

**HSC-PBPP APPROVED COVID-19 applications: 09 October 2020**

<b>Application Reference (click on reference for lay summary)</b>	<b>Applicant</b>	<b>Applicant Organisation</b>	<b>Title and Purpose of study</b>	<b>Level of Approval</b>	<b>Outcome</b>	<b>Date Approval Letter Sent</b>	<b>Clocked time (days)</b>
<a href="#">1920-0272</a>	Diogo Marques	NSS Health Protection Scotland (now part of Public Health Scotland)	<b>SARS Co-V-2/COVID-19 enhanced surveillance</b> For the enhanced surveillance of patients with COVID-19 for public health reporting.	COVID19 rapid review panel	COVID19 Approved with recommendations	02/04/2020	5
<a href="#">2021-0001</a>	Professor Jennifer J Kurinczuk	University of Oxford	<b>Neonatal complications of coronavirus disease (COVID-19)</b> Use of BPSU methodology to determine the effects of COVID-19 on babies born to mothers infected with COVID-19	COVID19 rapid review panel	COVID19 Approved with recommendations	06/04/2020	4
<a href="#">2021-0002</a>	Dr Nicole Priddee	Scottish National Blood Transfusion Service (SNBTS)	<b>Convalescent Plasma collection and distribution for management of COVID 19</b> For SNBTS to obtain plasma from people who have recovered from COVID-19 infection, as a treatment for COVID-19 (part of the RECOVERY trial).	COVID19 rapid review panel	COVID19 Approved with recommendations	08/04/2020	5
<a href="#">1920-0282</a>	Professor Richard Haynes	University of Oxford	<b>RECOVERY trial</b> For recruitment of COVID-19 patients for trial of known treatments for other infections or inflammatory conditions, to	COVID19 rapid review panel	COVID19 Approved with recommendations	15/04/2020	5

			determine whether they could be repurposed for COVID-19.				
<a href="#">1920-0273</a>	Professor Malcolm Gracie Semple	University of Liverpool	<b>COVID-19 Clinical Information Network (CO-CIN)</b> Central clinical network for UK-wide surveillance of COVID-19 patients. Information from this would feed into the national response to COVID-19.	COVID19 rapid review panel	COVID19 Approved with recommendations	17/04/2020	4
<a href="#">2021-0008</a>	Carole Morris	Public Health Scotland	<b>Scottish Collaborative COVID Research Data Platform</b> eDRIS application for national datasets to be held in the National Safe Haven for the ready linkage to other data for HSC-PBPP-approved surveillance and research applications for COVID-19.	COVID19 rapid review panel	COVID19 Approved with recommendations	23/04/2020	5
<a href="#">2021-0013</a>	Dr David A McAllister	Public Health Scotland	<b>COVID19 in healthcare workers, including primary and secondary care</b> For monitoring and surveillance of healthcare workers, to determine whether particular groups are at higher risk of COVID-19 infection.	COVID19 rapid review panel	COVID19 Approved with recommendations	24/04/2020	5
<a href="#">1920-0279</a>	Professor Chris Robertson	Public Health Scotland and Strathclyde University	<b>Early Assessment of COVID-19 epidemiology and Vaccine/anti-viral Effectiveness (EAVE II) – A change from PAC/National Caldicott to PBPP and an</b>	COVID19 rapid review panel	COVID19 Approved with recommendations	05/05/2020	5

			<p><b>amendment of Early estimation of pandemic influenza Antiviral and Vaccine Effectiveness (EAVE) - use of a unique community and laboratory national linked dataset (PAC 11\46\23) to include COVID-19</b></p> <p>For using GP data to monitor COVID-19 infection in the community</p>				
<a href="#">2021-0007</a>	Professor Rowland Kao	University of Edinburgh	<p><b>The Scotland Coronavirus Model (SCoVMod)</b></p> <p>Use of aggregated COVID-19, health data and other publically available datasets for COVID-19 modelling in Scotland</p>	Tier 1 panel	COVID19 Approved with recommendations	12/05/20	6
<a href="#">2021-0019</a>	Dr Philip Dunne	NHS Greater Glasgow and Clyde	<p><b>Audit of Upper GI Bleeding in the Covid-19 Pandemic</b></p> <p>Audit of the effects of a change in practice, implemented due to COVID-19.</p>	Tier 1 panel	COVID-19 approved	12/05/20	4
<a href="#">2021-0041</a>	Dr Shamez Ladhani	PublicHealth England	<p><b>Enhanced surveillance of multisystem inflammatory syndrome temporally associated with Covid 19 in children in the UK and Republic of Ireland through the BPSU</b></p> <p>Use of BPSU surveillance methods to determine the extent and symptoms of the inflammatory syndrome associated with COVID19 infection in children</p>	COVID19 rapid review panel	COVID19 Approved with recommendations	19/05/20	5

<a href="#">2021-0024</a>	Dr Louise Marryat	University of Edinburgh	<b>COVID-19 in pregnancy</b> Review of births in March/April 2020 compared with the same time period in 2019 to determine the effects of COVID19 and lockdown on pregnancy outcomes	Tier 1 panel	COVID19 Approved with recommendations	26/05/20	8
<a href="#">2021-0051</a>	Dr Kyle Gibson	NHS Lothian	<b>Pulmonary Embolism in COVID-19 Patients requiring Critical Care</b> Audit of patients in critical care infected with COVID19 and who also have pulmonary embolism	Tier 1 panel	COVID19 Approved with recommendations	10/06/20	9
<a href="#">2021-0054</a>	Dr Thomas Manship	NHS Lothian	<b>Scottish study on the impact of COVID-19 on chronic liver disease</b> Audit of the rates of admissions for liver disease during lockdown for COVID19 compared with previous years	Tier 1 panel	COVID19 Approved with recommendations	10/06/20	4
<a href="#">2021-0033</a>	Professor Bryan Williams	University College London	<b>CAPACITY-COVID: Cardiac complications in Patients with SARS Corona vlrus 2 regisTrY</b> Related to the COCIN study to set up a registry to study cardiac complications in patients infected with COVID19	COVID19 rapid review panel	COVID19 Approved with recommendations	11/06/20	7
<a href="#">2021-0049</a>	Dr Michael McGettrick	NHS Greater Glasgow and Clyde	<b>Pulmonary Thromboembolism in Covid-19 pneumonia</b> Review of factors that affect development of Pulmonary embolism in COVID-19	COVID19 rapid review panel	COVID19 Approved with recommendations	15/06/20	9

