Randomised Evaluation of COVID-19 Therapy: the RECOVERY trial

Collaborators' Meeting

26th October 2020

Agenda

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1. Introductions
2. Update on progress
3. REGN-COV2
4. Tocilizumab
5. Other developments
6. Trial procedures
7. Pregnancy update
8. Q&A

Introductions

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- One of the central study team will talk to the agenda
- If you have questions please enter them into the “Q&A” on the right side of your screen.
- Questions may be answered directly or to the whole group

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PROGRESS UPDATE

Current trial design

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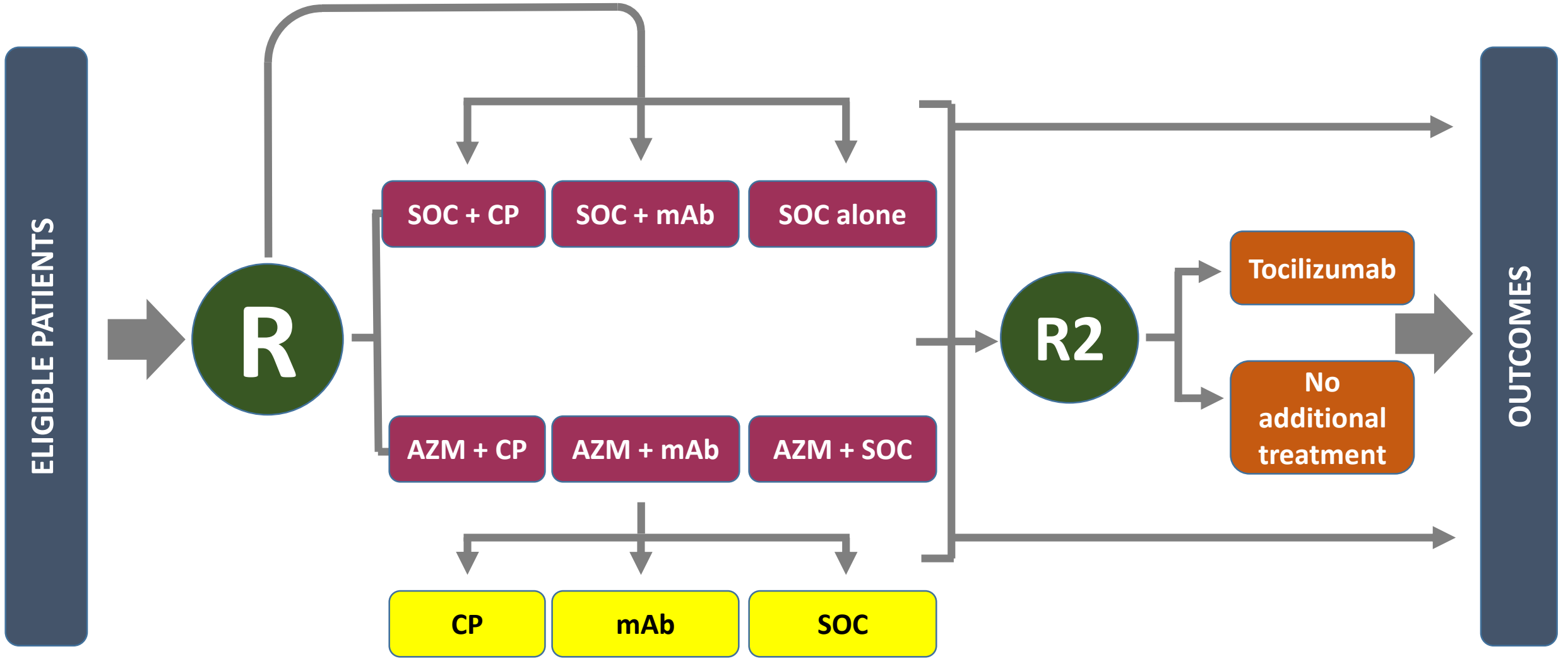

Recruitment by site and by time

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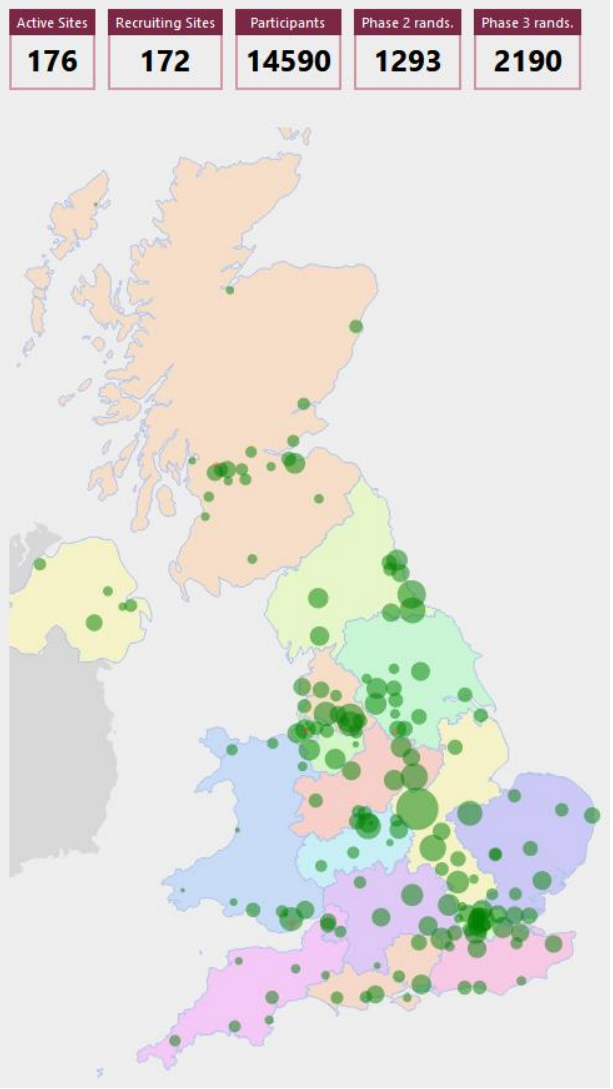

