

## Update on COVID-19 research in Suffolk and NE Essex – 05/03/2021

### COVID-19 Research findings and updates:

**‘A silent epidemic of grief’: a survey of bereavement care provision in the UK and Ireland during the COVID-19 pandemic** [published in BMJ Open](#). The first major study of pandemic-related changes in bereavement care, from the University of Cambridge, has found that the switch to remote working has helped some services to reach out, but many feel they do not have capacity to meet people’s needs. Read more [here](#).

**Coping with remote consultations to reduce the risk of Covid-19.** The Rapid COVID-19 Intelligence to Improve Primary Care Response (RAPCI) study has found that the rapid shift to remote GP consulting was successful and maintained a focus on vulnerable patients during the pandemic. Concerns were raised by GPs, however, that remote consulting may have risks and would need adjusting after the pandemic. See press [release](#) and the [RAPCI Study infographic](#). The paper: ‘The implementation of remote consulting in UK primary care following the COVID-19 pandemic: a mixed methods longitudinal study’ by Mairead Murphy et al. Published in [British Journal of General Practice](#).

**[World's first coronavirus Human Challenge study receives ethics approval in the UK.](#)** The UK will be the first country in the world to run a Covid-19 human challenge study, in which up to 90 healthy volunteers aged 18 - 30 years will be exposed to Covid-19 in a safe and controlled environment to increase understanding of how the virus affects people.

**[PRINCIPLE COVID-19 treatments trial widens to include under 50s.](#)** The trial will now include participants either aged 18-64 with shortness of breath from the illness or certain underlying health conditions that put them at risk of severe illness, and those aged over 65. Previously, only people with COVID-19 aged 50 or over and at most risk of complications from the illness were eligible to join the PRINCIPLE trial. By expanding parts of the trial to include people aged under 50, the study will provide new insights into whether treatments can help those at greater risk of severe COVID-19 illness. Researchers will also evaluate the gout drug **colchicine**, an inexpensive anti-inflammatory commonly used to treat gout, which is the fifth medication to be investigated in PRINCIPLE.

**The RECOVERY Trial** -in the past two weeks, Eastern Trusts have recruited 13.5% of all COVID-19 admissions into this trial. This is a tremendous achievement in recruiting patients, huge thanks go to clinical and research teams in 11 participating Trusts in the Eastern region (including NNUH, JPUH, QEHKL, SNEFT and West Suffolk Trusts). Every hospitalised patient in the UK with suspected or confirmed COVID-19 may be invited to participate in the RECOVERY Trial. [Colchicine arm has been halted](#) after analysis from the Data Monitoring Committee, there is no significant improvement in patient outcomes. The RECOVERY is currently testing the following potential treatments for Covid-19: REGN-COV2 monoclonal antibodies directed against coronavirus; aspirin, baricitinib and dimethyl fumarate.

### Vaccine trials and other New COVID-19 studies:

**[CoVLP- A Randomized, Observer-Blind, Placebo-Controlled, Phase 2/3 Study to Assess the Safety, Efficacy, and Immunogenicity of a Recombinant Coronavirus-Like Particle COVID-19 Vaccine in Adults 18 Years of Age or Older and Children and Adolescents 5-17 Years of Age.](#)** This new vaccine study will open at the end of March at the NNUH with local practices supporting participants’ identification, with the aim to recruit 250 participants.

**The Novavax Vaccine Trial** currently on going at NNUH has been granted approval from the F.D.A. to change the trial to a crossover design, in which participants will receive a second round of jabs. Those who were in a placebo group will get the vaccine in the second round, and those who received a

vaccine will get a placebo. This will help reassure potential volunteers that they will eventually receive the vaccine even if they were in the placebo group. The crossover phase is due to start at the NNUH at the end of March and will involve around 250 participants.

**[New! CCP-Cancer UK: Clinical Characterisation Protocol for Severe Emerging Infections in the UK \(CCP-UK\) - a prospective companion study for patients with Cancer and COVID-19](#)** is aiming to obtain additional data from patients with cancer who were/are recruited into the Principal CCP-UK study, which is being run at ESNEFT and WSH Trusts. This study is designed to supplement the Principal CCP-UK protocol. The study will run for 2 years.