<a href="#">2021-0030</a>	Dr Prabhu Arumugam	Genomics England Limited	<b>GenOMICC Study</b> Study of genetic and clinical factors involved in different responses to COVID-19	COVID19 rapid review panel	COVID19 Approved with recommendations	24/06/21	10
<a href="#">2021-0042</a>	Dr David Fitzpatrick	University of Stirling	<b>Covid-19: Prehospital identification and management of people presenting to the ambulance service</b> Study of paramedic management of COVID-19	Tier 1 panel	COVID19 Approved with recommendations	14/07/20	6
<a href="#">2021-0077</a>	Dr Nick Hamilton	University College, London	<b>COVIDTrach</b> A study of the outcomes and risks of tracheostomy in COVID-19 patients	Tier 1 panel	COVID19 Approved with recommendations	14/07/20	8
<a href="#">2021-0117</a>	Dr David Henderson	Edinburgh Napier University	<b>Community based COVID-19 mortality</b> Analysis of COVID-19 deaths	Tier 1 panel	COVID19 Approved with recommendations	30/07/2020	7
<a href="#">2021-0116</a>	Dr Rachael Wood	Public Health Scotland	<b>COVID-19 in Pregnancy in Scotland (COPS)</b> Analysis of the effects of COVID-19 on pregnancy outcomes in Scotland	COVID19 rapid review panel	COVID19 Approved with recommendations	06/08/2020	5
<a href="#">2021-0073</a>	Dr David McAllister	Public Health Scotland	<b>COVID19 in secondary, primary, early years and additional needs teachers and teaching assistants</b>	COVID19 rapid review panel	COVID19 Approved with recommendations	10/08/2020	5
<a href="#">2021-0100</a>	Prof John Crichton	NHS Lothian	<b>Predictors of Outcomes for Mental Health Inpatients Diagnosed with Covid 19</b>	Tier 1 panel	COVID19 Approved with recommendations	11/08/2020	13
<a href="#">2021-0098</a>	Dr Alasdair Jubb	Cambridge University Hospitals	<b>European Society of Intensive Care Medicine UNITE – COVID STUDY</b>	Tier 1 panel	COVID19 Approved with recommendations	12/08/2020	12

<a href="#">2021-0082</a>	Dr Josie Evans	University of Stirling	<b>Ambulance call-outs for psychiatric emergencies during the COVID-19 pandemic</b>	Tier 1 panel	COVID19 Approved with recommendations	12/08/2020	12
<a href="#">2021-0102</a>	Professor Cathie Sudlow	Health Data Research UK	<b>CVD-COVID-UK</b>	COVID19 rapid review panel	COVID19 Approved with recommendations	13/08/2020	8
<a href="#">2021-0064</a>	Dr Frederick Ho	University of Glasgow	<b>COVID-19 Infection and Subsequent Thromboembolic Event</b>	Tier 1 panel	COVID19 Approved with recommendations	20/08/2020	23
<a href="#">2021-0134</a>	Professor Sharon Hutchinson	Public Health Scotland	<b>Impact of COVID-19 on prisoners in Scotland</b>	Tier 1 panel	COVID19 Approved	16/09/2020	7
<a href="#">2021-0025</a>	Dr Satveer Mahil	Guy's and St Thomas' NHS Foundation Trust / King's College London	<b>PsoProtect (Psoriasis Patient Registry for Outcomes, Therapy and Epidemiology of Covid-19 infection)</b>	Tier 1 panel	COVID19 Approved with recommendations	16/09/2020	20
<a href="#">2021-0018</a>	Dominic Cushnan	NHS England	<b>National COVID-19 Chest Image Database (NCCID)</b>	Tier 1 panel	COVID19 Approved with recommendations	22/09/2020	22
<a href="#">2021-0148</a>	Albert King	Scottish Government	<b>The Scotland Coronavirus Model (Regression Modelling)</b>	COVID19 rapid review panel	COVID19 Approved with recommendations	29/09/2020	4
<a href="#">2021-0129</a>	Albert King	Scottish Government	<b>Carehomes Analysis</b>	COVID19 rapid review panel	COVID19 Approved with recommendations	01/10/2020	6

<a href="#">2021-0115</a>	Professor S Vittal Katikireddi	University of Glasgow	<b>Early pandemic evaluation and enhanced surveillance of COVID-19 (EAVE II): additional analysis of social and ethnic inequalities</b>	COVID19 rapid review panel	COVID19 Approved with recommendations	08/10/2020	17
2021-0124	Dr Agnes Tello	University of St. Andrews	<b>Characterisation of COVID-19 outcomes in a high-risk cohort: Assessment of background levels of autoantibodies as a prognostic marker for severe COVID-19 infection</b>	Tier 1 panel	COVID19 Approved with recommendations	09/10/2020	9

**Amendments to existing PBPP-approved applications, now requesting COVID-19 data**

<b>Application Reference</b>	<b>Applicant</b>	<b>Applicant Organisation</b>	<b>Title and Purpose of study</b>	<b>Level of Approval</b>	<b>Outcome</b>	<b>Date Approval Letter Sent</b>
1617-0147	Professor Helen Colhoun	University of Edinburgh	<p align="center"><b>Extending our understanding of the impact of diabetes in Scotland: A project to support continuing Scottish diabetes data linkage</b></p> <p>Amendment request for addition of COVID19 data to determine the interaction between COVID19 and diabetes</p>	Panel Manager	COVID19 approval	06/04/20
1617-0147	Professor Helen Colhoun	University of Edinburgh	<p align="center"><b>Extending our understanding of the impact of diabetes in Scotland: A project to support continuing Scottish diabetes data linkage</b></p> <p>Amendment request to provide diabetes data for the Scottish COVID research data platform (related to 2021-0008 Morris)</p>	Panel Manager	COVID19 approval	17/04/20
1617-0265	Robin Flaig	University of Edinburgh	<p align="center"><b>UK Biobank prospective cohort – longitudinal follow-up through linkage to health-related records in Scotland</b></p> <p>Amendment request for addition of COVID19 data for cohort members</p>	Tier 1 panel	COVID19 approved with conditions	23/04/20
1819-0030	Jenny Simons	Scottish Government and NHS National Services Scotland	<p align="center"><b>Persons at risk database (PARD)</b></p> <p>Amendment request for addition of geographical location data to help implement shielding of vulnerable people in response to COVID19 outbreak</p>	PBPP Chair	COVID19 approval	24/04/20
1617-0147	Professor Helen Colhoun	University of Edinburgh	<p align="center"><b>Extending our understanding of the impact of diabetes in Scotland: A project to support continuing Scottish diabetes data linkage</b></p> <p>Amendment request for addition of healthcare worker status to determine whether healthcare workers with diabetes are at increased risk of COVID19 infection or adverse outcomes (related to 2021-0013 McAllister)</p>	Panel Manager	COVID19 approval	30/04/20

