

Update on COVID-19 research in Suffolk – 20/08/2020

Key Updates:

- Work continues to look at how we can support and deliver the COVID-19 vaccine studies that are starting to coming through – these are large scale studies requiring cross-sector working and require innovative thinking as to how to deliver at scale across the region whilst taking into account safety considerations and necessary staffing resources, and work is ongoing to link in with planning for the Flu vaccination campaign. The national registry for COVID-19 vaccine studies is still open to interested individual – so please click [here](#) for further information and to sign up.
- **The new [Virus Watch Study](#) is now underway.** Virus watch is a household community cohort study of COVID-19 which aims to understand community incidence, symptom profiles, and transmission of COVID-19 in relation to population movement and behaviour. The study is funded by UK Research and Innovation (UKRI), and by the Department of Health and Social Care through the National Institute for Health Research (NIHR) and run from the University College London. Recruitment has just started with a postal invitation to a randomly selected household, and first 4500 participants have signed up so far with a national target of 42,000 involved, 10,000 of whom will be asked to give COVID-19 swabs and lab tests, with additional households being recruited through advertisement and social media.
Locally four primary care sites (with additional satellite practices) have been pre-selected to host clinics for taking study samples.
- The **SIREN: Sarscov2 Immunity & REinfection EvaluatioN** study looking into the impact of detectable anti SARS-COV2 antibody on the incidence of COVID-19 in healthcare workers study has recruited **200** participants from **West Suffolk Hospital**

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 ¹
1.	Principle: Platform randomised trial of Interventions against Covid-19 with older people https://www.phctrials.ox.ac.uk/principle-trial	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) hydroxychloroquine – recruitment paused Azithromycin – recruitment started	Primary Care	Sites activated: Suffolk: The Peninsula Practice; The Two Rivers; Victoria Surgery The Christmas Maltings & Clements Practice Chesterfield Drive	NEE: Colchester Medical Practice Castle Gardens Medical Centre; Parsons Health Medical Centre; Shrub End Surgery; Wimpole Rd Surgery; Great Bentley Surgery Ambrose Group	Colchester MP: 1 The Peninsula: 1 Haven Health: 1 Long Melford: 1 The Riverside HC:1 Nationally: 712

¹ Data collected from national research database – figures may lag behind actual figures

		Other medications may be added to the trial at a later point.		Haven Health Derby Road	Ardleigh Colne Medical Practice West Mersea Rowhedge Riverside	Study is now looking to engage care homes
2.	FLU-CATS: 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.	VIVALDI 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.		Local recruitment – 26 Nationally: 3,760

Cross Sector Studies

	Study Title	Study aim	Study setting	Local status	Recruitment ²
1	Chloroquine prevention of coronavirus disease (COVID-19) in the healthcare setting; a randomised, placebo-controlled prophylaxis study (COPCOV) http://copcov.org/	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	MHRA approved study to restart Nationally recruited: 73
2.	CROWN CORONATION Chloroquine Repurposing to healthWorkers for Novel Coronavirus mitigation <i>Study being amended to look at other prophylactic treatments</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

² Data collected from national research database – figures may lag behind actual figures

	<i>instead of chloroquine / hydroxychloroquine</i>				
3	Virus Watch	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 (MERMAIDS): 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 (BASIL-C19)	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 (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

Secondary Care Studies

	Study Title	Study aim	Study setting	Local status	Recruitment ³
1.	RECOVERY: 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: Lopinavir-Ritonavir (arm closed-shown no clinical benefit; read more here), Interferon β, corticosteroids⁴, and Remdesivir, Hydroxychloroquine (arm closed; read more here), Tocilizumab, Dexamethasone, convalescent plasma. Other treatments may soon emerge that require evaluation. The supply arrangements for each medicine for RECOVERY trial are described here .	Secondary care; (Paediatric and neonatal arm to be added soon)	Open sites: ESNEFT (Ipswich and Colchester) WSH	WSH: 70 Ipswich Hospital: 107 Nationally: 12,233
2	RECOVERY-RS (Respiratory support) https://warwick.ac.uk/fac/sci/med/research/ctu/trials/recovery-rs/	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	Ipswich: 1 Colchester:2 Nationally: 158
3.	Re-MAP Cap: Randomized, Embedded, Multifactorial, Adaptive Platform trial for Community-Acquired Pneumonia https://www.remapcap.org/	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) : 1 Nationally: 504

³ Data collected from national research database – figures may lag behind actual figures

⁴ 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.	CCP-UK 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: 787 WSH: 267 Nationally: 77,005
5.	UKOSS: Pandemic Influenza in Pregnancy https://www.npeu.ox.ac.uk/ukoss/current-surveillance/covid-19-in-pregnancy	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.	GenOMICC 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: 6 WSH:1 Nationally: 3,275
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	Recruitment now complete Nationally recruited: 1,633
8.	PAN COVID : Pregnancy and Neonatal Outcomes in COVID-19 https://pan-covid.org/	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)	Ipswich: 2 Colchester: 8 West Suffolk: 1 Nationally: 2,643
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.	TACTIC-R (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: 1 Nationally recruited: 24
11.	SIREN : 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	WSH: 200 ⁵ Nationally recruited: 6,889

⁵Local update

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