

CASE RECORD FORM INSTRUCTIONS

SEVERE ACUTE RESPIRATORY INFECTION NATURAL HISTORY & BIOLOGICAL SAMPLING STUDY

DESIGN OF THIS CASE RECORD FORM (CRF)

This CRF is divided into 4 main forms: a "RAPID" (page 1) form with basic admission and outcome data; a "CORE" form with more detailed presentation (pages 2-3) and outcome (pages 4-6) data; a "DAILY" form (page 7) for daily laboratory and clinical data; and a set of "SUPPLEMENTAL" (Page 8-13) forms for overflow data and other investigations. These forms should be used in one of the defined combinations below according to the site's resource availability and scientific interests.

HOW TO USE THIS CRF

Each site may choose the amount of data to collect based on available resources and the number of patients enrolled to date. Ideally, data on patients presenting early in an outbreak will be collected using the Tier 2 combination and schedule of forms outlined below. Sites without the capacity to collect the periodic daily data requested in Tier 2, or who have already collected large numbers of Tier 2 patient data may choose the Tier 1 collection, which includes admission (Day 1) and outcome data only. Sites with very low resources or very high patient numbers may select Tier 0. The decision is up to the site Investigators and may be changed throughout the data collection period. All high quality data is valuable for analysis.

Tier 0 – Complete the 1-page RAPID CRF for each patient – For low resource sites or sites that have already enrolled large numbers of patients on Tier 1/2 collection.

Tier 1 – **Complete the RAPID CRF, CORE CRF and DAILY CRF on Day 1 only for each patient.** – For sites that do not have the resources to collect the additional daily data included in Tier 2.

Tier 2 - Complete the RAPID CRF, CORE CRF and DAILY CRF on Days 1 & 2 of hospital admission*, Days 1 & 2 of ICU admission* (if applicable) and each day that biological samples are taken for research purposes. – For patients who present early in the outbreak or sites with available resources.

*Note that Day 1 & 2 of hospital admission and/or Day 1 & 2 of ICU admission may be retrospective data if the patient is enrolled after the admission date.

Tier 3 – Analysis modules that address specific additional scientific questions (e.g. epidemiology). These may be completed in addition to the Tier chosen **according to the scientific interests of the site**. If you would like to suggest a new module for inclusion in these forms please contact us at the email below.

GENERAL GUIDANCE

- The CRF is designed to collect data obtained through patient examination, patient interview and review of hospital notes.
- Patient numbers consist of a 3-digit site code and a 4 digit patient number. You can obtain a site code by registering on the data management system at https://www.cliresdms.org. Patient numbers should be assigned sequentially for each site beginning with 0001. In the case of a single site recruiting patients on different wards, or where it is otherwise difficult to assign sequential numbers, it is acceptable to assign numbers in blocks. E.g. Out-patient ward will assign numbers from 0001 onwards. In-patient ward will assign numbers from 5001 onwards. Alpha characters can also be used. E.g. Out-patient ward will assign A001 onwards. In-patient ward will assign B001 onwards. Please enter the patient identification code at the top of each and every sheet.
- Complete every line of every section, except for where the instructions say to skip a section based on certain responses.
- Selections with square boxes (□) are single selection answers (choose one answer only). Selections with circles (**O**) are multiple selection answers (choose as many answers as are applicable).
- It is important to know when the answer to a particular question is not known. Please mark the 'Unknown' box if this is the case. If an 'Unknown' box is not shown, please see the CRF Completion Guidelines for further guidance. For laboratory values, please enter "NA" in the data space when results are Not Available.
- Some sections have open areas where you can write in additional information. To permit standardised data entry, please avoid writing additional information outside of these areas.
- We recommend writing clearly in black or blue 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 patient together e.g. with a staple or in a folder that is unique to the patient.
- Please enter data on the electronic data capture system at https://www.cliresdms.org. If your site would like to collect data independently, we are happy to support the establishment of local databases (see contact below).
- Please contact us at <u>isaric@oucru.org</u> if we can help with databases, if you have comments and to let us know that you are using the forms.

Version 29JAN14 - CASE REPORT FORM INSTRUCTIONS

RAPID CASE RECORD FORM - Severe Acute Respiratory Infection





PATIENT IDENTIFICATION NUMBER:

(3 digit site code - 4 digit sequential patient code)

[__][__] - [__][__][__][

This is the 1-page (Tier 0) RAPID clinical data set. Please complete for ALL patients. Complete sections 1-4 at admission. Complete section 5 upon ICU admission (if applicable). Complete section 6 after discharge/death. Enter data to the online database at https://www.cliresdms.org