1819-0224	Archie Campbell	University of Edinburgh	<b>Generation Scotland linkage</b> Amendment request for addition of COVID19 data for cohort member	Tier 1 panel	COVID19 approval	15/05/20
1617-0147	Professor Helen Colhoun	University of Edinburgh	<b>Extending our understanding of the impact of diabetes in Scotland: A project to support continuing Scottish diabetes data linkage</b> Amendment request for monthly updates of prescribing data for COVID19 patients with diabetes from PHS to determine any adverse or good effects of specific drug treatments.	Panel Manager	COVID19 approval	27/05/20
1617-0147	Professor Helen Colhoun	University of Edinburgh	<b>Extending our understanding of the impact of diabetes in Scotland: A project to support continuing Scottish diabetes data linkage</b> Amendment request for monthly updates of SMR01 for COVID19 patients with diabetes to be sent from PHS to explore the impact of prior events such as hypoglycaemia as risk factors.	Panel Manager	COVID19 approval	03/06/20
1920-0273	Professor Malcolm Gracie Semple	University of Liverpool	<b>COVID-19 Clinical Information Network (CO-CIN)</b> Central clinical network for UK-wide surveillance of COVID-19 patients. Information from this would feed into the national response to COVID-19. Amendment request for addition of researchers.	Panel Manager	COVID19 approval	15/06/20
2021-0007	Professor Rowland Kao	University of Edinburgh	<b>The Scotland Coronavirus Model (SCoVMod)</b> Use of aggregated COVID-19, health data and other publically available datasets for COVID-19 modelling in Scotland. Amendment request for addition of variables.	Panel Manager	COVID19 approval	15/06/20
2021-0007	Professor Rowland Kao	University of Edinburgh	<b>The Scotland Coronavirus Model (SCoVMod)</b> Use of aggregated COVID-19, health data and other publically available datasets for COVID-19 modelling in Scotland. Amendment request for addition of variables.	Panel Manager	COVID19 approval	15/06/20
2021-0282	Professor Richard Haynes	University of Oxford	<b>RECOVERY trial</b> For recruitment of COVID-19 patients for trial of known treatments for other infections or inflammatory conditions, to determine whether they could be repurposed for COVID-19.	COVID19 rapid review panel	COVID19 approval	25/06/20

			Amendment request for increase in patient group and addition of variables.			
2021-0007	Professor Rowland Kao	University of Edinburgh	<b>The Scotland Coronavirus Model (SCoVMod)</b> Amendment request for addition of researchers.	eDRISRC	COVID19 approval	02/07/2020
2021-0024	Dr. Louise Marryat	University of Edinburgh	<b>COVID19 in pregnancy</b> Amendment request increase the time-period of data for analysis.	Panel Manager	COVID19 approval	03/07/2020
1516-0438	Dr Jennifer Burton	University of Glasgow	<b>Admission to a care home from hospitals across Scotland – exploring practice and the role of dementia</b> Amendment to determine the movement of patients during COVID-19 pandemic.	Panel Manager	COVID19 approval with conditions	04/08/2020
1920-0282 SR285	Prof Richard Haynes	University of Oxford	<b>RECOVERY trial</b> Amendment to approve statistical analysis at a different location	Panel Manager	COVID19 approval with conditions	05/08/2020
2021-0082	Dr Josie Evans	University of Stirling	<b>Ambulance call-outs for psychiatric emergencies during the COVID-19 pandemic</b> Addition of researcher	eDRISRC	COVID19 Approved	02/09/2020
1920-0273	Prof Calum Semple	University of Liverpool	<b>COCIN</b> Amendment for update of researcher details	eDRISRC	COVID19 Approved	16/09/2020
1920-0273	Prof Calum Semple	University of Liverpool	<b>COCIN</b> Amendment for additions of researchers	eDRISRC	COVID19 Approved	25/09/2020
2021-0013	Dr David McAllister	Public Health Scotland	<b>COVID19 in healthcare workers, including primary and secondary care</b> Amendment for addition of two variables	Panel Manager	COVID19 Approved	07/10/2020

1920-0097	Professor Scott Nelson	University of Glasgow	<b>Association of lifestyle factors, pre-existing medical conditions, the COVID-19 pandemic and related healthcare and public health interventions with perinatal, childhood and maternal outcomes - a population-based linkage study</b> Addition of datasets and variables to investigate the direct and indirect effects of COVID-19 and the response to it on lifestyle factors that affect pregnancy, and maternal, perinatal and childhood outcomes.	Tier 1	COVID19 approval	09/10/2020
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## **Appendix: Lay summaries of approved COVID-19 applications**

1920-0272 Diogo Marques

### **SARS Co-V-2/COVID-19 enhanced surveillance**

COVID-19 emerged as a novel Coronavirus infection identified initially in Wuhan City in China at the end of 2019. The infection spread rapidly within China and is now affecting many other countries worldwide with a number of countries reporting large outbreaks. As of 05.03.20, the UK has confirmed 90 cases of the infection. The virus that causes COVID-19 has been officially designated SARS-CoV-2 by the World Health Organisation, and the outbreak was designated a Public health Emergency of International Concern on 30th January 2020.

Current understanding of the extent of infection, the epidemiology, infectivity and other aspects of this illness are based on testing of symptomatic people who meet an agreed case definition based on specific respiratory symptoms and a history of either contact with a known case or travel to designated risk areas (see HPS website for risk areas: <https://www.hps.scot.nhs.uk/web-resources-container/covid-19-risk-areas/>).

As with any outbreak of a new disease, this approach has limitations, for example it will fail to identify asymptomatic carriers if they exist, it will fail to identify those who present with atypical symptoms and it will fail to detect people whose exposure is in a country or region where the virus is only beginning to emerge. In Italy, for example, evidence suggests the virus may have been circulating for some weeks before the recently identified upsurge in clinical cases.

This is true of many novel and indeed established pathogens, and routine surveillance systems are designed to run alongside clinically-led testing to enhance the epidemiological understanding of the pathogen, provide early warning signals, inform control measures and enable monitoring of the effectiveness of control measures, and, from modelled data, make inferences about what to expect in the future and the likely impact of the disease on the population.

This proposal is to seek approval to extend existing respiratory surveillance systems, long established in HPS (GP sentinel swabbing, SARI), to add COVID-19 and SARS-CoV-2 to these surveillance schemes with immediate effect. The additional data collected would include positive and negative respiratory viral screens for SARS-CoV-2 and collection of relevant enhanced surveillance metadata such as travel history, comorbidities and other emerging risk factors, and other metadata on control measures (e.g. vaccine status or antiviral treatment/prophylaxis) when available.

The proposal also includes screening for SARS-CoV-2 of all respiratory viral samples submitted to the West of Scotland Specialist Virology Centre (WOSSVC) from the community or secondary care settings. No additional enhanced surveillance metadata will be collected for these cases, but positive and negative laboratory results will be extracted from ECOSS.

## 1920-0273 Professor Malcolm Gracie Semple

### **COVID-19 Clinical Information Network (CO-CIN)**

The COVID-19 Clinical Information Network (CO-CIN) has been established by the UK Government Chief Medical Officer to collate rapidly the clinical information of people admitted to hospital with COVID-19, analyse that information in real-time and provide reports to policy makers to inform public health and clinical care policies. This project is now live with recruitment of 7471 patients as of 06/04/2020.

The network includes all the devolved nations of the UK.

As CO-CIN currently operates, it does not collect personal identifiers. The investigators wish to add personal identifiers (CHI/NHS number) to the CO-CIN case report form. This is because there is a need to link COVID-19 CRF data to routinely collected national health care data sets, which can only be done if direct identifiers are collected to enable this. Linking information from prior and future primary care and hospital data and from death registries will massively enhance the ability of the CO-CIN dataset to address clinically relevant questions about the determinants of good or poor outcome following hospitalisation with COVID 19 infection. The CO-CIN study also needs to collect direct identifiers to ensure that no individual is counted more than once and to enable the identification of rare recurrent episodes of hospitalisation with COVID-19 infection. Finally, the study requires access to information about all COVID-19 laboratory test positive patients to ensure recruitment, clinical data collection and data linkages for all eligible patients.

