CCP UK SARI CRF Completion Guidance
V6.0 01/03/2021
(To be used in conjunction with V10.0 CRF)

1 - CLINICAL INCLUSION CRITERIA

IMPORTANT CHANGES FOR SECOND WAVE OF COVID-19 (January 2021- until next notice)

CLINICAL INCLUSION CRITERIA
Proven infection with pathogen of Public Health Interest: ☐ YES ☐ NO *N.B. For acute covid-19, please only collect data from proven (laboratory test-positive) people.* **OR** **Adult or child who meets Case Definition for Multisystem Inflammatory Syndrome (MIS-C/MIS-A) :** ☐ YES ☐ NO *N.B. This group should be recruited regardless of covid-19 test as this syndrome can occur after mild disease in the community which has gone untested.*

Tier Zero will only include proven (test positive) COVID-19/ SARS-COV-2. Due to extreme capacity pressure, we are reducing enrolment to 1 in 10 positive cases. We suggest any local quasi-random process be used such as picking every tenth positive case from a laboratory report list so as to reduce sampling bias. We are keen for you to develop your local solution. In addition we may request you to collect data on people infected by "variants of concern" and other pathogens of public health interest as a priority. Recognising limited capacity for follow-up please complete OUTCOME CRF at day 28 as final.

Tiers 1 and 2 Biological sampling with consent, will only apply to patients admitted with vaccine failure (COVID >28d after vaccination), *re-infection, co-infection (flu/RSV), COVID associated hyper inflammation (MIS-A/MIS-C/PINS-TS), or samples from patients with pathogens of public health interest including people identified as infected with SARS-CoV "variants of concern".* We may request sampling from people infected by "variants of concern" and other pathogens of public health interest. Ideally, data and samples will be collected with consent using Tier 2 of the protocol schedule. We recognise conditions of surge so may ask only for Tier 1 samples, or even a subset of samples.

For all tiers please collect:

Please complete the **ADMISSION CRF** and **DAILY CRF** for the first day of hospital admission (day 1), the **DAILY CRF** again for the first day of any ICU admission, then the **OUTCOME CRF** at day 28.

N.B. For patients receiving **Remdesivir, Tocilizumab, and Sarilumab,** please complete an extra **DAILY CRF** for **first day** that such a drug is dosed and for day 14 after drug initiation (if patient remains admitted). **Collection of this data is requested by the CMOs in all nations.**

Patients with *confirmed Covid-19* with any of the following syndromes should be recruited to **tiers 1 or 2:**

- **Re-infection**. The patient had Covid-19 more than 21 days ago:
    1. See criteria for identifying suspected re-infection on page 4.
    2. If you think a patient has suspected re-infection, please call 0300 365 4423to discuss.
- **Co-infection**. The patient has **confirmed co-infection** with:
    1. Influenza A or B virus; or,
    2. Respiratory syncytial virus (RSV).
- **Clinical suspicion of Multisystem Inflammatory Syndrome in Adults (MIS-A) or Children (MIS-C/PIMS-TS)**
- **Vaccine failure.** Admitted with proven Covid-19 >28 days after vaccination.
- **Infection with variant of concern or other pathogen of public health interest**. The study team may request priority data collection or biological sampling with consent from persons with a "variant of concern" or other pathogen of public health interest in response to information from the relevant public health agency.
- **All children (less than 19 years old).**

CCP UK SARI CRF Completion Guidance
V6.0 01/03/2021
(To be used in conjunction with V10.0 CRF)

Definitions:

INFLAMMATION - Children and adolescents

WHO preliminary criteria Multisystem inflammatory syndrome in children and adolescents temporally related to COVID-19

Children and adolescents 0–19 years of age with fever ≥ 3 days

AND any two of the following:

1. Rash or bilateral non-purulent conjunctivitis or muco-cutaneous inflammation signs (oral, hands or feet).
2. Hypotension or shock.
3. Features of myocardial dysfunction, pericarditis, valvulitis, or coronary abnormalities (including ECHO findings or elevated Troponin/NT-proBNP),
4. Evidence of coagulopathy (by PT, PTT, elevated d-Dimers).
5. Acute gastrointestinal problems (diarrhoea, vomiting, or abdominal pain).

AND

Elevated markers of inflammation such as ESR, C-reactive protein, or procalcitonin.

AND

No other obvious microbial cause of inflammation, including bacterial sepsis, staphylococcal or streptococcal shock syndromes.

AND

Evidence of COVID-19 (RT-PCR, antigen test or serology positive), or likely contact with patients with COVID-19

INFLAMMATION - Adults

We deliberately do not give criteria to avoid selection bias. Adults with an inflammatory should to be identified at clinical discretion.
If you think a patient meets these criteria or wish to discuss**, please call 0300 365 4423**.

RE-INFECTION

To be considered a suspected Covid-19 re-infection the patient should meet one prior Covid-19 criterion and one timing criterion. If you think a patient meets these criteria or wish to discuss, **please call 0300 365 4423**.

Prior Covid-19 criteria

- A positive test for virus (PCR or antigen) or antibodies, in the community or in a hospital. Evidence of this can be from the patient's own recollection, or from medical records.
- Patient-reported symptoms strongly suggestive of Covid-19, including cough, fever and altered taste/smell

Timing criteria

- If the patient was previously hospitalized with Covid-19, they must be more than 21 days from discharge from acute hospital (not including rehabilitation hospital).
- If the patient was not hospitalised but had symptoms of Covid-19, they must be more than 21 days from last symptoms.
- If the patient did not have symptoms, they must be more than 21 days from their last positive Covid-19 test.

VACCINE FAILURE

- Admission with Covid-19 more than 28 days after vaccination. Please call **0300 365 4423**.

CCP UK SARI CRF Completion Guidance
V6.0 01/03/2021
(To be used in conjunction with V10.0 CRF)

2– DEMOGRAPHICS

In REDCap to enable version 9.7 onwards of the CRFR please ensure you have selected the fields for:

- **The new shoter CRF version**
- **And the field for the 9.7 CRF**

These are located at the top of the incliusion page in REDCap

Please record NHS number, DOB & postcode for all participants
(*note Northern Ireland is not to collect these details)

Ethnic group: If other, please exclude nationality as nations often include many different ethnic groups (For example, Singaporean is the nationality but the ethnic grouping within Singapore could be East Asian, South Asian etc.) for other, please write the full name of the ethnic group of the patient. Please do not enter a letter or number corresponding to a local/national ethnicity coding system.

If the patient's ethnicity is not known, please place a cross (X) in the 'Unknown' box.

Post-partum: Defined as within six weeks (42d) of delivery.

If the baby is positive for COVID-19 **please complete a separate form for the baby as well.**

Vaccination status

This is a new section as part of version 9.7 onwards

- Please confirm if any known COVID or Flu vaccination has been received and the date given.
- Please confirm if they have been given an open label vaccine (approved)
- Please confirm if recruit has been part of a vaccine trial – mark 'yes' even if blinded / not received live vaccine
- **If part of a vaccine trial please complete the 'study participation eCRF'**

DEMOGRAPHICS

Sex at Birth: ☐ Male ☐ Female ☐ Not specified **Date of birth** [_D_][_D_]/[_M_][_M_]/[_Y_][_Y_][_Y_][_Y_]

If date of birth is Not Known (N/K) record Age: [___][___][___]years **OR** [___][___]months

Postcode: [___][___][___][___] [___][___][___]

England & Wales NHS number , Scotland CHI: [___][___][___] [___][___][___] [___][___][___][___]
NB Northern Ireland Health & Care Number is not being collected at this time

Ethnic group *(check all that apply)*:

OArab OBlack OEast Asian OSouth Asian OWest Asian OLatin American OWhite OAboriginal/First Nations

OOther: _____ ☐N/K

Employed as a Healthcare Worker? ☐YES ☐NO ☐N/K

Pregnant? ☐ YES ☐ NO ☐ N/K **If YES: Gestational weeks assessment: [___][___] weeks**

POST PARTUM (within six weeks of delivery)? ☐YES ☐NO or ☐N/K *(skip this section - go to INFANT)*

Pregnancy Outcome: ☐Live birth ☐Still birth Delivery date: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

Has infant(s) been tested for Mother's infection? ☐YES ☐NO ☐N/K If YES: ☐Positive ☐Negative

IF POSITIVE PLEASE COMPLETE A SEPARATE CASE REPORT FORM FOR THE INFANT(s)

INFANT – Less than 1 year old? ☐YES ☐NO *(skip this section)* Birth weight: [___].[___]kg ☐N/K

Gestational: ☐ Term birth (≥37wk GA) ☐Preterm birth (<37wk GA) if <37wk Estimated gestation _____weeks ☐N/K

Breastfed? ☐YES ☐NO ☐N/K If YES: ☐Currently breastfed ☐Breastfeeding discontinued ☐N/K

VACCINATION STATUS

Has the patient received a Covid-19 vaccine (open label licenced product) ☐YES ☐NO ☐N/K

date of first vaccine dose if known: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ☐N/K

date of second vaccine dose if known: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ☐N/K

Vaccine type/ Manufacturer: ☐ Pfizer- BioNTECH ☐ Oxford-AstraZeneca ☐ Moderna ☐ Other _____ ☐N/K

has the patient been involved in a vaccine COVID trial? ☐YES ☐NO ☐N/K

date if known (first trial vaccination): [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ***(please complete study participation CRF page 3 of outcome CRF)***

Has patient received a 2020/21 seasonal influenza vaccine ☐YES ☐NO ☐N/K

date if known: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ☐N/K

CCP UK SARI CRF Completion Guidance
V6.0 01/03/2021
(To be used in conjunction with V10.0 CRF)

3- ADMISSION CRF- onset and admission

Symptom onset: Please confirm symptom onset date or confirm if patient was asymptomatic.

Admission date: the date admitted to facility regardless of reason (i.e. If non-COVID admission)

Is patient being re-admitted with COVID 19? For the purposes of this study please only include re-admissions where the re-admission is **COVID related.**

To log re-admissions:

- Start a new record/ REDCap ID
- Mark 'yes' a re-admission on this page
- Record previous ID if known, if not known don't worry as we can also use NHS number to link records
- **Please only record re-admissions for those remaining or testing positive.**

Re-infections

- Start a new record/ REDCap ID
- Mark 'yes' suspected re-infection on this CRF page
- Complete the re-infection CRF

Transfer from another facility?
For patients transferring to you:

- Start a new record/ REDCap ID
- Mark 'yes' a transfer from another facility
- Day 1= the first 24 hours with you

For those transferring from you: complete outcome CRF at the point of transfer with outcome logged as 'transfer to another facility'.

If symptoms start after swab please over write this page to collect symptom details.

ONSET AND ADMISSION

Date of first/earliest symptom: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] **OR** ☐ **Asymptomatic**

Admission date at this facility: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

Is the patient being readmitted with Covid-19? ***(Please only add re-admission episodes for COVID related complications or patients remaining positive. Assign new subject ID)*** ☐YES ☐NO ☐N/K

Previous participant ID : I__II__II__II__II__I--I__II__II__II__I ☐ NK

Please provide reason for readmission: _____ ☐N/K

Is this a suspected re-infection with COVID-19? Defined as proven (PCR or antibody test) or highly probable (clinical case definition met) more than 21 days prior to this new laboratory proven covid-19 infection ☐YES ☐NO ☐N/K
If yes, please complete REINFECTION FORM and seek consent for biological sampling, ideally at Tier 2)

Is this a NIGHTINGALE or other SURGE FACILITY ☐YES ☐NO ☐N/K

Transfer from other facility? ☐YES-other facility is a study site ☐YES-other facility is not a study site ☐NO ☐N/K

If YES: Name of transfer facility:_____ ☐N/K

If YES: Admission date at previous facility *(DD/MM/YYYY)*: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ☐N/K

If YES-Study Site: Participant ID # at previous facility: I__II__II__II__II__I--I__II__II__II__I

OR ☐Same as above

3- ADMISSION CRF- Vital Signs and Signs and Symptoms

Vital Signs

These should be recorded on the **DATE OF ADMISSION** (even if this was a while ago, for a non COVOID reason)

SIGNS & SYMPTOMS

This should be the signs and symptoms at the start of the **COVID episode**

*Please note if new symptoms develop throughout illness course, they do not need to be captured here, we just need those at infection start

Definitions:

Temperature: peripheral body temperature (rectal if <3 months)

Heart rate: beats per minute this may be measured manually or by electronic monitoring.

Respiratory rate (RR)

Enter the respiratory rate in breaths per minute. Manual rather than electronic measurement is preferred where possible (this is achieved by counting the number of breaths for one minute, counting how many times the chest rises within this time period). Record the highest respiratory rate documented on admission.

Systolic BP

Please enter the systolic blood pressure measured in millimetres of mercury (mmHg), in the relevant sections. For example, if the blood pressure is 120/85 mmHg, enter 120 in the section marked 'systolic BP'. Use any recognised method for measuring blood pressure.

Diastolic BP

Please enter the diastolic blood pressure measured in millimetres of mercury (mmHg), in the relevant sections. For example, if the blood pressure is 120/85 mmHg, enter 85 in the section marked 'diastolic BP'. Use any recognised method for measuring blood pressure.

Severe dehydration?

Signs of severe dehydration include thirst, dry mucous membranes, low volumes of dark-coloured urine, sunken eyes, reduced skin elasticity.

Sternal capillary refill time > 2 seconds?

Sternal capillary refill time is measured by pressing on the sternum for five seconds with a finger or thumb until the underlying skin turns white and then noting the time in seconds needed for the colour to return once the pressure is released.

Oxygen saturation

For all patients, irrespective of ventilation or supplemental oxygen requirement, please enter the percentage oxygen saturation (the percentage of haemoglobin binding sites in the bloodstream occupied by oxygen) at the time of admission. This may be measured by pulse oximetry or by arterial blood gas analysis.