1. SITE				
Clinical centre: Country:				
Date of patient enrolment: (DD/MM/YYYY): [][]/[][]/[_2_][][]				
2. DEMOGRAPHICS				
Sex at Birth: Image: The second				
If date of birth unknown: Estimated age [][]years OR [][]months				
Pregnant? YES NO Unknown Not Applicable If YES: Gestation age of fetus (nearest week): [][]				
3. INFECTIOUS RESPIRATORY DIAGNOSIS				
Influenza: YES- Confirmed YES- Probable NO If YES: H7N9 H5N1 Other:				
Coronavirus: YES- Confirmed YES- Probable NO If YES: MERS-CoV Other:				
Other: YES- Confirmed YES- Probable NO If YES: Other:				
Unknown:				
4. ONSET & ADMISSION				
Date of onset of first/earliest symptom (DD/MM/YYYY): [][]/[][]/[2_][_0_][][]				
Date of admission to this hospital (DD/MM/YYYY): [][]/[][]/[2_][0_][]				
5. INTENSIVE CARE OR HIGH DEPENDENCY CARE UNIT ADMISSION				
Admitted to ICU (or high dependency unit)? TYES (complete the rest of this section) NO (skip the rest of section 6)				
Date of ICU admission (DD/MM/YYYY): [][]/[][]/[2_][][]				
Record most abnormal value in first 24 hours of ICU admission (Mark units if choice is given. If Not Available write "NA"):				
Mechanical ventilation TYES NO				
FiO ₂ (0.21-1.0): [].[] or [][]L/min PaO ₂ [][]□kPa or □mmHg or SaO ₂ :[][]%				
Platelet Count [][][]x10 9/L Bilirubin [][_]µmol/L				
Creatinine [][][]□µmol/L <i>or</i> □mg/dL Mean arterial pressure [][]mmHg				
Glasgow Coma Score (out of 15): [][] Urine output [][][]mL/24 hours Check if estimated				
Any vasopressor/inotropic support on 1 st day of ICU admission? IVES INO (if NO, answer the next 3 questions NO) Dopamine <5µg/kg/min OR Dobutamine OR Milrinone OR Levosimendan:				
LNO Dopamine 5-15µg/kg/min OR Epinephrine/Norepinephrine < 0.1µg/kg/min OR vasopressin OR phenylephrine: YES				
□NO Dopamine >15µg/k/min OR Epinephrine/Norepinephrine > 0.1µg/kg/min: □YES □NO				
Date of ICU discharge (DD/MM/YYYY): [][]/[]/[2_][0_][] Discharge status: Alive				

6. OUTCOME

CORE CASE RECORD FORM - Severe Acute Respiratory Infection				
World Health	PATIENT IDENTIFI	CATION NUMBER:		
World Health Organization	(3 digit site code – 4 digit se	quential patient code) [][] ·	- [][][]	
During hospital admission did the pat	ient at any time receive:			
Supplemental O2: YES NO	Invasive ventilation \Box Y	ES NO Non-invasive ventilation	on: 🗆 YES 🖾 NO	
ECMO/ECLS: YES NO	Dialysis: SYES NO			
Final Outcome: Discharged alive	Still in hospital Transf	erred to other facility Died Pallia	ative discharge	
Date of final outcome (DD/MM/YY)	(Y): [][]/[][_]/[2][0_][][]		
Complete sections 1-3 at admission (Tier 1 &	Tier 2). Enter data to the onl	ine database at https://www.cliresdms.org		
1. DEMOGRAPHICS				
Weight on admission (whole number)][][]□kg <i>or</i> □lbs □]Unknown Height: [][]□cm	<i>or</i> □inches □Unknown	
If age <5 years: Mid-upper-arm circum	ference [][]mm [Unknown/Not applicable		
Ethnicity (check all that apply): OArab	OBlack OEast Asian	OSouth Asian OWest Asian O	Latin American	
OWhite/Caucasian OAb	original/First Nations	Other:		
Transferred from another facility? \Box Y	ES □NO □Unknown If YE	S: Name of transferring facility:		
If YES: Date admitted to other facil	ity (DD/MM/YYYY): [][_]/[][]/[2_][0_][]	[] 🗆 Unknown	
Did the patient travel in the 14 days p	rior to first symptom onset	? 🗆 YES 🗆 NO 🗆 Unknown		
If YES, state location(s) & date(s): (Country:	City/Region:		
	Return Date (DD/MM/YYYY): [][]/[][]/[_2_][_0_][] □Unknown (more space is available on the SUPPLEMENTARY DATA FORM – CORE – SECTION 1 – TRAVEL)			
•	Did the patient have contact with live/dead animals, raw meat or insect bites in the 14 days prior to first symptom onset? □YES □NO □Unknown If YES, complete the CORE – SECTION 1 - ANIMAL EXPOSURE section of the SUPPLEMENTARY DATA FORM.			
2. CO-MORBIDITIES & RISK FAC	TORS (existing PRIOR TO ADM	ISSION & that are active problems) (Charlson I	ndex will be calculated at analysis)	
Chronic cardiac disease	□YES □NO □Unknown	Metastatic solid tumour	□YES □NO □Unknown	
Chronic pulmonary disease (not asthma)	□YES □NO □Unknown	Any malignancy including leukaemia & lymphoma	□YES □NO □Unknown	
Physician diagnosed asthma	□YES □NO □Unknown	AIDS / HIV	□YES □NO □Unknown	
Renal disease	□YES □NO □Unknown	Obese as defined by clinical staff	□YES □NO □Unknown	
Moderate or severe liver disease	□YES □NO □Unknown	Diabetes with chronic complications	□YES □NO □Unknown	
Mild liver disease	□YES □NO □Unknown	Rheumatologic disease	□YES □NO □Unknown	
Chronic neurological disease	□YES □NO □Unknown	Dementia	□YES □NO □Unknown	
Hemiplegia or paraplegia	□YES □NO □Unknown			
History of recurrent fever prior to admission? Yes No Unknown				
Proven malaria since onset of sympto	Proven malaria since onset of symptoms?			
Receiving immunosuppressants (including inhaled/oral corticosteroids) prior to admission? DYES DNO DUnknown If YES, complete the CORE – SECTION 2 - ADMISSION IMMUNOSUPPRESSANTS section of the SUPPLEMENTARY DATA FORM.				
Treated with anti-infectives for this illness episode prior to admission? TYES TO UNKnown If YES, complete the CORE – SECTION 2 - ADMISSION ANTI-INFECTIVES section of the SUPPLEMENTARY DATA FORM.				
POST PARTUM? TYES ONO or Not Applicable (<i>skip this section - go to INFANT</i>) Pregnancy Outcome: Live birth Still birth				
Delivery date (DD/MM/YYYY) [][]/[]/[2_][0_][]				