### **Other news of interest**

**[The StatinWise Trial finds no overall effect of statins on muscle pain.](#)** Statins are widely used to prevent heart disease and stroke and while severe side effects are rare, many people believe that statins can cause muscle pain and stiffness, even though there is no clear clinical trial evidence to support this. This belief has led to patients stopping treatment, exposing them to an increased risk of serious heart problems. The Statin WISE NIHR funded trial, set to establish the effect of statins on muscle symptoms, involved 200 patients from 50 general practices in England and Wales (including 6 GPs in Norfolk and Waveney). The findings are published in the [BMJ](#).

**[Raising awareness of the risks of developing dementia.](#)** Two animations have been developed to raise awareness of the risks of developing dementia for patients being treated with anticholinergics, a group of medicines is commonly prescribed for depression, psychosis, bladder disorders, Parkinson's disease, and epilepsy. The campaign is based on research which has found that anticholinergics taken by people aged 55 years old and over, for the equivalent of three years or more, may increase the risk of developing dementia. The original paper can be accessed [here](#) and to view the animations please click [here](#).

**[A large landmark new programme of health research on screening for undiagnosed atrial fibrillation, the heart condition responsible for one in ten strokes will involve 2100 people in East Anglia.](#)** The £3m trial called SAFER is funded by the National Institute for Health Research (NIHR) is to start has been designed so that it can continue safely during the COVID pandemic. All the screening will be done remotely, at home, via a small hand-held electronic device, Zenicor-ECG. The device takes readings of the heart's rhythm and sends the data to the researchers automatically. The SAFER will begin recruiting people aged 70 or over via GPs in East Anglia over the next few months, before being scaled up later this year, to recruit overall 126,000 people across the country to take part.

**[Persistent inequalities in hospice care provision have been revealed in a study of the demography of hospice populations carried out at the University of Cambridge.](#)** The systematic review of literature found persistent inequalities in hospice care provision: patients without cancer, the oldest old, ethnic minorities and those living in rural or deprived areas are under-represented in hospice populations. The effect of gender and marital status was inconsistent and there was a limited literature concerning hospice service access for the LGBTQ+ community, homeless people and those living with HIV/AIDS, diabetes and cystic fibrosis. The findings are published in the [BMJ](#)

**[What can primary care do about health inequalities?](#)** Researchers from Cambridge and Oxford are launching an NIHR-funded research study to find out how actions taken in primary care services and GP surgeries around the country can affect health inequalities and what should change. The EQUALISE Study will explore which interventions and aspects of routine general practice increase or decrease inequalities for the main drivers of inequalities in life expectancy: cardiovascular disease, cancer, diabetes or Chronic Obstructive Pulmonary Disease (COPD). The study undertakes a theory-driven review of the existing evidence and aims to develop guidance which can be used in general practice to reduce inequalities and improve services for patients.

The tables below give an overview of all COVID-19 research activity across Suffolk. Please note that this information is provided for reference only and not for external publication.

### Primary Care Studies

	Study Title	Study aim	Study setting	Local status		Recruitment <sup>1</sup>
1.	<b>Principle:</b> Platform randomised trial of Interventions against Covid-19 with older people <a href="https://www.phctrials.ox.ac.uk/principle-trial">https://www.phctrials.ox.ac.uk/principle-trial</a>	To test different medications to see whether this reduces the need for hospitalisation or will speed up recovery in older patients (65+ or 50-64 with a pre-existing condition) <b>hydroxychloroquine</b> – recruitment paused <b>Azithromycin</b> – recruitment started Other medications may be added to the trial at a later point.	Primary Care	<b>Sites activated:</b> <b>Suffolk:</b> The Peninsula Practice; The Two Rivers; Victoria Surgery The Christmas Maltings & Clements Practice Chesterfield Drive Haven Health Derby Road	<b>NEE:</b> Colchester Medical Practice Castle Gardens Medical Centre; Parsons Health Medical Centre; Shrub End Surgery; Wimpole Rd Surgery; Great Bentley Surgery Ambrose Group Ardleigh Colne Medical Practice West Mersea Rowhedge Riverside	67 across Suffolk &NEE practices  Nationally: 4,488
2.	<b>FLU-CATS:</b> Evaluation and refinement of pandemic influenza community assessment tools	An observational study of pandemic influenza community assessment tools which is being amended to pick up COVID-19 patients	Primary care	Awaiting revised protocol for COVID-19		Not yet set up
3.	<b>VIVALDI</b> COVID-19 in care homes	An observational study to understand SARS-COV-2 infection immunity and its duration in care home staff and residents in the UK	Care Homes	3 care homes in Suffolk / NEE are signed up.		North Court Care Home: 26 Catchpole Court Care Home: 36 Kingfisher House Care Home: 50  Nationally: 5,502