Applications are being made to PBPP for recruitment and data linkages across Scotland, and to the Confidentiality Advisory Group for recruitment in England and Wales. Applications to various data custodians in England and Wales for linked data are also being prepared.

CO-CIN will collate information about COVID-19 hospitalised patients, including NHS Number (England), Community Health Index (Scotland) and equivalents in Wales and Northern Ireland, age, sex, underlying medical problems and current medications, information about treatment in hospital and finally the outcome of their episode of illness. Individual patient information will not be made publicly available. Reports will only include summary information for groups of patients. Aggregate extracts will be shared with Public Health England, Health Protection Scotland and the World Health Organisation.

## 1920-0279 Professor Chris Robertson

**Early Assessment of COVID-19 epidemiology and Vaccine/anti-viral Effectiveness (EAVE II) – A change from PAC/National Caldicott to PBPP and an amendment of Early estimation of pandemic influenza Antiviral and Vaccine Effectiveness (EAVE) - use of a unique community and laboratory national linked dataset (PAC 11\46\23) to include COVID-19**

This study will provide real time surveillance and research on the COVID19 pandemic in Scotland. It will permit the estimation of the risk to the whole population and relatively small subgroups and areas. This study, known by the acronym EAVE-2, is based upon a previous pandemic preparedness project known as EAVE (Early Estimation of vaccine and Anti-Viral Effectiveness) which is an NIHR-funded project on pandemic influenza. EAVE created a Scotland-wide cohort of 227,000 individuals recruited from 40 general practices together with stored serology samples from 1,000 individuals. EAVE has also established a national electronic cohort though linking health data sets from general practice, prescribing, hospitalisations and virology testing using the unique Community Health Identification (CHI) number for residents of Scotland.

## 1920-0282 Professor Richard Haynes

### **RECOVERY trial**

The RECOVERY trial is a study which is testing treatments for COVID-19. This condition is caused by a type of virus called SARS-CoV-2, or coronavirus for short. About 19 out of 20 patients who get coronavirus get better without coming to hospital. Of those who are admitted to hospital, most also get better, but some may need oxygen or mechanical ventilation before they do so. However, a few percent do not get better.

There are no drugs of proven value against COVID-19 although there are several which may turn out to be helpful (or possibly harmful) when added to the usual standard of care. This study aims to find out whether any of these additional treatments are of any help. These treatments have been recommended for testing by the expert panel that advises the Chief Medical Officer in England. These include tablets, injections and also inhaled medicines. Although these treatments show promise, nobody knows if any will be more effective in helping patients recover than the usual standard of care given in hospitals (which all patients will receive).

The treatments, which may be given in addition to usual care in participating hospitals, are: Lopinavir-Ritonavir (commonly used to treat HIV); dexamethasone (a type of steroid, used in a range of conditions to reduce inflammation); hydroxychloroquine (a treatment for malaria); or azithromycin (a common antibiotic). Other treatments may be added to the protocol during the trial.

## 2021-0001 Professor Jennifer J Kurinczuk

### **Neonatal complications of coronavirus disease (COVID-19)**

Coronavirus disease (COVID-19) is an international public health crisis and is rapidly spreading around the world. So far it looks like most newborn babies and infants are not severely affected, but this is based on small numbers of cases so there might be important effects of COVID-19 in babies that we don't yet know about.

There are three main ways that COVID-19 might affect newborns and babies that need neonatal care:

1. Newborn babies might catch COVID-19 before, during or soon after birth and this may lead to problems with breathing or feeding that need support in hospital.
2. COVID-19 could affect babies that are already on neonatal units with other medical conditions (like being very premature) that make them more at risk of severe infection.
3. COVID-19 might affect that way that pregnant women are looked after in pregnancy or labour which could lead to problems for some babies, even if they do not catch COVID-19

We plan to look at how COVID-19 is affecting newborns and babies on neonatal units in the United Kingdom through the British Paediatric Surveillance Unit (BPSU). To do this we will ask paediatricians to report any baby that is affected by COVID-19 as described above.

We will then ask paediatricians looking after babies affected by COVID-19 some simple questions about how the baby is affected, what treatment they need, and what happens after the infection. We will use information that is routinely collected by doctors and nurses on neonatal units and paediatric intensive care units to better understand what medical treatments babies with COVID-19 receive. We will also link up with a similar surveillance study looking at COVID-19 in pregnant women and work with Public Health Scotland (PHS) and similar organisations in England, Wales, and Northern Ireland to get a complete picture of the neonatal complications of COVID-19.

2021-0002 Dr Nicole Priddee

### **Convalescent Plasma collection and distribution for management of COVID 19**

There are no licensed treatments available for COVID 19 but clinical trials of various drugs and vaccine development are underway. The use of passive immunity, i.e. antibodies from people who have recovered from this disease, appears to be safe and clinically effective (7&8).

SNBTS propose to gain access to details of patients diagnosed with COVID 19 in Scotland, currently held centrally by HPS (PHS from 1.4.2020), to enable recruitment of those who meet donor selection criteria to donate COVID 19 convalescent plasma. This will allow SNBTS to manufacture and distribute COVID 19 convalescent plasma to treat people with or at risk of COVID 19 infection primarily through the convalescent plasma arm of the Randomised Evaluation of COVID 19 Therapy (RECOVERY) trial, other clinical trials using convalescent plasma (eg REMAP CAP) and/or for compassionate use on a named patient basis.

The RECOVERY trial is being co-ordinated centrally by the Nuffield Department of Population Health in Oxford, with the convalescent plasma arm being developed and led in collaboration with NHS Blood and Transplant (NHSBT) (5). The ReMAP CAP trial is being co-ordinated by Tony Gordon, looking at management of community acquired pneumonia in

intensive care settings. They are currently developing a convalescent plasma arm in collaboration with NHS Blood and Transplant (9).

There is Scottish clinical interest in acquiring COVID 19 convalescent plasma as part of clinical trials and potentially for compassionate use.

## 2021-0007 Professor Rowland Kao

### **The Scotland Coronavirus Model (SCoVMod)**

The “Scotland Coronavirus Model” is a computer simulation describing the spread of COVID-19. It will be used to inform Health Protection Scotland about the possible trajectory of future Scottish COVID-19 patterns (no. infections, hospitalisations, deaths, and recoveries) under different scenarios of disease control (e.g. easing lockdown restrictions by region, re-opening of schools etc.). SCoVMod uses human population density, age structure and commuter movements to predict how COVID-19 infection would spread in space and time. Past COVID-19 infection patterns are then used to identify model parameters that best explain them and to estimate uncertainty, also providing estimates of the hidden burden of infection in the population. Using publicly available data on COVID-19 deaths recorded by Health Board, SCoVMod generates a statistically consistent fit over time. This fit shows that the mean index of multiple deprivation index (SIMD) per Health Board is an important predictor of COVID-19 death rates. Thus substantially better predictions would be expected when using COVID-19 data at the same spatial resolution as the SIMD (i.e. “Data Zone” as used in the Scotland Census). In addition, data for the number of admissions, ICU patients and deaths per day in hospital will allow for better identification of where existing cases are being distributed to, and therefore under our model projections, where the burden to the healthcare system burden may lie.

