

## Update on COVID-19 research in Suffolk – 19/11/2020

### Key Updates:

- **NEW! RECAP (REmote Covid Assessment in Primary Care).** 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. The most widely used 'early warning score' is NEWS2 but this wasn't designed for use in COVID, and it's a hospital score. The research team will use features of COVID that are known to be markers of more serious disease. The study will take place using routine care for patients with suspected COVID-19 being seen and managed in primary care.

Practices need to be signed up to the Royal College of GPs (RCGP) Research Surveillance Centre (RSC) network to participate in this trial. If you would like to participate but are not part of the RSC network, you can find more about the network and how to join on the RCGP website. Some practices have already been approached directly by the RSC, others are being contacted by local Clinical Research Network. More information about the study can be found on RECAP website.

- **The Novavax study** Three Eastern were involved in this 12-month Phase 3 commercial study looking at the efficacy and safety of the Novavax vaccine in comparison with placebo. The trial is underway at East Suffolk and North Essex NHS Foundation Trust, supported by Primary Care research nurses. The trial closes to recruitment on Monday 30 November.

Here is some information about the Novavax vaccine and how it is different from vaccine developed by Pfizer, which has shown promising results in trials as highlighted in the most recent news worldwide. *The Novavax vaccine, NVX-CoV2373, contains purified pieces of the spike protein of SARS-CoV-2, the virus that causes COVID-19. These proteins are administered with an adjuvant, a molecule that enhances the immune response. When this vaccine is administered, the body recognises its contents as "foreign" and mounts a protective immune response. This vaccine is different from the vaccine developed by Pfizer, BNT162b2, which is based on the genetic material mRNA (or messenger ribonucleic acid). Such mRNA vaccines carry a piece of genetic material that codes for viral proteins, or parts of them. Once inside your cells, the mRNA instructs your cells' protein factories to make copies of these viral proteins which in turn stimulate a protective immune response.*

If staff wish to participate please go to the trial screening website

<http://www.covid19trial-uk.com/> - Staff are **advised to ensure they have had their flu vaccination** as they will be unable to have a flu, or any other vaccination for approximately 2 months after enrolment in the study. Participants must also not have had a lab confirmed COVID-19 infection.

- **SIREN:** The impact of detectable anti SARS-COV2 antibody on the incidence of COVID-19 in healthcare workers. This study aims to find out whether healthcare workers who have evidence of prior COVID-19, 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. West Suffolk Hospital Foundation Trust recruited 500 participants (placing WSH in top 12 recruiters out of 116 participating Trusts). East Suffolk and North Essex NHS Foundation Trust 350 participants.

- **NHS CHECK:** Health & Experiences of staff working at NHS Trusts and Nightingale Hospitals 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. <https://www.kcl.ac.uk/news/nhs-check-study-to-explore-the-effect-of-the-covid-19-pandemic-on-nhs-staff> ESNEFT staff participated (350 recruits).
- **Psychological impact of the Coronavirus (COVID-19) pandemic and experience: An international survey,** funded by the Medical Research Council and sponsored by the Southern Health NHS Foundation Trust aims to explore the psychological impact of COVID-19 outbreak and the resultant restrictions in terms of behavioural, emotional and social factors. The general public, health professionals and those with pre-existing mental health conditions were invited via the Trusts and CCGs social media to complete the survey earlier in the summer. The first phase of the survey has now been completed with more than 29,000 responses from across the country (including **3,233 from the Eastern region**). The study team is preparing to send out the 2<sup>nd</sup> phase questionnaire to measure the impact of restrictions being in place for a longer time period.
- **39% of Eastern GPs have taken part in research this year,** which puts our region on top of the league, above other 14 Local Clinical Research Networks. It is very important to recognise this significant achievement by Suffolk Practices and the level of engagement with research in primary care during the time of COVID-19 pandemic.

