

1. Patient Eligibility Criteria & Enrolment Information

Subject ID Code _____

INCLUSION CRITERIA - Indicate YES or NO for each of the following:

	Yes	No
Patient's age is newborn to 17 years inclusive	<input type="radio"/>	<input type="radio"/>
Patient has received any dose of any vasoactive infusion for at least 1 hour and no more than 6 hours at the time of enrollment	<input type="radio"/>	<input type="radio"/>

Specify type of vasoactive agent (check all that apply):

- Dopamine
- Epinephrine
- Norepinephrine
- Milrinone
- Vasopressin
- Phenylephrine
- Other

Specify other type of vasoactive agent: _____

PATIENT IS NOT ELIGIBLE

If yes to the above inclusion criteria, provide the date and time that the patient met criteria: _____

EXCLUSION CRITERIA - Indicate YES or NO for each of the following:

	Yes	No
Patient has known or suspected hypothalamic, pituitary or adrenal disease	<input type="radio"/>	<input type="radio"/>
Patient currently receiving steroids for shock prior to randomization	<input type="radio"/>	<input type="radio"/>
Patient for whom withdrawal of treatment is anticipated	<input type="radio"/>	<input type="radio"/>
Patient is less than 38 weeks corrected gestational age on admission	<input type="radio"/>	<input type="radio"/>
Patient is pregnant	<input type="radio"/>	<input type="radio"/>
Patient had cardiac surgery immediately prior to admission to PICU	<input type="radio"/>	<input type="radio"/>

- Patient whose first vasoactive infusion dose was administered >24 hours post PICU admission
- Patient who is no longer on a vasoactive infusion at the time of study enrollment, and/or is expected to no longer be on a vasoactive infusion when the first study drug dose is administered
- Patient for whom primary cardiogenic shock is suspected
- Patients for whom spinal shock is suspected
- Patients for whom hemorrhagic shock is suspected
- Patients previously enrolled in the STRIPES study
- Patients who are started on a vasoactive agent for reasons not related to shock
- Physician refusal

Is the patient eligible for the STRIPES Study? All inclusion criteria must be YES and all exclusion criteria must be NO for patient to be eligible for study

Yes

No

Date eligibility was confirmed: _____

Time eligibility was confirmed: _____

Consent & Enrolment

Date of enrolment into study: _____

Time of enrolment into study: _____

Please indicate pharmacy status at the time of enrollment:

- Patient enrolled during pharmacy hours of operation for research
- Patient enrolled off hours (call-back required to enroll patient)

Was the patient enrolled in the study using deferred consent? Yes No

Reason deferred consent model was used instead of informed consent (e.g. parents not present at bedside, insufficient time between notification of study team and enrolment deadline to obtain informed consent, legal guardian too distressed to approach within the enrolment window)

Was informed consent obtained following enrolment using deferred consent? Yes No

Date informed consent was obtained:

Time informed consent was obtained:

If informed consent was refused, did the parent/legal guardian give the study team permission to continue collecting data?

Yes No

If no, indicate the date that data collection was stopped:

If no, indicate the time that data collection was stopped:

2. General Demographic Baseline Information

General Demographic & Baseline Information

Patient Age: Please select the patient's age category

- Patient is < 1 week (record age below in days only)
- Patient is < 1 month (record age below in weeks only)
- Patient is < 1 year (record age below in months only)
- Patient is >1 year (record age below in years and months)

Patient age - Days

Patient age - Weeks

Patient age - Months

Patient age - Years

Gender:

- Male Female

Weight (kg):

(1 decimal place)

Admission to hospital - Date:

Admission to hospital - Time:

Admission to PICU - Date:

Admission to PICU - Time:

Admission Diagnosis:

Discharge Diagnosis:

Chronic pre-existing medical condition(s)?