## 2021-0008 Carole Morris

### **Scottish Collaborative COVID Research Data Platform**

The Scottish Government COVID-19 Advisory Group will be a time limited expert group chaired by Professor Andrew Morris, Professor of Medicine at the University of Edinburgh and Director of Health Data Research UK (HDRUK). The advisory group will consider the scientific and technical concepts and processes that are key to understanding the evolving COVID-19 situation and potential impacts in Scotland. The advisory group will apply the advice coming to the four nations from the Scientific Advisory Group on Emergencies (SAGE) and other appropriate sources of evidence and information and use it to inform local decisions in Scotland during the pandemic. (See document 0 Scottish Government CMO COVID advisory group - data and evidence strategy - 30 March 2020.pdf)

A COVID Data Task Force has been established under this group to oversee the need for rapid access to data to support urgent research to help inform decision making and protect the population. The COVID Data Task Force has representatives from key stakeholders such

as Public Health Scotland (PHS), HDRUK, Administrative Data Research (ADR) and Academia. Its remit will be to work with data controllers to identify and agree the datasets that are key to supporting rapid research and analysis.

Currently, providing the data required for urgent COVID-related research could take several months which would severely delay this urgent critical work. The purpose of this project is to gather all relevant data (as specified by the COVID Data Task Force), link these datasets (which will include key health and non-health data) and hold it within the National Safe Haven. This will allow a rapid provision of data for any urgent COVID-related research projects, which is currently not possible.

This application is to create the data resource only. All projects that wish to use this data will require approval from the original data controllers or their agreed approval mechanisms (e.g. Public Benefit and Privacy Panel for Health data) before any access to this data will be given.

## 2021-0013 Dr David A McAllister

### **COVID19 in healthcare workers, including primary and secondary care**

By the nature of their work, healthcare workers (HCWs) have greater exposure to SarsCoV2 than the general population. To inform HCWs and make optimal decisions about minimising risk, we need to know whether and how this increased exposure translates to an increased risk of COVID19-related (i) hospitalisation, (ii) mechanical ventilation and (iii) death. We need to know both the overall risk, and the risk according to the HCWs role as well as their age, sex and the presence/absence of any underlying long-term conditions.

To inform infection transmission models (such as the produced by the Imperial College London team) to help stop the spread of COVID19, it is also necessary to estimate how much transmission is occurring through healthcare workers.

Please also note that healthcare workers within diabetes may be at particular risk. In order to address this issue, Professor Helen Colhoun will be putting in a separate PBPP application (an amendment) to link the same databases described in this application (SWISS and GPCD) to the existing Scottish diabetes cohort. That application will refer to the list of variables from this document.

## 2021-0018 Dominic Cushnan

### **National COVID-19 Chest Image Database (NCCID)**

The National COVID-19 Chest Imaging Database (NCCID) is a joint initiative established by NHSX and the British Society of Thoracic Imaging (BSTI) to create a centralised UK database of chest X-ray, CT and MRI images.

This aims to support a better understanding of the disease and develop technology that will enable the best care for patients who are hospitalised with a severe infection.

The benefits of collecting chest imaging data are extensive. This data has the potential to:

- enable faster patient assessment in A&E;
- save radiologists' time;
- increase the safety and consistency of care across the UK.

The NCCID database will support clinicians and researchers to better investigate the disease and will provide technology developers with the right data to improve already existing models and develop new solutions to support the response to COVID-19.

To better support researchers in Scotland, a copy of the image and clinical data will also be held in the National Safe Haven. A full PBPP application will be submitted to create this associated research database.

## 2021-0019 Dr Philip Dunne

### **Audit of Upper GI Bleeding in the Covid-19 Pandemic**

Bleeding in the upper gastro-intestinal tract (UGIB) is a common reason for presentation to hospital. Patients with suspected UGIB require an endoscopy test to confirm the diagnosis, apply treatment if necessary, and to facilitate timely discharge from hospital. The Glasgow Blatchford Score (GBS) is a risk assessment tool used for patients with suspected UGIB. Currently, patients are deemed "low-risk" (if GBS = 0-1) and can be discharged from hospital to reattend for a planned out-patient endoscopy. Patients with a GBS of ≥2 remain in hospital for an in-patient endoscopy.

In light of the COVID-19 pandemic together with the aerosol generating nature of endoscopy and related issues of patient and staff safety, the British Society of Gastroenterology have recommended scaling down of endoscopy to "true emergencies" only. Therefore, the "low-risk" threshold has been temporarily extended to a GBS score of 0-3. This has minimised demand for inpatient endoscopy. Patients with a GBS of ≥4, will still require an inpatient endoscopy due to the higher rates of endoscopic treatment required and lower survival in this group.

We would like to audit the impact of this change to determine whether it has had a negative effect on patient care, as well as assess the prevalence of Covid-19 and its effect on patient outcomes, amongst those presenting with suspected UGIB.

2021-0024 Dr Louise Marryat

### **COVID-19 in pregnancy**

Pregnant women are at particular risk when contracting COVID-19 as pregnancy is an 'immuno-suppressive condition', where the body is less able to combat infection than usual. Early evidence, thus far based on case studies, suggests the possibility of negative outcomes associated with COVID-19, including miscarriage and premature birth. Additionally, in many countries, pregnant women are being required to self-isolate for substantial periods of time. They may receive less antenatal care, and less formal/informal support. Choice is also being restricted in where and how to give birth, with home births and non-emergency caesarean sections being limited. Although current NHS guidance suggests COVID-19 carries modest risk for pregnancy or giving birth during the quarantine period, there is little supporting evidence.

This project aims to look at routine data on all births during the first two months of 'lockdown' in the UK, and compare these with data from the same months in 2018, to explore outcomes for both mothers and infants. We will explore experience of labour (including place of delivery, induction, and type of delivery), birth outcomes (such as gestation, birth weight, and time spent in neonatal care), as well as early infancy outcomes (such as breastfeeding at discharge). Outcomes for women with confirmed

2021-0025 Dr Satveer Mahil

### **PsoProtect (Psoriasis Patient Registry for Outcomes, Therapy and Epidemiology of Covid-19 infection)**

PsoProtect is an international registry for reporting outcomes of COVID-19 in individuals with psoriasis. Cases of COVID-19 in psoriasis are reported by clinicians using the online PsoProtect case report form, which collects de-identified data only. The information provided has the potential to rapidly inform clinicians when assessing risk and treating COVID-19 in patients with psoriasis. It may help to improve our understanding of how factors such as immunomodulator treatments and underlying health conditions affect outcomes of COVID-19 in psoriasis. Please see attached protocol for further information (1.282395\_PsoProtect\_Research\_Database \_Protocol\_v3\_18.04.2020\_clean)

This PBPP Application Form is for PsoProtect only (for healthcare professionals to report cases, as detailed above), but to give some further context, we have also launched PsoProtectMe, which is an online self-report survey for people with psoriasis from any country in the world. People with psoriasis are invited to complete the survey, whether or not they have had symptoms of COVID-19. The information collected in PsoProtectMe will help to improve our understanding of patients' experiences, symptoms and health behaviours during the pandemic.

