CRF Completion Guide

DESIGN OF THIS CASE REPORT FORM (CRF)

This CRF is set up in modules to be used for recording data on the ISARIC_nCov Core Database or for independent studies.

Module 1 and Module 2 complete on the first day of admission or on first day of COVID-19 assessment.
Module 2 also complete on first day of admission to ICU or high dependency unit. In addition, complete daily for as many days as resources allow up to a maximum of 14 days. Continue to follow-up patients who transfer between wards.
Module 3 (Outcome) complete at discharge or death

GENERAL GUIDANCE

- The CRF is designed to collect data obtained through examination, interview and review of hospital notes. Data may be collected prospectively or retrospectively if the patient is enrolled after the admission date.
- Participant Identification Numbers consist of a 5 digit site code and a 4 digit participant number. You can obtain a site code and registering on the data management system by contacting *ncov@isaric.org*. 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.
- Printed paper CRFs may be used for later transfer of the data onto the electronic database.
- For participants who return for re-admission to the same site, **start a new form with the same Participant Identification Number**. Please check "YES-admitted previously" in the ONSET & ADMISSION section. Enter as 2 separate entries in the electronic database.
- For participants who transfer between two sites that are both collecting data on this form, it is preferred to have the data entered by a single site as a single admission, under the same Participant Identification Number. When this is not possible, the first site should record "Transfer to other facility" as an OUTCOME, and the second site should start a new form with a new patient number and indicate "YES-transferred" in ONSET & ADMISSION.
- Complete every line of every section, except where the instructions say to skip a section based on a response.
- Selections with circles (O) are single selection answers (choose one answer only). Selections with square boxes (☐) are multiple selection answers (choose as many answers as are applicable).
- Mark 'Not done' 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.
- If using paper CRFs, we recommend writing clearly in 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.
- Please transfer all paper CRF data to the electronic database. All paper CRFs needs to be stored locally, do not send any forms to us. Data are accepted only via secure electronic database.
- Please enter data on the electronic data capture system at https://ncov.medsci.ox.ac.uk/. If your site would like to collect data independently, we are happy to support the establishment of locally hosted databases.
- Please contact us at *ncov@isaric.org* if you need help with databases, if you have comments and to let us know that you are using the forms.

CRF Completion Guide

FURTHER GUIDANCE AND DEFINITIONS

Comorbidities

Comorbidities present before the onset of COVID-19 and are still present. Do not include those that developed following the onset of COVID-19 symptoms. More detailed guidance is provided.

Hospital admission

For patients who were admitted to hospital with COVID-19 or symptoms consistent with possible COVID-19 infection, please enter details for the date of hospital admission. For patients with a clear alternative diagnosis leading to admission who subsequently acquired COVID-19, original admission date should be provided, but all subsequent references to admission should be taken as referring to day COVID-19 was first clinically suspected (or within the first 24 hours after first day of suspected or confirmed COVID-19 infection).

Where a patient was admitted via multiple hospital departments, count admission from the time they came to the first department during the visit that led to their admission (e.g. arrival at the Emergency Department).

Oxygen therapy

Include any form of supplemental oxygen received using any methods.

Invasive ventilation

Please include any mechanical ventilation delivered following intubation or via a tracheostomy. Do not include patients who are breathing independently via a tracheostomy.

Non-invasive ventilation

Please include any positive-pressure treatment given via a tight-fitted mask. This can be continuous positive pressure (CPAP) or bi-level positive pressure (BIPAP).

Renal replacement therapy or dialysis

Please include any form of continuous renal replacement therapy or intermittent haemodialysis.

Worst result

References to 'worst result' refer to those furthest from the normal physiological range or laboratory normal range.

Results that were rejected by the clinical team (e.g. pulse oximetry on poorly perfused extremities, haemolysed blood samples, contaminated microbiology results) should not be reported.

The following measures should be considered as a single observation and entered together:

Blood gas results: Please report the measures from the blood gas with the lowest pH (most acidotic).

Blood pressure: Please report the systolic and diastolic blood pressure from the observation with the lowest mean arterial pressure (if mean arterial pressure has not been calculated, report the measurement with lowest systolic blood pressure).

Respiratory rate: If both abnormal low and high rate observed, record the abnormally high rate.

MODULE 1: PRESENTATION/ADMISSION CASE REPORT FORM

CLINICAL INCLUSION CRITERIA

Suspected or confirmed novel coronavirus (COVID-19) infection:

Select yes if patient has either clinically suspected or laboratory-confirmed SARS-CoV-2 /COVID-19 infection.

DEMOGRAPHICS

Enrolment date: Date of enrolment into the study or for in-patients is the date that COVID-19 was first assessed as suspected or confirmed by a clinician.

Ethnic group:

Please enter all that apply of the following choices which best describe the patient's ethnicity or major ethnic group at birth. 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.) Cross (X) all that apply. If 'Other' 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 week of delivery.

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

ONSET & ADMISSION

Onset date of first/earliest symptom:

Please provide the date of patient reported onset of the first symptom that you clinically believe was related to this episode of COVID-19 infection.

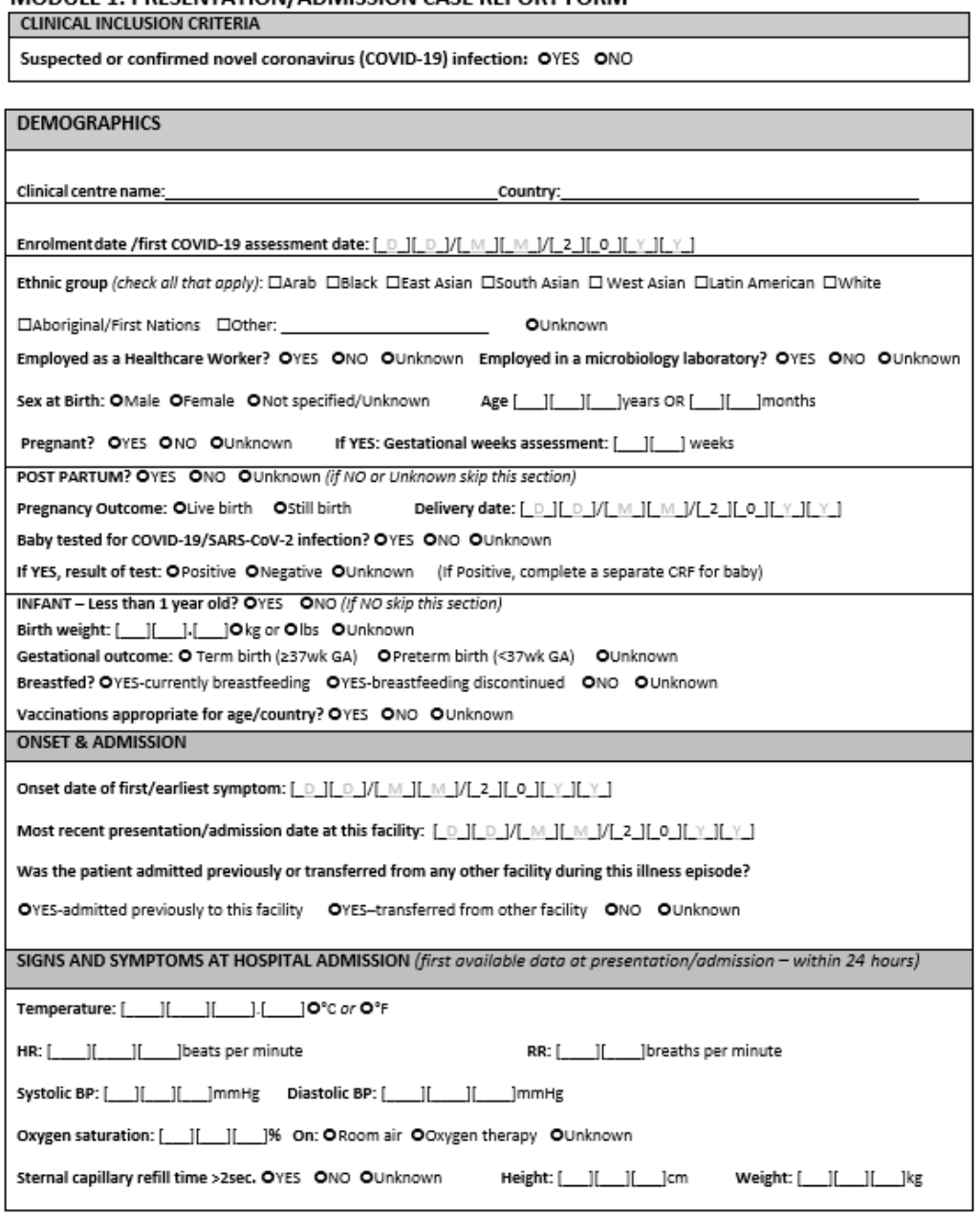
Most recent presentation/admission date at this facility:

Where a patient was admitted via multiple hospital departments, count admission from the time they came to the first department during the visit that led to their admission (e.g. arrival at the Emergency Department). For patients with a clear alternative diagnosis leading to admission who subsequently acquired COVID-19 report the date of admission as the day they were admitted to the healthcare facility.

Was the patient admitted previously or transferred from any other facility during this illness episode?

For participants who return for re-admission to the same site, start a new form with the same Participant Identification Number. Please check "YES-admitted previously to this facility". Enter as 2 separate entries in the electronic database.

For participants who transfer between two sites that are both collecting data on this form, it is preferred to have the data entered by a single site as a single admission, under the same Participant Identification Number. When this is not possible, the first site should record "Transfer to other facility" as an OUTCOME, and the second site should start a new form with a new patient number and indicate "YES-transferred from other facility" in ONSET & ADMISSION.



MODULE 1: PRESENTATION/ADMISSION CASE REPORT FORM

CLINICAL INCLUSION CRITERIA

Suspected or confirmed novel coronavirus (COVID-19) infection: O YES O NO

DEMOGRAPHICS

Clinical centre name:_____ Country:_____

Enrolment date /first COVID-19 assessment date: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

Ethnic group *(check all that apply)*: ☐Arab ☐Black ☐East Asian ☐South Asian ☐ West Asian ☐Latin American ☐White

☐Aboriginal/First Nations ☐Other: _____ O Unknown

Employed as a Healthcare Worker? O YES O NO O Unknown Employed in a microbiology laboratory? O YES O NO O Unknown

Sex at Birth: O Male O Female O Not specified/Unknown Age [___][___][___]years OR [___][___]months

Pregnant? O YES O NO O Unknown If YES: Gestational weeks assessment: [___][___] weeks

POST PARTUM? O YES O NO O Unknown *(if NO or Unknown skip this section)*

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

Baby tested for COVID-19/SARS-CoV-2 infection? O YES O NO O Unknown

If YES, result of test: O Positive O Negative O Unknown (If Positive, complete a separate CRF for baby)

INFANT – Less than 1 year old? O YES O NO *(If NO skip this section)*

Birth weight: [___][___].[___] O kg or O lbs O Unknown

Gestational outcome: O Term birth (≥37wk GA) O Preterm birth (<37wk GA) O Unknown

Breastfed? O YES-currently breastfeeding O YES-breastfeeding discontinued O NO O Unknown

Vaccinations appropriate for age/country? O YES O NO O Unknown

ONSET & ADMISSION

Onset date of first/earliest symptom: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

Most recent presentation/admission date at this facility: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

Was the patient admitted previously or transferred from any other facility during this illness episode?

