ISRCTN13953727 https://doi.org/10.1186/ISRCTN13953727

# Assessing patients' risk of COVID-19 severe infection: developing a risk prediction score

**Submission date**
19/10/2020

**Recruitment status**
No longer recruiting

**Registration date**
02/11/2020

**Overall study status**
Completed

**Last Edited**
29/08/2023

**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
New methods to assess and improve the management of Covid-19 patients are essential to maximise safety for patients and health care providers.
The RECAP (Remote COVID-19 Assessment in Primary Care) project emerged as a collaboration between the University of Oxford and Imperial College London with the aim of developing a tool to assist primary care providers in the identification of those COVID-19 patients at risk of becoming severe, in order to enable the rapid escalation of their treatment and increase the chances of better outcomes.

Who can participate?
We are recruiting primary care centres across England to collaborate with us in the identification and assessment of patients with signs and symptoms of Covid-19 and recording patient's characteristics at the time of appointment (either face-to-face or video/telephone consultation). Any practice is welcome to collaborate as long as it uses an electronic medical record system that supports the Covid-19 assessment template developed for the study. Practices may be asked to join the RCGP Research and Surveillance Centre in order to participate since this will ensure data collected can be linked to hospital outcomes. Patients recruited must have signs and symptoms of Covid-19 infection, be 18 years old or older, and be able to provide inform consent.

What does the study involve?
Interested practices will be accepted into the study by a member of the study team, who will provide more information on the study. The participation involves the deployment of the Covid-19 electronic template in EMIS or SystmOne each time the general practitioner identifies a patient that fulfils the inclusion criteria. Patients' consent will be recorded by clicking a box in the template. Once the completed template is saved, the data will be automatically extracted for the study.

What are the possible benefits and risks of participating?
General practitioners and patients will benefit from a more systematic assessment of the patient's condition thanks to the use of the Covid-19 assessment template in their electronic medical records. Moreover, when the risk prediction score is developed, general practitioners

will be able to identify patients at risk of severe disease and escalate their treatment as appropriate, which will hopefully improve patient safety and disease outcomes. We do not anticipate any risks for patients or general practitioners taking part in the study.

Where is the study run from?
Imperial College London and University of Oxford (UK)

When is the study starting and how long is it expected to run for?
May 2020 to February 2022

Who is funding the study?
1. NIHR Oxford Biomedical Research Centre (UK)
2. NIHR Imperial Biomedical Research Centre (UK)
3. NIHR Imperial Patient Safety Translational Research Centre (UK)
4. Economic and Social Research Council (UK)
5. Community Jameel Imperial College Covid-19 Excellence Fund (UK)

Who is the main contact?
Dr Ana Belen Espinosa-Gonzalez
a.espinosa-gonzalez15@imperial.ac.uk

# Contact information

### Type(s)
Scientific

### Contact name
Dr Ana Belen Espinosa Gonzalez

### ORCID ID
https://orcid.org/0000-0002-8226-416X

### Contact details
10th Floor Queen Elizabeth Queen Mother Wing
St Mary's Hospital South Wharf Road
London
United Kingdom
W2 1NY
+44 (0)7472035868
a.espinosa-gonzalez15@imperial.ac.uk

# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### Integrated Research Application System (IRAS)
283024

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number
IRAS 283024, CPMS 45890

# Study information

### Scientific Title
Remote COVID-19 Assessment in Primary Care: a learning system approach to develop an early warning score for use by primary care practitioners

### Acronym
RECAP

### Study objectives
Early warning scores (EWSs) are often used in medicine these days. For example, the National Early Warning Score (NEWS2) is used in hospitals to alert nurses and doctors to someone who is deteriorating and may need urgent assessment and treatment. This validity of this score to identify Covid-19 patients at risk of severity has been a subject of intense debate among clinicians and academic community during the height of the first Covid-19 wave. It considers features such as pulse, blood pressure, respiratory rate, oxygen saturation level and conscious level. The more abnormal these features are, the sicker the patient is likely to be. However, the use of NEWS2 outside the hospital setting has not been validated, and, more importantly, it is not COVID-19-specific. We would like to develop an EWS that is both COVID-19-specific and that can be used by general practitioner's (GPs) when dealing with patients with signs and symptoms of Covid-19 infection.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 27/05/2020, North West-Greater Manchester East Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8199; gmeast.rec@hra.nhs.uk), ref: 20/NW/0266