CORE CASE RECORD FORM - Severe Acute Respiratory Infection			
World Health Organization		FICATION NUMBER: sequential patient code)] - [][][][]
Baby tested for Mom's infecti	i on? □YES □NO □Unknown	If YES: Positive Negative Me	ethod:
INFANT – Less than 1 year old?		Birth weight if known: [][].	[]□kg or □lbs □Unknown
Gestation: □ Term-born (≥37v			
Breastfed? 🗆 YES 🗐 NO 🗇 U	Inknown If YES: 🗆 Still brea	stfeeding Discontinued at [][_] weeks
Development appropriate for	age? YES NO Unknown	Vaccinations appropriate for age/c	ountry? YES NO Unknown
Any other risk factor(s) consid	ered relevant:		
3 SIGNS AND SYMPTOMS A		(first available data at presentation,	ladmission - within 24
hours)		i finst avaliable data at presentation,	aumission – within 24
Temperature: [][].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[].[_].[]□°C or □°F HR: [][][]beats per minute RR:][]breaths per minute
Systolic BP: [][][]mmHg	Diastolic F	3P: [][]mmHg	
	-		
Severe dehydration? UYES NO	UUnknown Sternal ca	pillary refill time >2secs? UYES N	O LIUnknown
O ₂ saturation: [][]% On: □Room air □Supplemental O ₂ □Unknown			
Admission signs and sympton	ns (observed/reported at adm	ission and associated with this episo	de of acute illness)
History of fever (>38°C)	□YES □NO □Unknown	Lower chest wall indrawing	□YES □NO □Unknown
Cough	□YES □NO □Unknown	Headache	□YES □NO □Unknown
with sputum production	□YES □NO □Unknown	Altered consciousness/confusion	□YES □NO □Unknown
bloody sputum/haemoptysis	□YES □NO □Unknown	Seizures	□YES □NO □Unknown
Sore throat	□YES □NO □Unknown	Abdominal pain	□YES □NO □Unknown
Runny nose (rhinorrhoea)	□YES □NO □Unknown	Vomiting/nausea	□YES □NO □Unknown
Ear ache	□YES □NO □Unknown	Diarrhoea	□YES □NO □Unknown
Wheezing	□YES □NO □Unknown	Conjunctivitis	□YES □NO □Unknown
Chest pain	□YES □NO □Unknown	Skin rash	□YES □NO □Unknown
Chest pain Muscle aches (myalgia)	UYES UNO UUnknown UYES NO UUnknown	Skin rash Skin ulcers	LYES LNO LUnknown LYES LNO LUnknown
Muscle aches (myalgia)	□YES □NO □Unknown	Skin ulcers	□YES □NO □Unknown

CORE CASE RECORD FORM - Severe Acute Respiratory Infection





PATIENT IDENTIFICATION NUMBER:

(3 digit site code – 4 digit sequential patient code)

[__][__] - [__][__][__][__]

Complete OUTCOME sections 4-9 after discharge/death. Additional information can be recorded on the SUPPLEMENTARY DATA FORM. Daily information is recorded on the DAILY RECORD FORM.