O YES-admitted previously to this facility O YES–transferred from other facility O NO O Unknown

SIGNS AND SYMPTOMS AT HOSPITAL ADMISSION *(first available data at presentation/admission – within 24 hours)*

Temperature: [____][____][____].[____] O °C *or* O °F

HR: [____][____][____]beats per minute RR: [____][____]breaths per minute

Systolic BP: [___][___][___]mmHg Diastolic BP: [____][____][____]mmHg

Oxygen saturation: [___][___][___]% On: O Room air O Oxygen therapy O Unknown

Sternal capillary refill time >2sec. O YES O NO O Unknown Height: [___][___][___]cm Weight: [___][___][___]kg

SIGNS AND SYMPTOMS AT HOSPITAL ADMISSION

Please provide details of clinical observations made as close to presentation/admission, or within 24 hours of admission. For observations not made immediately at admission, please record the first available data (patient reported and/or from medical records) within 24 hours of admission. For patients with a clear alternative diagnosis leading to admission who subsequently acquired COVID-19, complete these observations for the 24 hours after onset of symptoms of suspected or confirmed COVID-19 infection.

Temperature

Please enter the peripheral body temperature (rectal if < 3 months) in the space provided and indicate the unit of measurement, either degrees Celsius (°C) or Fahrenheit (°F).

Heart rate (HR)

Enter the heart rate measured in 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.

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.

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.

MODULE 1: PRESENTATION/ADMISSION CASE REPORT FORM

CLINICAL INCLUSION CRITERIA

Suspected or confirmed novel coronavirus (COVID-19) infection: O YES O NO

DEMOGRAPHICS

Clinical centre name:_____ **Country:**_____

Enrolment date /first COVID-19 assessment date: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

Ethnic group *(check all that apply)*: ☐Arab ☐Black ☐East Asian ☐South Asian ☐ West Asian ☐Latin American ☐White ☐Aboriginal/First Nations ☐Other: _____ OUnknown

Employed as a Healthcare Worker? O YES O NO O Unknown **Employed in a microbiology laboratory?** O YES O NO O Unknown

Sex at Birth: O Male O Female O Not specified/Unknown **Age** [___][___][___]years OR [___][___]months

Pregnant? O YES O NO O Unknown **If YES: Gestational weeks assessment:** [___][___] weeks

POST PARTUM? O YES O NO O Unknown *(if NO or Unknown skip this section)*

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

Baby tested for COVID-19/SARS-CoV-2 infection? O YES O NO O Unknown

If YES, result of test: O Positive O Negative O Unknown (If Positive, complete a separate CRF for baby)

INFANT – Less than 1 year old? O YES O NO *(If NO skip this section)*

Birth weight: [___][___].[___] O kg or O lbs O Unknown

Gestational outcome: O Term birth (≥37wk GA) O Preterm birth (<37wk GA) O Unknown

Breastfed? O YES-currently breastfeeding O YES-breastfeeding discontinued O NO O Unknown

Vaccinations appropriate for age/country? O YES O NO O Unknown

ONSET & ADMISSION

Onset date of first/earliest symptom: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

Most recent presentation/admission date at this facility: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_]

Was the patient admitted previously or transferred from any other facility during this illness episode?

O YES-admitted previously to this facility O YES–transferred from other facility O NO O Unknown

SIGNS AND SYMPTOMS AT HOSPITAL ADMISSION *(first available data at presentation/admission – within 24 hours)*

Temperature: [____][____][____].[____] O °C *or* O °F

HR: [____][____][____]beats per minute **RR:** [____][____]breaths per minute

Systolic BP: [___][___][___]mmHg **Diastolic BP:** [____][____][____]mmHg

Oxygen saturation: [___][___][___]% **On:** O Room air O Oxygen therapy O Unknown

Sternal capillary refill time >2sec. O YES O NO O Unknown **Height:** [___][___][___]cm **Weight:** [___][___][___]kg

SIGNS AND SYMPTOMS ON ADMISSION

Please provide details of clinical observations made as close to presentation/admission, or within 24 hours of admission. For observations not made immediately at admission, please record the first available data (patient reported and/or from medical records) within 24 hours of admission. For patients with a clear alternative diagnosis leading to admission who subsequently acquired COVID-19, complete these observations for the 24 hours after onset of symptoms of suspected or confirmed COVID-19 infection.

PRE-ADMISSION MEDICATION *(taken within 14 days of admission/presentation at healthcare facility)*

Angiotensin converting enzyme inhibitors (ACE inhibitors): Include alacepril, captopril, zefnopril, enalapril, ramipril, quinapril, perindopril, lisinopril, benazepril, imidapril, trandolapril, and cilazapril.

Angiotensin II receptor blockers (ARBs): Examples include losartan, irbesartan, olmesartan, candesartan, valsartan, fimasartan, azilsartan, saprisartan and telmisartan

Non-steroidal anti-inflammatory (NSAIDs): Examples include aspirin, ibuprofen, naproxen, celecoxib, diclofenac, diflunisal, etodolac, indomethacin, ketoprofen, ketorolac, nabumetone, oxaprozin, piroxicam, salsalate, sulindac, tolmetin

Oral steroids: Examples include prednisolone, betamethasone, dexamethasone, hydrocortisone, methylprednisolone, deflazacort and fludrocortisone. Only list medications taken orally. Please list generic names.

Other immunosuppressant agents (not oral steroids): Examples include tofacitinib, cyclosporine, tacrolimus, sirolimus, everolimus, azathioprine, leflunomide, mycophenolate and biologics such as abatacept, adalimumab, anakinra, certolizumab, etanercept, adalimumab, infliximab and rituximab. Please list generic names.

Antivirals: Examples include ribavirin, lopinavir, ritonavir, remdesivir, oseltamivir, zanamivir, acyclovir, ganciclovir, and interferons. Please list generic names. Topical preparations should not be recorded.

Antibiotics: 'Antibiotic' refers to any agent(s) that selectively target bacteria. Please list generic names. Topical preparations should not be recorded.

Other targeted COVID-19 Medications: Includes for example: chloroquine, hydroxychloroquine, Interferon antibodies, convalescent plasma or any other COVID-19 therapeutics not included in the categories listed above. Please list generic names.

MODULE 1: PRESENTATION/ADMISSION CASE REPORT FORM

SIGNS AND SYMPTOMS ON ADMISSION *(Unk = Unknown)*

History of fever	O YES O NO O Unk	Fatigue / Malaise	O YES O NO O Unk
Cough O YES-non-productive O YES-productive O YES-with haemoptysis O NO O Unk		Anorexia	O YES O NO O Unk
		Altered consciousness/confusion	O YES O NO O Unk
Sore throat	O YES O NO O Unk	Muscle aches (myalgia)	O YES O NO O Unk
Runny nose (rhinorrhoea)	O YES O NO O Unk	Joint pain (arthralgia)	O YES O NO O Unk
Wheezing	O YES O NO O Unk	Inability to walk	O YES O NO O Unk
Shortness of breath	O YES O NO O Unk	Abdominal pain	O YES O NO O Unk
Lower chest wall indrawing	O YES O NO O Unk	Diarrhoea	O YES O NO O Unk
Chest pain	O YES O NO O Unk	Vomiting / Nausea	O YES O NO O Unk
Conjunctivitis	O YES O NO O Unk	Skin rash	O YES O NO O Unk
Lymphadenopathy	O YES O NO O Unk	Bleeding (Haemorrhage)	O YES O NO O Unk
Headache	O YES O NO O Unk	If YES, specify site(s):	
Loss of smell (Anosmia)	O YES O NO O Unk	Other symptom(s)	O YES O NO O Unk
Loss of taste (Ageusia)	O YES O NO O Unk	If YES, specify:	
Seizures	O YES O NO O Unk		

PRE-ADMISSION MEDICATION *(taken within 14 days of admission/presentation at healthcare facility)*

Angiotensin converting enzyme inhibitors (ACE inhibitors)	O YES O NO O Unk
Angiotensin II receptor blockers (ARBs)	O YES O NO O Unk
Non-steroidal anti-inflammatory (NSAIDs)	O YES O NO O Unk
Oral steroids	O YES O NO O Unk If YES, agent(s):
Other immunosuppressant agents (not oral steroids)	O YES O NO O Unk If YES, agent(s):
Antivirals	O YES O NO O Unk If YES, agent(s):
Antibiotics	O YES O NO O Unk If YES, agent(s):
Other targeted COVID-19 Medications	O YES O NO O Unk If YES, agent(s):

CO-MORBIDITIES AND RISK FACTORS *(existing prior to admission and ongoing)*

Chronic cardiac disease *(not hypertension)*	O YES O NO O Unk	Chronic hematologic disease	O YES O NO O Unk
Hypertension	O YES O NO O Unk	AIDS / HIV O YES-on ART O YES-not on ART	O NO O Unk
Chronic pulmonary disease *(not asthma)*	O YES O NO O Unk	Diabetes Mellitus O YES-Type 1 O YES -Type 2	O NO O Unk
Asthma *(physician diagnosed)*	O YES O NO O Unk	Rheumatologic disorder	O YES O NO O Unk
Chronic kidney disease	O YES O NO O Unk	Dementia	O YES O NO O Unk
Obesity *(as defined by clinical staff)*	O YES O NO O Unk	Tuberculosis	O YES O NO O Unk
Moderate or severe liver disease	O YES O NO O Unk	Malnutrition	O YES O NO O Unk
Mild liver disease	O YES O NO O Unk	Smoking O YES O Never smoked O Former smoker	O Unk
Asplenia	O YES O NO O Unk	Other relevant risk factor(s)	O YES O NO O Unk
Chronic neurological disorder	O YES O NO O Unk	If YES, specify:	
Malignant neoplasm	O YES O NO O Unk		

CO-MORBIDITIES AND RISK FACTORS

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.

Hypertension

Elevated arterial blood pressure diagnosed clinically, >140mmHg systolic or >90mmHg diastolic.

Chronic pulmonary disease (not asthma)

Please include any of chronic obstructive pulmonary disease (chronic bronchitis, chronic obstructive pulmonary disease (COPD), 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

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.

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

Asplenia

Please include any of splenectomy, non-functional spleen, and congenital asplenia**.**

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.