### Study design
Multi-centre observational prospective cohort study.

### Primary study design
Observational

### Study type(s)
Other

### Health condition(s) or problem(s) studied
Prognosis of patients with a clinical diagnosis of Covid-19 infection

### Interventions
Based on an initial model previously defined with qualitative data, the study team will firstly design a template to be completed by GPs when assessing patients with signs and symptoms of

Covid-19 infection. The template will be activated in either EMIS or SystmOne software, which are widely used in GP practices across England. Once the template is completed, the anonymised patient information will be linked to hospital outcomes. In North West London, primary care data is already linked to hospital data. In other sites, patients' consent for data linkage will be requested at the time of filling the template (by clicking a box on the template).

Once we have collected primary care data on patients with possible Covid-19 infection and linked their data to hospital outcomes, we will run logistic regressions analysis to identify those patients' characteristics (symptoms, signs, age, ethnicity) that seem to predict patients' outcomes (i.e., hospital admission, ICU admission and death). Models obtained through classical statistical methods will be compared with predictive models obtained with machine learning techniques.

Finally, the patients' characteristics that seem to have higher predictive power will be included in the final risk prediction score that will be built into the electronic Covid-19 templates in EMIS and SystmOne. This will guide GPs on the management of Covid-19 patients and allow early escalation of patients' treatment in cases of high likelihood of severity.

### Intervention Type
Other

### Primary outcome(s)
Hospital admission defined as hospital stay of 24 hours or longer during the period of study measured using patient records

### Key secondary outcome(s))
1. Intensive Care Unit admission defined as admission in an intensive care unit of any length during the period of study measured using patient records
2. Death during the period of study measured using patient records

### Completion date
02/02/2022

## Eligibility

### Key inclusion criteria
Patients:
1. At least 18 years old
2. Seek care at their primary care centre for signs and symptoms compatible with Covid-19 infection
3. Consent for their data to be linked to hospital data (only for practices outside North West London).

Primary care practices:
1. Based in NWL CCG or belong to the RCGP Research and Surveillance Centre
2. Use SystmsOne or EMIS software

### Participant type(s)
Patient

### Healthy volunteers allowed

No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Total final enrolment
8311

### Key exclusion criteria
Primary care practice sites:
Not using a compatible electronic record system or using a remote monitoring system that cannot provide an output that is at least mapped to the appropriate SNOMED concepts

### Date of first enrolment
01/10/2020

### Date of final enrolment
28/02/2021

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**Imperial College London**
North West London CRN
10th Floor Queen Elizabeth Queen Mother Wing
St Mary's Hospital South Wharf Road
London
United Kingdom
W2 JNY

### Study participating centre
**University of Oxford**
RCGP Research and Surveillance Centre
Radcliffe Primary Care Building
Radcliffe Observatory Quarter
Woodstock Road

Oxford
United Kingdom
OX2 6GG

# Sponsor information

**Organisation**
Imperial College London

**ROR**
https://ror.org/041kmwe10

# Funder(s)

**Funder type**
University/education

**Funder Name**
Community Jameel Imperial College COVID-19 Excellence Fund

**Funder Name**
NIHR Oxford Biomedical Research Centre

**Alternative Name(s)**
NIHR Biomedical Research Centre, Oxford, OxfordBRC, OxBRC

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Research institutes and centers

**Location**
United Kingdom

**Funder Name**
Patient Safety Translational Research Centre

**Alternative Name(s)**
NIHR Imperial Patient Safety Translational Research Centre, PSTRC, NIHR Imperial PSTRC

**Funding Body Type**
Government organisation

**Funding Body Subtype**
Research institutes and centers

**Location**
United Kingdom

**Funder Name**
Economic and Social Research Council

**Alternative Name(s)**
Economic and Social Research Council (ESRC), ESRC

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
United Kingdom

**Funder Name**
NIHR Imperial Biomedical Research Centre

**Alternative Name(s)**
NIHR Imperial BRC, Imperial Biomedical Research Centre, BRC

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Research institutes and centers

**Location**
United Kingdom

# Results and Publications

**Individual participant data (IPD) sharing plan**

All data generated or analysed during this study will be included in the subsequent results publication

## IPD sharing plan summary

Other

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | Development and validation of RECAP prediction tools | 01/09/2022 | 29/08/2023 | Yes | No |
| Protocol article | | 25/05/2021 | 05/05/2021 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |