. Data will be held within a secure UCL server as for the SAFER study. We will keep all information about you safe and secure.

Nose and throat swab samples, saliva, crevicular fluid and blood samples will be stored in freezers in the Virology Department of UCLH, APDU UCLH, UCL or at the Francis Crick Institute. To make full use of your samples, we ask that you "gift" your samples to UCLH. We will store them for up to 10 years so that we may use them in the future or send to collaborators involved in infection research globally (universities, NHS organisations or companies involved in health and care research in this country or abroad). We would not send your personal details (see above), all samples will be anonymous and only transferred under UCLH Sponsor and study approved material transfer agreements (MTA).

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

You can find out more about how we use your information at www.hra.nhs.uk/information-about-patients/ and UCLH.IGQueries@nhs.net, and by asking one of the research team or by sending an email to: eleni.nastouli@nhs.net or Catherine.houlihan5@nhs.net

What if there is a problem?

Any complaints should be dealt with in the usual way through the NHS Complaints Procedure. If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions, contact details are at the end of this document. If you remain unhappy and wish to complain formally, you can do this via the hospital's

Site: University College London Hospitals (UCLH) NHS Foundation Trust
Address:
Ground Floor Atrium, University College Hospital, 235 Euston Road, London NW1 2BU

Tel: 020 3447 3042
Email:

When contacting, please quote the UCLH study / Sponsor reference number: **136676**.

What will happen to the results of the research study?

The overall findings from the study will be shared with participants and published in peer-reviewed literature. No results from staff members will be linked to their personal medical records at any point. Participants who receive real-time results positive for SARS-CoV-2 PCR will be encouraged to contact their occupational health team and line manager to inform them.

Once we have finished the study, we will keep some of the data so we can check the results and for future research. This data will be kept for 20 years (which is similar to other COVID-19 studies). We will write our reports in a way that no-one can work out that you took part in the study. At the end of the research your samples will be disposed of in accordance with the Human Tissue Authority's Code of Practice.

Organisation and funding of the study

The research study is funded by the Medical Research Council (MRC), MC_PC_19082, and UCLH Charity. It is Sponsored by University College London Hospitals (UCLH) Foundation Trust and carried out by a research team from the Department of Virology, UCLH, Camden and Islington NHS Trust, and the University College London Farr Institute, Centre for Behaviour Change and departments of Population, Policy and Practice, Infection and Population Health, Epidemiology and Public Health, Infection and Immunity and Science and Technology Studies, and the University of Leeds.

Time to Consider

You can decide to participate after reading this information form and completing the consent form, or you can take time to decide whether to participate.

Who has reviewed this study?

All research in the NHS is reviewed by an independent group of people, called a Research Ethics Committee (REC) which is there to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable ethical opinion by the Cambridgeshire and Hertfordshire REC {approval / date TBC} and the Health Research Authority (HRA) in accordance with UK research regulations.

Who Should You Contact with Questions?

You will be emailed a copy of this information sheet and the signed consent form to keep. If you have any problems or questions about this study or your rights as a patient in clinical research you should contact:

Study contact email: uclh.saferstudy@nhs.net

Study doctors:
UCLH:
Dr Catherine Houlihan: Catherine.houlihan5@nhs.net
Dr Eleni Nastouli: eleni.nastouli@nhs.net
Dr Patricia Miralhes: patricia.miralhes1@nhs.net
Camden and Islington Highgate Mental Health Care Trust:
Harry Clark: researchteam@candi.nhs.uk

Telephone contact (between 0900 and 1700 Monday-Friday):

UCLH SAFER-PLUS study mobile phone number: 07790972176
Camden and Islington Highgate Mental Health Centre (Harry Clark): 0203 317 7616

Thank you for reading the Patient information sheet and for considering taking part in this study. If you have any further questions, please talk to the study doctor or nurse.