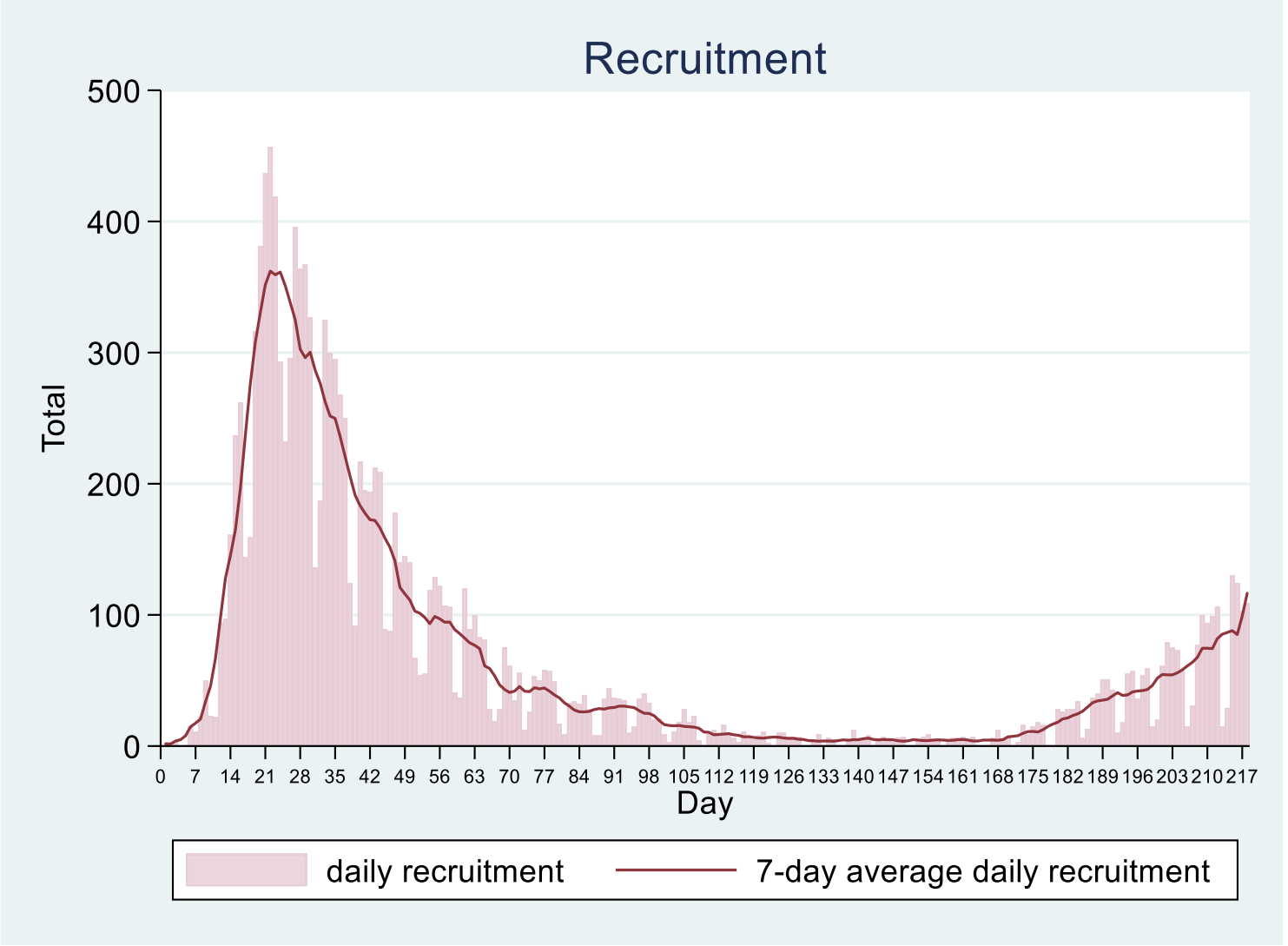

Recruitment

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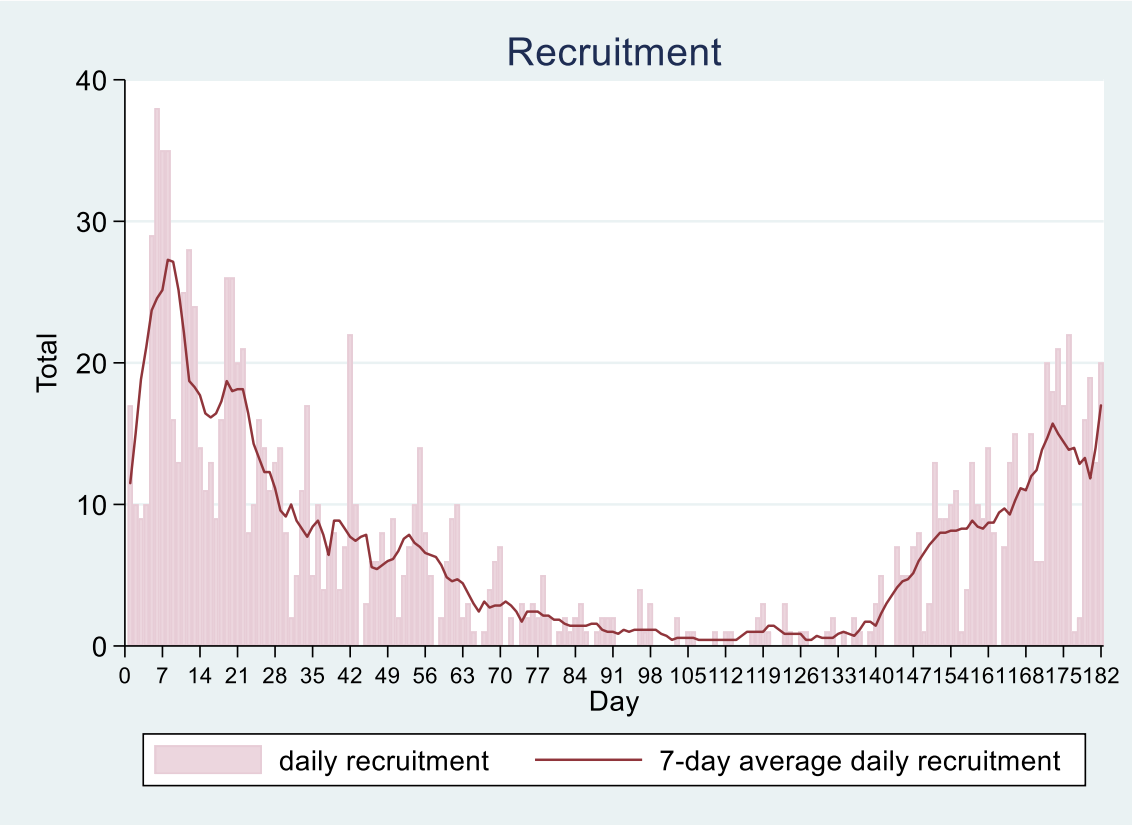
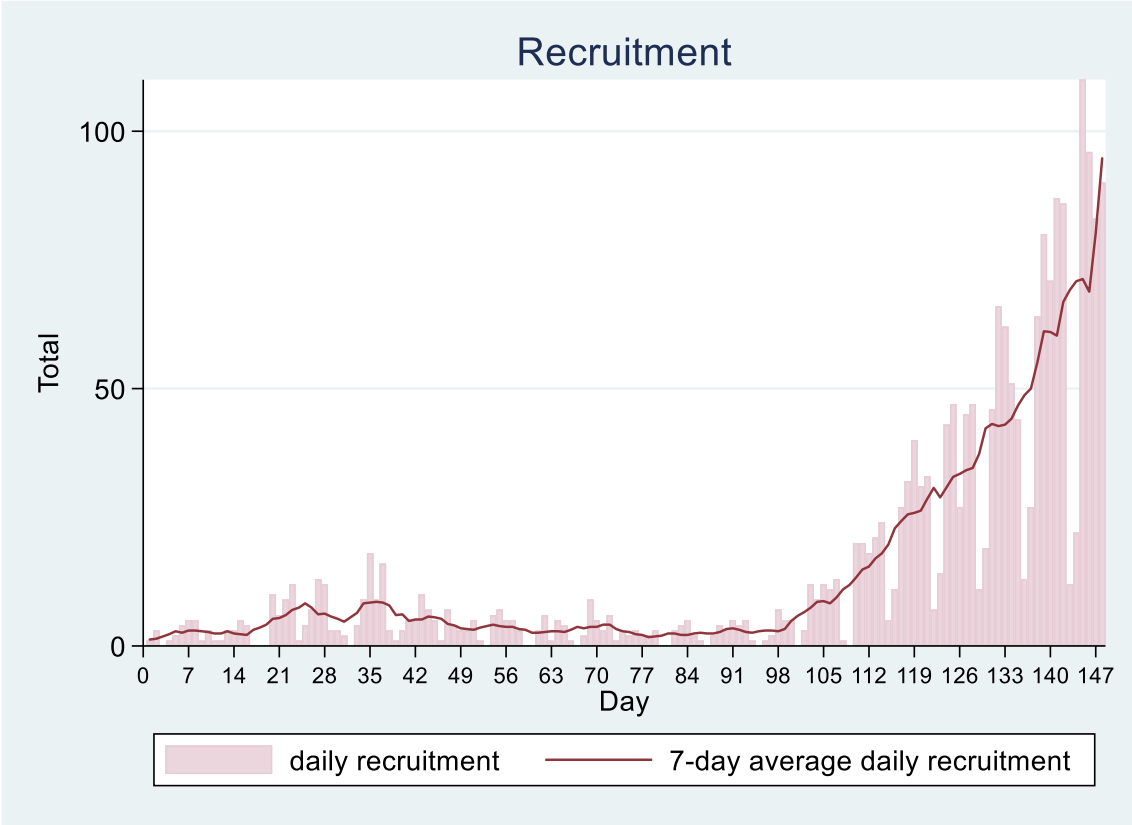
- Tocilizumab vs control