## 2021-0030 Dr Prabhu Arumugam

### **GenOMICC Study**

Genomics England is partnering with the GenOMICC consortium, Illumina and the NHS to study the genetic code of thousands of patients affected with COVID-19. The aim is to help scientists understand whether a person's genes may influence their susceptibility to the virus and therefore why some patients with COVID-19 experience a mild infection, while others are affected much more severely. The study is led by Dr Kenneth Baillie, University of Edinburgh. We propose to study the genomes of up to 20,000 people currently or previously in an intensive care unit with COVID-19, and up to 15,000 individuals who have mild or moderate symptoms. We can then bring the patients' genome data together with data about their individual strain of the virus, which is being established by the COVID-19 Genomics UK Consortium, for a deeper understanding of the impact of different strains on patients with different genes. The study hopes to gain new insights into why some people are at greater risk of developing life-threatening symptoms, identify treatments which have the best chance of success in clinical trials, and potentially identify people at extreme risk if they develop COVID-19.

## 2021-0033 Professor Bryan Williams

### **CAPACITY-COVID: Cardiac complications in Patients with SARS Corona vlrus 2 regisTrY**

Coronavirus disease (COVID-19) is a rapidly emerging pandemic caused by an infection with SARS-CoV-2. Most patients require admission to the hospital due to the development of pneumonia, which may necessitate mechanical ventilator support. Besides the respiratory symptoms, some patients develop severe cardiac damage (1, 2). In addition, underlying cardiovascular disease may worsen the prognosis of these patients (2). There are concerns that the use of angiotensin-converting enzyme (ACE) inhibitors, angiotensin II type-I receptor blockers (ARBs), ibuprofen and thiazolidinedione's can worsen the course of COVID-19. These concerns are based on the fact that SARS-CoV-2 bind to their target cells through the ACE2 receptor. The expression of the ACE2 receptor can be substantially increased with the use of these drugs (3). To gain insight into the rate of cardiac complications and the course of COVID-19 in patients with underlying cardiac disease, high-quality data collection is needed. In prior pandemics data collection was not done in a standardized manner. It is of pivotal importance that the data collection during the COVID-19 pandemic is standardized. Cardiac complications in Patients with SARS Corona vlrus 2 regisTrY (CAPACITY) offers a WHO-recommended comprehensive data collection tool that facilitates uniform data collection on patients infected with SARS-CoV-2 with cardiovascular disease.

## 2021-0041 Dr Shamez Ladhani

### **Enhanced surveillance of multisystem inflammatory syndrome temporally associated with Covid 19 in children in the UK and Republic of Ireland through the BPSU**

The British Paediatric Surveillance Unit (BPSU), based within the Royal College of Paediatrics and Child Health (RCPCH), supports the surveillance of rare conditions affecting children in the United Kingdom (UK) and Republic of Ireland (ROI). Every month, the BPSU asks paediatricians across the UK and ROI whether they have seen children presenting with specified rare conditions. If they have, the paediatrician is asked to provide clinical information on the child to the team leading surveillance of that particular condition.

The BPSU is already supporting surveillance of SARS-CoV-2 infection/Covid 19 disease in very young babies. The BPSU is now seeking to separately establish surveillance of multisystem inflammatory syndrome in children. This syndrome may be occurring more commonly than usual since the start of the Covid 19 pandemic.

## 2021-0042 Dr David Fitzpatrick

### **Covid-19: Prehospital identification and management of people presenting to the ambulance service**

Paramedics face unprecedented challenges in identifying and appropriately managing patients with Covid 19 (C-19). Little is known about C-19 patients or how the decisions the paramedics make affect their outcomes. We will analyse routinely collected patient data to investigate how C-19 patients present to paramedics, the decisions paramedics make about their transportation to hospital, whether these patients access other services and how these decisions affect patient outcomes.

## 2021-0049 Dr Michael McGettrick

### **Pulmonary Thromboembolism in Covid-19 pneumonia**

There are emerging reports of Covid-19 disease leading to a higher number of people suffering blood clots within the lung (pulmonary embolus (PE)). There may be a number of reasons for this, including, firstly, that that patients are immobile during the illness and, secondly, the virus causes abnormalities in blood clotting, making it more likely for the blood to clot in the veins and arteries.

We intend to look at the number of patients with pulmonary embolus who were Covid-19 positive on swab tests or have changes consistent with Covid-19 on CT scans across Scotland between 23<sup>rd</sup> March and 31<sup>st</sup> May 2020. We also plan to assess the results of blood test results (D-dimer troponin, Lactate, lymphocytes, C-reactive protein) can predict the presence of pulmonary embolus. We also plan to look for evidence of other medical diagnoses in the patients with pulmonary embolus to assess for any risk factors that may increase the risk of PE.

By using the existing figures from the Scottish Government on the number of Covid-19 diagnoses in Scotland, we will be able to estimate the incidence. This data includes the

number of hospitalised patients. We plan to compare the findings with existing reports on the frequency of pulmonary embolus in other infections of the lung to determine if there is increased risk in Covid-19. This will inform clinicians, decision makers and public health about the perceived increased risk of venous thromboembolism in this population.

2021-0051 Dr Kyle Gibson

### **Pulmonary Embolism in COVID-19 Patients requiring Critical Care**

A number of adults have been admitted to Critical Care Units in Scotland with COVID-19 and significant blood clots in the blood vessels supplying the lungs (pulmonary embolism). This is concerning as ICU clinicians have noted anecdotally that there are more people being admitted with the condition than they would expect to see, and the pattern of the disease is more severe. This proposal seeks to understand how often this is happening, the symptoms and signs patients have when they arrive in hospital, the factors which increase the likelihood of this happening, the treatment provided and the outcome of patients. This will help the understanding of this potential complication of COVID-19 and/or the lockdown.

2021-0054 Dr Thomas Manship

### **Scottish study on the impact of COVID-19 on chronic liver disease**

We have seen very few patients with chronic liver disease (CLD) admitted with COVID-19. This is interesting as it is one of the few leading causes of mortality in the UK where the prevalence is not declining and CLD patients are in the high risk group for COVID-19 infection.

We therefore are interested in how COVID-19 has affected the care of CLD patients being admitted to hospital. We plan to analyse those patients with CLD admitted in April 2020 (during the COVID-19 pandemic) and comparing them to and auditing them against those admitted in April 2017, '18 and '19.

2021-0064 Dr Frederick Ho

### **COVID-19 Infection and Subsequent Thromboembolic Event**

Early reports from hospital studies have shown that people who have had COVID-19 are more likely to develop blood clots. This might explain why there have been more strokes than usual among healthy young people. But the studies done so far have been small and of poor quality. We will use existing data covering the whole of Scotland to study whether people who have had COVID-19 infection go on to have more blood clots in the brain (stroke), heart (heart attacks), lungs or legs.