4. COMPLICATIONS: At any time during hospitalisation did the patient experience (complete every line):			
Viral pneumonitis	□YES □NO □Unknown	Cardiac arrest	□YES □NO □Unknown
Bacterial pneumonia	□YES □NO □Unknown	Bacteraemia	□YES □NO □Unknown
Acute lung injury / ARDS	□YES □NO □Unknown	Coagulopathy or DIC	□YES □NO □Unknown
Pneumothorax	□YES □NO □Unknown	Anaemia	□YES □NO □Unknown
Pleural effusion	□YES □NO □Unknown	Rhabdomyolysis or myositis	□YES □NO □Unknown
Bronchiolitis	□YES □NO □Unknown	Acute renal injury/failure	□YES □NO □Unknown
Meningitis/Encephalitis	□YES □NO □Unknown	Gastrointestinal bleeding	□YES □NO □Unknown
Seizure(s)	□YES □NO □Unknown	Pancreatitis	□YES □NO □Unknown
Stroke	□YES □NO □Unknown	Hepatic dysfunction	□YES □NO □Unknown
Congestive heart failure	□YES □NO □Unknown	Hyperglycemia	□YES □NO □Unknown
Endo/myo/peri-carditis	□YES □NO □Unknown	Hypoglycemia	□YES □NO □Unknown
Cardiac arrhythmia	□YES □NO □Unknown	Other	□YES □NO □Unknown
Cardiac ischaemia	□YES □NO □Unknown	Specify:	L

5. PATHOGEN TESTING: (more space is available on the SUPPLEMENTARY DATA FORM – CORE – SECTION 5 – PATHOGEN TESTING) Was pathogen testing performed during this illness episode? \Box YES (complete below) \Box NO \Box Unknown

Sample Collection Date (DD/MM/YYYY)	Sample Type	Method	Result	Pathogen Tested
//20	Nasal/NP swab	□PCR □Culture □Other	□Positive □Unknown □Negative	Specify:
//20	Throat swab	□PCR □Culture □Other	□Positive □Unknown □Negative	Specify:
//20	Combined nasal/NP + Throat swab	□PCR □Culture □Other	□Positive □Unknown □Negative	Specify:
//20	Sputum	□PCR □Culture □Other	□Positive □Unknown □Negative	Specify:
//20	Broncho-alveolar lavage (BAL)	□PCR □Culture □Other	□Positive □Unknown □Negative	Specify:
//20	Endotracheal aspirate (ETA)	□PCR □Culture □Other	□Positive □Unknown □Negative	Specify:
//20	Stool/Rectal swab	□PCR □Culture □Other	□Positive □Unknown □Negative	Specify:
//20	Urine	□PCR □Culture □Other	□Positive □Unknown □Negative	Specify:
//20	Blood	□PCR □Culture □Other	□Positive □Unknown □Negative	Specify:
//20	Other (specify):	□PCR □Culture □Other	□Positive □Unknown □Negative	Specify:

CORE CASE RECORD FORM - Severe Acute Respiratory Infection

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ISARIC

World Health Organization



(3 digit site code - 4 digit sequential patient code)

[__][__] - [__][__][__][__]

6. OTHER INFECTIONS: Did the patient test positive for any other infection? DYES DNO DUNKNOWN If YES, specify. (more space is available on the SUPPLEMENTARY DATA FORM – CORE – SECTION 6 – OTHER INFECTIONS)					
Sample/Detection Date (DD/MM/YYYY)	Sample Type (choose from list in #5 above)	Type of Infection	Pathogen		
//20	Specify:	□ Bacterial □ Viral □ Fungal □ Other:	Specify:		
//20	Specify:	□ Bacterial □ Viral □ Fungal □ Other:	Specify:		
//20	Specify:	□ Bacterial □ Viral □ Fungal □ Other:	Specify:		
//20	Specify:	□ Bacterial □ Viral □ Fungal □ Other:	Specify:		
7. TREATMENT: At	ANY time during hospitalisation,		complete every line)		
Supplemental oxygen?	P □YES □NO □Unknown	If '	YES, total duration:days		
If YES: First day (DD/I	им/үүүү): [][]/[][]/	[2][0][][]□Un	known		
-	лм/үүүү): [][]/[][]/				
	cal ventilation? (e.g. BIPAP, CPAP)				
Invasive mechanical ventilation (Any)? DYES DNO DUnknown If YES, total duration:days If YES: First day (DD/MM/YYYY): []/[]/[]/[][]/[] Durknown					
Last day (<i>DD/MM/YYYY</i>): [][]/[][]/[2_][0_][] □Unknown					
	ntilation?				
_	ation?				
	: Oxide?				
Extracorporeal membrane oxygenation (ECMO) or interventional lung-assist therapy (iLA)?					
-	None □Unknown □Not available at		/ES, total duration: days		
If YES: First day (DD/I	мм/үүүү): []/[]/[]/	[2][0][][]□Un	known		
	лм/үүүү): [][]/[][]/				
Renal replacement the	erapy (RRT) or dialysis? 🗆 YES 🗐 NG	D □UnknownIf	YES, total duration: days		
	им/үүүү): [][]/[][]/				
	Last day (<i>DD/MM/YYYY</i>): [][]/[][]/[2_][0_][] □Unknown				
	rs? 🗆 YES 🗆 NO 🗇 Unknown		YES, total duration:days		
	мм/үүүү): [][]/[][]/		known		
	лм/үүүү): [][]/[][]/		known		
	nge?	Oral rehydration therapy?	IYES INO IUnknown		
Intravenous Immunog	lobulin? 🗆 YES 🗆 NO 🗆 Unknown	Blood transfusion or produ	cts? 🗆 YES 🗆 NO 🗆 Unknown		
OTHER intervention (p	lease specify):				