- Convalescent plasma vs REGN-COV2 vs control



Recruitment

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- As local outbreaks occur, please consider discussing with your teams how to ensure that all available admissions with Covid-19 are identified and enrolled if possible
  - Daily catch-up with admitting teams
  - Links with laboratory for all positive swabs among patients to be reported

- Average recruitment remains at about 12% of all COVID-19 admissions, but with significant variation between sites

Recruitment

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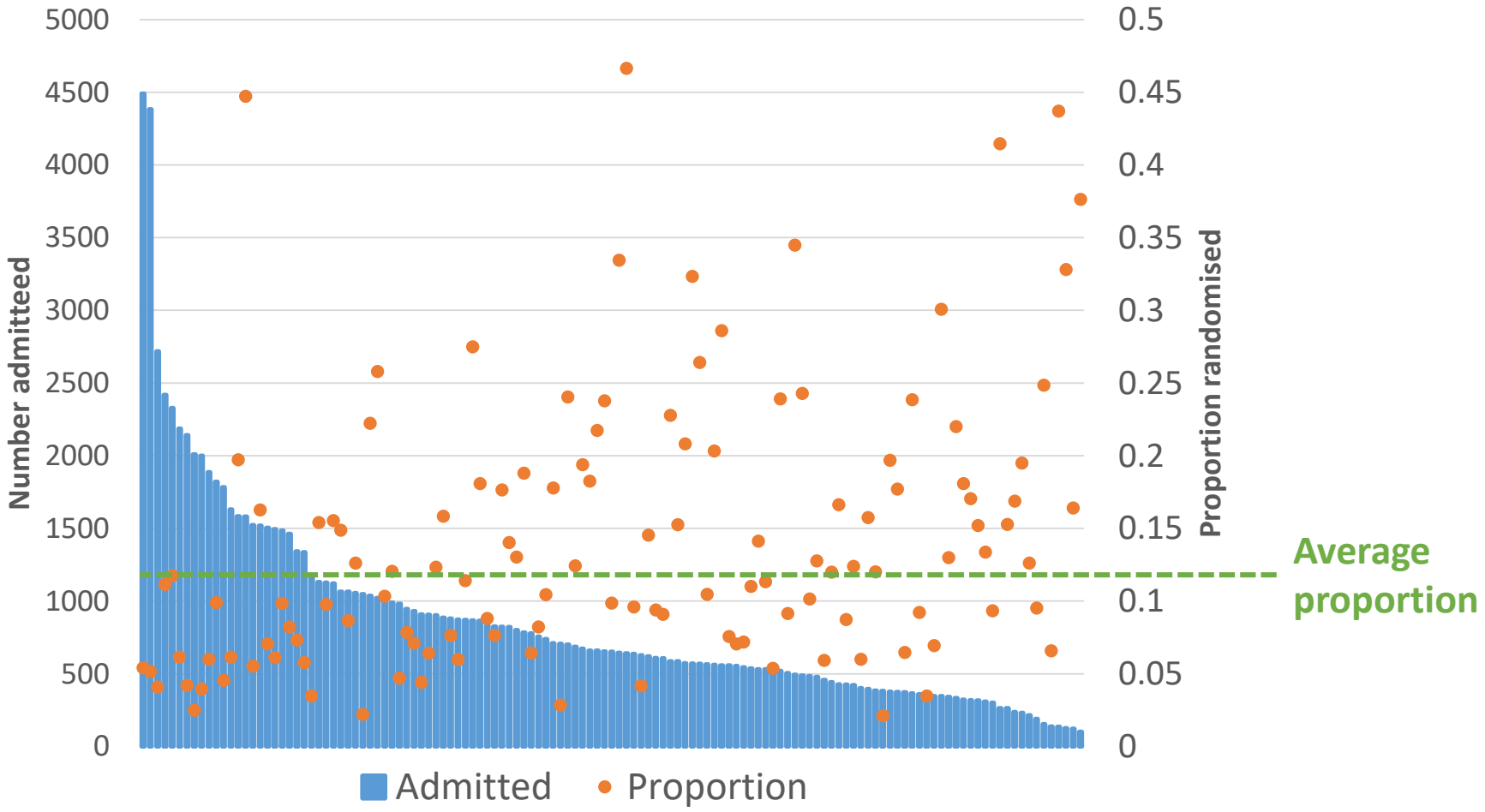

Recruitment

- Pilot of additional funding for weekend working in November

- Potential adoption onto NIHR Associate PI scheme (more details will follow)

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REGN-COV2

REGN-COV2

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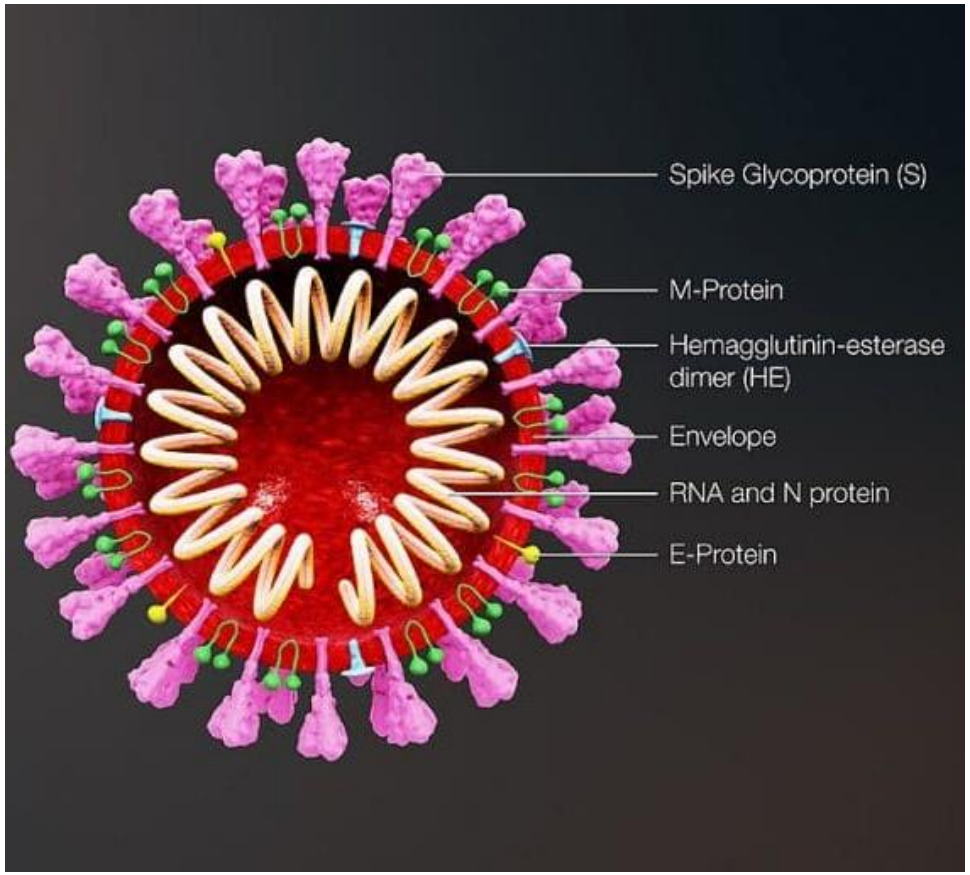
- REGN-COV2 is a mixture of two monoclonal antibodies (mAbs: REGN10933 and REGN10987)