MODULE 1: PRESENTATION/ADMISSION CASE REPORT FORM

SIGNS AND SYMPTOMS ON ADMISSION *(Unk = Unknown)*			
History of fever	O YES O NO O Unk	Fatigue / Malaise	O YES O NO O Unk
Cough O YES-non-productive O YES-productive O YES-with haemoptysis O NO O Unk		Anorexia	O YES O NO O Unk
		Altered consciousness/confusion	O YES O NO O Unk
Sore throat	O YES O NO O Unk	Muscle aches (myalgia)	O YES O NO O Unk
Runny nose (rhinorrhoea)	O YES O NO O Unk	Joint pain (arthralgia)	O YES O NO O Unk
Wheezing	O YES O NO O Unk	Inability to walk	O YES O NO O Unk
Shortness of breath	O YES O NO O Unk	Abdominal pain	O YES O NO O Unk
Lower chest wall indrawing	O YES O NO O Unk	Diarrhoea	O YES O NO O Unk
Chest pain	O YES O NO O Unk	Vomiting / Nausea	O YES O NO O Unk
Conjunctivitis	O YES O NO O Unk	Skin rash	O YES O NO O Unk
Lymphadenopathy	O YES O NO O Unk	Bleeding (Haemorrhage)	O YES O NO O Unk
Headache	O YES O NO O Unk	If YES, specify site(s):	
Loss of smell (Anosmia)	O YES O NO O Unk	Other symptom(s)	O YES O NO O Unk
Loss of taste (Ageusia)	O YES O NO O Unk	If YES, specify:	
Seizures	O YES O NO O Unk		

PRE-ADMISSION MEDICATION *(taken within 14 days of admission/presentation at healthcare facility)*	
Angiotensin converting enzyme inhibitors (ACE inhibitors)	O YES O NO O Unk
Angiotensin II receptor blockers (ARBs)	O YES O NO O Unk
Non-steroidal anti-inflammatory (NSAIDs)	O YES O NO O Unk
Oral steroids	O YES O NO O Unk If YES, agent(s):
Other immunosuppressant agents (not oral steroids)	O YES O NO O Unk If YES, agent(s):
Antivirals	O YES O NO O Unk If YES, agent(s):
Antibiotics	O YES O NO O Unk If YES, agent(s):
Other targeted COVID-19 Medications	O YES O NO O Unk If YES, agent(s):

CO-MORBIDITIES AND RISK FACTORS *(existing prior to admission and ongoing)*			
Chronic cardiac disease *(not hypertension)*	O YES O NO O Unk	Chronic hematologic disease	O YES O NO O Unk
Hypertension	O YES O NO O Unk	AIDS / HIV O YES-on ART O YES-not on ART O NO O Unk	
Chronic pulmonary disease *(not asthma)*	O YES O NO O Unk	Diabetes Mellitus O YES-Type 1 O YES -Type 2 O NO O Unk	
Asthma *(physician diagnosed)*	O YES O NO O Unk	Rheumatologic disorder	O YES O NO O Unk
Chronic kidney disease	O YES O NO O Unk	Dementia	O YES O NO O Unk
Obesity *(as defined by clinical staff)*	O YES O NO O Unk	Tuberculosis	O YES O NO O Unk
Moderate or severe liver disease	O YES O NO O Unk	Malnutrition	O YES O NO O Unk
Mild liver disease	O YES O NO O Unk	Smoking O YES O Never smoked O Former smoker O Unk	
Asplenia	O YES O NO O Unk	Other relevant risk factor(s)	O YES O NO O Unk
Chronic neurological disorder	O YES O NO O Unk	If YES, specify:	
Malignant neoplasm	O YES O NO O Unk		

CO-MORBIDITIES, continued

Chronic hematologic disease

Any long-term disorder of the red or white blood cells, platelets or 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.

AIDS/HIV

History of laboratory-confirmed HIV infection. Indicate whether or not the patient is on ART (antiretroviral therapy)

Diabetes Mellitus

Type 1 or Type 2 diabetes mellitus requiring oral or subcutaneous treatment. Please indicate whether type 1 or type 2.

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

Tuberculosis

Patients currently receiving treatment for tuberculosis. Do not include latent tuberculosis.

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.

MODULE 1: PRESENTATION/ADMISSION CASE REPORT FORM

SIGNS AND SYMPTOMS ON ADMISSION *(Unk = Unknown)*			
History of fever	O YES O NO O Unk	Fatigue / Malaise	O YES O NO O Unk
Cough O YES-non-productive O YES-productive O YES-with haemoptysis O NO O Unk		Anorexia	O YES O NO O Unk
		Altered consciousness/confusion	O YES O NO O Unk
Sore throat	O YES O NO O Unk	Muscle aches (myalgia)	O YES O NO O Unk
Runny nose (rhinorrhoea)	O YES O NO O Unk	Joint pain (arthralgia)	O YES O NO O Unk
Wheezing	O YES O NO O Unk	Inability to walk	O YES O NO O Unk
Shortness of breath	O YES O NO O Unk	Abdominal pain	O YES O NO O Unk
Lower chest wall indrawing	O YES O NO O Unk	Diarrhoea	O YES O NO O Unk
Chest pain	O YES O NO O Unk	Vomiting / Nausea	O YES O NO O Unk
Conjunctivitis	O YES O NO O Unk	Skin rash	O YES O NO O Unk
Lymphadenopathy	O YES O NO O Unk	Bleeding (Haemorrhage)	O YES O NO O Unk
Headache	O YES O NO O Unk	If YES, specify site(s):	
Loss of smell (Anosmia)	O YES O NO O Unk	Other symptom(s)	O YES O NO O Unk
Loss of taste (Ageusia)	O YES O NO O Unk	If YES, specify:	
Seizures	O YES O NO O Unk		

PRE-ADMISSION MEDICATION *(taken within 14 days of admission/presentation at healthcare facility)*	
Angiotensin converting enzyme inhibitors (ACE inhibitors)	O YES O NO O Unk
Angiotensin II receptor blockers (ARBs)	O YES O NO O Unk
Non-steroidal anti-inflammatory (NSAIDs)	O YES O NO O Unk
Oral steroids	O YES O NO O Unk If YES, agent(s):
Other immunosuppressant agents (not oral steroids)	O YES O NO O Unk If YES, agent(s):
Antivirals	O YES O NO O Unk If YES, agent(s):
Antibiotics	O YES O NO O Unk If YES, agent(s):
Other targeted COVID-19 Medications	O YES O NO O Unk If YES, agent(s):

CO-MORBIDITIES AND RISK FACTORS *(existing prior to admission and ongoing)*			
Chronic cardiac disease *(not hypertension)*	O YES O NO O Unk	Chronic hematologic disease	O YES O NO O Unk
Hypertension	O YES O NO O Unk	AIDS / HIV O YES-on ART O YES-not on ART O NO O Unk	
Chronic pulmonary disease *(not asthma)*	O YES O NO O Unk	Diabetes Mellitus O YES-Type 1 O YES -Type 2 O NO O Unk	
Asthma *(physician diagnosed)*	O YES O NO O Unk	Rheumatologic disorder	O YES O NO O Unk
Chronic kidney disease	O YES O NO O Unk	Dementia	O YES O NO O Unk
Obesity *(as defined by clinical staff)*	O YES O NO O Unk	Tuberculosis	O YES O NO O Unk
Moderate or severe liver disease	O YES O NO O Unk	Malnutrition	O YES O NO O Unk
Mild liver disease	O YES O NO O Unk	Smoking O YES O Never smoked O Former smoker O Unk	
Asplenia	O YES O NO O Unk	Other relevant risk factor(s)	O YES O NO O Unk
Chronic neurological disorder	O YES O NO O Unk	If YES, specify:	
Malignant neoplasm	O YES O NO O Unk		

MODULE 2: DAILY CASE REPORT FORM
SIGNS AND SYMPTOMS

Temperature

Please enter the peripheral body temperature (rectal if < 3 months) in the space provided and indicate the unit of measurement, either degrees Celsius (°C) or Fahrenheit (°F).

Heart rate (HR)

Enter the heart rate measured in 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). If both abnormal low and high rate observed, record the abnormally high rate.

Systolic BP

Please report the systolic and diastolic blood pressure from the observation with the lowest mean arterial pressure (if mean arterial pressure has not been calculated, report the measurement with lowest systolic blood pressure).

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

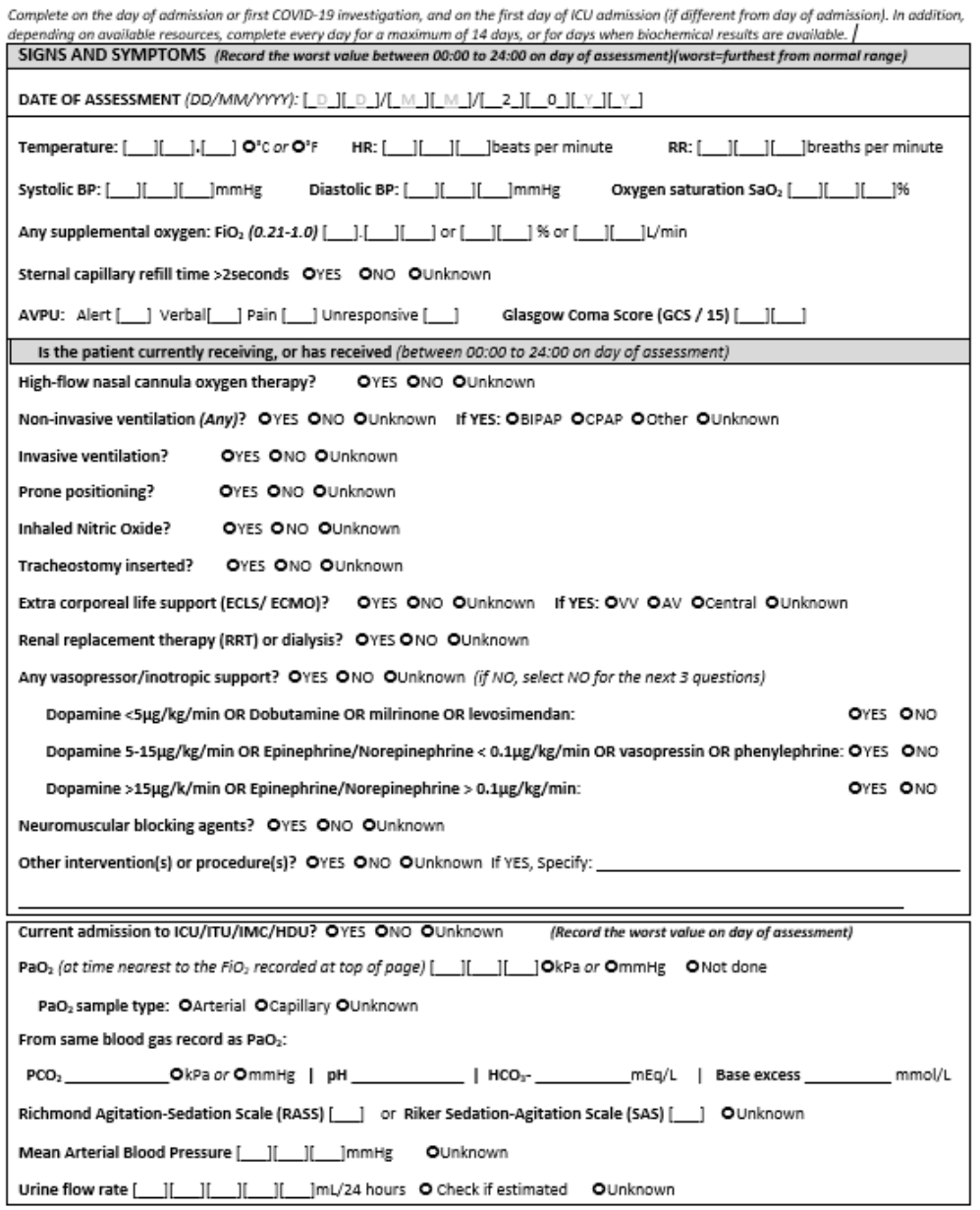
Please enter the diastolic blood pressure measured in millimetres of mercury (mmHg), in the relevant sections. For example, if the blood pressure is 120/85 mmHg, enter 85 in the section marked 'diastolic BP'. Use any recognised method for measuring blood pressure.

Oxygen saturation SaO_2

For all patients, irrespective of ventilation or supplemental oxygen requirement, please enter the percentage oxygen saturation. This may be measured by pulse oximetry or by arterial blood gas analysis.

Any supplemental oxygen: FiO_2 (0.21-1.0)

This is a key indicator to complete for all patients. If the patient received any form of supplemental oxygen through a mask or nasal cannula that delivers a known concentration of oxygen or is being ventilated, please provide the fraction of inspired oxygen (FiO_2) delivered. For patients receiving oxygen through any means, such as a face mask or nasal cannula, that does not deliver a known oxygen concentration provide the maximum flow rate received on day of completion in L/min.



MODULE 2: DAILY CASE REPORT FORM

Complete on the day of admission or first COVID-19 investigation, and on the first day of ICU admission (if different from day of admission). In addition, depending on available resources, complete every day for a maximum of 14 days, or for days when biochemical results are available.

SIGNS AND SYMPTOMS *(Record the worst value between 00:00 to 24:00 on day of assessment)(worst=furthest from normal range)*

DATE OF ASSESSMENT *(DD/MM/YYYY)*: [_D_][_D_]/[_M_][_M_]/[__2_][__0_][_Y_][_Y_]

Temperature: [___][___].[___] O°C *or* O°F HR: [___][___][___]beats per minute RR: [___][___][___]breaths per minute

Systolic BP: [___][___][___]mmHg Diastolic BP: [___][___][___]mmHg Oxygen saturation SaO_2 [___][___][___]%

Any supplemental oxygen: FiO_2 *(0.21-1.0)* [___].[___][___] or [___][___] % or [___][___]L/min

Sternal capillary refill time >2seconds OYES ONO OUnknown

AVPU: Alert [___] Verbal[___] Pain [___] Unresponsive [___] Glasgow Coma Score (GCS / 15) [___][___]

Is the patient currently receiving, or has received *(between 00:00 to 24:00 on day of assessment)*

High-flow nasal cannula oxygen therapy? OYES ONO OUnknown

Non-invasive ventilation *(Any)*? OYES ONO OUnknown If YES: OBIPAP OCPAP OOther OUnknown

Invasive ventilation? OYES ONO OUnknown

Prone positioning? OYES ONO OUnknown

Inhaled Nitric Oxide? OYES ONO OUnknown

Tracheostomy inserted? OYES ONO OUnknown

Extra corporeal life support (ECLS/ ECMO)? OYES ONO OUnknown If YES: OVV OAV OCentral OUnknown

Renal replacement therapy (RRT) or dialysis? OYES ONO OUnknown

Any vasopressor/inotropic support? OYES ONO OUnknown *(if NO, select NO for the next 3 questions)*

Dopamine <5µg/kg/min OR Dobutamine OR milrinone OR levosimendan: OYES ONO

Dopamine 5-15µg/kg/min OR Epinephrine/Norepinephrine < 0.1µg/kg/min OR vasopressin OR phenylephrine: OYES ONO

Dopamine >15µg/k/min OR Epinephrine/Norepinephrine > 0.1µg/kg/min: OYES ONO

Neuromuscular blocking agents? OYES ONO OUnknown

Other intervention(s) or procedure(s)? OYES ONO OUnknown If YES, Specify: _____

_____

Current admission to ICU/ITU/IMC/HDU? OYES ONO OUnknown *(Record the worst value on day of assessment)*

PaO_2 *(at time nearest to the FiO_2 recorded at top of page)* [___][___][___]OkPa *or* OmmHg ONot done

PaO_2 sample type: OArterial OCapillary OUnknown

From same blood gas record as PaO_2:

PCO_2 _____OkPa *or* OmmHg | pH _____ | HCO_3- _____mEq/L | Base excess _____ mmol/L

Richmond Agitation-Sedation Scale (RASS) [___] or Riker Sedation-Agitation Scale (SAS) [___] OUnknown

Mean Arterial Blood Pressure [___][___][___]mmHg OUnknown

Urine flow rate [___][___][___][___][___]mL/24 hours O Check if estimated OUnknown

SIGNS AND SYMPTOMS, continued

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.

AVPU

Alert – responding to voice – responding to pain – unresponsive: please state the least responsive condition of the patient during the calendar day (not counting normal sleep). On day of admission record the value as close to admission as possible before treatments have been administered. For daily records, if the patient is being sedated on the day of assessment record the value before the sedation.

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. If the patient is sedated on the day of assessment these parameters should correspond to the values observed before sedation. For daily recording, if the patient is fully sedated for the duration of the day of assessment (from 00:00 to 24:00) record non testable. Glasgow Coma Score: https://www.glasgowcomascale.org/downloads/GCS-Assessment-Aid-English.pdf?v=3

Current admission to ICU/ITU/IMC/HDU?

If the patient has been admitted to an intensive care, intensive therapy, intermediate care or high dependency unit please tick 'yes'. If the patient is on a general care ward then select 'no' or 'Unknown'.

PaO_2 (*at time nearest to the FiO_2 recorded at top of page)*

PaO_2 (partial pressure of oxygen in blood) as determined by arterial/ capillary blood gas analysis. This PaO_2 must correspond with the oxygen therapy documented in the FiO_2 field. Please fill in the lowest value in either mmHg or kPa depending on the output of your blood gas analyser. If the PaO_2 is not known, place NA in the data field.

From the same blood gas record as PaO_2:

$PaCO_2$ is the partial pressure of carbon dioxide measured in the sample. pH is the measure of the activity of the (solvated) hydrogen ion (H+) measured in the sample. HCO_3- refers to the bicarbonate measured in the blood gas sample. Base excess refers to standardised base excess (SBE). If standardised base excess is not reported, enter the base excess value presented, this can be either a positive or negative value.

Richmond Agitation-Sedation Scale (RASS)

RASS – If done, enter the lowest calculated value (between -5 and 4) on the date of assessment.

Riker Sedation-Agitation Scale (SAS)

SAS - If done, enter the lowest calculated value (between 1 and 7) on the date of assessment.

MODULE 2: DAILY CASE REPORT FORM

Complete on the day of admission or first COVID-19 investigation, and on the first day of ICU admission (if different from day of admission). In addition, depending on available resources, complete every day for a maximum of 14 days, or for days when biochemical results are available.

SIGNS AND SYMPTOMS *(Record the worst value between 00:00 to 24:00 on day of assessment)(worst=furthest from normal range)*

DATE OF ASSESSMENT *(DD/MM/YYYY)*: [_D_][_D_]/[_M_][_M_]/[__2_][__0_][_Y_][_Y_]

Temperature: [___][___].[___] O°C *or* O°F **HR:** [___][___][___]beats per minute **RR:** [___][___][___]breaths per minute

Systolic BP: [___][___][___]mmHg **Diastolic BP:** [___][___][___]mmHg **Oxygen saturation SaO_2** [___][___][___]%

Any supplemental oxygen: FiO_2 *(0.21-1.0)* [___].[___][___] or [___][___] % or [___][___]L/min

Sternal capillary refill time >2seconds OYES ONO OUnknown

AVPU: Alert [___] Verbal[___] Pain [___] Unresponsive [___] **Glasgow Coma Score (GCS / 15)** [___][___]

Is the patient currently receiving, or has received *(between 00:00 to 24:00 on day of assessment)*

High-flow nasal cannula oxygen therapy? OYES ONO OUnknown

Non-invasive ventilation *(Any)*? OYES ONO OUnknown **If YES:** OBIPAP OCPAP OOther OUnknown

Invasive ventilation? OYES ONO OUnknown

Prone positioning? OYES ONO OUnknown

Inhaled Nitric Oxide? OYES ONO OUnknown

Tracheostomy inserted? OYES ONO OUnknown

Extra corporeal life support (ECLS/ ECMO)? OYES ONO OUnknown **If YES:** OVV OAV OCentral OUnknown

Renal replacement therapy (RRT) or dialysis? OYES ONO OUnknown

Any vasopressor/inotropic support? OYES ONO OUnknown *(if NO, select NO for the next 3 questions)*

Dopamine <5µg/kg/min OR Dobutamine OR milrinone OR levosimendan: OYES ONO

Dopamine 5-15µg/kg/min OR Epinephrine/Norepinephrine < 0.1µg/kg/min OR vasopressin OR phenylephrine: OYES ONO

Dopamine >15µg/k/min OR Epinephrine/Norepinephrine > 0.1µg/kg/min: OYES ONO

Neuromuscular blocking agents? OYES ONO OUnknown

Other intervention(s) or procedure(s)? OYES ONO OUnknown If YES, Specify: _____

_____

Current admission to ICU/ITU/IMC/HDU? OYES ONO OUnknown *(Record the worst value on day of assessment)*

PaO_2 *(at time nearest to the FiO_2 recorded at top of page)* [___][___][___]OkPa *or* OmmHg ONot done

PaO_2 sample type: OArterial OCapillary OUnknown

From same blood gas record as PaO_2:

PCO_2 _____ OkPa *or* OmmHg | **pH** _____ | **HCO_3-** _____mEq/L | **Base excess** _____ mmol/L

Richmond Agitation-Sedation Scale (RASS) [___] or **Riker Sedation-Agitation Scale (SAS)** [___] OUnknown

Mean Arterial Blood Pressure [___][___][___]mmHg OUnknown

Urine flow rate [___][___][___][___][___]mL/24 hours O Check if estimated OUnknown

LABORATORY RESULTS

Please record all laboratory results available on day of admission, or the day that COVID-19 was first clinically suspected in patients already admitted to hospital, and on day of admission to ICU/HDU.
For daily records: record the date of assessment as the day the blood sample/s were taken.. If the unit of measurement is not shown on the paper form it will likely appear in the dropdown list in the eCRF. If you cannot find the correct unit on the eCRF please use a unit converter, such as: http://unitslab.com/ or equivalent or email ncov@isaric.org to let us know.
'Worst value' refers to values furthest from the normal physiological range or laboratory normal range. Results that were rejected by the clinical team (e.g. haemolysed blood samples, contaminated microbiology results) should not be reported.

Haemoglobin (Hb or Hgb) refers to haemoglobin concentration measurement in blood.

WBC count is the total white blood cell count in blood.

Haematocrit (Ht or HCT), also known as packed cell volume (PCV) or erythrocyte volume fraction (EVF), is the volume percentage (%) of red blood cells in blood.

APTT is the activated partial thromboplastin time. Record the highest value.

APTR is the activated partial thromboplastin ratio. Record the highest value.

PT is the prothrombin time. Record the highest value.

INR is the international normalised ratio. Record the highest value.

ALT/SGPT: ALT is alanine transaminase (also called serum glutamic pyruvate transaminase, SGPT). Record the highest value.

Total Bilirubin refers to total bilirubin measured in the blood. Record the highest value.

AST/SGOT is aspartate transaminase (also called serum glutamic oxaloacetic transaminase, SGOT). Record the highest value.

Blood urea nitrogen is also known as 'urea', measured in a blood sample. Record the highest value.

Lactate refers to blood lactate. Record the highest value.

Creatinine refers to serum creatinine. Record the highest value.

Procalcitonin or PCT refers to blood procalcitonin. Record the highest value.

CRP is C-reactive protein and refers to the blood (serum or plasma) CRP level. Record the highest value.

LDH is lactate dehydrogenase. Record the highest value.

Creatine kinase (CK, or creatine phosphokinase, CPK) refers to total creatine kinase measured in the blood. Record the highest value.

Troponin I Record the highest value

D-dimer Record the highest value

Ferritin Record the highest value

IL-6 is Interleukin 6. Record the highest value

MODULE 2: DAILY CASE REPORT FORM

Complete on the day of admission or first COVID-19 investigation, and on the first day of ICU admission (if different from day of admission). In addition, depending on available resources, complete every day for a maximum of 14 days, or for days when biochemical results are available.

LABORATORY RESULTS (on admission, on any admission to ICU, then daily) – 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/A'):

LABORATORY RESULTS *(*record units if different from those listed)*

Parameter	Value*	Not done	Parameter	Value*	Not done
Haemoglobin (g/L)		o	Urea (BUN) (mmol/L)		o
WBC count (x10^9/L)		o	Lactate (mmol/L)		o
Lymphocyte count (10^9/L)		o	Creatinine (µmol/L)		o
Neutrophil count (10^9/L)		o	Sodium (mmol/L)		o
Haematocrit (%)		o	Potassium (mmol/L)		o
Platelets (x10^9/L)		o	Procalcitonin (ng/mL)		o
APTT (seconds))		o	CRP (mg/L)		o
APTR		o	LDH (U/L)		o
PT (seconds)		o	Creatine kinase (U/L)		o
INR		o	Troponin I (ng/mL)		o
ALT/SGPT (U/L)		o	D-dimer (mg/L)		o
Total bilirubin (µmol/L)		o	Ferritin (ng/mL)		o
AST/SGOT (U/L)		o	IL-6 (pg/mL)		o
Glucose (mmol/L)		o			

MODULE 3: OUTCOME CASE REPORT FORM

TREATMENT

For all questions of duration, please count the number of calendar days that the patient received the treatment. For treatments that were stopped and restarted, count those days on which the treatment was given but don't count any calendar days on which it was not given at all.

Oxygen therapy

Complete this field for all patients. If the patient received any form of supplementary oxygen, via nose cannula, mask or non-invasive or invasive ventilation tick 'yes' and indicate the total days they received any form of oxygen (O_2) therapy.

If any supplemental oxygen (at any concentration) was given by any means of delivery **at any point** during the patient's hospital stay, place a cross in the box marked 'yes'. This includes any supplementary oxygen (O_2) delivered via non-invasive facemasks/nasal cannula/mask or via invasive mechanical ventilation. Please also indicate the maximum O_2 flow volume. If it is not possible to access record of the absolute highest O_2 volume delivered during the admission indicate the highest known.

Non-invasive ventilation (Any)

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 during their hospital stay, place tick 'yes' and enter the total duration in days if known.

Invasive ventilation (Any)

Invasive ventilation means that patient has undergone tracheal intubation, for the purpose of invasive mechanical ventilation. Invasive ventilation is a method to mechanically assist or replace spontaneous breathing in patients by use of a powered device that forces oxygenated air into the lungs. The mode of intubation may be orotracheal, nasotracheal, or via a cricothyrotomy or tracheotomy.

Prone Positioning

Prone ventilation refers to ventilation with the patient lying in the prone position. If the patient received prone ventilation at any time during their hospital stay, please tick 'yes' and indicate the total duration in days.

Renal replacement therapy (RRT) or dialysis

Renal replacement therapy includes haemodialysis, peritoneal dialysis (PD), intermittent haemodialysis (IHD), on-line intermittent haemofiltration (IHF), on-line haemodiafiltration (IHDF), continuous haemofiltration (CHF) and continuous haemodiafiltration (CHDF), continuous venovenous haemofiltration (CVVH), continuous venovenous haemodialysis (CVVHD), continuous venovenous haemodiafiltration (CVVHDF), slow continuous ultrafiltration (SCUF), continuous arteriovenous haemofiltration (CAVHD) and sustained low-efficiency dialysis (SLED).

Inotropes/vasopressors?

A vasopressor is a pharmaceutical agent that causes vasoconstriction. Agents include norepinephrine, epinephrine, vasopressin, terlipressin and phenylephrine. An inotrope is a pharmaceutical agent that alters the force of myocardial contractility. Commonly used 'positive' inotropes include dobutamine, dopamine, milrinone and adrenaline (epinephrine). If the patient received a vasopressor or inotrope for at least one hour during their hospital stay, place tick 'yes' and the total duration in days if known.

MODULE 3: OUTCOME CASE REPORT FORM

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

Any Oxygen therapy? O YES O NO O Unknown **If YES, total duration:** _____ days O Unknown

Maximum O_2 flow volume: O <2 L/min O 2-5 L/min O 6-10 L/min O 11-15 L/min O >15 L/min

Non-invasive ventilation? *(Any)* O YES O NO O Unknown **If YES, total duration:** _____ days O Unknown

Invasive ventilation? *(Any)* O YES O NO O Unknown **If YES, total duration:** _____ days O Unknown

Prone Positioning? O YES O NO O Unknown **If YES, total duration:** _____ days O Unknown

Inhaled Nitric Oxide? O YES O NO O Unknown

Tracheostomy inserted? O YES O NO O Unknown

Extracorporeal support (ECMO)? O YES O NO O Unknown **If YES, total duration:** _____ days O Unknown

Renal replacement therapy (RRT) or dialysis? O YES O NO O Unknown

Inotropes/vasopressors? O YES O NO O Unknown **If YES, total duration:** _____ days O Unknown

ICU or High Dependency Unit admission? O YES O NO O Unknown **If YES, total duration:** _____ days O Unknown

If YES, date of ICU admission: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] O Unknown

date of ICU discharge: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] O Unknown

COMPLICATIONS: At any time during hospitalisation did the patient experience: *(Unk = Unknown)*

Viral pneumonia/pneumonitis	O YES O NO O Unk	Stroke / Cerebrovascular accident	O YES O NO O Unk
Bacterial pneumonia	O YES O NO O Unk	Meningitis / Encephalitis	O YES O NO O Unk
Acute Respiratory Distress Syndrome	O YES O NO O Unk	Bacteremia	O YES O NO O Unk
If YES, specify: O Mild O Moderate O Severe O Unk		Coagulation disorder / DIC	O YES O NO O Unk
Pneumothorax	O YES O NO O Unk	Pulmonary embolism	O YES O NO O Unk
Pleural effusion	O YES O NO O Unk	Anemia	O YES O NO O Unk
Cryptogenic organizing pneumonia (COP)	O YES O NO O Unk	Rhabdomyolysis / Myositis	O YES O NO O Unk
Bronchiolitis	O YES O NO O Unk	Acute renal injury/ Acute renal failure	O YES O NO O Unk
Cardiac arrest	O YES O NO O Unk	Gastrointestinal haemorrhage	O YES O NO O Unk
Myocardial infarction	O YES O NO O Unk	Pancreatitis	O YES O NO O Unk
Cardiac ischaemia	O YES O NO O Unk	Liver dysfunction	O YES O NO O Unk
Cardiac arrhythmia	O YES O NO O Unk	Hyperglycemia	O YES O NO O Unk
Myocarditis / Pericarditis	O YES O NO O Unk	Hypoglycemia	O YES O NO O Unk
Endocarditis	O YES O NO O Unk	Other	
Cardiomyopathy	O YES O NO O Unk	If YES specify:	
Congestive heart failure	O YES O NO O Unk		
Seizure	O YES O NO O Unk		

COMPLICATIONS

Please select all that were clinically identified at any time during the hospital admission.
Do not include known comorbidities (e.g. previous atrial fibrillation should not be included but new onset during this admission should). Record physician diagnosed complications.

Viral pneumonitis/pneumonia
Clinically or radiologically diagnosed viral pneumonitis/pneumonia.

Bacterial pneumonia
Clinically or radiologically diagnosed bacterial pneumonia (including community, hospital and ventilator acquired) managed with antimicrobials. Bacteriological confirmation not required.

Acute Respiratory Distress Syndrome (ARDS)
Defined according to Berlin criteria as:

- Occurring within 1 week of a known clinical insult or worsening respiratory symptoms
- Bilateral radiological opacities not fully explained by effusions, lobar/lung collapse, or nodules
- Respiratory failure not fully explained by cardiac failure or fluid overload

The severity of the hypoxaemia defines the severity of the ARDS:
Mild ARDS: The PaO2/FiO2 is >200 mmHg, but ≤300 mmHg, on ventilator settings that include positive end-expiratory pressure (PEEP) or continuous positive airway pressure (CPAP) ≥5 cm H2O.
Moderate ARDS: The PaO2/FiO2 is >100 mmHg, but ≤200 mmHg, on ventilator settings that include PEEP ≥5 cm H2O.
Severe ARDS: The PaO2/FiO2 is ≤100 mmHg on ventilators setting that include PEEP ≥5 cm H2O. To determine the PaO2/FiO2 ratio, the PaO2 is measured in mmHg and the FiO2 is expressed as a decimal between 0.21 and 1. As an example, if a patient has a PaO2 of 60 mmHg while receiving 60% oxygen, then the PaO2/FiO2 is 60/0.6 = 100 mmHg.

Pneumothorax
Is defined as the abnormal presence of air in the pleural cavity (between the lungs and the chest wall), causing collapse of the lung. It may be diagnosed clinically, usually with radiological confirmation.

Pleural effusion
Is defined as increased amounts of fluid within the pleural cavity. It may be diagnosed clinically, with or without radiological or interventional confirmation.

Cryptogenic organizing pneumonia (COP)
Idiopathic diffuse interstitial lung disease, diagnosed radiologically (multiple consolidative or ground glass opacities) or histologically (granulation tissue and chronic inflammatory infiltrate in alveoli). Formerly known as bronchiolitis obliterans organizing pneumonia (BOOP)

Bronchiolitis
This is a clinical diagnosis.

Cardiac arrest
Sudden cessation of cardiac activity with no normal breathing and no signs of circulation.

MODULE 3: OUTCOME CASE REPORT FORM

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

Any Oxygen therapy? O YES O NO O Unknown **If YES, total duration:** _____ days O Unknown

Maximum O_2 flow volume: O <2 L/min O 2-5 L/min O 6-10 L/min O 11-15 L/min O >15 L/min

Non-invasive ventilation? *(Any)* O YES O NO O Unknown **If YES, total duration:** _____ days O Unknown

Invasive ventilation? *(Any)* O YES O NO O Unknown **If YES, total duration:** _____ days O Unknown

Prone Positioning? O YES O NO O Unknown **If YES, total duration:** _____ days O Unknown

Inhaled Nitric Oxide? O YES O NO O Unknown

Tracheostomy inserted? O YES O NO O Unknown

Extracorporeal support (ECMO)? O YES O NO O Unknown **If YES, total duration:** _____ days O Unknown

Renal replacement therapy (RRT) or dialysis? O YES O NO O Unknown

Inotropes/vasopressors? O YES O NO O Unknown **If YES, total duration:** _____ days O Unknown

ICU or High Dependency Unit admission? O YES O NO O Unknown **If YES, total duration:** _____ days O Unknown

If YES, date of ICU admission: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] O Unknown

date of ICU discharge: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] O Unknown

COMPLICATIONS: At any time during hospitalisation did the patient experience: *(Unk = Unknown)*

Viral pneumonia/pneumonitis	O YES O NO O Unk	Stroke / Cerebrovascular accident	O YES O NO O Unk
Bacterial pneumonia	O YES O NO O Unk	Meningitis / Encephalitis	O YES O NO O Unk
Acute Respiratory Distress Syndrome	O YES O NO O Unk	Bacteremia	O YES O NO O Unk
If YES, specify: O Mild O Moderate O Severe O Unk		Coagulation disorder / DIC	O YES O NO O Unk
Pneumothorax	O YES O NO O Unk	Pulmonary embolism	O YES O NO O Unk
Pleural effusion	O YES O NO O Unk	Anemia	O YES O NO O Unk
Cryptogenic organizing pneumonia (COP)	O YES O NO O Unk	Rhabdomyolysis / Myositis	O YES O NO O Unk
Bronchiolitis	O YES O NO O Unk	Acute renal injury/ Acute renal failure	O YES O NO O Unk
Cardiac arrest	O YES O NO O Unk	Gastrointestinal haemorrhage	O YES O NO O Unk
Myocardial infarction	O YES O NO O Unk	Pancreatitis	O YES O NO O Unk
Cardiac ischaemia	O YES O NO O Unk	Liver dysfunction	O YES O NO O Unk
Cardiac arrhythmia	O YES O NO O Unk	Hyperglycemia	O YES O NO O Unk
Myocarditis / Pericarditis	O YES O NO O Unk	Hypoglycemia	O YES O NO O Unk
Endocarditis	O YES O NO O Unk	Other	
Cardiomyopathy	O YES O NO O Unk	If YES specify:	
Congestive heart failure	O YES O NO O Unk		
Seizure	O YES O NO O Unk		

COMPLICATIONS, continued

Myocardial infarction

Myocardial ischaemia (MI) leading to injury/necrosis, diagnosed by clinical findings, altered electrocardiography and elevated cardiac enzymes.

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 arrhythmia

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

Myocarditis / Pericarditis

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

Endocarditis

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.

Cardiomyopathy

Structural and functional disorders of myocardium commonly diagnosed by echocardiography. Can be primary (genetic) or secondary (e.g. following myocardial infarction).

. Physician diagnosis,

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.

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.

Meningitis / Encephalitis

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

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 / DIC

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.

MODULE 3: OUTCOME CASE REPORT FORM

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

Any Oxygen therapy? O YES O NO O Unknown **If YES, total duration:** _____ days O Unknown

Maximum O_2 flow volume: O <2 L/min O 2-5 L/min O 6-10 L/min O 11-15 L/min O >15 L/min

Non-invasive ventilation? *(Any)* O YES O NO O Unknown **If YES, total duration:** _____ days O Unknown

Invasive ventilation? *(Any)* O YES O NO O Unknown **If YES, total duration:** _____ days O Unknown

Prone Positioning? O YES O NO O Unknown **If YES, total duration:** _____ days O Unknown

Inhaled Nitric Oxide? O YES O NO O Unknown

Tracheostomy inserted? O YES O NO O Unknown

Extracorporeal support (ECMO)? O YES O NO O Unknown **If YES, total duration:** _____ days O Unknown

Renal replacement therapy (RRT) or dialysis? O YES O NO O Unknown

Inotropes/vasopressors? O YES O NO O Unknown **If YES, total duration:** _____ days O Unknown

ICU or High Dependency Unit admission? O YES O NO O Unknown **If YES, total duration:** _____ days O Unknown

If YES, date of ICU admission: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] O Unknown

date of ICU discharge: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] O Unknown

COMPLICATIONS: At any time during hospitalisation did the patient experience: *(Unk = Unknown)*

Viral pneumonia/pneumonitis	O YES O NO O Unk	Stroke / Cerebrovascular accident	O YES O NO O Unk
Bacterial pneumonia	O YES O NO O Unk	Meningitis / Encephalitis	O YES O NO O Unk
Acute Respiratory Distress Syndrome	O YES O NO O Unk	Bacteremia	O YES O NO O Unk
If YES, specify: O Mild O Moderate O Severe O Unk		Coagulation disorder / DIC	O YES O NO O Unk
Pneumothorax	O YES O NO O Unk	Pulmonary embolism	O YES O NO O Unk
Pleural effusion	O YES O NO O Unk	Anemia	O YES O NO O Unk
Cryptogenic organizing pneumonia (COP)	O YES O NO O Unk	Rhabdomyolysis / Myositis	O YES O NO O Unk
Bronchiolitis	O YES O NO O Unk	Acute renal injury/ Acute renal failure	O YES O NO O Unk
Cardiac arrest	O YES O NO O Unk	Gastrointestinal haemorrhage	O YES O NO O Unk
Myocardial infarction	O YES O NO O Unk	Pancreatitis	O YES O NO O Unk
Cardiac ischaemia	O YES O NO O Unk	Liver dysfunction	O YES O NO O Unk
Cardiac arrhythmia	O YES O NO O Unk	Hyperglycemia	O YES O NO O Unk
Myocarditis / Pericarditis	O YES O NO O Unk	Hypoglycemia	O YES O NO O Unk
Endocarditis	O YES O NO O Unk	Other	
Cardiomyopathy	O YES O NO O Unk	If YES specify:	
Congestive heart failure	O YES O NO O Unk		
Seizure	O YES O NO O Unk		

Pulmonary embolism

Obstruction of pulmonary artery by thrombus, air or fat. Physician diagnosis based on clinical signs, computed tomographic pulmonary angiography and/or ventilation/perfusion scanning.

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.

MODULE 3: OUTCOME CASE REPORT FORM

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

Any Oxygen therapy? O YES O NO O Unknown **If YES, total duration:** _____ days O Unknown

Maximum O_2 flow volume: O <2 L/min O 2-5 L/min O 6-10 L/min O 11-15 L/min O >15 L/min

Non-invasive ventilation? *(Any)* O YES O NO O Unknown **If YES, total duration:** _____ days O Unknown

Invasive ventilation? *(Any)* O YES O NO O Unknown **If YES, total duration:** _____ days O Unknown

Prone Positioning? O YES O NO O Unknown **If YES, total duration:** _____ days O Unknown

Inhaled Nitric Oxide? O YES O NO O Unknown

Tracheostomy inserted? O YES O NO O Unknown

Extracorporeal support (ECMO)? O YES O NO O Unknown **If YES, total duration:** _____ days O Unknown

Renal replacement therapy (RRT) or dialysis? O YES O NO O Unknown

Inotropes/vasopressors? O YES O NO O Unknown **If YES, total duration:** _____ days O Unknown

ICU or High Dependency Unit admission? O YES O NO O Unknown **If YES, total duration:** _____ days O Unknown

If YES, date of ICU admission: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] O Unknown

date of ICU discharge: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] O Unknown

COMPLICATIONS: At any time during hospitalisation did the patient experience: *(Unk = Unknown)*

Viral pneumonia/pneumonitis	O YES O NO O Unk	Stroke / Cerebrovascular accident	O YES O NO O Unk
Bacterial pneumonia	O YES O NO O Unk	Meningitis / Encephalitis	O YES O NO O Unk
Acute Respiratory Distress Syndrome	O YES O NO O Unk	Bacteremia	O YES O NO O Unk
If YES, specify: O Mild O Moderate O Severe O Unk		Coagulation disorder / DIC	O YES O NO O Unk
Pneumothorax	O YES O NO O Unk	Pulmonary embolism	O YES O NO O Unk
Pleural effusion	O YES O NO O Unk	Anemia	O YES O NO O Unk
Cryptogenic organizing pneumonia (COP)	O YES O NO O Unk	Rhabdomyolysis / Myositis	O YES O NO O Unk
Bronchiolitis	O YES O NO O Unk	Acute renal injury/ Acute renal failure	O YES O NO O Unk
Cardiac arrest	O YES O NO O Unk	Gastrointestinal haemorrhage	O YES O NO O Unk
Myocardial infarction	O YES O NO O Unk	Pancreatitis	O YES O NO O Unk
Cardiac ischaemia	O YES O NO O Unk	Liver dysfunction	O YES O NO O Unk
Cardiac arrhythmia	O YES O NO O Unk	Hyperglycemia	O YES O NO O Unk
Myocarditis / Pericarditis	O YES O NO O Unk	Hypoglycemia	O YES O NO O Unk
Endocarditis	O YES O NO O Unk	Other	
Cardiomyopathy	O YES O NO O Unk	If YES specify:	
Congestive heart failure	O YES O NO O Unk		
Seizure	O YES O NO O Unk		

COMPLICATIONS, continued

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.