CORE CASE RECORD FORM - Severe Acute Respiratory Infection

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[][] - [][][][1
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World Health Organization	ISARIC	(3 digit site code – 4 digit sequ		- [][][]
8. MEDICATION: V	Vhile hospitalised	or at discharge, were a	ny of the following administered?	
Antivirals? UYES N	IO □Unknown If Y	ES: O Neuraminidase Inhi	bitors O Other Antibiotics?	□YES □NO □Unknown
Corticosteroids? □YE	S 🗆 NO 🗆 Unknown	n If YES: O Oral O Intrav	enous OInhaled Antifungals?	□YES □NO □Unknown
If any of the anti-infec CORTICOSTEROIDS sec			inistered, please complete the MEDICA	TION: ANTI-INFECTIVES &
Angiotensin convertin	ng enzyme inhibitors	(ACE-Is) or angiotensin r	eceptor blockers (ARBs)?	□Unknown
Statins?	Unknown If YES,	was the patient taking st	atins prior to admission? UYES UNC	D 🗆 Unknown
9. OUTCOME				
Transferred to anot	her facility: YES]NO □Unknown		
If YES , name of n	ew facility:		🗆 🗆 Unknown	
-	•		, skip the next 2 questions)]Same as prior to illness	Better 🗆 Unknown
Supplementa		-	/renal treatment? □YES □NO □Un ify (<i>multiple permitted</i>):	known
Deceased? DYES				
	use of death (one or	<i></i>		
	sfunction syndrome	□Acute lung injury	□Pneumonia	□Myocardial infarction
□Congestive hea		Dysrhythmia	□Chronic obstructive lung disease	□Pulmonary emboli
□Cerebrovascula		□Renal failure	□Liver failure	□Malignancy
□Other, specify:				
lf YES, contributo	ry cause(s) of death	(check all that apply):		
OMulti-organ dy	sfunction syndrome	OAcute lung injury	O Pneumonia	O Myocardial infarction
OCongestive hea	irt failure	O Dysrhythmia	OChronic obstructive lung disease	O Pulmonary emboli
O Cerebrovascula	ar disease	ORenal failure	OLiver failure	OMalignancy
O Other, specify:			Other, specify:	
_		on (check/complete all that	at apply):	
OH7N9 OH5I				
				_
				_
		′ DATA FORM – CORE – ADDITIO		
inore space is available				

DAILY CASE RECORD FORM - Severe Acute Respiratory Infection

World Health

Organization



(3 digit site code – 4 digit sequential patient code)

[__][__] - [__][__][__][__]

Tier 1 - complete form on Day 1 of hospital admission. Tier 2 – Complete form on Days 1 & 2 of hospital admission. If transferred to ICU care, please also complete on days 1 & 2 of ICU admission (note these days may be in the past if the patient is enrolled after admission). Additional information can be added to the SUPPLEMENTARY DATA FORM. Enter data to the database at https://www.cliresdms.org