- These are fully human antibodies directed against spike protein

- Two different antibodies mean that if virus mutates its spike protein such that one antibody doesn't bind so well, the other antibody probably still will

REGN-COV2 site setup

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1. Local PIs need to complete online training and confirmation form
   - They should ask other staff involved at site to also do this, but not require before site activation

2. Pharmacy need to be ready to support new arm
   - Review Pharmacy Manual on website and complete local risk assessment to determine where mAb will be prepared
   - Confirm staff details to RECOVERY team
   - Indicate when they will be ready to:
     1. Receive drug
     2. Support allocation to a trial participant

REGN-COV2 dos and don’ts

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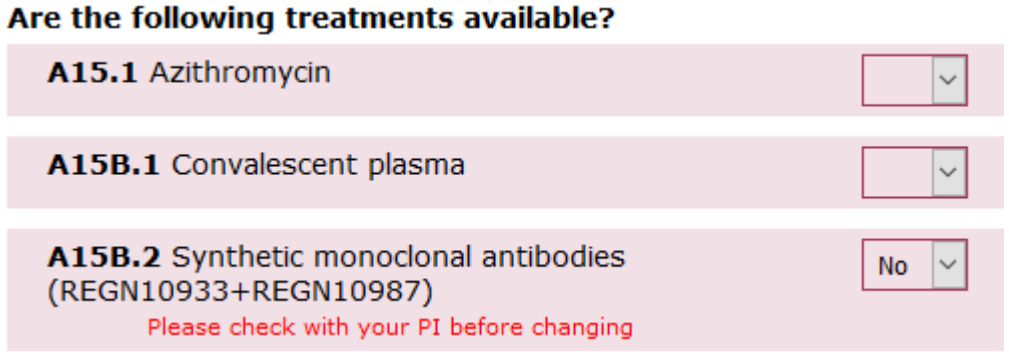
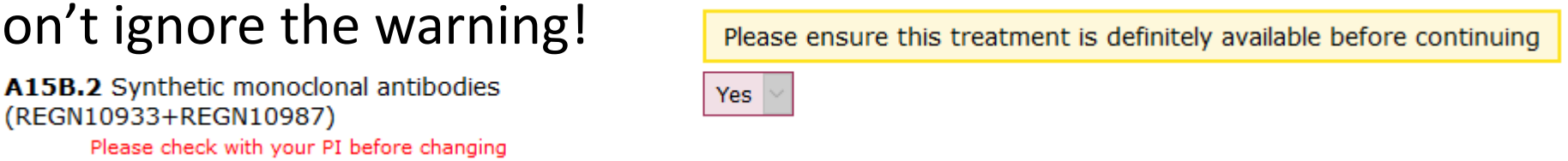
- Please **DO NOT** indicate REGN-COV2 is available if system suggests it is not *unless you are absolutely sure!*



- Please don’t ignore the warning!



- Otherwise the participant may be allocated a treatment they can’t have ☹

When to include REGN-COV2

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- REGN-COV2 should be administered as soon after randomisation as possible

- If being prepared in pharmacy, this may not be until next working day

- If delay is likely to be longer (e.g. at weekend), please indicate that mAb is unavailable on randomisation form so it will not be allocated

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TOCILIZUMAB

Tocilizumab

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- Several recent publications

Trial name	Number of participants	Number of deaths	HR (95% CI)
RCT-TCZ-COVID-19	126	4	2.1 (0.2-22.6)
CORIMUNO-19	131	15	0.92 (0.33-2.53)
BACC	243	12	1.52 (0.41-5.61)
COVACTA	438	86	1.02 (0.62-1.68)*
EMPACTA	389	~37*	not estimable

* Estimated from published data

- JAMA editorialist: “I plan to wait out the torrent of positive observational studies and reconsider tocilizumab’s use in COVID-19 if, and only if, more compelling data from randomized trials emerges.”

Tocilizumab

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- Nearly 1300 randomised
- Sufficient tocilizumab supply for 4000 randomised, but all now at sites
- Please ensure you consider this randomisation for appropriate participants:
  - On oxygen (or sats <92%)
  - CRP ≥75 mg/L

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OTHER DEVELOPMENTS

CTAP

Department of Health & Social Care

Guidance

Guidance: making a proposal for COVID-19 therapeutics clinical trials

Published 17 August 2020

Contents

Introduction

Given the success of the Phase III RECOVERY platform in delivering a single platform trial across the NHS, the UK Government has increased investment in an expanded platform which will operate for the next 24 months. This will include new treatments tested in Phase II and Phase III studies which will now be delivered through the RECOVERY platform (RECOVERY+) in patients admitted to hospital.

New treatments can be proposed for inclusion in the RECOVERY+ platform for both Phase II and Phase III trials. They will be considered by the UK COVID-19 Therapeutics Advisory Panel (UK-CTAP).

Subcommittees that have met to date:

- Antiviral
- Anticoagulation
- Immunomodulation
- Renin-angiotensin system

- One recommendation from CTAP is being discussed with manufacturer

- Outcome from anticoagulation subcommittee imminent

Pharmacogenomic substudy

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- Azithromycin known to prolong QT interval, but genetic determinants unknown

- Substudy for interested sites which requires:
  - ECG prior at baseline and 48h (uploaded to OpenClinica)
  - Co-enrolment into GenoMICC or ISARIC-4C encouraged (for genetic samples)

