

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

Sorry you're unwell and that you possibly have COVID-19. We hope that, like most people with this illness, you'll soon make an uneventful and speedy recovery. We are medical researchers from Imperial College London, University of Oxford and King's College London. 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?

Why have I been chosen to participate in the study?

You have been asked to participate because you are a patient at a GP practice, and as such you are a crucial part of the consultation. You would have been identified by your GP as someone who is assessed for potential COVID-19.

Do I have to take part?

No. Participation in the study is entirely voluntary and you may choose to withdraw at any time. Either your doctor or nurse should have asked you today whether you are happy for us to do data linkage with your records, or you may have been asked this via a technology platform or 'chatbot'. You won't have had much time to think about this, so rest assured: if you change your mind, let us know and we will remove your data from our system and not use it for research. Please contact the GP practice to inform them you would like to withdraw yourself from the study, your GP will then remove your data from the RECAP score. We won't be carrying out data linkage for a few weeks so you may choose to withdraw your data within 14 days after providing consent.

What does participation involve?

Attend a consultation (a phone or video consultation) whilst your GP uses their routine computer system (known as electronic health record) alongside the RECAP score.

Benefits of participation

In real time, your GP 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.

Confidentiality and storage of data

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 GP and hospital records and then removed. Data will be held securely at either Imperial College or the University of Oxford, depending on how your GP is involved. We won't use the data for any other purpose and the final data for analysis will be completely anonymised.

In North West London (NWL), we have an established integrated care system 'Whole Systems Integrated Care (WSIC)' available to clinicians and other health professionals who are providing direct care to over 2.4 million patients in north-west London. The linked integrated care data is available in a de-identified format for research purposes. Locality-based arrangements (e.g. in Oxfordshire) will be developed to ensure the highest level of governance in protection of patient 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. Imperial College London will keep your data for 10 years after the study has completed.

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. Note: No patient records or identifying information will be collected for this 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](#).

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 employees and service providers College (e.g. third parties processing data on our behalf)

What are your choices about how your information is used?

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.

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.

Who is funding the research?

The Medical Research Council (application in progress) is funding 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.

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 link.
Whole Systems Integrated Care (WSIC)

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