

ISARIC/WHO Clinical Characterisation Protocol for Severe Emerging Infections (UK)

SARI Case Report Form

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GENERAL GUIDANCE

- The CRF is designed to collect data obtained through examination, interview and review of hospital notes. Data may be collected retrospectively if the patient is enrolled after the admission date.
- Participant Identification Numbers consist of a 5-digit CPMS site code and a 4 digit participant number. You can obtain a site code by contacting your local R&D office or CCP@liverpool.ac.uk . Participant numbers should be assigned sequentially for each site beginning with 0001. In the case of a single site recruiting participants on different wards, or where it is otherwise difficult to assign sequential numbers, it is acceptable to assign numbers in blocks or incorporating alpha characters. E.g. Ward X will assign numbers from 0001 or A001 onwards and Ward Y will assign numbers from 5001 or B001 onwards. Enter the Participant Identification Number at the top of every page.
- Case Report Form Data should be entered to the central database at <https://ncov.medsci.ox.ac.uk>
- REDCap registration access is obtained by contacting ncov@isaric.org please state “[CCP-UK REDCap ACCESS]” in the title
- Please contact us at ncov@isaric.org we can help with database problems
- In the case of a participant transferring between study sites, it is preferred to maintain the same Participant Identification Number across the sites. When this is not possible, space for recording the new number is provided.
- Complete every line of every section, except for where the instructions say to skip a section based on certain responses.
- Selections with square boxes () are single selection answers (choose one answer only). Selections with circles () are multiple selection answers (choose as many answers as are applicable).
- Mark ‘N/A’ for any results of laboratory values that are not available, not applicable or unknown.
- Avoid recording data outside of the dedicated areas. Sections are available for recording additional information.
- We recommend writing clearly in black ink, using BLOCK-CAPITAL LETTERS.
- Place an (X) when you choose the corresponding answer. To make corrections, strike through (-----) the data you wish to delete and write the correct data above it. Please initial and date all corrections.
- Please keep all of the sheets for a single participant together e.g. with a staple or participant-unique folder.
- DO NOT SEND CRFs to anyone by email or post.
- These two FRONT PAGES do not need to be retained.

ISARIC/WHO Clinical Characterisation Protocol for Severe Emerging Infections**SARI Case Report Form****CORE CASE RECORD FORM**

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Date of enrolment [__] [__] / [__] [__] / [2_] [0_] [Y_] [Y_] Site Location _____

CLINICAL INCLUSION CRITERIAProven or high likelihood of infection with pathogen of Public Health Interest YES NO

Experience of the following symptoms during this illness episode: (one or more required for inclusion)

A history of self-reported feverishness or measured fever of $\geq 38^{\circ}\text{C}$: YES NOCough: YES NODyspnoea (shortness of breath) OR Tachypnoea*: YES NOClinical suspicion of ARI despite not meeting criteria above: YES NO** respiratory rate ≥ 50 breaths/min for <1 year; ≥ 40 breaths/min for 1-4 years; ≥ 30 breaths/min for 5-12 years; ≥ 20 breaths/min for ≥ 13 years***EPIDEMIOLOGICAL FACTORS**

In the 14 days before onset of illness had any of the following:

A history of travel to an area with documented cases of infection of a respiratory pathogen of public health interest in the context of an outbreak, suspected outbreak or incident of a respiratory pathogen of public health interest YES NO Not known**Close contact* with a confirmed or probable case of infection with the respiratory pathogen of public health interest, while that patient was symptomatic** YES NO Not known**Presence in a healthcare facility where infections caused by the respiratory pathogen of public health interest have been managed** YES NO Not known**Presence in a laboratory handling samples suspected or confirmed of having the respiratory pathogen of public health interest present** YES NO Not known**An otherwise unexplained respiratory illness in the context of an outbreak, suspected outbreak or incident of a respiratory pathogen of public health interest** YES NO Not known**Direct contact with animals in countries where the pathogen of public health interest is known to be circulating in animal populations or where human infections have occurred as a result of presumed zoonotic transmission** YES NO Not known