2021-0073 Dr David McAllister

### **COVID19 in secondary, primary, early years and additional needs teachers and teaching assistants**

Teachers and teaching assistants are in close contact with children. For this reason, they may be at increased risk of Sars-CoV-2 infection compared to the general population. To inform teachers, local authorities, and government, and to minimise risk, we need to determine of infection, hospitalisation, ICU admission and death in teachers and teaching assistants and (if the risk is high in teachers) their household contacts in February, March and April 2020. We need to know both the overall risk, and the risk according to the teacher or teaching assistant's setting (e.g. primary or secondary school) as well as their age, sex and the presence/absence of any underlying long-term conditions.

We then want to establish surveillance from August 2020 (or as soon as possible thereafter) to report on Sars-CoV-2 infection among teaching staff.

2021-0077 Dr Nick Hamilton

### **COVIDTrach**

When COVID-19 leads to a severe infection in the lung patients need to be placed on a ventilator. Clinical practice before the pandemic was for patients who were expected to be on the ventilator for over 7 days to undergo a tracheostomy, a surgical procedure to put a breathing tube through the neck into the airway. It is uncertain whether patients with COVID-19 also benefit from this operation due to the severity of their respiratory illness and high death rate. Furthermore, there is concern that opening the airway through the tracheostomy puts health care professionals performing the procedure at risk of being infected by the corona virus.

COVIDTrach is collaborative project by surgeons and intensive care doctors that looks at the outcomes of ventilated COVID-19 patients undergoing tracheostomy and evaluates the use of personal protective equipment and rate of COVID-19 infection amongst operators. So far data on 800 patients have been entered in an online database; this proposal focuses on expanding and completing this database to answer the fundamental questions of the safety and effectiveness of tracheostomy in COVID-19.

2021-0082 Dr Josie Evans

### **Ambulance call-outs for psychiatric emergencies during the COVID-19 pandemic**

It is likely that the COVID-19 pandemic and/or associated social distancing restrictions will have mental health implications for many people in Scotland, at a time when services are already under strain. This may precipitate some into mental health crises requiring emergency ambulance attendance. At least 10% of ambulance call-outs in Scotland are mental health related (9,014 such calls from 6,802 people in Scotland in 2011). We will

examine patterns of ambulance call-outs for emergency mental health crises during the COVID-19 pandemic. By comparing with an equivalent study period in 2019 during 'normal' times, this will:

1. Help to build an objective picture of the mental health consequences of the pandemic on the general population
2. Provide an indication of the knock-on effects on other NHS services

2021-0098 Dr Alasdair Jubb

### **European Society of Intensive Care Medicine UNITE – COVID STUDY**

The defining healthcare challenge of 2020 is the COVID19 pandemic. This novel disease has brought tens of thousands of people to hospital and many of these have required admission to the intensive care unit. One of the many difficulties faced by the ICU community across the world has been trying to understand and provide for the demands of this new illness. The pressures it has placed on some systems has meant that the normal standards of care have been hard to implement with potentially important effects on outcome. Descriptions of the burden of disease and organ system failure have only emerged in a piecemeal fashion, but it is clear that the experience can vary widely with location both within and between countries.

UNITE-COVID is the Europe-wide strategy co-ordinated by the European Society of Intensive Care Medicine to obtain a clear and detailed picture of the burden of COVID19. We will collect retrospective, cross-sectional, fully anonymised but detailed clinical data from all units that choose to participate at their point of maximum occupancy. We currently have expressions of interest from many units all across the UK we would estimate between 40 and 50 will submit data, but it may be more. This data is crucial both to understand the needs of patients and the units that are caring for them during the current wave and also to interpret outcomes. It will help guide service design and resilience for future waves and indeed other viral pandemics such as a severe influenza which remain a very real threat.

2021-0100 Professor John Crichton

### **Predictors of Outcomes for Mental Health Inpatients Diagnosed with Covid 19**

The Covid-19 pandemic poses huge risks to society but particularly to vulnerable individuals. Many studies have looked at predictors of outcomes in Covid 19 cases to enable us to identify vulnerability factors.

Mental health patients are both at increased risk of exposure to the virus as well as being at increased risk of more severe disease or complications for a variety of reasons. However this group have been overlooked in the majority of studies to date.

As well as an increased incidence of known vulnerability factors in this group such as co-morbidities, we hypothesise that this group could also harbour further risk factors as yet unidentified which may predict poorer outcome. This includes exposure to psychotropic medications known to affect immune responses or medications putting patients at risk of complications in the face of infection. Our main objective is to study and identify these potential additional vulnerability factors.

Management of inpatients on psychiatric wards during this pandemic has also proved a major challenge. We hypothesise that some of the difficulties experienced by these units may also increase the risk of patient's exposure to the virus. Such factors involve the difficulties in implementing social distancing and the use of restraint for acute behavioural disturbance. We intend to clarify the difficulties faced by individual units and investigate the difference.

## 2021-0102 Professor Cathie Sudlow

### **CVD-COVID-UK**

Patients with cardiovascular disease have increased risk of symptomatic SARS-CoV-2 infection and mortality. This could be due to cardiovascular conditions themselves (e.g., heart disease, stroke), their risk factors (e.g., age, raised blood pressure), medications, or combinations of these. Understanding which patients are affected and why will help in developing strategies to reduce this risk.

Just as important as the effects of pre-existing cardiovascular disease on COVID-19, are the impacts of COVID-19 on cardiovascular disease.

The *direct* impacts include immediate complications (e.g., acute cardiac injury, stroke) and potentially increased risk of heart attack, stroke and other cardiovascular events in the longer term, through inflammation, blood clotting risk or other factors. However, the nature and extent of these direct effects are not well understood.

The response by the government and health services to the COVID-19 pandemic also has *indirect* impacts on the presentation, diagnosis, management and outcomes of cardiovascular diseases. The numbers of people attending hospital with heart attack and stroke have declined dramatically in recent weeks. Further, patients are more often arriving too late for beneficial acute treatments (e.g., clot busting drugs) and after potentially preventable complications have developed. To inform government and NHS policy, we urgently need a deeper understanding of these unintended consequences.

We propose to address these issues through analyses of de-identified, linked, nationally collated healthcare datasets across the four nations of the UK, accessed within trusted research environments provided by the National Data Safe Haven in Scotland and equivalents in Wales, England and Northern Ireland.

2021-0115 Professor S Vittal Katikireddi

### **Early pandemic evaluation and enhanced surveillance of COVID-19 (EAVE II): additional analysis of social and ethnic inequalities**

Evidence suggests that ethnicity influences the risk of both infection and adverse outcomes for COVID-19. However, empirical research remains limited, especially within Scotland. Initial analyses within Scotland have not identified elevated risks, but they have been subject to major limitations arising from likely systematic misclassification of ethnicity. This is to be conducted as part of the wider project *Early pandemic evaluation and enhanced surveillance of COVID-19* (EAVE II) which will provide real time surveillance and research on the COVID19 pandemic in Scotland, and will permit the estimation of the risk to the whole population and relatively small subgroups and areas. EAVE II study aims to investigate the risk of COVID-19 in various at-risk groups of the population including ethnicity. The ethnicity study is a substudy of the EAVEII project that aims to assess the epidemiology of SARS-CoV-2 infection by ethnic group and investigate the mechanisms through which ethnic inequalities in COVID-19 arise. The Scottish Government have announced the establishment of an expert group to provide advice on ethnicity and COVID-19. Understanding whether ethnic inequalities are present in Scotland is therefore a major policy priority for Scottish Government. Given the increasingly consistent evidence that Black and South Asian ethnic groups are at increased risk internationally and in England, there is a need for more robust analyses within Scotland to describe the epidemiology and hence urgently inform the policy response required.

