

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

Submission date 19/10/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 02/11/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 29/08/2023	Condition category Infections and Infestations	<input type="checkbox"/> 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 informed 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

Study website

<https://imperialbrc.nihr.ac.uk/research/covid-19/covid-19-ongoing-studies/recap/>

Contact information

Type(s)

Scientific

Contact name

Dr Ana Belen Espinosa Gonzalez

ORCID ID

<http://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

EudraCT/CTIS number

Nil known

IRAS number

283024

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Cohort study

Study setting(s)

GP practice

Study type(s)

Other

Participant information sheet

https://imperialbrc.nihr.ac.uk/wp-content/uploads/2020/10/RECAP_Patient_information_Sheet.pdf

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 measure

Hospital admission defined as hospital stay of 24 hours or longer during the period of study measured using patient records

Secondary outcome measures

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

Overall study start date

15/05/2020

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

2,870

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**

England

United Kingdom

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

Sponsor details

Imperial College Healthcare NHS Trust

Room 215, Medical School Building

St Mary's Hospital

Praed Street

London

England

United Kingdom

W21NY

+44 (0)20 759 49459

Becky.ward@imperial.ac.uk

Sponsor type

University/education

Website

<https://www.ic.ac.uk/clinicalresearchgovernanceoffice>

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, 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)

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

Publication and dissemination plan

We are currently disseminating the study via Twitter and the Institute of Global Health Innovation blog, where we have scheduled an entry for November 2020.

We are preparing a manuscript to be submitted to a high-impact peer-reviewed journal at the end of the year or as soon as we have some preliminary results.

The protocol is available at <https://imperialbrc.nihr.ac.uk/wp-content/uploads/2020/10/RECAP-06-STUDY-PROTOCOL.pdf>

Intention to publish date

30/04/2021

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?
Protocol article	Development and validation of RECAP prediction tools	25/05/2021	05/05/2021	Yes	No
HRA research summary			28/06/2023	No	No
Results article		01/09/2022	29/08/2023	Yes	No