<sup>1</sup> Data collected from national research database – figures may lag behind actual figures

4.	<b>RECAP (REmote Covid Assessment in Primary Care).</b>	This research aims to develop a score for GPs to use when assessing how badly a patient is affected with COVID, to use over the phone or by video.	GPs and practices	Being set up across UK and Eastern	No recruits showed yet
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### Cross Sector Studies

	Study Title	Study aim	Study setting	Local status	Recruitment <sup>2</sup>
1	Chloroquine prevention of coronavirus disease (COVID-19) in the healthcare setting; a randomised, placebo-controlled prophylaxis study ( <b>COPCOV</b> ) <a href="http://copcov.org/">http://copcov.org/</a>	The aim of the study is to determine if hydroxychloroquine prophylaxis prevents symptomatic COVID-19 infection in front-line health care workers.	Secondary Care but with the expectation that frontline workers across all health and social care sectors would be able to take part as participants	East Suffolk and North Essex NHS Foundation Trust selected to participate;  WSH in set-up	MHRA approved study to restart  Nationally recruited: 88
2.	<b>CROWN CORONATION</b> Chloroquine Repurposing to healthWorkers for Novel Coronavirus mitigation <i>Study being amended to look at other prophylactic treatments instead of chloroquine / hydroxychloroquine</i>	The aim of the study is to determine the effectiveness of chloroquine/hydroxychloroquine prophylaxis in preventing symptomatic COVID-19 in healthcare workers at risk of SARS-CoV-2 exposure.	Secondary Care but with the expectation that frontline workers across all health and social care sectors would be able to take part as participants	ESNFT expected to take part	Not yet set up
3.	<b>Virus Watch</b>	An observational study into understanding community incidence, symptom profiles, and transmission of COVID-19 in relation to population movement and behaviour.	All sectors expected to be involved in collection of serum samples for participating households in Part 2 of the study. Part 1 is managed centrally	Colchester Medical Practice Howard House Surgery Oakfield Surgery Stowhealth The Chesterfield Drive Practice	Colchester Medical Practice: 79 Howard House Surgery: 36 Leiston Surgery: 71 Oakfield Surgery: 22 Stowhealth: 84 The Chesterfield Drive Practice: 82  Nationally recruited: 46,423

<sup>2</sup> Data collected from national research database – figures may lag behind actual figures

4.	Multi-centre European study of MAJOR Infectious Disease Syndromes ( <b>MERMAIDS</b> ): Acute Respiratory Infections in Adults	An observational study aims to identify host and pathogen related determinants of severity of community acquired acute respiratory infections in adults.	This study will enrol participants in both primary care and secondary care.	Trusts invited for expression of interest	Not yet set up  Nationally: 47
5.	Behavioural Activation in Social Isolation ( <b>BASIL-C19</b> )	This study is part of the MODS (Multi-Morbidity in Older adults with Depression Study) programme, looking at whether a talking treatment called Behavioural Activation (BA) can help improve a person's physical and psychological functioning, for example self-care and mood. The study is asking 'can we prevent or ameliorate depression and loneliness in older people with long term conditions who are under enforced COVID-19 isolation?'	Looking for Trust sites; with potential cross-sector involvement with primary care	Trusts invited for expression of interest	Not yet set up
6.	Post-hospitalisation COVID-19 study: a national consortium to understand and improve long-term health outcomes ( <b>PHOSP-COVID</b> )	The aim is to understand and improve long-term outcomes for survivors of hospitalisation with COVID-19. The PHOSP-COVID study is aligned to the clinical follow-up provided, but does not alter clinical care.	TBC	TBC	Not yet set up
7.	<b>Psychological Impact of COVID-19</b>  <b>N.B. the study adopted on NIHR portfolio but not badged with urgent public health status</b>	A survey to explore the psychological impact of COVID-19 outbreak and the resultant restrictions in terms of behavioural, emotional and social factors.	Advertised through social media via local Trusts and CCGs	Norfolk & Suffolk NHS foundation Trust (NSFT)	NSFT: 104
8.	<b>Novavax COVID Vaccine study</b> – A trial to evaluate SARS-CoV-2 Recombinant Nanoparticle vaccine	12-month placebo controlled trial to evaluate the safety and efficacy of the Novavax Vaccine in adults 18-84.	Study based at ESNEFT and supported by Primary Care team	ESNEFT; <b>recruitment completed</b>	ESNEFT: 168  Nationally: 15,203