* Close contact' is defined as:

- Health care associated exposure, including providing direct care for patients, e.g. health care worker, direct exposure to body fluids or specimens including aerosols, working with health care workers infected with the pathogen of public health interest, visiting patients or staying in the same close environment of relevant case.
- Working together in close proximity or sharing the same classroom environment with a relevant case
- Traveling together with in any kind of conveyance with a relevant case
- Living in the same household as a relevant case

CORE CASE RECORD FORM

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DEMOGRAPHICS

Sex at Birth: Male Female Not specified *Date of birth [_] [_] / [_] [_] / [_] [_] [_] [_]

* WHERE DATA IS BEING COLLECTED WITHOUT CONSENT FOR TIER ZERO, ONLY RECORD AGE AND NOT DATE OF BIRTH

If date of birth is unknown or for Tier Zero, record Age [_] [_] [_] years OR [_] [_] months

Ethnic group (check all that apply):

 Arab Black East Asian South Asian West Asian Latin American White Aboriginal/First NationsOther: _____ N/AEmployed as a Healthcare Worker? YES NO N/AEmployed in a Microbiology laboratory? YES NO N/APregnant? YES NO Unknown N/A If YES: Gestational weeks assessment: [_] [_] weeksPOST PARTUM (within six weeks of delivery)? YES NO or N/A (skip this section - go to INFANT)Pregnancy Outcome: Live birth Still birth Delivery date: [_] [_] / [_] [_] / [2] [0] [_] [_]Baby tested for Mother's ARI infection? YES NO N/A If YES: Positive Negative Method: PCR Other: _____INFANT – Less than 1 year old? YES NO (skip this section) Birth weight: [_] [_] . [_] [_] kg or [_] [_] lbs N/AGestational: Term birth (≥ 37 wk GA) Preterm birth (< 37 wk GA) if < 37 wk Estimated gestation _____ weeks N/ABreastfed? YES NO N/A If YES: Currently breastfed Breastfeeding discontinued at [_] [_] weeks N/AAppropriate development for age? YES NO N/AVaccinations appropriate for age/country? YES NO Unknown N/A

ONSET AND ADMISSION

Symptom onset date of first/earliest symptom: [_] [_] / [_] [_] / [2] [0] [_] [_]

Admission date at this facility: [_] [_] / [_] [_] / [2] [0] [_] [_]

Time of admission (24-hour format): [_] [_] / [_] [_]

Transfer from other facility? YES-facility is a study site YES-facility is not a study site NO N/AIf YES: Name of transfer facility: _____ N/AIf YES: Admission date at transfer facility (DD/MM/YYYY): [_] [_] / [_] [_] / [2] [0] [_] [_] N/AIf YES-Study Site: Participant ID # at transfer facility: Same as above Different: [_] [_] [_] - [_] [_] [_] [_] N/ATravel in the 14 days prior to first symptom onset? YES NO N/A If YES, complete the

If YES, state location(s) & date(s): Country: _____ City/Geographic area: _____

Return Date: [_] [_] / [_] [_] / [2] [0] [_] [_] N/A (if more use TRAVEL EXPOSURE CRF)

Contact with animals, raw meat or insect bites in the 14 days prior to symptom onset?

 YES NO Unknown N/A If YES, complete the ANIMAL EXPOSURE CRF

CORE CASE RECORD FORM

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ADMISSION AND DAILY TREATMENT (complete every line):**DATE OF ASSESSMENT** (DD/MM/YYYY): [_] [_] / [_] [_] / [_ 2] [_ 0] [_ Y] [_ Y]

Record the worst value between 00:00 to 24:00 on day of assessment (if Not Available write 'N/A'):