VITAL SIGNS AT HOSPITAL ADMISSION *-first available data at presentation/Admission to the facility.*
(This section should refer to data from the date of admission to this facility)

Temperature: [_][_].[_]°C **HR:** [_][_][_]beats per minute **RR:** [_][_]breaths per minute

Systolic BP: [_] [_] [_]mmHg **Diastolic BP:** [_][_][_]mmHg **Severe dehydration:** ☐YES ☐NO ☐N/K

Sternal capillary refill time >2seconds ☐YES ☐NO ☐N/K

Oxygen saturation: [_][_][_]% **On:** ☐Room air ☐Any Oxygen therapy ☐N/K

SIGNS AND SYMPTOMS- ***This section should refer to the start of the COVID episode***

History of fever	☐YES ☐NO ☐N/K	Lower chest wall indrawing	☐YES ☐NO ☐N/K
Cough	☐YES ☐NO ☐N/K	Headache	☐YES ☐NO ☐N/K
with sputum production	☐YES ☐NO ☐N/K	Altered consciousness/confusion	☐YES ☐NO ☐N/K
bloody sputum/haemoptysis	☐YES ☐NO ☐N/K	Seizures	☐YES ☐NO ☐N/K
Sore throat	☐YES ☐NO ☐N/K	Abdominal pain	☐YES ☐NO ☐N/K
Runny nose (Rhinorrhoea)	☐YES ☐NO ☐N/K	Vomiting / Nausea	☐YES ☐NO ☐N/K
Ear pain	☐YES ☐NO ☐N/K	Diarrhoea	☐YES ☐NO ☐N/K
Wheezing	☐YES ☐NO ☐N/K	Conjunctivitis	☐YES ☐NO ☐N/K
Chest pain	☐YES ☐NO ☐N/K	Skin rash	☐YES ☐NO ☐N/K
Muscle aches (Myalgia)	☐YES ☐NO ☐N/K	Skin ulcers	☐YES ☐NO ☐N/K
Joint pain (Arthralgia)	☐YES ☐NO ☐N/K	Lymphadenopathy	☐YES ☐NO ☐N/K
Fatigue / Malaise	☐YES ☐NO ☐N/K	Bleeding (Haemorrhage)	☐YES ☐NO ☐N/K
Shortness of breath (Dyspnoea)	☐YES ☐NO ☐N/K	If Bleeding: specify site(s):	_____
Disturbance or loss of taste (Ageusia)	☐YES ☐NO ☐N/K	Disturbance or loss of smell (Anosmia)	☐YES ☐NO ☐N/K
		None	☐YES ☐NO ☐N/K

4- ADMISSION FORM CONTINUED: Co-morbidities

Please record if any of these comorbidities **existed prior to admission.**

In general, do not include past comorbidities that are no longer ongoing. Additional details are given below. Where example conditions are given, these are not intended to be exhaustive and other conditions of equivalent severity should be included.

Chronic cardiac disease (not hypertension)

Please include any of coronary artery disease, heart failure, congenital heart disease, cardiomyopathy, rheumatic heart disease.

Chronic pulmonary disease (not asthma)

Please include any of chronic obstructive pulmonary disease (chronic bronchitis, emphysema), cystic fibrosis, bronchiectasis, interstitial lung disease, pre-existing requirement for long term oxygen therapy. Do not include asthma.

Asthma (physician diagnosed)

Clinician-diagnosed asthma

Chronic Kidney Disease

Please include any of clinician-diagnosed chronic kidney disease, chronic estimated glomerular filtration rate < 60 mL/min/1.73m^2, history of kidney transplantation

Moderate or severe liver disease

This is defined as cirrhosis with portal hypertension, with or without bleeding or a history of variceal bleeding.

Mild liver disease

This is defined as cirrhosis without portal hypertension or chronic hepatitis

Chronic neurological disorder

Please include any of cerebral palsy, multiple sclerosis, motor neurone disease, muscular dystrophy, myasthenia gravis, Parkinson's disease, stroke, severe learning difficulty

Malignant neoplasm

Current solid organ or haematological malignancy. Please do not include malignancies that have been declared 'cured' ≥5 years ago with no evidence of ongoing disease. Do not include non-melanoma skin cancers. Do not include benign growths or dysplasia.

AIDS/HIV

History of laboratory-confirmed HIV infection.

Chronic hematologic disease

coagulation system requiring regular or intermittent treatment. Do not include leukaemia, lymphoma or myeloma, which should be entered under malignancy. Do not include iron-deficiency anaemia which is explained by diet or chronic blood loss.

Obesity (as defined by clinical staff)

This refers to patients for whom an attending clinician has assessed them to be obese - ideally but not necessarily with an objective measurement of obesity, such as calculation of the body mass index (BMI of 30 or more) or measurement of abdominal girth.

Diabetes with complications

This is defined as diabetes mellitus (type I or type II) with evidence of one or more organ or tissue damage due to diabetes mellitus, irrespective of the need for current treatment of diabetes. Examples of chronic complications include: diabetic cardiomyopathy; diabetic nephropathy; diabetic neuropathy; diabetic retinopathy; diabetic myonecrosis; peripheral vascular disease; coronary artery disease; stroke (other examples exist).

Rheumatologic disorder

This is defined as an inflammatory and degenerative diseases of connective tissue structures. It includes chronic arthropathies and arthritis, connective tissue disorders and vasculitides.

Dementia

This is defined as clinical diagnosis of dementia

Malnutrition

Any clinically identified deficiency in intake, either of total energy or of specific nutrients that led to a dietetic intervention or referral prior to the onset of COVID-19 symptoms. Do not include people who needed supplementary nutrition solely due to reduced intake during their current illness episode.

Smoking

Smoking at least one cigarette, cigar, pipe or equivalent per day before the onset of the current illness. Do not include smoke-free tobacco products such as chewed tobacco or electronic nicotine delivery devices.

Other relevant risk factor List any significant risk factors or comorbidities that existed prior to admission, are ongoing, that are not already listed.

5- ADMISSION CRF continued- Vulnerable group

Please record if patient falls into any of the criteria listed here.

Definitions are provided within the CRF.

Is the patient thought to be a member of a CLINICALLY EXTREMELY VULNERABLE GROUP

Solid organ transplant recipients: ☐YES ☐NO ☐N/K

People with specific cancers: ☐YES ☐NO ☐N/K

- people with cancer who are undergoing active chemotherapy
- people with lung cancer who are undergoing radical radiotherapy
- people with cancers of the blood or bone marrow such as leukaemia, lymphoma or myeloma who are at any stage of treatment
- people having immunotherapy or other continuing antibody treatments for cancer
- people having other targeted cancer treatments which can affect the immune system, such as protein kinase inhibitors or PARP inhibitors
- people who have had bone marrow or stem cell transplants in the last 6 months, or who are still taking immunosuppression drugs

People with severe respiratory conditions including all cystic fibrosis, severe asthma requiring daily oral steroid or injectable maintenance therapy and severe chronic obstructive pulmonary requiring oxygen (COPD): ☐YES ☐NO ☐N/K

People with rare diseases and inborn errors of metabolism that significantly increase the risk of infections (such as Severe combined immunodeficiency (SCID), homozygous sickle cell): ☐YES ☐NO ☐N/K

People on immunosuppression therapies sufficient to significantly increase risk of infection: ☐YES ☐NO ☐N/K