2021-0116 Dr Rachael Wood

### **COVID-19 in Pregnancy in Scotland (COPS)**

The COVID-19 in Pregnancy in Scotland (COPS) study is a sub-study linked to EAVE II (Early Assessment of COVID-19 epidemiology and Vaccine/anti-viral Effectiveness). EAVE II is the key national study tracking the epidemiology of COVID-19 in the Scottish population. COPS will support EAVE II by providing more detailed information on the epidemiology of COVID-19 in pregnancy, and its impact on maternal, pregnancy, and neonatal outcomes.

In COPS, we will link together a range of routine health data sources to:

- Identify all women in Scotland who were pregnant on, or became pregnant after, 1st March 2020 (the date of the first confirmed case of SARS-CoV-2 infection in Scotland), and all live births in Scotland from 1st March 2020 onwards
- Identify women with confirmed, probable, or possible COVID-19 during their pregnancy
- Identify relevant maternal, pregnancy, and neonatal outcomes among women with, compared to without, COVID-19 during pregnancy. The outcomes examined will include maternal admission, severe disease, and death; congenital anomaly; pregnancy loss; fetal growth and preterm birth; and neonatal infection, admission, and death

We will also assess the proportion of confirmed cases of COVID-19 in neonates that were associated with maternal COVID-19. In addition, we will examine the extent to which

pregnant women and neonates with COVID-19 have been included in existing enhanced surveillance studies such as CO-CIN and BPSU studies.

This work is important as very little is known about the effects of COVID-19 in pregnancy: the evidence available to date is generally based on small case series. As far as we can tell just now, pregnant women do not appear to be at substantially increased risk of infection with SARS-CoV-2, or of developing severe COVID-19 once infection is present. However, there are suggestions that other adverse outcomes such as preterm delivery may be increased. Furthermore, some adverse outcomes (in particular congenital anomalies following infection in early pregnancy) may be unrelated to the severity of maternal infection (as is the case for other viral infections such as rubella and Zika), and there is as yet no evidence on these risks due to the inevitable lag times involved. COPS will address these uncertainties by providing population based information for the whole of Scotland on the incidence of, and outcomes following, COVID-19 in pregnancy.

COPS will use national datasets already held by Public Health Scotland plus primary care data provided from GP systems to PHS for the EAVE II study. Many of the national datasets required for COPS are also being used for the EAVE II study (for example, data on SARS-CoV-2 testing, unscheduled care, prescribing, hospital and critical care admissions, deaths). COPS will also use a number of additional datasets specifically required to identify pregnant women and relevant outcomes (for example, data on antenatal booking, termination of pregnancy, live and stillbirth registrations, and neonatal care). Data linkage and analysis will take place within Public Health Scotland. Results will be used by Public Health Scotland and the Scottish Government to inform ongoing control of the COVID-19 pandemic, and will be submitted for academic publication.

2021-0117 Dr David Henderson

### **Community based COVID-19 mortality**

Older people, particularly those living in care homes, have been profoundly affected by the COVID-19 pandemic in Scotland. As of the 5th July 2020, 76% of all deaths related to the virus occurred in those over the age of 75 and 90% in those over the age of 65. Almost half of COVID-19 deaths have occurred in care homes with a similar amount occurring in hospital. In terms of excess all-cause deaths (the number above the average of the past five years) a 67% increase has been recorded in care homes – much higher than seen in hospital or other settings.

To date, we know less about the characteristics of those that have died outside of hospital in relation to COVID-19 than those that did die in hospital. This study aims to help fill that gap in knowledge.

As Scotland moves out of the first wave of the COVID-19 pandemic, this research is urgently required to a) help inform policy and practice regarding potential future waves of the virus and b) help inform future research into what happened during the first wave.

## 2021-0129 Albert King

### **Carehomes Analysis**

Some care homes have been affected by COVID-19 more severely than others. We are seeking to understand whether there are modifiable factors that could reduce harm in the second wave.

There is an immediate operational need, tied to the second wave beginning now, to identify, at the care home level, factors that affect vulnerability of residents. We want to understand if there are links between care home outbreaks and care home use of agency staffing, staff to resident ratios, staff sickness absence, manager experience, care home quality rating etc.

A study, published in July 2020, systematically examines care-home outbreaks of COVID-19 in NHS Lothian using linked care-home, testing and mortality data for care-homes (<https://www.medrxiv.org/content/10.1101/2020.07.09.20149583v1>). Further analyses at a national level will focus on lessons learnt from the first wave and build on / enhance this work undertaken (in which analyses was carried out on limited care home service data) with more care home data from the various data controllers.

Much data exists already and the focus of this work will be on re-use of these existing datasets, held by Care Inspectorate, SSSC (Scottish Social Services Council), Scottish Government and NHS.

## 2021-0134 Professor Sharon Hutchinson

### **Impact of COVID-19 on prisoners in Scotland**

People in prisons are potentially more vulnerable to the COVID-19 pandemic than the general population. In the absence of prevention and control measures, the confined conditions in which prisoners live together for prolonged periods of time provides an environment for SARS-CoV-2 to spread quickly. Also, people in prisons typically have worse health conditions than the general population that could potentially heighten the risk of severe COVID-19 disease. Past experience shows that prisons can act as a source of infection and spread of infectious diseases both within and beyond prisons. Thus it is important to monitor the extent of testing, diagnosis and severity of disease for COVID-19 and overall mortality among prisoners in Scotland and those recently released from prison. Linkage of the Scottish Prison Service (SPS) Prisoner Records 2 (PR2) system on individuals held in custody to healthcare records held within Public Health Scotland will be used to examine the extent to which prisoners and those recently released from prison in Scotland are at different risk from COVID-19. This information is important to assess: i) the effectiveness of measures introduced to prevent and control transmission in the prison setting, and ii) the impact of COVID-19 and associated prevention measures on the health of individuals who have been in prison.

2021-0148 Albert King

**The Scotland Coronavirus Model (Regression Modelling)**

The University of Edinburgh have developed an agent based model for which they have submitted and receive approval under previous PBPP application (ref: Application number 2021-0007). They have now delivered a well-developed regression model based on this to the Scottish Government. Scottish Government are going to take over responsibility for running and developing this regression model. This application therefore seeks PBPP approval for access to the necessary data aligned to the initial request form from Edinburgh University to run this regression model within a secure environment. The University of Edinburgh project lead by Professor Kao is still ongoing.

This data will also be used to undertake our exceedance modelling which we run each day and publish each Thursday when appropriate on the Scottish Government website on a Thursday at local authority level (<https://www.gov.scot/collections/coronavirus-covid-19-modelling-the-epidemic/>)