Current admission to ICU/ITU/IMC/HDU? YES NO N/A**Done** YES NO FiO_2 (0.21-1.0) [_] [_] [_] or [_] [_] L/min**Done** YES NO SaO_2 [_] [_] [_] %**Done** YES NO PaO_2 at time of FiO_2 above [_] [_] [_] kPa or mmHg**Done** YES NO PaO_2 sample type: Arterial Venous Capillary N/A**Done** YES NO From same blood gas record as PaO_2 PCO_2 _____ kPa or mmHg**Done** YES NO pH _____**Done** YES NO HCO_3^- _____ mEq/L**Done** YES NO Base excess _____ mmol/L**Done** YES NO AVPU Alert [_] Verbal [_] Pain [_] Unresponsive [_] Glasgow Coma Score (GCS / 15) [_] [_]**Done** YES NO Systolic Blood Pressure [_] [_] [_] mmHg**Done** YES NO Diastolic Blood Pressure [_] [_] [_] mmHg**Done** YES NO Mean Arterial Blood Pressure [_] [_] [_] mmHg**Done** YES NO Urine flow rate [_] [_] [_] [_] [_] mL/24 hours Check if estimated

Is the patient currently receiving, or has received (from 00:00 to 24:00) on day of assessment) (apply to all questions in this section)

Non-invasive ventilation (e.g. BIPAP, CPAP)? YES NO N/A **Invasive ventilation?** YES NO N/A**High-flow nasal canula oxygen therapy?** YES NO N/A **ECLS/ECMO?** YES NO N/A**Dialysis/Hemofiltration?** YES NO N/A**Any vasopressor/inotropic support?** YES NO (if NO, answer the next 3 questions NO) N/ADopamine <5µg/kg/min OR Dobutamine OR milrinone OR levosimendan: YES NODopamine 5-15µg/kg/min OR Epinephrine/Norepinephrine < 0.1µg/kg/min OR vasopressin OR phenylephrine: YES NODopamine >15µg/k/min OR Epinephrine/Norepinephrine > 0.1µg/kg/min: YES NO**Neuromuscular blocking agents?** YES NO N/A **Inhaled Nitric Oxide?** YES NO N/A**Prone positioning?** YES NO N/A **Tracheostomy inserted?** YES NO N/A**Other intervention or procedure:** YES NO N/A If YES, Specify: _____

DAILY CASE RECORD FORM

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DAILY LABORATORY RESULTS

(DD/MM/YYYY): [__][__]/[__][__]/[2][0][__][__]

Record the worst value between 00:00 to 24:00 on day of assessment (if Not Available write 'N/A'):

Done YES NO Haemoglobin _____ g/L or g/dLDone YES NO WBC count _____ x10⁹/L or x10³/μLDone YES NO Lymphocyte count _____ cells/ μLDone YES NO Neutrophil count _____ cells/ μLDone YES NO Haematocrit [__][__]%Done YES NO Platelets _____ x10⁹/L or x10³/μL Done YES NO APTT/APTR _____Done YES NO PT _____ seconds or Done YES NO INR _____Done YES NO ALT/SGPT _____ U/L Done YES NO Total Bilirubin _____ μmol/L or mg/dLDone YES NO AST/SGOT _____ U/L Done YES NO Glucose _____ mmol/L or mg/dLDone YES NO Blood Urea Nitrogen (urea) _____ mmol/L or mg/dLDone YES NO Lactate _____ mmol/L or mg/dLDone YES NO LDH [__][__][__].[__] U/LDone YES NO Creatinine Kinase (CPK) [__][__][__].[__] U/LDone YES NO Creatinine _____ μmol/L or mg/dLDone YES NO Sodium [__][__][__][__] mEq/LDone YES NO Potassium [__][__].[__] mEq/LDone YES NO Procalcitonin [__][__].[__][__] ng/mLDone YES NO CRP [__][__][__].[__] mg/LChest X-Ray /CT performed? YES NO N/AIF Yes: Were infiltrates present? YES NO N/A