- Please e-mail recoverytrial@ndph.ox.ac.uk if interested

SOLIDARITY

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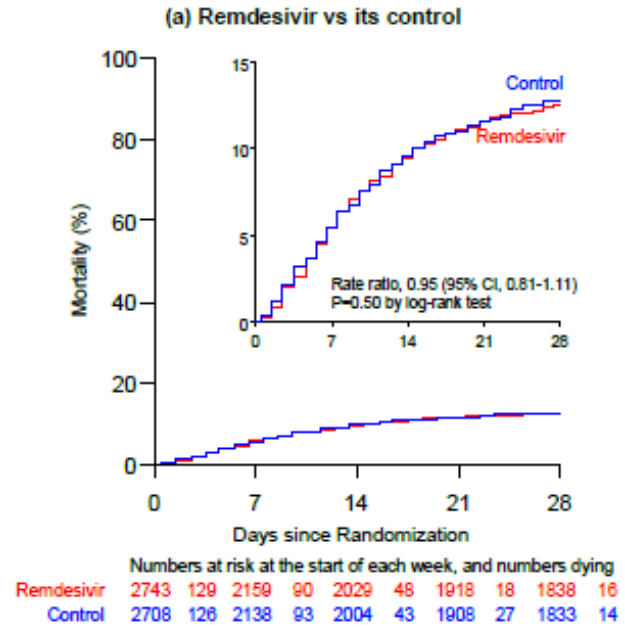
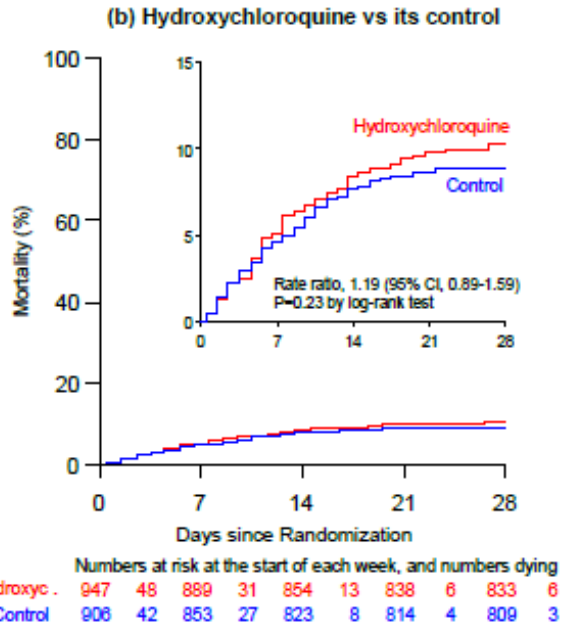
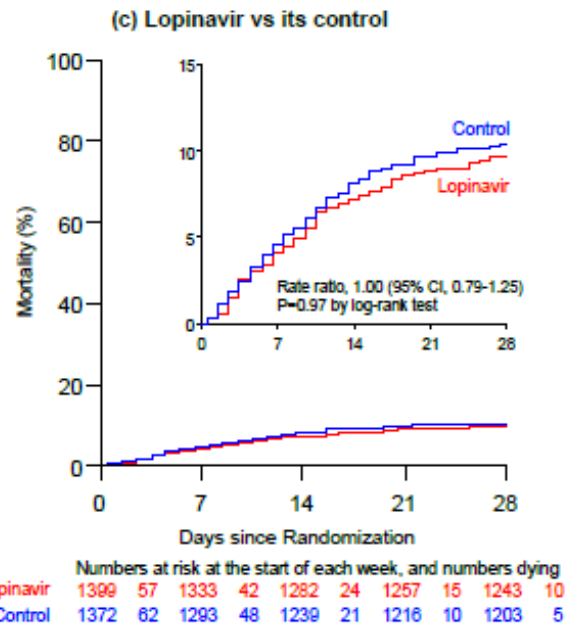
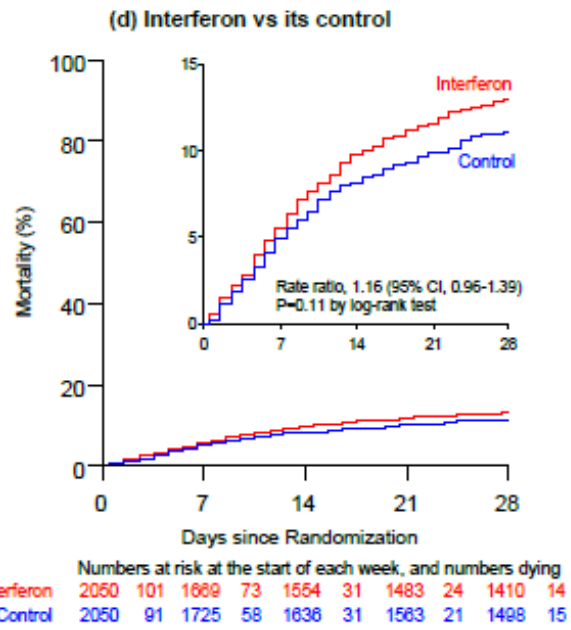
- 11,266 participants randomised in 30 countries









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TRIAL PROCEDURES

Serum samples

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- **All** participants entering antibody comparison (CP vs mAb vs control) need to have serum sample collected prior to randomisation

- Can be taken with G&S sample after consent prior to randomisation to limit venepunctures

- Must be taken for all participants in that comparison (regardless of allocation)

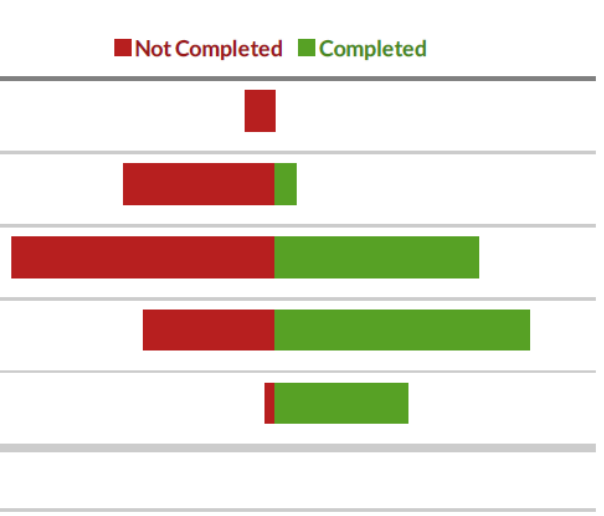
Completeness of follow-up

- Weekly reminders highlighting participants randomised >28 days ago without complete form **and also** those needing an Antibody Comparison 72h safety form

- Please do complete these as soon as possible

Follow-up form completion summary

Days Since Rand.	FU Not Completed	FU Completed	Total Rands.
7 ≤ 14	3 (100.0%)	0 (0.0%)	3
14 ≤ 21	15 (88.2%)	2 (11.8%)	17
21 ≤ 28	26 (56.5%)	20 (43.5%)	46
28 ≤ 35	13 (34.2%)	25 (65.8%)	38
> 35	1 (7.1%)	13 (92.9%)	14
Total	**58 (49.2%)**	**60 (50.8%)**	**118**



Carry on recruiting!

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- RECOVERY remains the largest global trial in COVID-19 and is an exemplar of what trials can do (both in and after pandemic)
- Current therapies are exciting, but need reliable data before they should be used routinely
- Thank you for your support!

Randomised Evaluation of COVID-19 Therapy: the RECOVERY trial

Collaborators' Meeting for Pregnancy

26 October 2020

RECOVERY for pregnant women

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1. Update on covid-19 and pregnancy
2. Update on adaptions
3. Update on UKOSS
4. Future plans
5. Q&A

Covid-19 and pregnancy

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RESEARCH

OPEN ACCESS

Check for updates

Characteristics and outcomes of pregnant women admitted to hospital with confirmed SARS-CoV-2 infection in UK: national population based cohort study

Marian Knight,[1] Kathryn Bunch,[1] Nicola Vousden,[2] Edward Morris,[3] Nigel Simpson,[4] Chris Gale,[5] Patrick O'Brien,[6] Maria Quigley,[1] Peter Brocklehurst,[7] Jennifer J Kurinczuk,[1] On behalf of the UK Obstetric Surveillance System SARS-CoV-2 Infection in Pregnancy Collaborative Group

For numbered affiliations see end of the article.

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Additional material is published online only. To view please visit the journal online.