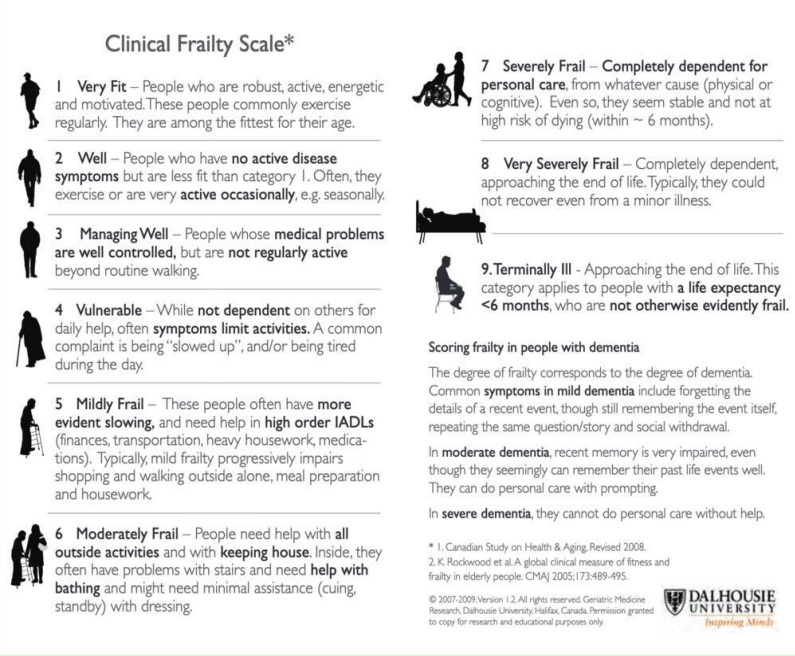
Women who are pregnant with significant heart disease, congenital or acquired: ☐YES ☐NO ☐N/K

6- ADMISSION CRF continued- Medications & Clinical frailty score

Pre -admission medication: please include all treatment/ medication given within the last 14 days, including the day of admission (not including anything given as hospital treatment)

Current medication on admission: Please include all medication taken in the 14 days prior to admission and the day of admission (excluding hospital medications)

Clinical frailty score: this is the score for the patient as they are usually (not whilst having active COVID)



Clinical Frailty Scale*

1 **Very Fit** – People who are robust, active, energetic and motivated. These people commonly exercise regularly. They are among the fittest for their age.

2 **Well** – People who have **no active disease symptoms** but are less fit than category 1. Often, they exercise or are very **active occasionally**, e.g. seasonally.

3 **Managing Well** – People whose **medical problems are well controlled,** but are **not regularly active** beyond routine walking.

4 **Vulnerable** – While **not dependent** on others for daily help, often **symptoms limit activities.** A common complaint is being "slowed up", and/or being tired during the day.

5 **Mildly Frail** – These people often have **more evident slowing,** and need help in **high order IADLs** (finances, transportation, heavy housework, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation and housework.

6 **Moderately Frail** – People need help with **all outside activities** and with **keeping house**. Inside, they often have problems with stairs and need **help with bathing** and might need minimal assistance (cuing, standby) with dressing.

7 **Severely Frail** – **Completely dependent for personal care**, from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within ~ 6 months).

8 **Very Severely Frail** – Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness.

9. **Terminally Ill** - Approaching the end of life. This category applies to people with **a life expectancy <6 months**, who are **not otherwise evidently frail.**

Scoring frailty in people with dementia

The degree of frailty corresponds to the degree of dementia. Common **symptoms in mild dementia** include forgetting the details of a recent event, though still remembering the event itself, repeating the same question/story and social withdrawal.

In **moderate dementia**, recent memory is very impaired, even though they seemingly can remember their past life events well. They can do personal care with prompting.

In **severe dementia**, they cannot do personal care without help.

* 1. Canadian Study on Health & Aging, Revised 2008.
2. K. Rockwood et al. A global clinical measure of fitness and frailty in elderly people. CMAJ 2005;173:489-495.

DALHOUSIE UNIVERSITY *Inspiring Minds*

PRE-ADMISSION MEDICATION Were any of the following taken within 14 days of admission?

Immunosuppressant e.g. oral (not inhaled) corticosteroids (not low dose hydrocortisone) ☐YES ☐NO ☐N/K	**Angiotensin converting enzyme inhibitors (ACEI)?** ☐YES ☐NO ☐N/K
Anti-infectives for this illness episode prior to admission? ☐YES ☐NO ☐N/K **If yes, specify:**_____	**Angiotensin II receptor blockers (ARBs)?** ☐YES ☐NO ☐N/K **Non-steroidal anti-inflammatory (NSAID)?** ☐YES ☐NO ☐N/K

CLINICAL FRAILTY SCORE
With reference to the Dalhousie University Clinical Frailty Score (see guidance page 3 of complete CRF)

Clinical Frailty Score	[___] value 1 to 9 or ☐N/K

CURRENT MEDICATION ON ADMISSION
Record medication the patient is currently taking or has taken within the past 14 days

Medication name *(generic name preferred):*

7- RE-INFECTION

Please complete this CRF page only where there is suspected re-infection

If previously enrolled, add the previous ID to the top of this eCRF, you do then not need to provide the rest of the details as these will be drawn from the data previously provided.

To be considered a suspected Covid-19 re-infection the patient should meet one prior Covid-19 criterion and one timing criterion. If you think a patient meets these criteria or wish to discuss, please call 0300 365 4423.

Prior Covid-19 criteria

- A positive test for virus (PCR or antigen) or antibodies, in the community or in a hospital. Evidence of this can be from the patient's own recollection, or from medical records.
- Patient-reported symptoms strongly suggestive of Covid-19, including cough, fever and altered taste/smell

Timing criteria

- If the patient was previously hospitalised with Covid-19, they must be more than 21 days from discharge from acute hospital (not including rehabilitation hospital).
- If the patient was not hospitalised but had symptoms of Covid-19, they must be more than 21 days from last symptoms.
- If the patient did not have symptoms, they must be more than 21 days from their last positive Covid-19 test.

Ensure on admission CRF page 1 it is marked 'YES' that this case of suspected re-infection.

We are asking for the previous COVID episode data here in case this was never previously captured (i.e. The patient had COVID in the community previously and was not admitted). Please complete this CRF page regardless of if there is a data set for the previous illness episode or not.

SUSPECTED RE-INFECTION WITH COVID-19: DETAILS OF PREVIOUS INFECTION	
Did the patient have a positive PCR (virus) test for SARS-CoV-2?	☐YES ☐NO ☐N/K
If yes, enter date of positive test: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]	
Did the patient have a positive antigen (virus) test for SARS-CoV-2?	☐YES ☐NO ☐N/K
If yes, enter date of positive test: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]	
Did the patient have a positive serology (antibody) test for SARS-CoV-2?	☐YES ☐NO ☐N/K
If yes, enter date of positive test: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]	
Symptom onset date of first/earliest symptom for previous infection: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] OR ☐ Asymptomatic	

