Imperial College London

UNIVERSITY OF OXFORD

Patient Participant Information Sheet
(Regulation 5 support)

RECAP (Remote COVID Assessment in Primary Care): a learning system approach to develop an early warning score for use by primary care practitioners

We are medical researchers from Imperial College London and University of Oxford. We would like to invite you to take part in a research study. Before you decide to participate, it is important for you to understand why this research is being done and what it will involve.

What is the purpose of the study?

We're trying to improve how to predict the severity of COVID-19 and identify the need for patient hospitalisation. Most people with COVID-19 feel poorly but then recover but about 10-20% people have a more severe illness. We're keen to pick those people up early.

We want to develop an 'early warning score' (known as RECAP) to guide medical professionals to determine the degree of illness of a patient. The RECAP score is for GPs to use when assessing how bad someone is with COVID-19 to use during consultations.

The research is called *data linkage*. Specific data from your electronic medical record relating to COVID-19 (such as your temperature, pulse, breathing rate and how bad you felt today when asked about your symptoms) will be sent to a secure data repository. We will then link your GP and hospital records to find out how you got on. We'll be looking for three things: survival rates after 8 weeks, whether people were admitted to intensive care, and whether they needed to be admitted to hospital at all.

We plan to do data linkage on several thousand people's records. This is important because we need a large sample to produce an accurate 'early warning score' for COVID-19. This will help GPs identify accurately who needs to be sent to hospital and who can safely stay at home. RECAP could save lives by both reducing the number of people who are sent to hospital unnecessarily and ensuring that nobody who does need urgent hospital assessment misses out.

Research question is as follows:
What is the predictive value of the RECAP score used for primary care assessment of COVID-19 patients?

What has happened in the RECAP study so far?

We recruited people with acute COVID 19 symptoms from general practices and from the NHS111 Covid Clinical assessment Service, people were asked for their consent prior to taking part. Recruitment was completed in June of 2021, and analysis in January 2022.

Additionally, we also obtained data that had already been collected as part of routine care, and where we were not able to ask people for individual consent (from Doctaly Assist and the NHS 111 Covid Clinical Assessment Service). Analysis of this data is still ongoing and details of this are covered in the below section 'How will we use information about you?'.

Why have I been chosen to participate in the study?

You would have been identified by your records in the South East London Doctaly assist service or the NHS 111 Covid Clinical Assessment Service (NHS111 CCAS) as someone who was assessed for potential COVID-19.

Do I have to take part?

If you have already had a 'national data opt-out code' placed in your records by your GP, then we will not have had access to your data. In addition, if you now wish to opt out, please let us know (see contacts below) and we may be able to delete your data. If you have sought medical care via Doctaly platform, you can also opt-out and withdraw. There will be a privacy notice stated in the Doctaly platform where you are able to state your preferences about research participation.

What does participation involve?

We will use your Doctaly Assist or NHS 111 data as described below under 'how we will use information about you'.

Benefits of participation

In real time, your GPs may be more aware and more reflexive of the criteria for referral to hospital for suspect COVID-19. In the longer term, your GP may have contributed to the production of a better RECAP score. Knowledge gathered will inform policy and practice dealing with COVID-19 pathways in primary care.

What if something goes wrong?

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during this study then you should immediately inform the Investigator Brendan Delaney (see contact details listed below). The normal National Health Service complaints mechanisms are also available to you.

How will we use information about you?

Importantly, the data from your record will not include your name, address or any identifying details other than your NHS number which will be used to link the NHS111 CCAS and hospital records and then removed. Data will be held securely at the University of Oxford. We won't use the data for any other purpose and the final data for analysis from Doctaly Assist will be completely anonymised. For NHS111 CCAS, we possess what was written on your record when the GP spoke to you ('text data'). Although we have taken steps to remove any personal data such as names and addresses, text data from CCAS cannot be completely de-identified. However no identifiable information is used in the analyses, which are all carried out in a secure system that does not allow export of any personal data.

Imperial College London is the sponsor for this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Oxford will keep your anonymised data for 10 years after the study has completed as the primary research data.

Legal Basis

As a university, we use personally identifiable information to conduct research to improve health, care and services. As a publicly funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in the research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research. The legal basis for section 2 is on the basis of the COPI notice until 30/6/22, and after 30/6/22 'regulation 5 approval'. Please see below for an explanation of these terms.