Cite this as: *BMJ* 2020;369:m2107
http://dx.doi.org/10.1136/bmj.m2107

Accepted: 27 May 2020

ABSTRACT

OBJECTIVES

To describe a national cohort of pregnant women admitted to hospital with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection in the UK, identify factors associated with infection, and describ
infection, fo

DESIGN

Prospective
using the U

SETTING

All 194 obst

over, and 145 (34%) had pre-existing comorbidities. 266 (62%) women gave birth or had a pregnancy loss; 196 (73%) gave birth at term. Forty one (10%) women admitted to hospital needed respiratory support, and five (1%) women died. Twelve (5%) of 265 infants tested positive for SARS-CoV-2 RNA, six of them within

Maternal, Newborn and Infant Clinical Outcome Review Programme

MBRRACE-UK
Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK

Saving Lives, Improving Mothers' Care

Rapid report: Learning from SARS-CoV-2-related and associated maternal deaths in the UK

RESEARCH

OPEN ACCESS

Check for updates

FAST TRACK

Clinical manifestations, risk factors, and maternal and perinatal outcomes of coronavirus disease 2019 in pregnancy: living systematic review and meta-analysis

John Allotey,[1,2] Elena Stallings,[3,4] Mercedes Bonet,[5] Magnus Yap,[6] Shaunak Chatterjee,[6] Tania Kew,[6] Luke Debenham,[6] Anna Clavé Llavall,[6] Anushka Dixit,[6] Dengyi Zhou,[6] Rishab Balaji,[6] Siang Ing Lee,[1] Xiu Qiu,[7,8,9] Mingyang Yuan,[1,7] Dyuti Coomar,[1] Madelon van Wely,[10] Elizabeth van Leeuwen,[11] Elena Kostova,[10] Heinke Kunst,[12,13] Asma Khalil,[14] Simon Tiberi,[12,13] Vanessa Brizuela,[5] Nathalie Broutet,[5] Edna Kara,[3] Caron Rahn Kim,[5] Anna Thorson,[5] Olufemi T Oladapo,[5] Lynne Mofenson,[15] Javier Zamora,[3,4,16] Shakila Thangaratinam,[2,17] for PregCOV-19 Living Systematic Review Consortium

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Additional material is published
ase visit

ABSTRACT

OBJECTIVE

To determine the clinical manifestations, risk factors, and maternal and perinatal outcomes in pregnant and recently pregnant women with suspected or confirmed coronavirus disease 2019 (covid-19).

DESIGN
Livin

DATA
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meta-analysis was performed, with estimates pooled as odds ratios and proportions with 95% confidence intervals. All analyses will be updated regularly.

RESULTS

77 studies were included. Overall, 10% (95% confidence interval 7% to14%; 28 studies, 11 432

EDITORIALS

Check for updates

Include pregnant women in research—particularly covid-19 research

Adapting interventions and changing attitudes will drive scientific progress

Marian Knight,[1] R Katie Morris,[2] Jenny Furniss,[3] Lucy C Chappell[4]

1 National Perinatal Epidemiology Unit, Nuffield Department of Population Health, University of Oxford, Oxford, UK

2 Institute of Applied Health Research, University of Birmingham, Birmingham, UK

3 UK Obstetric Surveillance System Steering Committee, National Perinatal Epidemiology Unit, Oxford, UK

4 School of Life Course Sciences, King's College London, London, London, UK

Correspondence to: L C Chappell
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Cite this as: *BMJ* 2020;370:m3305
http://dx.doi.org/10.1136/bmj.m3305
Published: 25 August 2020

The UK Confidential Enquiries into Maternal Deaths have repeatedly highlighted inequities in the medical treatment of pregnant and postpartum women, noting that women are denied investigations and life preserving treatments simply because they are pregnant or breastfeeding.[1,2] These inquiries emphasise that the default position should be to investigate and treat pregnant and breastfeeding women in the same way as non-pregnant women, unless there are clear reasons not to.[1]

Clinical trials, particularly those of drug treatments, have typically automatically excluded pregnant or breastfeeding women, meaning data are unavailable

or breastfeeding allows safety concerns to be allayed for women, their families, and healthcare professionals.

Even if regulatory barriers have been overcome, gatekeeping or inertia may occur if local ethics committees take an overwhelming precautionary approach, overriding recognition of the potential benefits of including pregnant and breastfeeding women. This problem can be mitigated by a strong network of maternity researchers, familiar with delivering drug trials in pregnancy, who can be rapidly mobilised to help implement studies.

Covid-19 and pregnancy

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Headline messages:

- Covid-19 affects pregnant women
- Additional risk factors identified
- Pregnant and postnatal women need evidence-based treatments
- Actively include pregnant and postnatal women in research

- RECOVERY trial has changed clinical practice, including for pregnant women

Covid-19 and pregnancy: RCOG

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THE ROYAL COLLEGE OF MIDWIVES

Royal College of Obstetricians & Gynaecologists

Coronavirus (COVID-19) Infection in Pregnancy

Information for healthcare professionals

Version 12: Published Wednesday 14 October 2020

The interim results of the RECOVERY trial demonstrated a significant reduction in 28-day mortality for individuals with COVID-19 requiring oxygen who were given steroid therapy (age-adjusted rate ratio 0.83; 95% CI 0.75–0.93; P<0.001),[103] and this has been recommended for use in the NHS.[104] The RECOVERY trial protocol for pregnancy recommends prednisolone 40 mg orally once daily, and, in women unable to take oral medicine, hydrocortisone 80 mg intravenously twice daily instead of dexamethasone treatment.[16 105 106]

Remdesivir is currently subject to a therapeutic alert for pregnancy; it should be avoided unless benefits outweigh risks, following multidisciplinary discussion.[107] Remdesivir is an antiviral medication which has been shown to be associated with a reduction in time to clinical improvement in individuals with severe COVID-19, median 11 versus 15 days, rate ratio 1.32 (95% CI 1.12–1.55).[108]

Pregnant women can be enrolled in the RECOVERY trial.

Where therapies or participation in trials are offered, they should also be considered for and offered to pregnant women.

RECOVERY for pregnant women

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HOME FOR PATIENTS FOR SITE STAFF RESULTS NEWS Search

For Site Staff / site teams

Site teams

This page contains additional information for RECOVERY site team members. Follow these links for guidance on randomisation and how to collect follow-up data.

RECOVERY Privacy Notice for Trial Staff

INTERVENTION INFORMATION

RECOVERY intervention sheet - dexamethasone (now only recruiting children)

RECOVERY intervention sheet - azithromycin

RECOVERY intervention sheet - tocilizumab

RECOVERY intervention sheet - assessing patients for risk of transfusion associated circulatory overload (TACO) prior to convalescent plasma transfusions

RECOVERY Laboratory Standard Operating Procedure (SOP) v2

REGN-COV2 administration quick reference guide

Arrhythmia sub study user guide

GUIDES FOR SPECIFIC PATIENT GROUPS

RECOVERY for paediatric patients

RECOVERY for patients with chronic kidney disease

RECOVERY for pregnant and breastfeeding women

RECOVERY and remdesivir

COLLABORATORS' MEETINGS SLIDES

We apologise if you were unable to join the meetings.

6 October 2020

5 October 2020

14 & 15 September 2020

3 & 4 August 2020

14 July 2020

13 July 2020

30 June 2020

29 June 2020

16 June 2020

15 June 2020

Pregnancy information document

RECOVERY
Randomised Evaluation of COVID-19 Therapy

RANDOMISED EVALUATION OF COVID-19 THERAPY (RECOVERY)

for pregnant and breastfeeding women

Pregnancy leads: Prof Lucy Chappell, Prof Marian Knight

	RECOVERY trial protocol	Adaption for pregnancy
Eligibility	Patients are eligible if all of the following are true: i. Hospitalised ii. SARS-CoV-2 infection iii. No medical history that might, in the opinion of the attending clinician, put the patient at significant risk if he/she were to participate in the trial	Same eligibility
Interventions	**First randomisation part A** • No additional treatment • Azithromycin **First randomisation part B** • Convalescent plasma • Synthetic neutralising antibodies **Second randomisation** • Tocilizumab	Same interventions
Follow-up/ outcomes	Ascertained at the time of death or discharge or at 28 days after randomisation (whichever is sooner): ➢ Vital status (alive/ dead, with date and presumed cause of death, if appropriate) ➢ Hospitalisation status (inpatient/ discharged, with date of discharge, if appropriate) ➢ Use of ventilation (none/ previous/ ongoing, with days of use and type, if appropriate) ➢ Use of renal dialysis or haemofiltration (none/ previous/ ongoing)	Same follow-up and outcomes, with addition of UKOSS COVID-19 case number (for pregnancy and baby information) to allow later data linkage
		Adaptions for breastfeeding
		The same interventions should be used. UKOSS COVID-19 case number added if available.