- Yes No

	Yes	No
Ex-microprem (long NICU course; < 26 weeks)	<input type="radio"/>	<input type="radio"/>
Chromosomal abnormality (eg. Trisomy 21, 22q11 microdeletion)	<input type="radio"/>	<input type="radio"/>
Meningomyelocele or Spina Bifida	<input type="radio"/>	<input type="radio"/>
Neurologic disease (eg. Seizure disorder, Hydrocephalus)	<input type="radio"/>	<input type="radio"/>
Chronic Lung Disease (eg. BPD, asthma, pulmonary hypertension)	<input type="radio"/>	<input type="radio"/>
Endocrine disease (eg. Diabetes, thyroid, parathyroid, adrenal)	<input type="radio"/>	<input type="radio"/>
GI disease (Crohn's, short gut, liver disease)	<input type="radio"/>	<input type="radio"/>
Renal disease (eg. Renal insufficiency, renal tubular acidosis)	<input type="radio"/>	<input type="radio"/>
Musculo-skeletal disease (eg. CP, myopathy)	<input type="radio"/>	<input type="radio"/>
Rheumatological disease (eg. SLE)	<input type="radio"/>	<input type="radio"/>
Inborn error of metabolism	<input type="radio"/>	<input type="radio"/>
Cancer/Oncologic disease	<input type="radio"/>	<input type="radio"/>
Psychiatric disorder (eg. Autism, ADHD, anxiety)	<input type="radio"/>	<input type="radio"/>
Mental Retardation (idiopathic)	<input type="radio"/>	<input type="radio"/>
Chronic Infection (specify below)	<input type="radio"/>	<input type="radio"/>
Congenital Heart Disease	<input type="radio"/>	<input type="radio"/>
Other (specify below)	<input type="radio"/>	<input type="radio"/>

Specify other pre-existing medical condition:

Specify type of pre-existing chronic infection:

3. PICU Admission PRISM III

PRISM III - Use values obtained during the first 12 hours of PICU admission**Systolic BP**

Use data from an arterial line if available and functioning. Use data collected by a cuff if arterial line is not available or if not functioning properly (i.e. dampened waveform).

Generally, a cardiac arrest involves more than 30 seconds of cardiac massage. For resuscitation with chest compressions and absent blood pressure, record the systolic blood pressure as "0".

Do not assess heart rate during crying or iatrogenic agitation

Heart Rate

For resuscitation with chest compressions and asystole, record the heart rate as "0".

Do not assess heart rate during crying or iatrogenic agitation.

Temperature

Record temperature in degrees Celsius.

Use rectal, oral, blood or axillary temperature. Specify the temperature route when prompted.

Pupillary Reflex/Mental Status

Include coma status if patient has known or suspected acute neurologic disease (i.e head trauma) or if there is reasonable possibility that acute neurologic disease is present. There must be a reasonable medical condition accounting for the neurologic dysfunction.

Do not include "chronic coma" or coma caused by drugs.

Do not include scores for at least 2 hours following anesthesia, sedation or paralysis.

Do not include "sleeping" as coma.

If the patient has been iatrogenically sedated or paralyzed during the entire PICU observation period, then use the most recent, accurate mental status assessment prior to the PICU admission (i.e. Emergency department, or if directly admitted to the PICU, use the pre-hospital assessment).

Pupils must be greater than 3 mm to qualify as fixed and dilated.

Pinpoint pupils are not included.

Unequal pupils must be a minimum of 1 mm difference.

Do not score chronically altered pupils from previous disease or pupils altered by drugs such as atropine.

Blood Gas/Acid Base

pH and PCO₂ may be obtained from arterial, venous, or capillary blood gas samples. Use arterial if available. If not, use venous. If both arterial and venous are not available, then use capillary.

Do not use PCO₂ samples obtained during brain death apnea testing.

Total CO₂ is obtained from the measured sample (done with electrolytes) and NOT the blood

gases. However, if your laboratory does not calculate the measured Total CO₂, use the 

bicarbonate value from the blood gas.

PaO2

Use arterial measurements only.

Glucose

Specify whether the value is recorded in mmol/L or mg/dL.

Avoid hemolyzed specimens.

Potassium

Avoid hemolyzed specimens.

Creatinine

Specify whether the value is recorded in umol/L or mg/dL.

Avoid hemolyzed specimens.

Blood Urea Nitrogen (BUN)

Specify whether the value is recorded in mmol/L or mg/dL.