SIGNS AND SYMPTOMS for PREVIOUS COVID-19 episode			
History of fever	☐YES ☐NO ☐N/K	Lower chest wall indrawing	☐YES ☐NO ☐N/K
Cough	☐YES ☐NO ☐N/K	Headache	☐YES ☐NO ☐N/K
with sputum production	☐YES ☐NO ☐N/K	Altered consciousness/confusion	☐YES ☐NO ☐N/K
bloody sputum/haemoptysis	☐YES ☐NO ☐N/K	Seizures	☐YES ☐NO ☐N/K
Sore throat	☐YES ☐NO ☐N/K	Abdominal pain	☐YES ☐NO ☐N/K
Runny nose (Rhinorrhoea)	☐YES ☐NO ☐N/K	Vomiting / Nausea	☐YES ☐NO ☐N/K
Ear pain	☐YES ☐NO ☐N/K	Diarrhoea	☐YES ☐NO ☐N/K
Wheezing	☐YES ☐NO ☐N/K	Conjunctivitis	☐YES ☐NO ☐N/K
Chest pain	☐YES ☐NO ☐N/K	Skin rash	☐YES ☐NO ☐N/K
Muscle aches (Myalgia)	☐YES ☐NO ☐N/K	Skin ulcers	☐YES ☐NO ☐N/K
Joint pain (Arthralgia)	☐YES ☐NO ☐N/K	Lymphadenopathy	☐YES ☐NO ☐N/K
Fatigue / Malaise	☐YES ☐NO ☐N/K	Bleeding (Haemorrhage)	☐YES ☐NO ☐N/K
Shortness of breath (Dyspnoea)	☐YES ☐NO ☐N/K	If Bleeding: specify site(s):	_____
Disturbance or loss of taste (Ageusia)	☐YES ☐NO ☐N/K	Disturbance or loss of smell (Anosmia)	☐YES ☐NO ☐N/K
		None	☐YES ☐NO ☐N/K
TREATMENT: During the previous episode, was the patient:			
Admitted to hospital:	☐YES ☐NO ☐N/K	Treated with:	
Treated with oxygen:	☐YES ☐NO ☐N/K	Dexamethasone	☐YES ☐NO ☐N/K
Admitted to HDU/ICU:	☐YES ☐NO ☐N/K	Any other steroid	☐YES ☐NO ☐N/K
Receive invasive ventilation:	☐YES ☐NO ☐N/K	Tocilizumab	☐YES ☐NO ☐N/K
Receive extracorporeal membrane oxygenation (ECMO)	☐YES ☐NO ☐N/K	Remdesivir	☐YES ☐NO ☐N/K
		Convalescent plasma	☐YES ☐NO ☐N/K
		Lopinavir/Ritonavir	☐YES ☐NO ☐N/K
		Interferon	☐YES ☐NO ☐N/K
		Chloroquine/Hydroxychloroquine	☐YES ☐NO ☐N/K

CCP UK SARI CRF Completion Guidance
V6.0 01/03/2021
(To be used in conjunction with V10.0 CRF)

8- DAILY CRF

Tier 0- please complete daily CRF for: day 1, any ICU admission day (using additional days in REDCap).

Tier 1 & 2- please complete the daily CRF for: day 1, day 3, 6 & 9 and any ICU day (using additional days in REDCap). Also where biological sampling falls out of sync with the data collection day please capture sampling daily data under 'additional days' Where samples are obtained, please record KIT NUMBER in REDCap.

The daily lab results should only be provided where they are collected on the SAME DAY as the daily data. (I.e. if bloods are collected at day 2 but not day 3, please DO NOT record).

For those receiving Remdesivir please complete a daily form for the first day drug was dosed & day 14 after drug started (if still admitted). This data is required by the CMOs of the four nations.

FiO_2 (0.21-1.0)
If the patient has not received supplemental oxygen therapy during 00:00 to 24:00 on day of assessment, enter 0.21. If the patient received supplemental oxygen through a mask that delivers a known concentration of oxygen (e.g. a venturi mask) or is being ventilated, please provide the fraction of inspired oxygen (FiO2) delivered. For patients receiving oxygen through a face mask that does not deliver a known oxygen concentration, provide the flow rate in L/min.
In REDCap there is a field for L/min, % and 0.21-1.0- please complete only the field that applies.

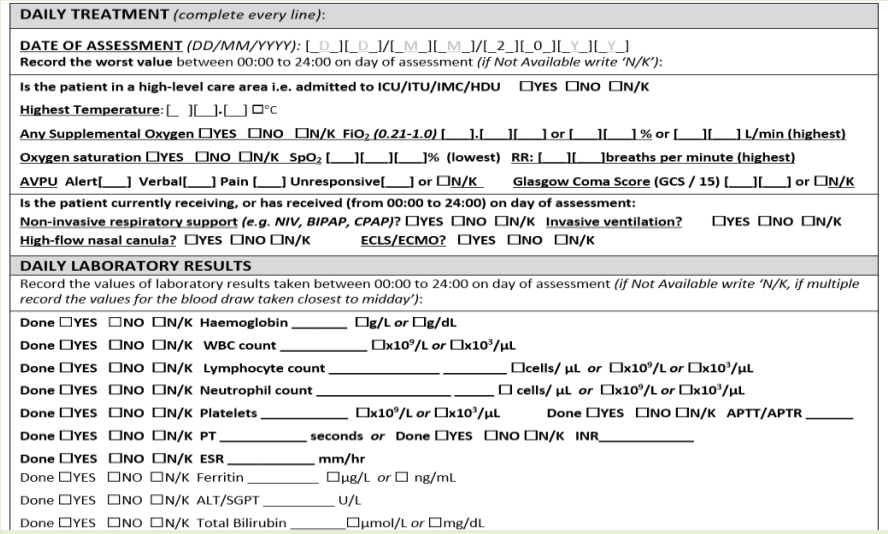
Glasgow Coma Score (GCS / 15)
Please state the lowest GCS recorded. For intubated patients and patients with a non-fenestrated tracheostomy, give 1 point for the voice component and calculate the total as usual. Suffixes such as t for tracheostomy cannot be entered on to the database. Glasgow Coma Score:
https://www.glasgowcomascale.org/downloads/GCS-Assessment-Aid-English.pdf?v=3

Please ensure in REDCap the field to confirm blood units is completed. **If unit does not appear in REDCap as per your source data, please contact ccp.REDCap@liverpool.ac.uk**

Most recent HbA1c: there is no timeframe for this, please record most recent. If no further HbA1c result was carried out on daily CRF past day 1 this can be left blank (no need to duplicate)

Chest x-ray: please record if carried out on the date of assessment, please check with local PI / clinician where there is uncertainty if infiltrates where present

Extra corporeal life support (ECLS)?
Extracorporeal Life Support (ECLS also known as extra-corporeal membrane oxygenation) is a variation of cardiopulmonary bypass, it maintains blood oxygenation in patients with life threatening respiratory or cardiac failure (or both). If the patient received ECLS at any time on the date of assessment, place a cross (X) in the relevant box ('yes', 'no', or 'N/A').



DAILY TREATMENT *(complete every line)*:

DATE OF ASSESSMENT *(DD/MM/YYYY)*: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]
Record the worst value between 00:00 to 24:00 on day of assessment *(if Not Available write 'N/K')*:

Is the patient in a high-level care area i.e. admitted to ICU/ITU/IMC/HDU ☐YES ☐NO ☐N/K

Highest Temperature: [_][__].[__] ☐°C

Any Supplemental Oxygen ☐YES ☐NO ☐N/K FiO_2 *(0.21-1.0)* [___].[___][___] or [___][___] % or [___][___] L/min (highest)

Oxygen saturation ☐YES ☐NO ☐N/K SpO_2 [___][___][___]% (lowest) RR: [___][___]breaths per minute (highest)

AVPU Alert[___] Verbal[___] Pain [___] Unresponsive[___] or ☐N/K Glasgow Coma Score (GCS / 15) [___][___] or ☐N/K

Is the patient currently receiving, or has received (from 00:00 to 24:00) on day of assessment:
Non-invasive respiratory support *(e.g. NIV, BIPAP, CPAP)*? ☐YES ☐NO ☐N/K Invasive ventilation? ☐YES ☐NO ☐N/K
High-flow nasal canula? ☐YES ☐NO ☐N/K ECLS/ECMO? ☐YES ☐NO ☐N/K