### Secondary Care Studies

	Study Title	Study aim	Study setting	Local status	Recruitment <sup>3</sup>
1.	<b>RECOVERY:</b> Randomised Evaluation of COVID-19 Therapy	To test if existing or new drugs can help patients hospitalised with confirmed COVID-19; The UK New and Emerging Respiratory Virus Threats Advisory Group (NERVTAG) advised that several possible treatments should be evaluated, including: <b>Lopinavir-Ritonavir</b> (arm closed-shown no clinical benefit; read more <a href="#">here</a> ), <b>Interferon <math>\beta</math>, corticosteroids<sup>4</sup>, and Remdesivir, Hydroxychloroquine</b> (arm closed; read more <a href="#">here</a> ), <b>Tocilizumab. Dexamethasone</b> (completed, benefits found read more <a href="#">here</a> ) <b>convalescent plasma</b> (closed to recruitment); <b>REGN-COV2 monoclonal antibodies directed against coronavirus; aspirin, colchicine, baricitinib and dimethyl fumarate.</b> The supply arrangements for each medicine for RECOVERY trial are described <a href="#">here</a> .	Secondary care; (Paediatric and neonatal arm to be added soon)	Open sites: ESNEFT (Ipswich and Colchester) WSH	WSH: 162 Ipswich Hospital: 381  Nationally: 38,360
2	<b>RECOVERY-RS (Respiratory support)</b>  <a href="https://warwick.ac.uk/fac/sci/med/research/ctu/trials/recovery-rs/">https://warwick.ac.uk/fac/sci/med/research/ctu/trials/recovery-rs/</a>	This study is aiming to determine if CPAP (continuous positive airway pressure) or HFNO (high flow nasal oxygen) is clinically effective compared to standard care (excluding CPAP or HFNO).	Secondary care	Open sites: Ipswich Hospital Colchester WSH	ESNEFT:9  Nationally: 1,220
3.	<b>Re-MAP Cap:</b> Randomized, Embedded, Multifactorial, Adaptive Platform trial for Community-Acquired Pneumonia  <a href="https://www.remapcap.org/">https://www.remapcap.org/</a>	The trial will look at a number of different treatment categories with an aim to determine the best clinically effective treatment for adult patients with CAP admitted to participating intensive care units with suspected or microbiological testing confirmed COVID-19 infection.	Secondary care/ICUs	All sites running RECOVERY study are invited to participate	ESNEFT:37  Nationally: 4,305

<sup>3</sup> Data collected from national research database – figures may lag behind actual figures

<sup>4</sup> Corticosteroids used in the trial are expected to be sourced by local pharmacy procurement team via their normal routes, all other medications for RECOVERY sourced centrally via PHE

4.	<b>CCP-UK</b> Clinical Characterisation Protocol for Severe Emerging Infection' study/(ISARIC-4C)	An observational study collecting samples and data from confirmed COVID-19 patients	Secondary care	All acute Trusts in the Eastern region activated;	ESNEFT: 2426 WSH: 983  Nationally: 177,785
5.	<b>UKOSS</b> : Pandemic Influenza in Pregnancy <a href="https://www.npeu.ox.ac.uk/ukoss/current-surveillance/covid-19-in-pregnancy">https://www.npeu.ox.ac.uk/ukoss/current-surveillance/covid-19-in-pregnancy</a>	An observational study via the UK Obstetric Surveillance System to collect information on pregnant women admitted to hospital with confirmed COVID-19	Secondary care / Trusts with Maternity Units	Open sites: Colchester; Ipswich hospitals; WSH	No recruitment data showing
6.	<b>GenOMICC</b> Genetics of susceptibility and mortality in critical care	An observational study to identify the specific genes that cause some people to be susceptible to specific infections and consequences of severe injury.	Secondary care	Ipswich Hospital open WSH reviewing	Ipswich Hospital: 64 WSH:1  Nationally: 10,196
7.	Coronavirus infection in primary or secondary immunosuppressed children.	An observational study designed to allow families of immunosuppressed children and young people to self-record their experiences of COVID-19 and other viral respiratory illnesses during the COVID-19 epidemic.	Secondary care	Not open to new sites currently	<b>Recruitment now complete</b>  Nationally recruited: 1,633
8.	<b>PAN COVID</b> : Pregnancy and Neonatal Outcomes in COVID-19 <a href="https://pan-covid.org/">https://pan-covid.org/</a>	A global registry of women with suspected or confirmed SARS-CoV-2 infection in pregnancy and their neonates, understanding natural history to guide treatment and prevention	Secondary care	Open sites: WSH ESNFT (Ipswich & Colchester)	ESNEFT: 38 West Suffolk:3  Nationally: 6,187
9.	Neonatal Complications of Coronavirus Disease (COVID-19) Study	This is a national surveillance programme using the standard British Paediatric Surveillance Unit (BPSU) approach. This study will run alongside and be cross-linked with the maternal surveillance study run through the United Kingdom Obstetric Surveillance System (UKOSS; CPMS: 14162), which is already in progress.	Secondary care	Open sites: WSH	There will be no consenting (no recruits) for this study as linked to another study