Frequently asked questions

1. **Are the drugs safe in pregnancy?** The pregnancy leads for the trial have reviewed the safety literature (Annex A), and experience around using these drugs for other conditions, and consider that participation in the trial is reasonable for pregnant and breastfeeding women. The regulators (MHRA and HRA) have agreed to the inclusion of pregnant women.

Eligibility = same

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2.1 Eligibility

Patients are eligible for the study if all of the following are true:

(i) Hospitalised
(ii) SARS-CoV-2 infection (clinically suspected[1] or laboratory confirmed)
(iii) No medical history that might, in the opinion of the attending clinician, put the patient at significant risk if he/she were to participate in the trial

- No criterion for ‘requiring oxygen’

Offer the RECOVERY trial if…

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- Are you uncertain about the benefits of treatment or not for this woman, and whether it might ‘treat’ or prevent deterioration?
- If you are uncertain, then provide the trial information to the woman, offer the trial and make a shared decision.

- **For any woman reportable to UKOSS, ask yourself whether you can offer her participation in RECOVERY**

Interventions = the same

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Current trial design

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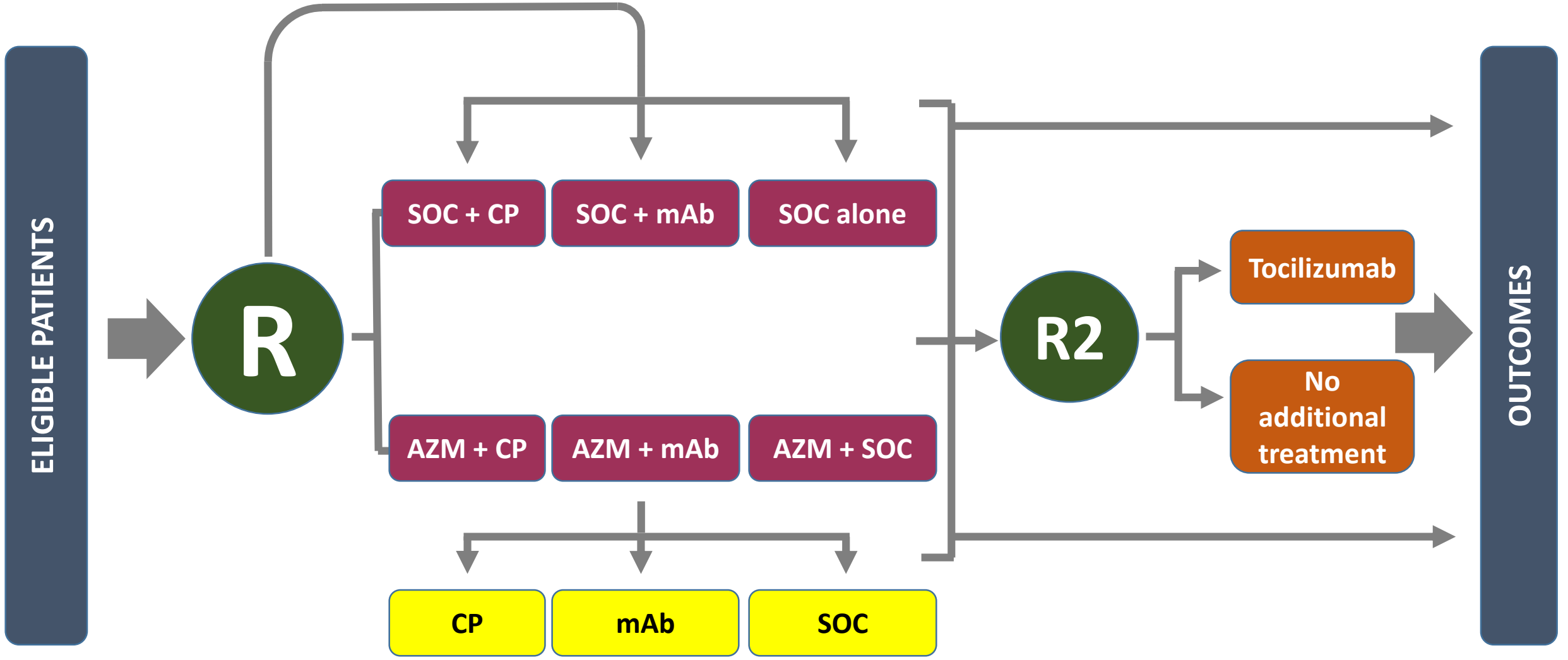

Use of drugs in pregnancy

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Azithromycin
Azithromycin is used in pregnancy to treat genital Chlamydia trachomatis infection, with a Cochrane systematic review and meta-analysis reporting fewer gastrointestinal side-effects compared to erythromycin, and inconsistent results on risk of preterm birth, preterm rupture of membranes, perinatal mortality and low birthweight, confounded by the indication for treatment.[1] A recent systematic review and meta-analysis of all macrolide antibiotics acknowledges potential bias in child outcome reports due to treatment indication.[2] The UK Teratology Information Service monograph concludes that there is no definitive evidence linking azithromycin with increased risk of miscarriage or congenital malformations (https://www.medicinesinpregnancy.org/bumps/monographs/USE-OF-MACROLIDES-IN-PREGNANCY/). Azithromycin is detected in only low levels in breastmilk and is not expected to cause adverse events in breastfed infants (reviewed in Lactmed database: www.ncbi.nlm.nih.gov/books/NBK501200/) Azithromycin has also been used in several trials in preterm infants as a prophylactic treatment to prevent bronchopulmonary dysplasia.[3]

Convalescent plasma (prepared with Dr Sue Pavord, Consultant Haematologist)
Convalescent plasma is plasma from people who had confirmed COVID-19 (SARS-Cov-2) infection, and have now recovered and been free of the infection for 28 days. The plasma contains antibodies that their immune systems have produced in fighting the virus. It is hoped that giving this plasma will help speed up recovery of a patient with active infection and improve their chances of survival. Plasma is already used as a treatment in pregnant patients who are bleeding,[4] or have particular blood conditions.[5, 6] The plasma being used in this trial is from a selected donor and hopefully contains anti-SARS-Cov-2 antibodies, but is otherwise no different. Plasma infusions can occasionally cause side effects. Mostly this is a rise in temperature, itching or a rash, and in very extreme cases, anaphylaxis. Other potential complications include breathlessness and changes in blood pressure. Monitoring of pulse and blood pressure takes place before and after the infusion. There is no risk of miscarriage or fetal loss, preterm birth, preterm rupture of membranes, perinatal mortality or low birthweight, from plasma transfusions and there are no concerns with breast feeding.