WBC and Platelets

Avoid hemolyzed specimens.

a. Lowest systolic BP applicable? Yes No

a. Lowest systolic BP _____
(mmHg)

b. Highest heart rate applicable? Yes No

b. Highest heart rate _____
(beats per minute)

c. Lowest temperature applicable? Yes No

c. Lowest temperature _____
(Celsius, 1 decimal place)

Lowest temperature route
 PR
 PO
 Ax
 Tymp
 Esoph
 Bladder

d. Highest temperature applicable? Yes No

d. Highest temperature _____
(Celsius, 1 decimal place)

Highest temperature route
 PR
 PO
 Ax
 Tymp
 Esoph
 Bladder

e. Pupillary reflexes

- 1 F&D
- Both F&D
- Other
- N/A

f. Lowest GCS

- Not applicable
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 10
- 11
- 12
- 13
- 14
- 15

g. Lowest pH applicable?

- Yes
- No

g. Lowest pH

(2 decimal places)

h. Highest pH applicable?

- Yes
- No

h. Highest pH

(2 decimal places)

i. Lowest total CO2 applicable?

- Yes
- No

i. Lowest total CO2

(mmol/L)

j. Highest total CO2 applicable?

- Yes
- No

j. Highest total CO2

(mmol/L)

k. Lowest PaO2 applicable?

- Yes
- No

k. Lowest PaO2

(mmHg)

l. Highest PCO2 applicable?

- Yes
- No

l. l. Highest PCO2

(mmHg)

m. Highest glucose applicable?

- Yes
- No

m. Highest glucose: unit of measurement

- mmol/L
- mg/dL

m. Highest glucose (mmol/L)

(mmol/L, 1 decimal place)

m. Highest glucose (mg/dL)

(mg/dL, 1 decimal place)

n. Highest K+ applicable?

- Yes
- No

n. Highest K+ (mmol/L)

(mmol/L, 1 decimal place)

o. Highest creatinine applicable?

- Yes
- No

Highest creatinine: unit of measurement

umol/L mg/dL

o. Highest creatinine (umol/L)

(umol/L 1 decimal place)

o. Highest creatinine (mg/dL)

(mg/dL 1 decimal place)

p. Highest BUN applicable?

Yes No

Highest BUN: unit of measurement

mmol/L mg/dL

p. Highest BUN (mmol/L)

(mmol/L, 1 decimal place)

p. Highest BUN (mg/dL)

(mg/dL, 1 decimal place)

q. Lowest WBC applicable?

Yes No

q. Lowest WBC (X 109/L)

(1 decimal place, (X 109/L))

r. Highest PT or PTT applicable?

Yes, PT Yes, PTT
 No

r. Highest PTT (secs)

(seconds, 1 decimal place)

r. Highest PT (secs)

(seconds, 1 decimal place)

t. Lowest platelet count applicable?

Yes No

t. Lowest Platelet Count (X 109/L)

((X 109/L))

Other factors (check all that apply):

- Non-operative CV disease
- Post-operative
- Chromosomal anomaly
- Acute diabetes (i.e. DKA)
- Cancer
- Admission from Inpatient unit (exclude post-operative patient)
- Previous ICU admission
- Pre-ICU CPR
- None

4. PELOD-2 Organ Dysfunction Score on Admission and Daily Until Off of Vasoactive Agents

PELOD-2

Please complete the PELOD-2 score at PICU admission and for day 2-7 of PICU admission. Please use midnight to midnight as the 24 hour schedule.

All variables must be collected, but measurements can be done only if justified by the patient's clinical status. If a variable is not measured, it should be considered normal. If a variable is measured more than once in 24 hr, enter the most abnormal value.

Glasgow Coma Scale (GCS)

Assess only patients with known or suspected acute central nervous system disease. Use the lowest value.

If sedated, paralyzed or intubated, record the estimated GCS before these events.

Pupils

Non-reactive pupils must be > 3 mm.

Do not assess during crying or after iatrogenic pupillary dilatation.

Heart rate and mean arterial pressure

Do not assess during crying or iatrogenic agitation.

PaO₂/FiO₂ ratio

Use the arterial measurement of PaO₂ only.

PaO₂/FiO₂ ratio is considered normal in children with cyanotic heart disease.

FiO₂ = Fraction of inspired oxygen.