OUTCOME CASE RECORD FORM**TREATMENT: At ANY time during hospitalisation, did the patient receive/undergo:**ICU or High Dependency Unit admission? YES NO N/A..... If YES, total duration: _____ daysDate of ICU admission: [D_][D_]/[M_][M_]/[2_][0_][Y_][Y_] N/AICU discharge date: [D_][D_]/[M_][M_]/[2_][0_][Y_][Y_] N/AOxygen therapy? YES NO N/ANon-invasive ventilation? (e.g. BIPAP, CPAP) YES NO N/AInvasive ventilation (Any)? YES NO N/A If YES, total duration: _____ daysProne Ventilation? YES NO N/AInhaled Nitric Oxide? YES NO N/ATracheostomy inserted? YES NO N/AExtracorporeal (ECMO) support? YES NO N/A If YES, total duration: _____ daysRenal replacement therapy (RRT) or dialysis? YES NO N/AInotropes/vasopressors? YES NO N/A If YES, total duration: _____ days

OTHER intervention or procedure (please specify): _____

OUTCOME CASE RECORD FORM

COMPLICATIONS: At any time during hospitalisation did the patient experience:			
Viral pneumonia	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A	Cardiac arrest	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Bacterial pneumonia	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A	Bacteraemia	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Acute Respiratory Distress Syndrome	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A	Coagulation disorder / Disseminated Intravascular Coagulation	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Cryptogenic organizing pneumonia (COP)	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A	Anaemia	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Pneumothorax	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A	Rhabdomyolysis / Myositis	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Pleural effusion	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A	Acute renal injury/acute renal failure	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Bronchiolitis	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A	Gastrointestinal haemorrhage	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Meningitis / Encephalitis	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A	Pancreatitis	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Seizure	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A	Liver dysfunction	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Stroke / Cerebrovascular accident	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A	Hyperglycaemia	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Congestive heart failure	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A	Hypoglycaemia	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Endocarditis/Myocarditis/Pericarditis	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A	Other	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
Cardiac arrhythmia	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A	If yes, specify: _____ _____	
Cardiac ischemia	<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A		

STUDY PARTICIPATION

Is / Has the participant being recruited to a trial or multi-centre study during the period of their current illness (including initiation in the community and hospital)? YES NO

IF YES , specify

Name of study _____

Study Participant ID _____

Add another study? YES NO

IF YES , specify

Name of study _____

Study Participant ID _____

Add another study? YES NO

IF YES , specify

Name of study _____

Study Participant ID _____

OUTCOME CASE RECORD FORM

OUTCOME
<p>Outcome: <input type="checkbox"/> Discharged alive expected to survive <input type="checkbox"/> Hospitalization <input type="checkbox"/> Transfer to other facility <input type="checkbox"/> Death <input type="checkbox"/> Palliative discharge <input type="checkbox"/> Unknown</p> <p>Outcome date: [<u> </u>][<u> </u>]/[<u> </u>][<u> </u>]/[<u> </u>][<u> </u>][<u> </u>][<u> </u>] <input type="checkbox"/> N/A</p> <p>If Discharged alive:</p> <p style="margin-left: 20px;">Ability to self-care at discharge versus before illness: <input type="checkbox"/> Same as before illness <input type="checkbox"/> Worse <input type="checkbox"/> Better <input type="checkbox"/> N/A</p> <p style="margin-left: 20px;">If Discharged alive: Post-discharge treatment:</p> <p style="margin-left: 40px;">Oxygen therapy? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A Dialysis/renal treatment? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A</p> <p style="margin-left: 40px;">Other intervention or procedure? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A</p> <p style="margin-left: 40px;">If YES: Specify (multiple permitted): _____</p> <p style="margin-left: 20px;">If Transferred: Facility name: _____ <input type="checkbox"/> N/A</p> <p style="margin-left: 20px;">If Transferred: Is the transfer facility a study site? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A</p> <p style="margin-left: 20px;">If a Study Site: Participant ID # at new facility: <input type="checkbox"/> Same as above</p> <p style="margin-left: 20px;"><input type="checkbox"/> Different: [<u> </u>][<u> </u>][<u> </u>]-[<u> </u>][<u> </u>][<u> </u>][<u> </u>] <input type="checkbox"/> N/A</p>