Monoclonal antibodies (prepared with Dr Ken Hodson, Medical Director, UK TIS)
Monoclonal antibodies have been used as therapeutic agents in pregnancy over recent years, for a variety of conditions. Human monoclonal antibodies in use in pregnancy include anti-TNF agents, such as adalimumab, indicated for a variety of chronic inflammatory diseases such as rheumatoid arthritis and inflammatory bowel disease. Data have recently accumulated from a variety of cohort and registry studies indicating that such exposure in pregnancy was not associated with an increased risk for adverse pregnancy outcomes, when compared to unexposed pregnancies with the same underlying medical diseases.[7] This is supported by a consensus report on immunosuppressives and biologics during pregnancy and lactation, confirming no evidence of elevated adverse pregnancy outcomes or malformation risks.[8] Some monoclonal antibodies are transported across the placenta (and may also enter breast milk) but as REGN10933 and REGN10987 do not have any human targets such exposure should not be associated with risk of harm. Pregnant women, just like other patients with COVID-19, are at significant risk from the infection itself (particularly those in the third trimester.[9, 10] All pregnant women in RECOVERY are entered into the UK Obstetric Surveillance System which follows all pregnancies to their conclusion.[10] Given the early safety experience with REGN10933+REGN10987 it would appear

Follow-up = the same, + linkage

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NPEU

Nuffield Department of
POPULATION HEALTH

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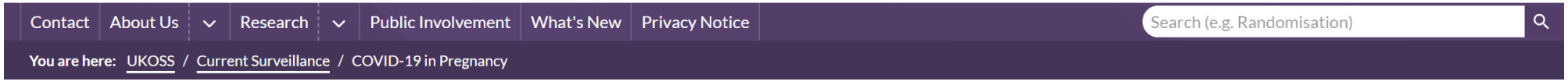

COVID-19 in Pregnancy

UKOSS
UK Obstetric Surveillance System

Key points

- Covid-19 is an infectious disease caused by a new strain of coronavirus.
- Covid-19 had not been detected in humans before the outbreak in December 2019.
- As the virus is new, little is known about its effect on certain groups of people, including pregnant women.

Surveillance period

1st March 2020 – 31st March 2021

Background

On this page

Update on progress

RECOVERY
Randomised Evaluation of COVID-19 Therapy

- 160 pregnancy leads identified, supported by research midwives
- Midwife champions on board

- 30 antenatal women recruited and more postpartum women

Gestation at symptom onset

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UKOSS
UK Obstetric Surveillance System

RESEARCH

OPEN ACCESS

Check for updates

Characteristics and outcomes of pregnant women admitted to hospital with confirmed SARS-CoV-2 infection in UK: national population based cohort study

	Number of women (%)
<22 weeks	22 (5)
22-27 weeks	60 (14)
28-36 weeks	170 (40)
37 or more weeks	172 (40)
Missing	3

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Outcomes for women
**updated 07/10/20

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	Number of women (%) (N=427)
Required critical care	41 (10)
Required ECMO	4 (1)
SARS-CoV-2 pneumonia on imaging	101 (24)
Final outcome	
Died	5 (1)
Discharged well	418 (98)
Missing	4 (1)

Maternal mortality rate 5.8 (95% CI 1.9 to 13.5) per 100,000 maternities

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Pregnancy and infant outcomes*

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	Number of women (%) (N=427)
Ongoing pregnancy/pregnancy outcome unknown	24 (6)
Pregnancy completed	403 (94)
Pregnancy loss	4 (1)
Stillbirth	3 (1)
Live birth	396 (98) (7 twin pregnancies)
Neonatal death	2 (1)
Gestation at birth (weeks)	
22-31	25 (6)
32-36	55 (14)
37 or more	315 (79)
Unknown	4 (1)
Mode of birth	
Caesarean – maternal indication due to SARS-CoV-2	43 (11)
Caesarean – other indication	164 (41)
Vaginal	192 (48)
Pre-eclampsia	10 (2)

* Updated 07/10/2020

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Infant outcomes (live born infants)

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	Live born infants of women with Sars-CoV-2 (N=401)
	Number (%)
NICU Admission	85 (21)
Positive SARS-CoV-2 test	
No	388 (97)
Positive test <12 hrs of age	6 (1) Only 1 (0.2%) had confirmed infection
Positive test ≥12 hrs of age	7 (2)

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ICNARC data (critical care)

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icnarc intensive care national audit & research centre
25 years and counting...

Napier House
24 High Holborn
London WC1V 6AZ
email: COVID-19@icnarc.org
www.icnarc.org

ICNARC report on COVID-19 in critical care:

England, Wales and Northern Ireland

23 October 2020

Table 2. Patient characteristics: medical history

Medical history	Patients with confirmed COVID-19	
	Admitted from 1 Sep (N=1761)	Admitted up to 31 Aug (N=10,904)
Dependency prior to admission to acute hospital, n (%) [N=1567]		
Able to live without assistance in daily activities	1391 (88.8)	9653 (89.4)
Some assistance with daily activities	174 (11.1)	1109 (10.3)
Total assistance with all daily activities	2 (0.1)	40 (0.4)
Very severe comorbidities *, n (%) [N=1600]		
Cardiovascular	16 (1.0)	70 (0.6)
Respiratory	24 (1.5)	126 (1.2)
Renal	24 (1.5)	186 (1.7)
Liver	9 (0.6)	50 (0.5)
Metastatic disease	11 (0.7)	59 (0.5)
Haematological malignancy	27 (1.7)	212 (2.0)
Immunocompromise	79 (4.9)	386 (3.6)
CPR within previous 24h, n (%) [N=1618]		
In the community	8 (0.5)	50 (0.5)
In hospital	12 (0.7)	76 (0.7)
Prior hospital length of stay [N=1726]		
Mean (SD)	2.3 (4.5)	2.5 (6.2)
Median (IQR)	1 (0, 3)	1 (0, 3)
Currently or recently pregnant, n (% of females aged 16-49) [N=144]		
Currently pregnant	15 (10.4)	29 (3.7)
Recently pregnant (within 6 weeks)	6 (4.2)	41 (5.2)
Not known to be pregnant	123 (85.4)	718 (91.1)

Recognition of severe illness

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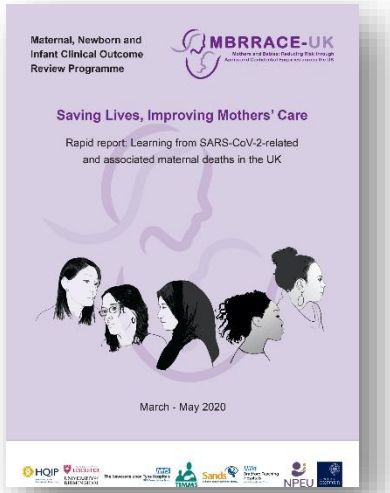
MBRRACE-UK
Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK



A woman in her third trimester of pregnancy presented to the Emergency Department with a one week history of symptoms of COVID-19. Her observations were documented using a National Early Warning Score (NEWS) and not a modified early obstetric warning score (MEOWS). She had a respiratory rate of 36 but this was not recognised as significant. Her first review by a member of obstetric staff was eleven hours after she attended, when a junior obstetrician identified no obstetric concerns. She deteriorated a few days later and was documented to need high dependency or intensive care but no beds were available in either high dependency or intensive care areas. Her care was discussed with a consultant obstetrician at the time of her deterioration and a decision made for a caesarean birth. Following the birth, it was again noted that no beds were available and she was transferred back to a general ward where she deteriorated. She was intubated and transferred to the intensive care unit but her condition continued to worsen and she died a few days later.

Ensure all pregnant or post-partum women with COVID-19 receive multidisciplinary team care and obstetric leadership with daily review. This is essential in order to ensure timely recognition of deterioration, early assessment of the need for iatrogenic birth to help respiratory function and identification of postnatal complications.

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Next steps

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- Anticipate ongoing new cases over coming weeks
- Check team (and new doctors) are ready for recruitment
- Think through pathways for notification of cases
- Use UKOSS as prompt to help (and for outcomes)
- Link with main RECOVERY research teams
- Embed into usual practice
- Offer trial

Q&A

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