PaCO₂

May be measured from arterial, capillary, or venous samples.

Invasive Ventilation

The use of mask ventilation is not considered invasive.

PELOD - Admission date: _____

a. Glasgow Coma Score - Admission (Lowest)

- Not applicable
- 3
- 4
- 5
- 6
- 7
- 8
- 9
- 10
- 11
- 12
- 13
- 14
- 15

b. Pupillary Reaction - Admission

- Both reactive Both fixed
- No data

c. Lactatemia (mmol/L) - Admission available?

- Yes No

c. Lactatemia (mmol/L) - Admission (Highest)

_____ (mmol/L, 1 decimal place)

d. Mean Arterial Pressure (mmHg) - Admission available?

- Yes No

d. Mean Arterial Pressure (mmHg) - Admission (Lowest)

_____ (mmHg)

e. Creatinine (umol/L) - Admission available?

- Yes No

e. Creatinine (umol/L) - Admission (Highest)

_____ (umol/L, 1 decimal place)

PaO2 and FiO2 (%) - Admission available?

- Yes No

f. PaO2 (mmHg) - Admission

_____ (mmHg (value entered must be collected at same time as value entered for FiO2 below))

FiO2 (%) - Admission

_____ (% (value entered must be collected at same time as value entered for PaO2 above))

PaO2/FiO2 ratio (Lowest):

_____ (Will be automatically calculated)

g. PCO2 (mmHg) - Admission available?

- Yes No

g. PCO2 (mmHg) - Admission (Highest)

_____ (mmHg)

h. Invasive Ventilation - Admission

- Yes No

i. WBC Count (X 109/L) - Admission available?

- Yes No

i. WBC Count (X 109/L) - Admission (Lowest)

_____ (1 decimal place, (X 109/L))

j. Platelets (X 109/L) - Admission available?

- Yes No

j. Platelets (X 109/L) - Admission (Lowest)

_____ ((X 109/L))

Day 2

Day 2 - Is the patient still on vasoactive agents?

 Yes No

PELOD - Day 2 date:

a. Glasgow Coma Score - Day 2 (Lowest)

 Not applicable 3 4 5 6 7 8 9 10 11 12 13 14 15

b. Pupillary Reaction - Day 2

 Both reactive Both fixed No data

c. Lactatemia (mmol/L) - Day 2 available?

 Yes No

c. Lactatemia (mmol/L) - Day 2 (Highest)

(mmol/L, 1 decimal place)

d. Mean Arterial Pressure (mmHg) - Day 2 available?

 Yes No

d. Mean Arterial Pressure (mmHg) - Day 2 (Lowest)

(mmHg)

e. Creatinine (umol/L) - Day 2 available?

 Yes No

e. Creatinine (umol/L) - Day 2 (Highest)

(umol/L, 1 decimal place)PaO₂ and FiO₂ (%) - Day 2 available? Yes Nof. PaO₂ (mmHg) - Day 2_____
(mmHg (value entered must be collected at same time as value entered for FiO₂ below))FiO₂ (%) - Day 2_____
(% (value entered must be collected at same time as value entered for PaO₂ above))PaO₂/FiO₂ ratio (Lowest):_____
(Will be automatically calculated)g. PCO₂ (mmHg) - Day 2 available? Yes Nog. PCO₂ (mmHg) - Day 2 (Highest)_____
(mmHg)

h. Invasive Ventilation - Day 2

 Yes Noi. WBC Count (X 10⁹/L) - Day 2 available? Yes Noi. WBC Count (X 10⁹/L) - Day 2 (Lowest)_____
(1 decimal place, (X 10⁹/L))j. Platelets (X 10⁹/L) - Day 2 available? Yes No

j. Platelets (X 109/L) - Day 2 (Lowest)

(X 109/L)

Day 3

Day 3 - Is the patient still on vasoactive agents?

 Yes No

PELOD - Day 3 date:

a. Glasgow Coma Score - Day 3 (Lowest)

 Not applicable 3 4 5 6 7 8 9 10 11 12 13 14 15

b. Pupillary Reaction - Day 3

 Both reactive Both fixed No data

c. Lactatemia (mmol/L) - Day 3 available?

