

# Early Pandemic Evaluation and Enhanced Surveillance of the coronavirus COVID-19 (EAVE II)

<b>Submission date</b> 10/08/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 17/11/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/05/2022	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Following the emergence of the novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in December 2019 and the ensuing COVID-19 pandemic, population-level surveillance and rapid assessment of the effectiveness and safety of existing or new therapeutic or preventive interventions is needed to ensure that interventions are targeted to those at highest risk of serious illness or death from COVID-19. We aim to determine the attack rate of SARS-CoV-2, the uptake, and effectiveness of any new pandemic vaccine (once available) and any protective effect conferred by existing or new antimicrobial drugs and other therapies.

### Who can participate?

The setting for this project will be approximately all general practices based throughout Scotland, these practices have about 5,400,000 people registered with them and will be included in the project.

### What does the study involve?

Data from the general practices will be linked to data from related healthcare appointments, blood tests, and virus tests to create an anonymised national dataset that will allow estimates of attack rate and vaccine or antiviral effectiveness and safety.

### What are the possible benefits and risks of participating?

There will be no risks and no direct benefit to patients, rather this project will help inform policymakers, clinicians and the public on the progress of the epidemic and the relative benefits of any public interventions deployed such as antiviral medicines or vaccines.

### Where is the study run from?

The project is being jointly led by Public Health Scotland and the Universities of Edinburgh, Strathclyde, Aberdeen, St Andrews and Glasgow (UK).

### When is the study starting and how long is it expected to run for?

From 2020 to September 2021.

Who is funding the study?

The project is funded by the Medical Research Council (MR/R008345/1) and supported by the Scottish Government (UK).

Who is the main contact?

Professor Aziz Sheikh

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## Contact information

### Type(s)

Scientific

### Contact name

Prof Aziz Sheikh

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

114474

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

IRAS 114474

## Study information

### Scientific Title

Early Pandemic Evaluation and Enhanced Surveillance of COVID-19 (EAVE II): an observational study using linked Scottish national data

**Acronym**

EAVE II

**Study objectives**

To describe the epidemiology of COVID-19 in Scotland using linked routine sources of primary, secondary, mortality, and virological/serological testing data, and in due course, to help establish the effectiveness and safety of existing or new therapeutic interventions against the coronavirus that are not subjected to formal clinical trials.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 08/07/2020, South East Scotland Research Ethics Committee 02 (Waverley Gate 2-4, Waterloo Place, Edinburgh, EH1 3EG UK; +44 (0)131 536 900; Joyce.Clearie@nhslothian.scot.nhs.uk), ref: 12\SS\0201

**Study design**

Prospective observational cohort study

**Primary study design**

Observational

**Study type(s)**

Other

**Health condition(s) or problem(s) studied**

COVID-19 (SARS-CoV-2 infection)

**Interventions**

This is an observational study, no intervention will be given to patients. Any vaccine programmes implemented in Scotland will be assessed for effectiveness. The study will assess these vaccine programmes using linked routine sources of primary, secondary, mortality, and virological /serological testing data from approximately 5.4million individuals registered with a primary care practice across Scotland. A national linked dataset of patient-level primary care data, out-of-hours, hospitalisation, mortality and laboratory data will be assembled. Self-controlled study designs will be explored to estimate the risk of therapeutic and prophylactic-related adverse events.

**Intervention Type**

Biological/Vaccine

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Vaccine programmes implemented in Scotland

**Primary outcome(s)**

1. Laboratory confirmed SARS-CoV-2 measured using virological/serological tests between baseline and 9 months
2. Serum from blood samples taken from biochemistry tests (or rapid antibody tests if available) will be used to determine exposure to SARS-CoV-2 infection by the presence of antibodies between baseline and 9 months
3. SARS-CoV-2 infection-related clinical outcomes including general practice, COVID-19 centres and out-of-hours consultations, hospital admissions including secondary bacterial infections and multidrug-resistant bacteria associated with these infections, emergency admissions, out of hours consultations, and deaths between baseline and 9 months

### **Key secondary outcome(s)**

1. Vaccine uptake proportions measured using primary care practice and hospital data between baseline and 18 months
2. Prevention and reduction of SARS-CoV-2 infection-related general practice consultations, hospital admissions including secondary bacterial infections, emergency admissions, out of hours consultations and deaths due to therapies, vaccines, and antimicrobials between baseline and 18 months
3. Adverse events related to therapies, for example, vaccine, antimicrobial administration, or other therapies measured using participant data between baseline and 18 months

### **Completion date**

30/09/2021

## **Eligibility**

### **Key inclusion criteria**

All (anonymised) patient data will be collected

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

All

### **Sex**

All

### **Key exclusion criteria**

Does not meet inclusion criteria

### **Date of first enrolment**

01/04/2020

### **Date of final enrolment**

31/12/2020

# Locations

## Countries of recruitment

United Kingdom

Scotland

## Study participating centre

**The University of Edinburgh**

Usher Institute

Old Medical School

Teviot Place

Edinburgh

United Kingdom

EH8 9AG

# Sponsor information

## Organisation

Academic and Clinical Centre Office for Research and Development (ACCORD) (UK)

# Funder(s)

## Funder type

Research organisation

## Funder Name

Medical Research Council

## Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to public benefit and privacy approvals that state only aggregate data can be published from this project

## IPD sharing plan summary

Not expected to be made available

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		01/05/2022	26/05/2022	Yes	No
<a href="#">Protocol article</a>	protocol published at:	21/06/2020		Yes	No
<a href="#">Preprint results</a>	non-peer-reviewed results	19/02/2021	23/03/2021	No	No