MODULE 3: OUTCOME CASE REPORT FORM

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

Any Oxygen therapy? O YES O NO O Unknown **If YES, total duration:** _____ days O Unknown

Maximum O_2 flow volume: O <2 L/min O 2-5 L/min O 6-10 L/min O 11-15 L/min O >15 L/min

Non-invasive ventilation? *(Any)* O YES O NO O Unknown **If YES, total duration:** _____ days O Unknown

Invasive ventilation? *(Any)* O YES O NO O Unknown **If YES, total duration:** _____ days O Unknown

Prone Positioning? O YES O NO O Unknown **If YES, total duration:** _____ days O Unknown

Inhaled Nitric Oxide? O YES O NO O Unknown

Tracheostomy inserted? O YES O NO O Unknown

Extracorporeal support (ECMO)? O YES O NO O Unknown **If YES, total duration:** _____ days O Unknown

Renal replacement therapy (RRT) or dialysis? O YES O NO O Unknown

Inotropes/vasopressors? O YES O NO O Unknown **If YES, total duration:** _____ days O Unknown

ICU or High Dependency Unit admission? O YES O NO O Unknown **If YES, total duration:** _____ days O Unknown

If YES, date of ICU admission: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] O Unknown

date of ICU discharge: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] O Unknown

COMPLICATIONS: At any time during hospitalisation did the patient experience: *(Unk = Unknown)*

Viral pneumonia/pneumonitis	O YES O NO O Unk	Stroke / Cerebrovascular accident	O YES O NO O Unk
Bacterial pneumonia	O YES O NO O Unk	Meningitis / Encephalitis	O YES O NO O Unk
Acute Respiratory Distress Syndrome	O YES O NO O Unk	Bacteremia	O YES O NO O Unk
If YES, specify: O Mild O Moderate O Severe O Unk		Coagulation disorder / DIC	O YES O NO O Unk
Pneumothorax	O YES O NO O Unk	Pulmonary embolism	O YES O NO O Unk
Pleural effusion	O YES O NO O Unk	Anemia	O YES O NO O Unk
Cryptogenic organizing pneumonia (COP)	O YES O NO O Unk	Rhabdomyolysis / Myositis	O YES O NO O Unk
Bronchiolitis	O YES O NO O Unk	Acute renal injury/ Acute renal failure	O YES O NO O Unk
Cardiac arrest	O YES O NO O Unk	Gastrointestinal haemorrhage	O YES O NO O Unk
Myocardial infarction	O YES O NO O Unk	Pancreatitis	O YES O NO O Unk
Cardiac ischaemia	O YES O NO O Unk	Liver dysfunction	O YES O NO O Unk
Cardiac arrhythmia	O YES O NO O Unk	Hyperglycemia	O YES O NO O Unk
Myocarditis / Pericarditis	O YES O NO O Unk	Hypoglycemia	O YES O NO O Unk
Endocarditis	O YES O NO O Unk	Other	
Cardiomyopathy	O YES O NO O Unk	If YES specify:	
Congestive heart failure	O YES O NO O Unk		
Seizure	O YES O NO O Unk		

DIAGNOSTICS

Was patient clinically diagnosed with COVID-19?

Please record if the patient was clinically diagnosed with COVID-19, even if resources did not allow testing or if laboratory results were negative but the clinician judged that based on symptoms, onset and clinical case definitions COVID-19 infection was the most likely cause of the symptoms experienced.

Please complete all of the Diagnostics section even if results were negative, to monitor co-infection risk and rates.

Clinical pneumonia diagnosed?

Tick 'yes' f this was a Physician diagnosis.

Chest X-Ray/ CT performed?

Record if X-ray and/or CT were performed, even if no infiltrates were present.

Details of pathogen testing per biospecimen type

If the patient had samples taken for pathogen detection testing during their hospital stay, please complete a row for every type of sample collected (e.g. nasal/NP swab, sputum, etc.).

Where both positive and negative results for a particular sample type exist (from samples taken at different time points during the patient's hospital stay) please record the earliest positive result.

If only multiple negative results exist for a particular sample type (from samples taken at different time points during the patient's hospital stay), please document the earliest negative result.

MODULE 3: OUTCOME CASE REPORT FORM

DIAGNOSTICS

Was patient clinically diagnosed with COVID-19? ○YES ○NO ○Unknown

Was pathogen testing done during this illness episode? ○YES *(complete section)* ○NO ○Unknown

Coronavirus: ○Positive ○Negative ○Not done **If Positive:** ○COVID-2019/ SARS-CoV2 ○MERS CoV ○Other CoV: ___________ ○Unknown

Influenza : ○Positive ○Negative ○Not done **If Positive:** ○A/H3N2 ○A/H1N1pdm09 ○A/H7N9 ○A/H5N1 ○A-not typed ○B ○Other:___________ ○Unknown

RSV: ○Positive ○Negative ○Not done

Adenovirus: ○Positive ○Negative ○Not done

Bacteria: ○Positive ○Negative ○Not done **If Positive, specify:** ________ ________ ○Unknown

Other pathogen/s detected: ○YES ○NO ○Unknown **If YES, specify all:**_______________○Unknown

****

Clinical pneumonia diagnosed? ○YES ○NO ○Unknown

Chest X-Ray performed? ○YES ○NO ○Unknown **If Yes: Were infiltrates present?** ○YES ○NO ○Unknown

CT performed? ○YES ○NO ○Unknown **If Yes: Were infiltrates present?** ○YES ○NO ○Unknown

Collection Date *(DD/MM/YYYY)*	Biospecimen Type	Laboratory test Method	Result	Pathogen Tested/Detected
_D_ _D_ /_M_ _M_ /20_Y_ _Y_	○Nasal/NP swab ○Throat swab ○Combined nasal/NP+throat swab ○Sputum ○BAL ○ETA ○Urine ○Feces/rectal swab ○Blood ○Other, *Specify:* ________	○PCR ○Culture ○Other, *Specify:* ________	○Positive ○Negative ○Unknown	________
_D_ _D_ /_M_ _M_ /20_Y_ _Y_	○Nasal/NP swab ○Throat swab ○Combined nasal/NP+throat swab ○Sputum ○BAL ○ETA ○Urine ○Feces/rectal swab ○Blood ○Other, *Specify:* ________	○PCR ○Culture ○Other, *Specify:* ________	○Positive ○Negative ○Unknown	________
_D_ _D_ /_M_ _M_ /20_Y_ _Y_	○Nasal/NP swab ○Throat swab ○Combined nasal/NP+throat swab ○Sputum ○BAL ○ETA ○Urine ○Feces/rectal swab ○Blood ○Other, *Specify:* ________	○PCR ○Culture ○Other, *Specify:* ________	○Positive ○Negative ○Unknown	________
_D_ _D_ /_M_ _M_ /20_Y_ _Y_	○Nasal/NP swab ○Throat swab ○Combined nasal/NP+throat swab ○Sputum ○BAL ○ETA ○Urine ○Faeces/rectal swab ○Blood ○Other, *Specify:* ________	○PCR ○Culture ○Other, *Specify:* ________	○Positive ○Negative ○Unknown	________
_D_ _D_ /_M_ _M_ /20_Y_ _Y_	○Nasal/NP swab ○Throat swab ○Combined nasal/NP+throat swab ○Sputum ○BAL ○ETA ☐Urine ○Feces/rectal swab ○Blood ○Other, *Specify:* ________	○PCR ○Culture ○Other, *Specify:* ________	○Positive ○Negative ○Unknown	________

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

Antiviral or COVID-19 targeted agent

Record all antivirals administered from date of admission or during the hospitalisation. Record the total number of days the treatment was given.

For other antiviral or COVID-19 targeted agents record any medications given to treat COVID-19 that are not already pre-specified elsewhere in this section. Additional space is available under 'Other treatments…' at the end of this section if required.

Antibiotic

'Antibiotic' refers to any agent(s) are substances naturally produced by microorganisms or their derivatives that selectively target microorganisms. These substances are used in the treatment of bacterial and other microbial infections. Topical preparations are not included.

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.

Antifungal Agent

'Antifungal agent' refers to any agent(s) prescribed specifically to treat systemic or topical infections caused by fungi. Examples include fluconazole, amphotericin, caspofungin, anidulafungin, posaconazole, itraconazole (note that other examples exist). Topical preparations should not be recorded.

Other treatment administered for COVID-19

Record any other medications, experimental or re-purposed, administered to modify the course of COVID-19 during the admission (including as part of a clinical trial). This could include convalescent plasma, immuno-modulatory agents and anti-viral agents not already recorded above.

MODULE 3: OUTCOME CASE REPORT FORM

MEDICATION: While hospitalised or at discharge, were any of the following administered? *(Unk=Unknown)*

Antiviral or COVID-19 targeted agent? O YES O NO O Unknown If YES, specify all agents and duration:

☐ Ribavirin Date commenced [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] Duration: _____ days O Unk

☐ Lopinavir/Ritonavir Date commenced [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] Duration: _____ days O Unk

☐ Remdesivir Date commenced [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] Duration: _____ days O Unk

☐ Interferon alpha Date commenced [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] Duration: _____ days O Unk

☐ Interferon beta Date commenced [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] Duration: _____ days O Unk

☐ Chloroquine/hydroxychloroquine Date commenced [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] Duration: _____days O Unk

☐ Other _____ Date commenced [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] Duration: _____days O Unk

****

Antibiotic? O YES O NO O Unk If yes, specify all:

Agent:_____ Date commenced [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] Duration: ____ days O Unk

Agent:_____ Date commenced [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] Duration: ____ days O Unk

Agent:_____ Date commenced [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] Duration: ____ days O Unk

****

Corticosteroid? O YES O NO O Unk If YES, Route: ☐ Oral ☐ Intravenous (IV) ☐ Inhaled O Unk

If YES Oral or IV, please provide agent: _____ and max. daily dose & unit:_____

Date commenced [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] O Unk Duration: _____ days O Unk

****

Heparin? O YES O NO O Unk If YES, Route: ☐ Subcutaneous ☐ Intravenous (IV) O Unk

If YES: ☐ Unfractionated ☐ Low molecular weight ☐ Fondaparinux O Unk Maximum daily dose & unit:_____

Date commenced [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] O Unk Duration: _____ days O Unk

****

Antifungal agent? O YES O NO O Unk

****

Other treatments administered for COVID-19 including experimental or compassionate use? O YES O NO O Unk

If yes, specify agent, maximum daily does and duration:

Agent: _____ Maximum daily dose & unit: _____ O Unk

Date of commencement [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] O Unk Duration: _____ days O Unk

Agent:_____ Maximum daily dose & unit: _____ O Unk

Date of commencement [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] O Unk Duration: _____ days O Unk

OUTCOME

Outcome: O Discharged alive O Hospitalised O Transfer to other facility O Death O Palliative discharge O Unknown

Outcome date: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] O Unknown

If Discharged alive:

Ability to self-care at discharge versus before illness: O Same as before illness O Worse O Better O Unknown

Post-discharge treatment: Oxygen therapy? O YES O NO O Unknown

OUTCOME

Discharged alive can mean discharge to their usual place of residence before their illness, to the home of a relative or friend, or to a social care facility, because their illness is no longer severe enough to warrant treatment in a medical facility.