1. DATE OF ASSESSMENT (<i>DD/MM/YYYY</i>): [][]/[]/[2][0_][] (may not be the date of completion)
2. DAILY TREATMENT (complete every line):
Is the patient currently admitted to ICU/ITU/IMC/HDU?
Record the most abnormal value in the previous 24 hours (if Not Available write "NA"):
FiO ₂ (0.21-1.0) [].[] or []L/min SaO ₂ [][]%
PaO ₂ [][]
From same blood gas, record as PaO ₂ : PCO ₂ □kPa or □mmHg pH
HCO ₃ mEq/L Base excessmmol/L
Glasgow Coma Score (out of 15) [] Mean Arterial Blood Pressure [][]mmHg
Urine output [][][][]mL/24 hours
Is the patient currently receiving, or has s/he received in the past 24 hours (apply to all 14 questions in this boxed section) :
Mechanical ventilation: Non-invasive (eg. BIPAP, CPAP) YES NO Unknown Invasive YES NO Unknown
Oscillatory Ventilation? YES NO Unknown Extracorporeal membrane oxygenation (ECMO/ECLS) YES NO Unknown
Interventional lung-assist therapy (iLA)? UYES NO Unknown Dialysis/Hemofiltration? UYES NO Unknown
Any vasopressor/inotropic support?
Dopamine <5µg/kg/min OR Dobutamine OR milrinone OR levosimendan:
Dopamine 5-15 μ g/kg/min OR Epinephrine/Norepinephrine < 0.1 μ g/kg/min OR vasopressin OR phenylephrine: \Box YES \Box NO
Dopamine >15µg/k/min OR Epinephrine/Norepinephrine > 0.1µg/kg/min: LYES LYES LNO Oral rehydration only? □YES □NO □Unknown Intravenous Immunoglobulin? □YES □NO □Unknown
Blood transfusion or products? YES NO Unknown Plasmapheresis/Exchange? YES NO Unknown
Other intervention: \Box YES \Box NO \Box Unknown If YES , <i>specify</i> :
3. DAILY LABORATORY RESULTS Mark the correct unit if a choice is given. If Not Available enter "NA". Are results available for samples collected on <i>the date in section 1 above?</i> □YES (complete below) □NO (skip section below)
Haemoglobin $\Box g/L \text{ or } \Box g/dL$ Haematocrit% WBC count $\Box x 10^9/L \text{ or } \Box x 10^3/\mu L$
Platelets □x10 ⁹ /L or □x10 ³ /μL □APTT PT seconds or □INR
Altright or matching Platelets matching matching
AST/SGOT U/L Glucose□mmol/L <i>or</i> □mg/dL Erythrocyte Sed Rate mm/h
ଞ୍ଚି Blood Urea Nitrogen (urea) ロmmol/L <i>or</i> ロmg/d LDH U/L
Creatine kinase CPK U/L Creatinine □μmol/L or □mg/d
Lactate □mmol/L <i>or</i> □mg/dL

Version 29JAN14 – DAILY – Multiple - Day 1&2 hospital admission + Day 1&2 ICU admission + sampling days 7* *FOR TIER 2 DATA COLLECTION THERE WILL BE MULTIPLE "PAGE #7 s" – ONE FOR EACH COLLECTION DAY





PATIENT IDENTIFICATION NUMBER:

(3 digit site code – 4 digit sequential patient code)

[__][__] - [__][__][__]

EXTRA SPACE FOR INFORMATION ON THE CORE DATA FORM

Use this form to record information that does not fit the space provided in the CASE REPORT FORM or where detailed. All information from the CASE REPORT FORM and this SUPPLEMENTARY DATA FORM should be entered into the appropriate sections of the electronic CASE REPORT FORM at https://www.cliresdms.org

CORE - SECTION 1 - TRAVEL: Did the patient travel in the 14 days prior to first symptom onset? If > 1 location & date list:				
Country:City/R	egion:	Return Date (DD/MM/YYYY):/		
/20				
Country: City/R	egion:	Return Date (DD/MM/YYYY):/		
/20	-0 -			
Current City (D				
/20 City/R	egion:	Return Date (<i>DD/MM/YYYY</i>):/		
the 14 days prior to first symptom onset	? Complete each line below.	vith live/dead animals, raw meat or insect bites in ntact and date of exposure (DD/MM/YYYY)		
Birds (e.g. chickens, turkeys, ducks)	□YES □NO □Unknown			
Bats	□YES □NO □Unknown			
Livestock (e.g. goats, cattle, camels)	□YES □NO □Unknown			
Horses	□YES □NO □Unknown			
Hares/ Rabbits	□YES □NO □Unknown			
Pigs	□YES □NO □Unknown			
Non-human primates	□YES □NO □Unknown			
Rodents (e.g. rats, mice, squirrels)	□YES □NO □Unknown			
Insect bites (e.g. tick, flea, mosquito)	□YES □NO □Unknown			
Reptiles or amphibians	□YES □NO □Unknown			
Household pets or other animals living in his/her home (e.g. cats, dogs, other)	□YES □NO □Unknown			
Any animal droppings or nests	□YES □NO □Unknown			
Any sick or dead animals	□YES □NO □Unknown			
Raw animal meat or blood	□YES □NO □Unknown			
Skinned, dressed or eaten wild game	□YES □NO □Unknown			
Visited live animal market, farm or zoo	□YES □NO □Unknown			
Participated in animal surgery or necropsy	□YES □NO □Unknown			

World Health Organization	PATIENT IDENTIFICATION NUMBER: (3 digit site code - 4 digit sequential patient code) [][][] - [][][][]
Any other animal contacts:	□YES □NO □Unknown





PATIENT IDENTIFICATION NUMBER:

(3 digit site code - 4 digit sequential patient code)

[__][__] - [__][__][__][__]

EXTRA SPACE FOR INFORMATION ON THE CORE DATA FORM - CONTINUED

Use this form to record information that does not fit the space provided in the CASE REPORT FORM or where detailed. All information from the CASE REPORT FORM and this SUPPLEMENTARY DATA FORM should be entered into the appropriate sections of the electronic database at https://www.cliresdms.org

CORE - SECTION 2 – ADMISSION IMMUNOSUPPRESSANTS: Receiving immunosuppressants (including inhaled/oral					
corticosteroids) prior to admission	corticosteroids) prior to admission? Enter the details below.				
Name of immunosuppressant	Dose and frequency	Route of administration	Duration		
		□IV □oral □inhaled	□days □weeks		
	□unknown	□other □unknown	□unknown		
		□IV □oral □inhaled	□days □weeks		
	□unknown	□other □unknown	□unknown		
		□IV □oral □inhaled	□days □weeks		
	□unknown	□other □unknown	□unknown		
		□IV □oral □inhaled	□days □weeks		
	□unknown	□other □unknown	□unknown		
		□IV □oral □inhaled	□days □weeks		
	□unknown	□other □unknown	□unknown		

CORE - SECTION 2 – ADMISSION ANTI-INFECTIVES: Treated with anti-infectives (antibiotics and anti-virals) for this illness **episode prior to admission**? *Enter details below.*

Name of medication	Dose and frequency	Start date	End date	Route of
(generic name preferred)		(DD/MM/YYYY)	(DD/MM/YYYY)	administration
	□unknown		□On-going	□IV □oral □inhaled
		//20	//20	□other □unknown
	□unknown		□On-going	□IV □oral □inhaled
		//20	//20	□other □unknown
	□unknown		□On-going	□IV □oral □inhaled
		//20	//20	□other □unknown
	□unknown		□On-going	□IV □oral □inhaled
		//20	//20	□other □unknown
	□unknown		□On-going	□IV □oral □inhaled
		//20	//20	□other □unknown

CORE - SECTION 5 – PATHOGEN TESTING: Was pathogen testing performed during this illness episode? Add details of testing which did not fit in the CORE CASE REPORT FORM.

Sample Collection Date (DD/MM/YYYY)	Sample Type (from list on CORE Section 5)	Method	Result	Pathogen Tested
//20		□PCR □Culture □Other	□Positive □Unknown □Negative	Specify:
//20		□PCR □Culture □Other	□Positive □Unknown □Negative	Specify:
//20		□PCR □Culture □Other	□Positive □Unknown □Negative	Specify:
//20		□PCR □Culture □Other	□Positive □Unknown □Negative	Specify:
//20		□PCR □Culture □Other	□Positive □Unknown □Negative	Specify:
//20		□PCR □Culture □Other	□Positive □Unknown □Negative	Specify:





PATIENT IDENTIFICATION NUMBER:

(3 digit site code - 4 digit sequential patient code)

[__][__] - [__][__][__]

EXTRA SPACE FOR INFORMATION ON THE CORE DATA FORM - CONTINUED

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CORE - SECTION 6 – OTHER INFECTIONS: Did the patient test positive for any other infection? Add details of testing which did not fit in the CORE CASE REPORT FORM.				
Sample/Detection Date (DD/MM/YYYY)	Sample/Detection Sample Type Date (DD/MM/YYYY) (specify from list on CORE Section 5)		Pathogen (specify)	
/ /20		□Bacterial □Viral □Fungal □Other:		
		□Bacterial □Viral □Fungal		
/ /20		□Other:		
		□Bacterial □Viral □Fungal		
//20		□Other:		
		□Bacterial □Viral □Fungal		
//20		□Other:		
		□Bacterial □Viral □Fungal		
//20		□Other:		
		□Bacterial □Viral □Fungal		
//20		DOther:		
		□Bacterial □Viral □Fungal		
//20		□Other:		
		□Bacterial □Viral □Fungal		
//20		□Other:		

CORE – ADDITIONAL INFORMATION: Detail any additional information not captured in the CASE REPORT FORM.





PATIENT IDENTIFICATION NUMBER:

(3 digit site code - 4 digit sequential patient code)

[__][__] - [__][__][__]

EXTRA SPACE FOR INFORMATION ON THE CORE DATA FORM - CONTINUED

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	ATION: ANTI-INFECTIVES & (at discharge. Use as many po		all anti-infectives and cor	ticosteroids administered
Name of medication (generic name preferred)	Dose and frequency (specify or unknown)	Start date (DD/MM/YYYY)	End date (DD/MM/YYYY)	Route of administration
	□unknown	//20	□On-going //20	□IV □oral □inhaled □other □unknown
	□unknown	//20	□On-going /_20	□IV □oral □inhaled □other □unknown
	□unknown	//20	□On-going //20	□IV □oral □inhaled □other □unknown
	□unknown	//20	□On-going //20	□IV □oral □inhaled □other □unknown
	□unknown	//20	□On-going //20 □On-going	IV Doral Dinhaled
	□unknown	//20	//20 /20	□IV □oral □inhaled □other □unknown □IV □oral □inhaled
	□unknown	//20	//20 /20	□other □unknown □IV □oral □inhaled
	□unknown	//20	//20 /20	□other □unknown □IV □oral □inhaled
	□unknown	//20	//20 /On-going	□other □unknown □IV □oral □inhaled
	□unknown	//20	//20 0n-going	□other □unknown □IV □oral □inhaled
	□unknown	//20	//20 □on-going	□other □unknown □IV □oral □inhaled
	□unknown	//20	//20 □On-going	□other □unknown □IV □oral □inhaled
		//20	//20 On-going	□other □unknown □IV □oral □inhaled
		//20	//20 On-going	□other □unknown □IV □oral □inhaled
	□unknown □unknown	//20	//20 On-going	□other □unknown □IV □oral □inhaled
		//20	//20 □On-going / /20	□other □unknown □IV □oral □inhaled
		//20 //20	//20 Don-going //20	□other □unknown □IV □oral □inhaled □other □unknown
	□unknown	//20	//20 Don-going / /20	□IV □oral □inhaled □other □unknown
	□unknown	//20	//20 Don-going / /20	□IV □oral □inhaled □other □unknown
	□unknown	//20	//20	□IV □oral □inhaled □other □unknown

EPIDEMIOLOGY CASE RECORD FORM - Severe Acute Respiratory Infection

World Health	ISARIC	PATIENT IDENTIFICATION NUMBER	k:
Organization		(3 digit site code – 4 digit sequential patient code)	[][][] = [][][][]

ADDITIONAL EPIDEMIOLOGICAL INVESTIGATIONS (Tier 3)

Investigations additional to those on the CASE REPORT FORMs may be of interest to some sites. Some examples of relevant data are below and can be completed at the discretion of the site. All information should be entered into the appropriate sections of the electronic database at https://www.cliresdms.org

EXPOSURES IN THE PREVIOUS 14 DAYS:			
Contact (confirmed case): UYES NO	Unknown	Contact (probable or suspe	cted case): YES NO
Unknown			
Travel: TYES NO Unknown	Animal: DYES	S NO Unknown	Occupational: TYES NO
Unknown			

LIVING SITUATION: What was the primary living situation of the patient in the 14 days before presentation to hospital?					
□Home. # of people at home ir	cluding patient:	□Military base	□Shelter	□Jail	
□Boarding school/dormitory □Other:	□Nursing home/long-ter	rm healthcare facility	,		

OCCUPATION: What is the patient's occupation?

VACCINATION HISTORY:
Influenza immunization this season?
If YES: >14 days prior to illness
If YES: Immunization type received this season: TIV (injected)
If YES, <9 years old and first flu vaccination: How many vaccinations were received this season? 1 dose 12 doses
Pneumococcal vaccination ever? Yes No Unknown If Yes: Age at receipt of pneumococcal vaccine: years old Unknown If YES: Type of vaccine: D7-valent conjugate D13-valent conjugate D23-valent polysaccharide DUnknown
Haemophilus influenzae type b vaccination Yes No Unknown If Yes, age at receipt of haemophilus vaccine: years old Unknown
RSV immunization Palivizumab (if applicable) Yes No Unknown

PHARMACOKINETIC CASE RECORD FORM - Severe Acute Respiratory Infection





PATIENT IDENTIFICATION NUMBER:

(3 digit site code - 4 digit sequential patient code)

[__][__] - [__][__][__]

PHARMACOKINETIC INVESTIGATIONS (Tier 3)

Pharmacokinetic data can be collected on this form. All information should be entered into the appropriate sections of the electronic database at https://www.cliresdms.org

PHARMACOKINETICS (PK) O	F ANTIMICROBIALS / IMMUI	NOMODULATORY DRUGS			
Drug under study:	Specify:				
Start date of drug prescription:	Date (DD/MM/YYYY) [][][]		
Prescribed times of administration:	Specify All:				
Precise time of 1 st PK blood draw today:	Time (24 hour clock H H : M M)	:			
Precise time of 2 nd PK blood draw today:	Time (24 hour clock H H : M M)	:			
Precise time of 3 rd PK blood draw today:	Time (24 hour clock H H : M M)	:			
Please	record all doses of the drug under	study given in the last 24hrs:			
Dose:	Route of administration	*Precise* Time Drug Given (if infusion: Start Time) (24 hour clock HH:MM)	*Precise* End Time (infusion only) (24 hour clock HH:MM)		
Amount: Units:	□IV □oral □inhaled □other:	::	::		
Amount: Units:	□IV □oral □inhaled □other:	:	:		
Amount: Units:	□IV □oral □inhaled □other:	:	::		
Amount: Units:	□IV □oral □inhaled □other:	::	::		
Amount: Units:	□IV □oral □inhaled □other:	:	:		
Amount: Units:	□IV □oral □inhaled □other:	:	::		