DAILY LABORATORY RESULTS
Record the values of laboratory results taken between 00:00 to 24:00 on day of assessment *(if Not Available write 'N/K, if multiple record the values for the blood draw taken closest to midday')*:

Done ☐YES ☐NO ☐N/K Haemoglobin _____ ☐g/L *or* ☐g/dL
Done ☐YES ☐NO ☐N/K WBC count _____ ☐x10⁹/L *or* ☐x10³/µL
Done ☐YES ☐NO ☐N/K Lymphocyte count _____ _____ ☐cells/ µL *or* ☐x10⁹/L *or* ☐x10³/µL
Done ☐YES ☐NO ☐N/K Neutrophil count _____ _____ ☐ cells/ µL *or* ☐x10⁹/L *or* ☐x10³/µL
Done ☐YES ☐NO ☐N/K Platelets _____ ☐x10⁹/L *or* ☐x10³/µL Done ☐YES ☐NO ☐N/K APTT/APTR _____
Done ☐YES ☐NO ☐N/K PT _____ seconds *or* Done ☐YES ☐NO ☐N/K INR_____
Done ☐YES ☐NO ☐N/K ESR _____ mm/hr
Done ☐YES ☐NO ☐N/K Ferritin _____ ☐µg/L *or* ☐ ng/mL
Done ☐YES ☐NO ☐N/K ALT/SGPT _____ U/L
Done ☐YES ☐NO ☐N/K Total Bilirubin _____☐µmol/L *or* ☐mg/dL

Invasive ventilation?
Invasive ventilation means that patient has undergone tracheal intubation or via tracheostomy for the purpose of mechanical ventilation. If invasive ventilation was used at any time on the date of assessment, place a cross.

Non-Invasive Respiratory support (e.g. NIV, BIPAP, CPAP) ?
If the patient received non-invasive ventilation (NIV), defined as the provision of ventilatory support through the patient's upper airway using a mask or similar device, at any time on the date of assessment, place a cross (X) in the box marked 'yes'. If they did not, place a cross in the box marked 'no'. If the answer is not known, place a cross the box marked 'N/A'.
Please note that BiPAP and CPAP ventilation modes are not unique to NIV; they can also be given via invasive mechanical ventilation, so please check.

High Flow nasal:
-compressed oxygen/air delivered at high velocity with humidification through nasal cannula. It is a form of escalated therapy. In children it is given at a flow rate of 1-2L/kg.
-Supplementary oxygen delivered through a facemask is not often humidified and is delivered on the ward. Whilst supplementary oxygen can be given up flows of 15L this is usually an interim/temporary measure. It is very unlikely to be given for long periods in children. In adults, 15L via facemask would not be classed as high flow therapy as it would be suboptimal. In children 15L via facemask would not be given directly for longer periods (7.5kg-15kg children). Where it is given for longer periods it is usually wafting oxygen at a distance.
-In summary, high flow oxygen should refer to patients on humidified oxygen via nasal cannula. The most common devices used for high flow are Vapotherm and Airvo.

9- OUTCOME- PATHOGEN DIAGNOSIS

Please record if the following where positive/ negative or not tested

- COVID
- Influenza
- RSV
- Adenovirus
- **Any other respiratory virus (please use drop down provided, if 'other' please record full pathogen name as it appears in the lab report)**

***For any diagnoses captured here ensure the testing details are recorded under 'pathogen testing' section.**

Section 1: Respiratory virus PCR or antigen tests (NOT serology/antibody tests)

	Tested and POSITIVE (please tick)	Tested and NEGATIVE (Please tick)	NOT TESTED (please tick)
COVID-19 / SARS-CoV-2	Yes☐	☐	☐
Influenza virus *NB: Please do not enter Haemophilus influenza or parainfluenza virus here – enter them under "other" below*	Yes ☐ Please confirm type: ☐ A/H3N2 ☐ A/H1N1pdm09 ☐ A/H7N9 ☐ A not typed other A ☐_____ ☐ B not typed ☐ Other type (specify):_____	☐	☐
Respiratory syncytial virus (RSV)	Yes ☐	☐	☐
Adenovirus	Yes ☐	☐	☐
Other	Yes ☐ please specify :_____		

9- OUTCOME- PATHOGEN TESTING

Please record the testing details of ALL tests carried out in the illness episode via swabs/ blood cultures/ sputum or BAL/ETA)

Where there where multiple negative results from a single sample, just capture once as 'obtained: negative'.

For the organism cultured please pick from the drop down provided in REDCap, if 'other' please record as it appears in the lab report (i.e. the full organism name).

Section 2: Pathogen Testing Details

(Please record the details of all tests carried out during this illness episode below -including the details of the tests indicated above).

	Select one:	Organism	Date sample obtained
Nasal and/ or throat swab	☐ Obtained: positive ☐ Obtained: negative ☐ Not obtained	....	....
Blood culture	☐ Obtained: positive ☐ Obtained: negative ☐ Not obtained	....	....
Sputum	☐ Obtained: positive ☐ Obtained: negative ☐ Not obtained	....	....
Deep respiratory sample (BAL/ETA)	☐ Obtained: positive ☐ Obtained: negative ☐ Not obtained	....	....

10- OUTCOME- MEDICATIONS

Please include any hospital administered given medications (including admission day and discharge day)

Dexamethasone- 6mg OD is the standard adult dose, for any variation on dose/ frequency please capture below.

While hospitalised or at discharge, were any of the following administered?

Antiviral Agent

'Antiviral Agent' refers to any agent(s) prescribed to treat or prevent viral infections by interfering with the viral replication cycle. If the patient received antivirals at any time during their hospital stay, place a cross in the box marked 'yes' and also indicate the type of antiviral agent.

Remdesivir & L6 Inhibitors:

Please record the date of first & last dose.

Corticosteroid

'Corticosteroids' (commonly referred to as 'steroids') refers to all types of therapeutic corticosteroid, made in the adrenal cortex (the outer part of the adrenal gland). They are also made in the laboratory.

Examples include: prednisolone, prednisone, methyl-prednisolone, dexamethasone, hydrocortisone, fluticasone, betamethasone (note that other examples exist). Topical preparations are not included, but inhaled preparations are included. The indication for administering corticosteroids does not need to be directly related to the treatment of COVID-19.

If a corticosteroid was administered at any point during the patient's hospital stay or was prescribed at the time of discharge from the hospital, place a cross (X) in the box marked 'yes' and place a cross (X) to indicate the route of administration (oral, intravenous or inhaled). Please also enter the type of corticosteroid and the dose.

Off lable/ compassionate use medication: Off label medications are those which are used for purposes other than their original license– an example would be hydroxychloroquine – this is not licensed to be used to treat COVID-19. Or medications used in patients not they are not licensed for e.g. children or elderly patients. Compassionate medications which are not currently licensed to treat seriously ill patient.

MEDICATION: While hospitalised or at discharge, were any of the following administered?