Hospitalized means they are still in hospital but have recovered from COVID-19 infection and the form has been completed as the patient is in a part of the hospital for care of other conditions and where the form will not be completed at a later date.

Transfer to other facility means they have been transferred to another facility that provides medical care. This could be a specialist centre for more intensive treatment or a step-down for rehabilitation. It does not include facilities that solely provide social care (these patients should be listed as discharged alive).

Death means the patient died in the hospital.

Palliative discharge means the patient has been discharged with the expectation that they will not recover from this or other co-existing illness. This could be to a specialist hospice facility, or to their usual home address with anticipatory end of life medications.

Outcome date Please state the date for the outcome listed above.

If Discharged Alive:

Ability to self-care at discharge versus before illness: the patient is able to care for themselves at discharge (in terms of activities of daily living) at the same level as before they developed illness then tick 'same as before illness'. If their ability to self-care has decreased or increased, then tick the appropriate circle ('worse' or 'better').

Post-discharge treatment (Complete this section only if the patient is alive).

Oxygen therapy includes, NIV or home ventilation (respiratory support/treatment).

MODULE 3: OUTCOME CASE REPORT FORM

MEDICATION: While hospitalised or at discharge, were any of the following administered? *(Unk=Unknown)*

Antiviral or COVID-19 targeted agent? O YES O NO O Unknown If YES, specify all agents and duration:

☐ Ribavirin Date commenced [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] Duration: _____ days O Unk

☐ Lopinavir/Ritonavir Date commenced [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] Duration: _____ days O Unk

☐ Remdesivir Date commenced [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] Duration: _____ days O Unk

☐ Interferon alpha Date commenced [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] Duration: _____ days O Unk

☐ Interferon beta Date commenced [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] Duration: _____ days O Unk

☐ Chloroquine/hydroxychloroquine Date commenced [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] Duration: _____days O Unk

☐ Other _____ Date commenced [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] Duration: _____days O Unk

****

Antibiotic? O YES O NO O Unk If yes, specify all:

Agent:_____ Date commenced [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] Duration: ____ days O Unk

Agent:_____ Date commenced [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] Duration: ____ days O Unk

Agent:_____ Date commenced [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] Duration: ____ days O Unk

****

Corticosteroid? O YES O NO O Unk If YES, Route: ☐ Oral ☐ Intravenous (IV) ☐ Inhaled O Unk

If YES Oral or IV, please provide agent: _____ and max. daily dose & unit:_____

Date commenced [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] O Unk Duration: _____ days O Unk

****

Heparin? O YES O NO O Unk If YES, Route: ☐ Subcutaneous ☐ Intravenous (IV) O Unk

If YES: ☐ Unfractionated ☐ Low molecular weight ☐ Fondaparinux O Unk Maximum daily dose & unit:_____

Date commenced [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] O Unk Duration: _____ days O Unk

****

Antifungal agent? O YES O NO O Unk

****

Other treatments administered for COVID-19 including experimental or compassionate use? O YES O NO O Unk

If yes, specify agent, maximum daily does and duration:

Agent: _____ Maximum daily dose & unit: _____ O Unk

Date of commencement [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] O Unk Duration: _____ days O Unk

Agent:_____ Maximum daily dose & unit: _____ O Unk

Date of commencement [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] O Unk Duration: _____ days O Unk

OUTCOME

Outcome: O Discharged alive O Hospitalised O Transfer to other facility O Death O Palliative discharge O Unknown

Outcome date: [_D_][_D_]/[_M_][_M_]/[_2_][_0_][_Y_][_Y_] O Unknown

If Discharged alive:

Ability to self-care at discharge versus before illness: O Same as before illness O Worse O Better O Unknown

Post-discharge treatment: Oxygen therapy? O YES O NO O Unknown

CORE CRITICAL CARE MODULE

Complete this form for anyone receiving critical care regardless of type of ward, in addition to the CORE COVID-19 CRF.

Admission date: this is the date the patient was admitted to the critical care ward.

Interventional clinical study: this could be a trial of a therapeutic agent (e.g. anti-viral, immunomodulator, convalescent plasma) or supportive intervention (e.g. high flow oxygen).

Reason for admission: these are the diagnoses/complications that required critical care management as assessed by a physician select all that apply.

Clinical Frailty Scale: see last page

Severity scores:
Complete if assessed or score recorded in the medical notes.

PELOD score: see https://sfar.org/scores2/pelod2.php

PRISM III score: see https://www.cpccrn.org/calculators/prismiicalculator/

Fluid balance: net fluid balance over 24h assessment day or prior to assessment

Nutrition: select route of the main type of nutrition on day of assessment from parenteral, enteral (including nasogastric or gastrostomy/jejunostomy), or NPO (*nil per os* – no oral intake).

Physical mobility: score from options 0 to 10, record **best** score.

CRITICAL CARE MODULE PART B

ICU/HDU ADMISSION FORM

ICU ADMISSION DATE *(DD/MM/YYYY):* [_D_][_D_]/[_M_][_M_]/[__2_][__0_][_Y_][_Y_]

Enrolment in interventional clinical study? O YES O NO O Unknown **If YES,** name of study:_____ or

Treatment/s trialled:_____

_____ O Unknown

Reason for ICU admission (tick all that apply): ☐ Respiratory failure ☐ Septic shock ☐ Venous thromboembolism

☐ Cardiovascular complications ☐ Acute kidney injury ☐ Acute liver injury ☐ Neurological complications ☐ Secondary infection

☐ Pancreatic injury ☐ Disseminated intravascular coagulation ☐ Pregnancy related complications ☐ Rhabdomyolysis

☐ OTHER (please specify) _____ O Unknown

Clinical Frailty Score (CFS/9) [_____] O Unknown **Acute renal failure?** O YES O NO O Unknown

DAILY FORM (Complete daily for duration of ICU/ITU/IMC/HDU admission)
(between 00:00 to 24:00 on day of assessment) Record the 'worst' value on the day of assessment.

IF patient is <18 years: **PELOD Total Score** [_____] O Unknown **PRISM III score:** [_____] O Unknown

Fluid balance (in last 24 hours) (mL) _____ ☐ Unknown

Nutrition O Parenteral O Enteral O NPO O Unknown **Best physical mobility** [___]/10 *(see scoring below)* O Unknown

0 Passively moved by staff (incl. passive cycling only)
1 Any activity in bed, but not moving out of or over edge of bed (incl. cycling)
2 Passively moved to chair (no standing or sitting at edge of bed)
3 Actively sitting over side of bed with some trunk control (may be assisted)
4 Standing
5 Transferring from bed to chair
6 Marching on the spot (at bedside; > 2steps/foot)
7 Walking with assistance of 2 or more people (>5m)
8 Walking with assistance of 1 person (>5m)
9 Walking independently with gait aid (>5m)
10 Walking independently without gait aid (>5m)

Type of ventilation:

Record all types of ventilation received on day of assessment on or after admission to the critical care ward (ICU/HDU.

Abbreviations:

ETT: endotracheal tube

BIPAP: bi-level positive airway pressure

CPAP: continuous positive airway pressure

CRRT: continuous renal replacement therapy

IHD: intermittent haemodialysis

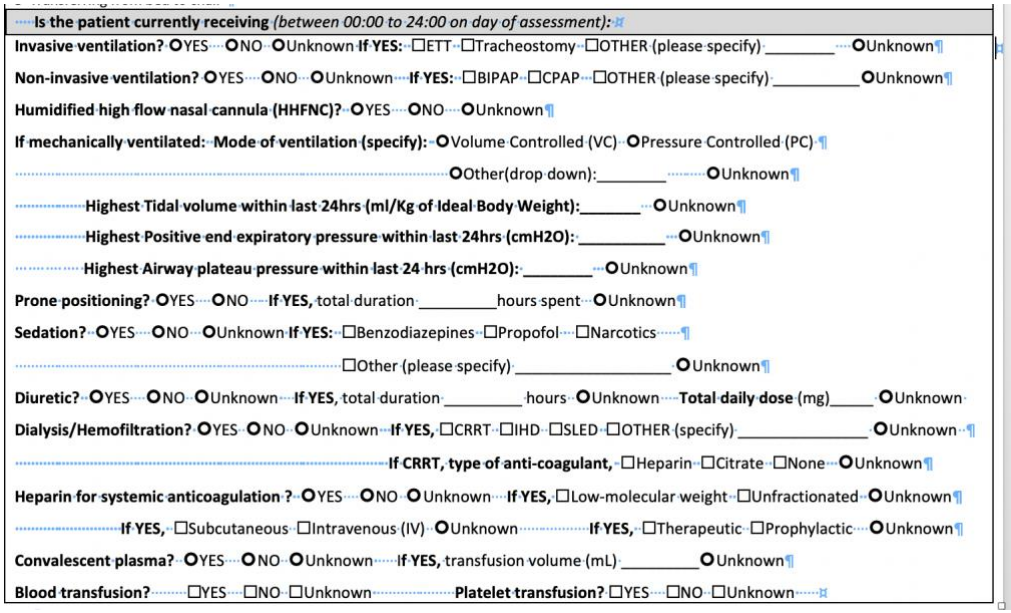
SLED: sustained low efficiency dialysis

For modes of ventilation (invasive, non-invasive, humidified high flow nasal cannula) please select all modes the patient received during the 24 hour assessment day.

Modes of mechanical ventilation:

- Synchronized Intermittent Mandatory Ventilation – Volume-Controlled (SIMV-V)
- Synchronized Intermittent Mandatory Ventilation – Pressure-Controlled (SIMV-P)
- Volume Controlled Ventilation
- Pressure Controlled Ventilation
- Pressure Regulated Volume Control (PRVC)
- Airway Pressure Release Ventilation (APRV)
- Pressure Support Ventilation (PSV)
- Volume Support Ventilation (VSV)
- High Frequency Oscillatory (HFO)
- Bilevel Positive Airway Pressure (BiPAP)
- Continuous Positive Airway Pressure (CPAP)
- Proportional Assist Ventilation (PAV)
- Neurally Adjusted Ventilatory Assist (NAVA)

Record highest tidal volume and airway pressures.



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.

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