 Yes No

c. Lactatemia (mmol/L) - Day 3 (Highest)

(mmol/L, 1 decimal place)

d. Mean Arterial Pressure (mmHg) - Day 3 available?

 Yes No

d. Mean Arterial Pressure (mmHg) - Day 3 (Lowest)

(mmHg)

e. Creatinine (umol/L) - Day 3 available?

 Yes No

e. Creatinine (umol/L) - Day 3 (Highest)

(umol/L, 1 decimal place)

PaO2 and FiO2 (%) - Day 3 available?

 Yes No

f. PaO2 (mmHg) - Day 3

(mmHg (value entered must be collected at same time as value entered for FiO2 below))

FiO2 (%) - Day 3

(% (value entered must be collected at same time as value entered for PaO2 above))

PaO2/FiO2 ratio (Lowest):

(Will be automatically calculated)

g. PCO2 (mmHg) - Day 3 available?

 Yes No

g. PCO2 (mmHg) - Day 3 (Highest)

(mmHg)

h. Invasive Ventilation - Day 3

 Yes No

i. WBC Count (X 109/L) - Day 3 available?

 Yes No

i. WBC Count (X 109/L) - Day 3 (Lowest)

(1 decimal place, (X 109/L))

j. Platelets (X 109/L) - Day 3 available?

Yes No

j. Platelets (X 109/L) - Day 3 (Lowest)

((X 109/L))

Day 4

Day 4 - Is the patient still on vasoactive agents?

Yes No

PELOD - Day 4 date:

a. Glasgow Coma Score - Day 4 (Lowest)

- Not applicable
 3
 4
 5
 6
 7
 8
 9
 10
 11
 12
 13
 14
 15

b. Pupillary Reaction - Day 4

- Both reactive Both fixed
 No data

c. Lactatemia (mmol/L) - Day 4 available?

Yes No

c. Lactatemia (mmol/L) - Day 4 (Highest)

(mmol/L, 1 decimal place)

d. Mean Arterial Pressure (mmHg) - Day 4 available?

Yes No

d. Mean Arterial Pressure (mmHg) - Day 4 (Lowest)

(mmHg)

e. Creatinine (umol/L) - Day 4 available?

Yes No

e. Creatinine (umol/L) - Day 4 (Highest)

(umol/L, 1 decimal place)

PaO2 and FiO2 (%) - Day 4 available?

Yes No

f. PaO2 (mmHg) - Day 4

(mmHg (value entered must be collected at same time as value entered for FiO2 below))

FiO2 (%) - Day 4

(% (value entered must be collected at same time as value entered for PaO2 above))

PaO2/FiO2 ratio (Lowest):

(Will be automatically calculated)

g. PCO2 (mmHg) - Day 4 available?

Yes No

g. PCO2 (mmHg) - Day 4 (Highest)

(mmHg)

- h. Invasive Ventilation - Day 4 Yes No
- i. WBC Count (X 109/L) - Day 4 available? Yes No
- i. WBC Count (X 109/L) - Day 4 (Lowest) _____
(1 decimal place, (X 109/L))
- j. Platelets (X 109/L) - Day 4 available? Yes No
- j. Platelets (X 109/L) - Day 4 (Lowest) _____
((X 109/L))

Day 5

- Day 5 - Is the patient still on vasoactive agents? Yes No
- PELOD - Day 5 date: _____
- a. Glasgow Coma Score - Day 5 (Lowest) Not applicable
 3
 4
 5
 6
 7
 8
 9
 10
 11
 12
 13
 14
 15
- b. Pupillary Reaction - Day 5 Both reactive Both fixed
 No data
- c. Lactatemia (mmol/L) - Day 5 available? Yes No
- c. Lactatemia (mmol/L) - Day 5 (Highest) _____
(mmol/L, 1 decimal place)
- d. Mean Arterial Pressure (mmHg) - Day 5 Yes No
- d. Mean Arterial Pressure (mmHg) - Day 5 (Lowest) _____
(mmHg)
- e. Creatinine (umol/L) - Day 5 Yes No
- e. Creatinine (umol/L) - Day 5 (Highest) _____
(umol/L, 1 decimal place)
- PaO2 and FiO2 (%) - Day 5 available? Yes No
- f. PaO2 (mmHg) - Day 5 _____
(mmHg (value entered must be collected at same time as value entered for FiO2 below))
- FiO2 (%) - Day 5 _____
(% (value entered must be collected at same time as value entered for PaO2 above))
- PaO2/FiO2 ratio (Lowest): _____
(Will be automatically calculated)