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	Primary Care	<b>Sites activated:</b> The Peninsula	<b>NEE:</b> Colchester Medical Practice Castle Garden	15 across Suffolk & NEE  Nationally: 1,993

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

	Study Title	Study aim	Study setting	Local status	Recruitment <sup>[1]</sup>
		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.		<p>a Practice; The Two Rivers; Victoria Surgery The Christmas Maltings &amp; Clements Practice Chesterfield Drive Haven Health Derby Road</p> <p>s 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</p>	Study is now looking to engage care homes
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	Care Homes	3 care homes in Suffolk / NEE are signed up.	North Court Care Home: 26 Catchpole Court Care Home: 36

	Study Title	Study aim	Study setting	Local status	Recruitment <sup>[1]</sup>
		home staff and residents in the uk			Kingfisher House Care Home: 50  Local recruitment – 26  Nationally: 3,760
4	<b>NEW 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

### 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	The aim of the study is to determine the effectiveness of	Secondary Care but with the	ESNFT expected	Not yet set up

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

	Study Title	Study aim	Study setting	Local status	Recruitment <sup>[2]</sup>
	healthWorkers for Novel Coronavirus mitigation <i>Study being amended to look at other prophylactic treatments instead of chloroquine / hydroxychloroquine</i>	chloroquine/hydroxychloroquine prophylaxis in preventing symptomatic COVID-19 in healthcare workers at risk of SARS-CoV-2 exposure.	expectation that frontline workers across all health and social care sectors would be able to take part as participants	to take part	
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	Sites to be confirmed.	Not yet set up
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	Looking for Trust sites; with potential cross-sector involvement with primary care	Trusts invited for expression of interest	Not yet set up

	Study Title	Study aim	Study setting	Local status	Recruitment <sup>[2]</sup>
		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?'			
6	Post-hospitalisation COVID-19 study: a national consortium to understand and improve long-term health outcomes (PHOSP-COVID)	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

### 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	Secondary care; (Paediatric and neonatal arm to be added soon)	Open sites: ESNEFT (Ipswich and Colchester) WSH	WSH: 74 Ipswich Hospital: 137  Nationally : 17,768

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

	Study Title	Study aim	Study setting	Local status	Recruitment <sup>[3]</sup>
		<p>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></b>, <b>corticosteroids<sup>[4]</sup></b>, and <b>Remdesivir</b>, <b>Hydroxychloroquine</b> (arm closed; read more <a href="#">here</a>), <b>Tocilizumab</b>, <b>Dexamethasone</b>, <b>convalescent plasma</b>. Other treatments may soon emerge that require evaluation. The supply arrangements for each medicine for RECOVERY trial are described <a href="#">here</a>.</p>			
2	<p><b>RECOVERY-RS (Respiratory support)</b></p> <p><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></p>	<p>This study is aiming to determine if CPAP (continuous positive airway pressure) or</p>	Secondary care	Open sites: Ipswich Hospital Colchester WSH	ESNEFT:7 Nationally : 422

<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

	Study Title	Study aim	Study setting	Local status	Recruitment <sup>[3]</sup>
		HFNO (high flow nasal oxygen) is clinically effective compared to standard care (excluding CPAP or HFNO).			
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	ESNFT (Colchester Hospital) : 9 Nationally : 1487
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;	ESNFT: 822 WSH: 292 Nationally : 101,595
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	Secondary care / Trusts with Matern	Open sites: Colchester;	No recruitment data showing

	Study Title	Study aim	Study setting	Local status	Recruitment <sup>[3]</sup>
		collect information on pregnant women admitted to hospital with confirmed COVID-19	ity Units	Ipswich hospitals; WSH	
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: 18 WSH:1  Nationally : 5,593
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	Secondary care	Open sites: WSH ESNFT (Ipswich &	ESNEFT: 26 West Suffolk: 2  Nationally : 4,087

	Study Title	Study aim	Study setting	Local status	Recruitment <sup>[3]</sup>
		pregnancy and their neonates, understanding natural history to guide treatment and prevention		Colchester)	
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-	Secondary care	Several sites in Eastern are being set up  Opened sites:	WSH: 1  Nationally recruited: 124

	Study Title	Study aim	Study setting	Local status	Recruitment <sup>[3]</sup>
		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.		WSH	
1 1.	<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	Secondary care	Currently is being set up in secondary care – all trusts expected to take part as part of Trust wide antibody	WSH: 500 <sup>5</sup> ESNEFT: 350  Nationally recruited: 6,889

	Study Title	Study aim	Study setting	Local status	Recruitment <sup>[3]</sup>
		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.		y screening processes  Open sites: WSH ESNEFT	
1 2	<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	Secondary care	Open sites: ESNEFT	ESNEFT: 356  Nationally recruited: 21,346

	Study Title	Study aim	Study setting	Local status	Recruitment <sup>[3]</sup>
		and wellbeing. NHS staff will be invited to participate, to complete an online survey module and an intervention evaluation module			

<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/>

Best wishes

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