Antiviral agent? ☐YES ☐NO ☐N/K If YES, tick all the apply: ORibavirin OLopinavir/Ritonavir OInterferon alpha OInterferon beta OChloroquine / Hydroxychloroquine OOseltamivir (Tamiflu©) OZanamivir

OOther or novel antiviral _____

ORemdesivir If YES: first dose: [_D_][_D_]/[_M_][_M_]/[_Y_][_Y_] and last dose [_D_][_D_]/[_M_][_M_]/[_Y_][_Y_]

O IL6 inhibitor IF YES which ☐Tocilizumab ☐Other IL6 inhibitor_____

IL6 inhibitor first dose: [_D_][_D_]/[_M_][_M_]/[_Y_][_Y_] and last dose [_D_][_D_]/[_M_][_M_]/[_Y_][_Y_]

Antibiotic? ☐YES ☐NO ☐N/K If YES: specify type(s): _____ _____ _____

Corticosteroid? ☐YES ☐NO ☐N/K

If yes, please confirm type: ☐ Dexamethasone ☐ Methylprednisolone ☐ Prednisolone ☐ Other, please specify _____

Route: ☐ Oral ☐ Intravenous ☐ Inhaled, maximum daily dose: _____

If given Dexamethasone, was this given as 6mg once per day (od) ? ☐YES ☐NO ☐N/K, for how many days _____

If no, another dosing regimen used please confirm:

Other Dexamethasone route	Other Dexamethasone Dose	Other Dexamethasone Frequency	Number of days given
☐ Oral ☐ Intravenous	_____ mg	☐ BD ☐ TDS ☐QDS ☐Other_____	
☐ Oral ☐ Intravenous	_____ mg	☐ BD ☐ TDS ☐QDS ☐Other_____	
☐ Oral ☐ Intravenous	_____ mg	☐ BD ☐ TDS ☐QDS ☐Other_____	

Antifungal agent? ☐YES ☐NO ☐N/K If YES: which _____

Off-label / Compassionate Use medications? ☐YES ☐NO ☐N/K If YES: which _____

Interleukin inhibitors ☐YES ☐NO ☐N/K If YES: which _____ Convalescent plasma ☐YES ☐NO ☐N/K

11- OUTCOME- TREATMENT

Intensive Care Unit (ICU) or High Dependency Unit (HDU) Admission?

Where a patient had more than 1 ICU admission within a record please record all episode here (the date admitted/ discharged repeats in REDCap)

Please enter the total number of days the patient was admitted to the ICU/HDU, this should include all ICU/HDU admissions if there were more than one. Count any day in which the patient was in ICU/HDU during that 24-hour period.

As the interim outcome is captured at day 28, discharge or death there is a chance the patient may still be receiving ICU care at day 28, please use options for **'still in ICU'** there are also options for 'still on' for ventilation, ECMO etc. to indicate the level of support patient is receiving at day 28.

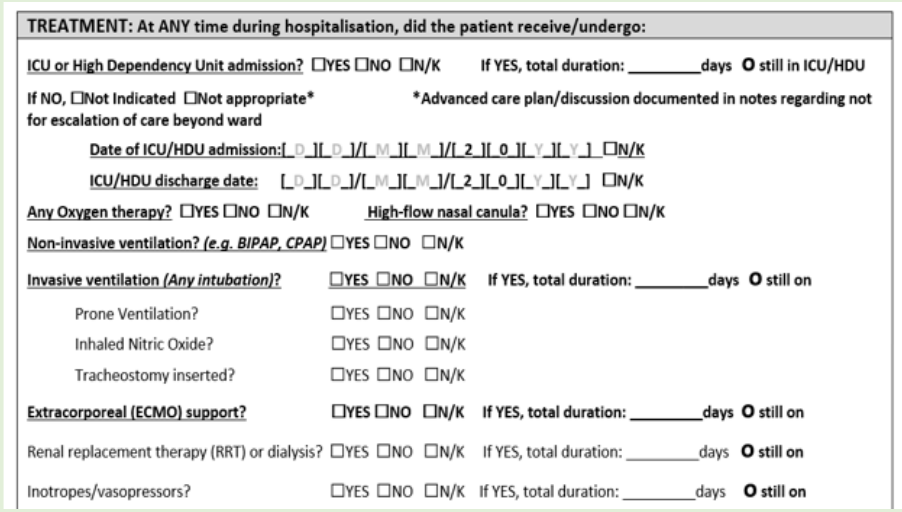
Please indicate if not admitted to ICU/ HDU during stay to confirm if this was due to:

- It was not indicated
- Not appropriate (*based on advanced care plan/ discussion documented in notes regarding not for escalation beyond ward)

Invasive ventilation?
Invasive ventilation means that patient has undergone tracheal intubation or via tracheostomy for the purpose of mechanical ventilation. If invasive ventilation was used at any time on the date of assessment, place a cross.

Non-Invasive Respiratory support (e.g. NIV, BIPAP, CPAP) ?
If the patient received non-invasive ventilation (NIV), defined as the provision of ventilatory support through the patient's upper airway using a mask or similar device, at any time on the date of assessment, place a cross (X) in the box marked 'yes'. If they did not, place a cross in the box marked 'no'. If the answer is not known, place a cross the box marked 'N/A'.
Please note that BiPAP and CPAP ventilation modes are not unique to NIV; they can also be given via invasive mechanical ventilation, so please check.

Extra corporeal life support (ECLS)?
Extracorporeal Life Support (ECLS also known as extra-corporeal membrane oxygenation) is a variation of cardiopulmonary bypass, it maintains blood oxygenation in patients with life threatening respiratory or cardiac failure (or both). If the patient received ECLS at any time on the date of assessment, place a cross (X) in the relevant box ('yes', 'no', or 'N/A').



TREATMENT: At ANY time during hospitalisation, did the patient receive/undergo:

ICU or High Dependency Unit admission? ☐YES ☐NO ☐N/K If YES, total duration: _____days O still in ICU/HDU

If NO, ☐Not Indicated ☐Not appropriate* *Advanced care plan/discussion documented in notes regarding not for escalation of care beyond ward

Date of ICU/HDU admission:[_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ☐N/K

ICU/HDU discharge date: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ☐N/K

Any Oxygen therapy? ☐YES ☐NO ☐N/K High-flow nasal canula? ☐YES ☐NO ☐N/K

Non-invasive ventilation? *(e.g. BIPAP, CPAP)* ☐YES ☐NO ☐N/K

Invasive ventilation *(Any intubation)*? ☐YES ☐NO ☐N/K If YES, total duration: _____days O still on

- Prone Ventilation? ☐YES ☐NO ☐N/K
- Inhaled Nitric Oxide? ☐YES ☐NO ☐N/K
- Tracheostomy inserted? ☐YES ☐NO ☐N/K

Extracorporeal (ECMO) support? ☐YES ☐NO ☐N/K If YES, total duration: _____days O still on

Renal replacement therapy (RRT) or dialysis? ☐YES ☐NO ☐N/K If YES, total duration: _____days O still on

Inotropes/vasopressors? ☐YES ☐NO ☐N/K If YES, total duration: _____days O still on

High Flow nasal:
compressed oxygen/air delivered at high velocity with humidification through nasal cannula. It is a form of escalated therapy. In children it is given at a flow rate of 1-2L/kg.

Supplementary oxygen delivered through a facemask is not often humidified and is delivered on the ward. Whilst supplementary oxygen can be given up flows of 15L this is usually an interim/temporary measure. It is very unlikely to be given for long periods in children. In adults, 15L via facemask would not be classed as high flow therapy as it would be suboptimal. In children 15L via facemask would not be given directly for longer periods (7.5kg-15kg children). Where it is given for longer periods it is usually wafting oxygen at a distance.

In summary, high flow oxygen should refer to patients on humidified oxygen via nasal cannula. The most common devices used for high flow are Vapotherm and Airvo.