- g. PCO2 (mmHg) - Day 5 available? Yes No
- g. PCO2 (mmHg) - Day 5 (Highest) _____
(mmHg)
- h. Invasive Ventilation - Day 5 Yes No
- i. WBC Count (X 109/L) - Day 5 available? Yes No
- i. WBC Count (X 109/L) - Day 5 (Lowest) _____
(1 decimal place, (X 109/L))
- j. Platelets (X 109/L) - Day 5 available? Yes No
- j. Platelets (X 109/L) - Day 5 (Lowest) _____
((X 109/L))

Day 6

- Day 6 - Is the patient still on vasoactive agents? Yes No
- PELOD - Day 6 date: _____
- a. Glasgow Coma Score - Day 6 (Lowest) Not applicable
 3
 4
 5
 6
 7
 8
 9
 10
 11
 12
 13
 14
 15
- b. Pupillary Reaction - Day 6 Both reactive Both fixed
 No data
- c. Lactatemia (mmol/L) - Day 6 available? Yes No
- c. Lactatemia (mmol/L) - Day 6 (Highest) _____
(mmol/L, 1 decimal place)
- d. Mean Arterial Pressure (mmHg) - Day 6 available? Yes No
- d. Mean Arterial Pressure (mmHg) - Day 6 (Lowest) _____
(mmHg)
- e. Creatinine (umol/L) - Day 6 available? Yes No
- e. Creatinine (umol/L) - Day 6 (Highest) _____
(umol/L, 1 decimal place)
- PaO2 and FiO2 (%) - Day 6 available? Yes No
- f. PaO2 (mmHg) - Day 6 _____
(mmHg (value entered must be collected at same time as value entered for FiO2 below))
- FiO2 (%) - Day 6 _____
(% (value entered must be collected at same time as value entered for PaO2 above))

PaO₂/FiO₂ ratio (Lowest):

(Will be automatically calculated)g. PCO₂ (mmHg) - Day 6 available? Yes Nog. PCO₂ (mmHg) - Day 6 (Highest)

(mmHg)

h. Invasive Ventilation - Day 6

 Yes Noi. WBC Count (X 10⁹/L) - Day 6 available? Yes Noi. WBC Count (X 10⁹/L) - Day 6 (Lowest)

(1 decimal place, (X 10⁹/L))j. Platelets (X 10⁹/L) - Day 6 available? Yes Noj. Platelets (X 10⁹/L) - Day 6 (Lowest)

((X 10⁹/L))**Day 7**

Day 7 - Is the patient still on vasoactive agents?

 Yes No

PELDO - Day 7 date:

a. Glasgow Coma Score - Day 7 (Lowest)

 Not applicable 3 4 5 6 7 8 9 10 11 12 13 14 15

b. Pupillary Reaction - Day 7

 Both reactive Both fixed No data

c. Lactatemia (mmol/L) - Day 7 available?

 Yes No

c. Lactatemia (mmol/L) - Day 7 (Highest)

(mmol/L, 1 decimal place)

d. Mean Arterial Pressure (mmHg) - Day 7 available?

 Yes No

d. Mean Arterial Pressure (mmHg) - Day 7 (Lowest)

(mmHg)

e. Creatinine (umol/L) - Day 7 available?

 Yes No

e. Creatinine (umol/L) - Day 7 (Highest)

(umol/L, 1 decimal place)PaO₂ and FiO₂ (%) - Day 7 available? Yes Nof. PaO₂ (mmHg) - Day 7

(mmHg (value entered must be collected at same time as value entered for FiO₂ below))

FiO2 (%) - Day 7

(% (value entered must be collected at same time as value entered for PaO2 above))

PaO2/FiO2 ratio (Lowest):

(Will be automatically calculated)

g. PCO2 (mmHg) - Day 7 available?