10.	<b>TACTIC-R</b> (Multiarm Therapeutic study in pre-ICU patients admitted with COVID-19 - Repurposed Drugs)	The TACTIC-R clinical trial is testing whether existing drugs, which are already used to treat other immune-related conditions, can prevent the development of severe symptoms in patients hospitalised with confirmed/strongly suspected COVID-19. This approach, known as repurposing, is a way of finding out whether existing therapies, which are likely to be readily available in hospitals, are effective in treating the disease.	Secondary care	Several sites in Eastern are being set up  Opened sites: WSH	WSH: 24  Nationally recruited: 419
11.	<b>SIREN</b> : Sarscov2 Immunity & REinfection EvaluationN - The impact of detectable anti SARS-COV2 antibody on the incidence of COVID-19 in healthcare workers	An observational study which aims to find out whether healthcare workers who have evidence of prior COVID-19 infection, detected by antibody assays (positive antibody tests), compared to those who do not have evidence of infection (negative antibody tests) are protected from future episodes of infection. For SARS CoV2 infection it is not yet known if the detection of antibodies protects people from future infection. This study aims to provide this very important information, which will help to understand the future impact of COVID-19 on the population.	Secondary care	Currently is being set up in secondary care – all trusts expected to take part as part of Trust wide antibody screening processes  Open sites: WSH ESNEFT	WSH: 471 ESNEFT: 346  Nationally recruited: 36,957
12	<b>NHS CHECK</b> : Health & Experiences of staff working at NHS Trusts and Nightingale Hospitals <a href="https://www.kcl.ac.uk/news/nhs-check-study-to-explore-the-effect-of-the-covid-19-pandemic-on-nhs-staff">https://www.kcl.ac.uk/news/nhs-check-study-to-explore-the-effect-of-the-covid-19-pandemic-on-nhs-staff</a>	Aims to establish a cohort of NHS-affiliated staff to investigate the short, medium and longer term psychosocial impact of the COVID-19 pandemic on staff performance and wellbeing. NHS staff will be invited to participate, to complete an online survey module and an intervention evaluation module	Secondary care	Open sites: ESNEFT	ESNEFT: 434  Nationally recruited: 25,694

13.	<a href="#">What's the STORY?</a>	This Oxford Vaccine Group study is investigating the serological profile of children and young adults to assess how well the population is protected from vaccine preventable disease. This study will involve blood sampling from people aged from birth to 24 years of age to look at their antibody levels against important infectious diseases.	Secondary care	Opened at: West Suffolk Hospital	WSH: 18  Nationally: 2,160
14.	<a href="#">CLARITY ImpaCt of bioLogic therApy on saRs-cov-2 Infection and immuniTY</a>	This study will provide an evidence base for safer prescribing of immunomodulator and biologic drugs in the COVID-19 era and inform public health policy regarding physical distancing measures, and future vaccination strategies. Although this study will define risk in IBD (Inflammatory Bowel Disease) patients, there are potentially important lessons to be learned for other patients across with other immune mediated diseases treated with similar therapies.	Secondary care	Open at ESNEFT	ESNEFT: 31  Nationally: 7,206

<sup>5</sup>Local update

A full list of all DHSC priority COVID-19 studies can be found at <https://www.nihr.ac.uk/covid-studies/>