COPI Notice

Data from this study is collected under COPI Notice (Control of Patient Information) issued by the Secretary of State for Health and Social Care, this means that data is collected without explicit consent, but on the explicit purpose of public benefit in terms of managing the COVID-19 pandemic. COPI Notice is due to expire on the 30.6.22. In order to continue to process patient data (without explicit consent) after 30.6.22 a long-term lawful basis (known as Regulation 5 support, or 'section 251' support) is obtained through applying to the Confidentiality Advisory Group (CAG).

Confidentiality Advisory Group (CAG)

CAG is an independent body which provides expert advice to the Health Research Authority (HRA) on the use of confidential patient information. After COPI Notice expires on 30.6.22, we require CAG's

recommendation to the HRA for support for continued access to certain patient data collected in the RECAP study.

What data was collected under the COPI Notice?
For patients recruited via CCAS (Covid Clinical Assessment Service), text data (rows of free-text entries) was collected under COPI Notice.

For patients recruited via the Doctaly platform, patients' clinical information as part of their clinical assessment with their primary care GPs was collected under the COPI Notice.

What happens under Regulation 5 support?
Data collected via the Doctaly platform under COPI has now been completely anonymised so does not require regulation 5 support. Only the free text data collected via CCAS requires regulation 5 support as it cannot be COMPLETELY anonymised (whilst text data cannot be completely de-identified, no identifiable information is used in the analyses).

International transfers

There may be a requirement to transfer information to countries outside the European Economic Area (for example, to a research partner). Where this information contains your data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a European Commission (**EC**) adequacy decision in respect of its data protection standards, Imperial College London will enter into a data-sharing agreement with the recipient organisation that incorporates EC approved standard contractual clauses that safeguard how your data is processed.

Sharing your information with others

For the purposes referred to in this privacy notice and relying on the bases for processing as set out above, we will share your data with certain third parties.

- other College employees, and service providers (e.g. third parties processing data on our behalf)
- the following Research Collaborators / Partners in the study;
- Third Party University – the University of Oxford are research collaborators in this study. University of Oxford are processing the data for linkage within their secure environment (ORCHID) and providing access to Imperial staff for analysis within Imperial College London secure environment (iCARE). As research collaborators this includes third parties the University of Oxford is collaborating with.
- Third Party Company – patients seen at CCAS will receive an SMS message about the RECAP study before their consultation via NHS Digital as part of the NHS111 case allocation system.

What are your choices about how your information is used?

If you are being seen at a GP practice you can stop being part of the study at any time, without giving a reason, we may keep information about you that we already have. If you are being seen at the Covid Clinical Assessment Service data obtained during the consultation may be used for the current research study. You will have the opportunity to provide your consent at the end of your GP consultation. Text data from patients who have previously used the CCAS service may also be used for the research study in an anonymised fashion, if you want to opt-out please also let the doctor know. As mentioned above, whilst text data cannot be completely de-identified no identifiable information is used in the analyses. If using the Doctaly platform, you can state your preferences by opting out and your data will be removed.

Where can you find out more about how your information is used

You can find out more about how we use your information by sending an email to the chief investigator of this study Professor Brendan Delaney (see bottom of information sheet)

Complaint

If you wish to raise a complaint on how we have handled your data, please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you are not satisfied with our response or believe we are processing your data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO). The ICO does recommend that you seek to resolve matters with the data controller (us) first before involving the regulator.

What will happen to the results of the research study?

We'll be publishing our results in a few months' time. The best way to find this will be via the link below. If you can't access the Internet, write to us (see below for a postal address) and we'll post you a summary.

https://www.imperial.ac.uk/people/brendan.delaney/publications.html

Who is funding the research?

Community Jameel Imperial College COVID-19 Excellence Fund, NIHR Oxford Biomedical Research Centre, NIHR Imperial Biomedical Research Centre, NIHR Imperial Patient Safety Translational Research Centre, Economic and Social Research Council, UKRI

GP practice sites and some research sites will be paid for including you in this study.

Who has reviewed the study?

This study was given favourable ethical opinion for conduct in the NHS by North West - Greater Manchester East Research Ethics Committee (reference 20/NW/0266).

Contact for Further Information

We can also send you more details of the study if you'd like that. Just email or write to the contact below.

Professor Brendan Delaney
Email: brendan.delaney@imperial.ac.uk
Postal address: Imperial College London Room 506, Medical School, Norfolk Place St Mary's Campus Post Code W21PG

We know this is a particularly difficult time, so we appreciate you taking the time to consider this request.

Professor Brendan Delaney — Imperial College London

Professors Trisha Greenhalgh and Simon de Lusignan — University of Oxford

If you want more information on how we store data, please see the below links.
Whole Systems Integrated Care (WSIC)

https://www.healthiernorthwestlondon.nhs.uk/news-resources/information-sharing