Yes No

g. PCO2 (mmHg) - Day 7 (Highest)

(mmHg)

h. Invasive Ventilation - Day 7

Yes No

i. WBC Count (X 109/L) - Day 7 available?

Yes No

i. WBC Count (X 109/L) - Day 7 (Lowest)

(1 decimal place, (X 109/L))

j. Platelets (X 109/L) - Day 7 available?

Yes No

j. Platelets (X 109/L) - Day 7 (Lowest)

((X 109/L))

5. Duration of Vasoactive Infusions Administered During PICU Admission

Vasoactive Infusions Administered During PICU Admission - Duration

Record if patient received any of the vasoactive infusions listed at any time during PICU admission. If yes, provide the start date/time and stop date/time for each vasoactive infusion. For "Other", please indicate the type of vasoactive infusion.

If a vasoactive infusion was stopped and then restarted within 6 hours, please include this period in the total duration. If a vasoactive infusion was stopped and then restarted after more than 6 hours, please record this second period in the "Other Vasoactive Infusion" section provided.

If the patient did not receive vasoactive infusions during PICU admission, please check "N/A" and proceed to Section 6.

The patient received Vasoactive Agents during PICU Admission

- Yes
 Not applicable
 (If N/A, proceed to Section 6)

If the patient was never administered vasoactive infusions, are you sure they have met the study inclusion criteria? Please verify the patient's eligibility and explain whether or not the patient is actually eligible.

Dopamine

Dopamine:

- Yes No

Start Date (Dopamine):

Start Time (Dopamine):

Stop Date (Dopamine):

Stop Time (Dopamine):

Epinephrine

Epinephrine:

- Yes No

Start Date (Epinephrine):

Start Time (Epinephrine):

Stop Date (Epinephrine):

Stop Time (Epinephrine):

Norepinephrine

Norepinephrine: Yes No

Start Date (Norepinephrine): _____

Start Time (Norepinephrine): _____

Stop Date (Norepinephrine): _____

Stop Time (Norepinephrine): _____

Dobutamine

Dobutamine: Yes No

Start Date (Dobutamine): _____

Start Time (Dobutamine): _____

Stop Date (Dobutamine): _____

Stop Time (Dobutamine): _____

Milrinone

Milrinone: Yes No

Start Date (Milrinone): _____

Start Time (Milrinone): _____

Stop Date (Milrinone): _____

Stop Time (Milrinone): _____

Phenylephrine

Phenylephrine: Yes No

Start Date (Phenylephrine): _____

Start Time (Phenylephrine): _____

Stop Date (Phenylephrine): _____

Stop Time (Phenylephrine): _____

Vasopressin

Vasopressin: Yes No

Start Date (Vasopressin): _____

Start Time (Vasopressin): _____

Stop Date (Vasopressin): _____

Stop Time (Vasopressin): _____

Other Vasoactive Infusion (1)

Other vasoactive infusion (1): Yes No

Specify type of other vasoactive infusion: _____

Start Date (Other vasoactive infusion): _____

Start Time (Other vasoactive infusion): _____

Stop Date (Other vasoactive infusion): _____

Stop Time (Other vasoactive infusion): _____

Other Vasoactive Infusion (2)

Other vasoactive infusion (2): Yes No

Specify type of other vasoactive infusion: _____

Start Date (Other vasoactive infusion): _____

Start Time (Other vasoactive infusion): _____

Stop Date (Other vasoactive infusion): _____

Stop Time (Other vasoactive infusion): _____

Other Vasoactive Infusion (3)

Other vasoactive infusion (3): Yes No

Specify type of other vasoactive infusion: _____

Start Date (Other vasoactive infusion): _____

Start Time (Other vasoactive infusion): _____

Stop Date (Other vasoactive infusion): _____

Stop Time (Other vasoactive infusion): _____

6. Daily Administration of Vasoactive Agents During PICU Admission

Vasoactive Infusions Administered Daily During PICU Admission

For each day of PICU admission, record if vasoactive agents were administered, and the specific type(s) of agent(s) used. Day 1 is the day of patient enrolment (i.e. the date that patient met eligibility). Record information on vasoactive agents up to Day 8 of PICU admission or until PICU discharge, whichever occurs first. If the patient was given any type of vasoactive agent that day, select "Yes". If the patient did not receive vasoactive agents that day, and is still admitted to the PICU, check "No". If the patient did not receive vasoactive agents that day, and is no longer admitted to the PICU, please check "Patient has been discharged".

