

## Update on COVID-19 research in Suffolk and NE Essex – 30/04/2021

### COVID-19 Research findings and updates:

The latest findings from the [National COVID-19 Infection Survey](#), as reported on the national media headlines, show that a single dose of either the Oxford-AstraZeneca or Pfizer-BioNTech vaccines leads to a substantial drop in the spread of COVID-19. A study of test results taken from more than 370,000 participants showed that in the three weeks after the first dose of either vaccine, rates of new infections had fallen by 65%. Symptomatic infections were down by 74% while infections without symptoms decreased 57%. A second study compared how antibody levels changed after one dose of either vaccine, or two doses of the Pfizer-BioNTech vaccine. Among all groups who had not contracted the virus, a single vaccine dose boosted levels of protection, although fewer antibodies were present in those over 60. However, older people had a significant boost in their antibody levels on receipt of a second jab of the Pfizer BioNTech vaccine, which led to high levels of protection for all groups. Read more [here](#) and you can access the pre-print papers for the two studies [here](#).

[GenOMICC COVID-19 study](#) looking into why some people become more severely affected than others and to help find better treatments is still looking for volunteers with mild symptoms who were not hospitalised with COVID-19, to match them closely in age and ethnicity to those who were severely affected and ended up in intensive care. The study is continuing to recruit in intensive care units across the country, including two Suffolk Trusts. If you have had COVID-19 please consider volunteering to participate. You can find out more and how to register on [study website](#)

[COVID-19 human challenge study](#) Healthy young people who have had Covid-19 are being asked to volunteer for a trial that will deliberately expose them to the pandemic virus in a safe and controlled environment to increase understanding of how the immune system copes second time round, which may help design better treatments and vaccines. Read [BBC News](#) report.

### New COVID-19 vaccine studies:

“**Cov-Compare**” (VLA2001-301) Phase 3 clinical trial of a new vaccine candidate developed by specialty vaccine company [Valneva](#). Unlike earlier COVID-19 vaccine studies, which involved a placebo dose, everyone involved in this trial will receive two active vaccine doses, administered in a four-week interval. Those enrolled in the study over the age of 30 will be randomised to receive two doses of either the Valneva vaccine, or the approved Oxford/AstraZeneca vaccine. Participants aged 18 - 29 can be enrolled into the study to receive the Valneva vaccine and will not be offered the approved Oxford/AstraZeneca vaccine. The new vaccine is the only inactivated, adjuvanted (an ingredient to create a strong immune response) COVID-19 vaccine in clinical development in Europe and is being manufactured at the company's site in Livingston, West Lothian. 4,000 volunteers are set to be recruited. [Read more here](#).

To register interest in vaccine studies please visit the [NHS COVID-19 Vaccine Research Registry](#).

## Other news of interest:

The **Programme on Adherence to Medication** (PAM) research team published the results of a randomised clinical controlled trial which tested the feasibility of a behavioural intervention to support medication adherence to patients prescribed treatment for hypertension in nine primary care practices across East of England and London. The intervention consisted of a Very Brief Advice (VBI) by a practice nurse or a health care assistant, followed by ongoing digital support in the form of text messages or a smartphone app. Read more [here](#).

**[Triage-driven diagnosis of Barrett esophagus for early detection of esophageal adenocarcinoma using deep learning](#)**- a paper published in *Nature Medicine* describes how AI 'deep learning' techniques can be used to triage suspected cases of Barrett oesophagus, a precursor to oesophageal cancer, potentially leading to faster and earlier diagnoses. Read more [here](#).

**Time for Primary Care Networks to act: Multiple conditions and health equity [free online webinar on 11<sup>th</sup> May](#)** from health and care charity coalition: The Richmond Group and Kaleidoscope H&C to discuss the role of PCNs in addressing the health inequalities faced by those living with multiple conditions.

**[Algorithms as good as doctors at predicting death in advanced cancer](#)** Two studies [Prognostic tools or clinical predictions](#) and [The Prognosis in Palliative care Study II](#) published in the journal PLOS ONE directly compare, for the first time, commonly used algorithms for predicting survival length (prognosis) against clinicians' predictions, and combine interviews with patients, carers and healthcare professionals to assess the perceived usefulness of prognosis tools.

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

Please note that it is understood that all medications unless indicated below are sources and provided centrally for use in these trials.

## 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	75 across Suffolk &NEE practices  Nationally: 4,854
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
4.	<b>RECAP (REmote Covid Assessment in Primary Care).</b>	<i>This</i> research aims to develop a score for GPs to use when assessing how badly a patient is	GPs and practices	Being set up across UK and Eastern		No recruits showed yet

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

		affected with COVID, to use over the phone or by video.			
5	<a href="#">Covid-19 Germ Defence Implementation</a>	Examine effects of randomising dissemination of Germ Defence website via GP practices on rates of respiratory infection, including covid-19 and seasonal flu.	Primary Care	3 practices in Suffolk and NEE (practices count as recruits) The study closed to recruitment of practices on 30/03/2021	10 Nationally: 459

### 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: 40 Leiston Surgery: 80 Oakfield Surgery: 22 Stowhealth: 84 The Chesterfield Drive Practice: 82

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

					Nationally recruited: 57,819
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: 170 Ipswich Hospital: 397  Nationally: 39,586
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: 1,278
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:38  Nationally: 4,410

<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: 3276 WSH: 1105  Nationally: 204,063
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: 72 WSH:1  Nationally: 12,416
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: 42 West Suffolk:5  Nationally: 7,469
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: 422
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: 598 ESNEFT: 352  Nationally recruited: 44,759
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: 93  Nationally: 2,762
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: 7,231
15.	<b>FALCON-C19</b>	Facilitating Accelerated CLinical evaluation Of Novel diagnostic tests for COVID-19. Study limited to working with human tissue samples and other biological samples and data.	Secondary care	Open at WSH	WSH: 97  Nationally: 4,475

<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/>