Renal replacement

Where given for partial days (i.e. given half a day's filtration record this as '1 day')

12- OUTCOME- COMPLICATIONS

Meningitis / Encephalitis

Inflammation of the meninges or the brain parenchyma. Select yes if diagnosed clinically, radiologically or microbiologically.

Seizure

Select 'yes' for any seizure regardless of cause (e.g. febrile or due to epilepsy)

Stroke / Cerebrovascular accident

Stroke may be a clinical diagnosis, with or without supportive radiological findings.

Congestive heart failure

Is defined as failure of the heart to pump a sufficient amount of blood to meet the needs of the body tissues, resulting in tissue congestion and oedema.

Endocarditis / Myocarditis / Pericarditis

Endocarditis is an inflammation of the endocardium (inner lining of the heart). Diagnosis is according to modified Duke criteria, using evidence from microbiological results, echocardiogram and clinical signs. Myocarditis / pericarditis refers to an inflammation of the heart or pericardium (outer lining of the heart). Diagnosis can be clinical, biochemical (cardiac enzymes) or radiological.

Cardiac arrhythmia

If a cardiac arrhythmia is identified and there is no previous record of it, select 'yes'.

Cardiac ischaemia

Is defined as diminished blood and oxygen supply to the heart muscle, also known as myocardial ischemia, it is confirmed by an electrocardiogram (showing ischaemic changes, e.g. ST depression or elevation) and/or cardiac enzyme elevation.

Cardiac arrest

Sudden cessation of cardiac activity.

Bacteraemia

Growth of bacteria on a blood culture. Select 'no' if the only bacteria grown were believed to be skin contaminants (e.g. coagulase negative Staphylococci or diphtheroids).

Coagulation disorder / Disseminated Intravascular Coagulation

Abnormal coagulation identified by abnormal prothrombin time or activated partial thromboplastin time.

Disseminated intravascular coagulation (DIC; consumption coagulopathy; defibrination syndrome) is defined by thrombocytopenia, prolonged prothrombin time, low fibrinogen, elevated D-dimer and thrombotic microangiopathy.

12- OUTCOME- COMPLICATIONS continued

Anaemia

Select 'yes' if haemoglobin levels were lower than age- and sex-specific thresholds listed below

	Haemoglobin threshold	
Age or gender group	**(g/L)**	**(mmol/l)**
Age 6 months to 5 years	110	6.8
Age 5–12 years	115	7.1
Age 12–15 years	120	7.4
Age > 15 years, non-pregnant women	120	7.4
Pregnant women	110	6.8
Age >15 years, men	130	8.1

Rhabdomyolysis / Myositis

Rhabdomyolysis is a syndrome characterised by muscle necrosis and the release of myoglobin into the blood. Muscle biopsy, electromyography, radiological imaging and the presence of myoglobinuria are not required for the diagnosis.

Myositis may be a clinical diagnosis with supporting evidence from laboratory tests e.g. elevated serum creatine kinase; histological confirmation is not required to make the diagnosis. Myositis can occur without progression to rhabdomyolysis.

Acute renal injury/Acute renal failure

Acute renal injury is defined as any of:

- Increase in serum creatinine by ≥0.3 mg/dL (≥26.5 µmol/L) within 48 hours
- Increase in serum creatinine to ≥1.5 times baseline, which is known or presumed to have occurred within the prior 7 days
- Urine volume <0.5 mL/kg/hour for 6 hours

Gastrointestinal haemorrhage

Refers to bleeding originating from any part of the gastrointestinal tract (from the oropharynx to the rectum).

Pancreatitis

Inflammation of the pancreas, diagnosed from clinical, biochemical, radiological or histological evidence.

Liver dysfunction

A finding that indicates abnormal liver function, may refer to any of the following:

- Clinical jaundice
- Hyperbilirubinaemia (blood bilirubin level twice the upper limit of the normal range)
- An increase in alanine transaminase or aspartate transaminase that is twice the upper limit of the normal range

Hyperglycaemia- For adults, is defined as an abnormally high level of glucose in the blood, blood glucose level that is consistently above 126mg/dL or 7 mmol/L. For children, is defined as a blood glucose level consistently above 8.3 mmol/L.

Hypoglycaemia- For adults, is defined as an abnormally low level of glucose in the blood, a blood glucose level that is consistently below 70mg/dL or 4 mmol/L. For children, is defined as a blood glucose level below 3 mmol/L.

Other- Please specify other complications in the space provided.

13- OUTCOME – STUDY PARTICIPATION

Please record if it is known if the patient has been recruited into another study during their illness episode.

STUDY PARTICIPATION

Is / Has the participant being/ been 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 _____

14- OUTCOME

Outcome should be completed at DAY 28 or discharge or death if this occurs before day 28.

If discharged alive:
-Please confirm the ability to self- care
- if the patient was receiving oxygen therapy
- the outcome date will be the date of discharge

If remains in hospital at day 28
- The outcome date will be the date of day 28 (in relation to day 1)
- Please confirm if they remain in hospital for: COVID reasons, non- COVID reasons, are well but are still admitted pending community placement

If transferred
- The outcome date will be the date of transfer
- Please confirm facility name if known & new study ID (If known)

Palliative discharge/ Death
- The outcome date will be the date of discharge/ death

PREGNANCY OUTCOME: If delivered during admission, please confirm:

POST PARTUM (within six weeks of delivery)? ☐YES ☐NO or ☐N/K

Pregnancy Outcome: ☐Live birth ☐Still birth Delivery date: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

Has infant(s) been tested for Mother's infection? ☐YES ☐NO ☐N/K If YES: ☐Positive ☐Negative

IF POSITIVE PLEASE COMPLETE A SEPARATE CASE REPORT FORM FOR THE INFANT(s)

OUTCOME: (complete at discharge, transfer death or DAY 28, whichever occurs first)

Outcome: ☐ **Discharged alive expected to survive**

☐ **Hospitalisation = Remains in Hospital ≥ Day 28 after symptom onset**

- if so ☐ **Ongoing health care needs relating to this admission for COVID-19**

OR

☐ **Ongoing health care needs NOT related to COVID episode**

OR

☐ **Medically fit for discharge (COVID-19 resolved) but remains in hospital for other reason (e.g. awaiting suitable care in community, resident in long term health care or mental health facility)**

☐ **Transfer to other facility** ☐ **Palliative discharge** ☐ **Death** ☐ **N/K**

Outcome date: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] ☐ **N/K**

If Discharged alive:

Ability to self-care at discharge versus before illness: ☐ Same as before illness ☐ Worse ☐ Better ☐ N/K

If Discharged alive: Post-discharge treatment:

Oxygen therapy? ☐ YES ☐ NO ☐ N/K

If Transferred: Facility name: _____ ☐ N/K

If Transferred: Is the transfer facility a study site? ☐ YES ☐ NO ☐ N/K

If a Study Site: Participant ID # at new facility: ☐ Same as above

☐ Different: [___][___][___][___][___]- [___][___][___][___] ☐N/K

15- WITHDRAWAL

The withdrawal CRF only needs to be completed for Tier 1 & Tier 2 where there is a withdrawal of consent.

Where a T1/2 patient withdraws consent they effectively become a T0 patient.

Should a patient want to withdraw ALL samples collected rather than just future samples please contact ccp@liverpool.ac.uk