For each vasopressor administered during PICU admission, indicate the highest daily dose.

Please use midnight to midnight as the 24 hour schedule.

If the patient did not receive any vasoactive infusions during PICU admission, check "N/A" and go to Section 7.

The patient received vasoactive infusions during PICU admission

- Yes
 Not applicable
 (If N/A, proceed to Section 7)

If the patient was never administered vasoactive infusions, are you sure they have met the study inclusion criteria? Please verify the patient's eligibility and explain whether or not the patient is actually eligible.

Day 1

Day 1 Date:

Patient received vasoactive agent on Day 1:

- Yes No

Dopamine:

- Yes No

Dopamine highest dose (mcg/kg/min):

(mcg/kg/min, 1 decimal place)

Epinephrine:

- Yes No

Epinephrine highest dose (mcg/kg/min):

(mcg/kg/min, 2 decimal places)

Norepinephrine:

- Yes No

Norepinephrine highest dose (mcg/kg/min):

(mcg/kg/min, 2 decimal places)

Milrinone:

- Yes No

Milrinone highest dose (mcg/kg/min):

(mcg/kg/min, 2 decimal places)

Vasopressin:

- Yes No

Vasopressin highest dose (units/kg/min):

(units/kg/min, 4 decimal places)

Other:

- Yes No

Specify type:

Other highest dose (units/kg/min): _____
(units/kg/min)

Day 2

Day 2 Date: _____

Patient received vasoactive agent on Day 2: Yes No Discharged

Dopamine: Yes No

Dopamine highest dose (mcg/kg/min): _____
(mcg/kg/min, 1 decimal place)

Epinephrine: Yes No

Epinephrine highest dose (mcg/kg/min): _____
(mcg/kg/min, 2 decimal places)

Norepinephrine: Yes No

Norepinephrine highest dose (mcg/kg/min): _____
(mcg/kg/min, 2 decimal places)

Milrinone: Yes No

Milrinone highest dose (mcg/kg/min): _____
(mcg/kg/min, 2 decimal places)

Vasopressin: Yes No

Vasopressin highest dose (units/kg/min): _____
(units/kg/min, 4 decimal places)

Other: Yes No

Specify type: _____

Other highest dose (units/kg/min): _____
(units/kg/min)

Day 3

Day 3 Date: _____

Patient received vasoactive agent on Day 3: Yes No Discharged

Dopamine: Yes No

Dopamine highest dose (mcg/kg/min): _____
(mcg/kg/min, 1 decimal place)

Epinephrine: Yes No

Epinephrine highest dose (mcg/kg/min): _____
(mcg/kg/min, 2 decimal places)

Norepinephrine: Yes No

Norepinephrine highest dose (mcg/kg/min): _____
(mcg/kg/min, 2 decimal places)

Milrinone: Yes No

Milrinone highest dose (mcg/kg/min): _____
(mcg/kg/min, 2 decimal places)

Vasopressin: Yes No

Vasopressin highest dose (units/kg/min): _____
(units/kg/min, 4 decimal places)

Other: Yes No

Specify type: _____

Other highest dose (units/kg/min): _____
(units/kg/min)

Day 4

Day 4 Date: _____

Patient received vasoactive agent on Day 4: Yes No Discharged

Dopamine: Yes No

Dopamine highest dose (mcg/kg/min): _____
(mcg/kg/min, 1 decimal place)

Epinephrine: Yes No

Epinephrine highest dose (mcg/kg/min): _____
(mcg/kg/min, 2 decimal places)

Norepinephrine: Yes No

Norepinephrine highest dose (mcg/kg/min): _____
(mcg/kg/min, 2 decimal places)

Milrinone: Yes No

Milrinone highest dose (mcg/kg/min): _____
(mcg/kg/min, 2 decimal places)

Vasopressin: Yes No

Vasopressin highest dose (units/kg/min): _____
(units/kg/min, 4 decimal places)

Other: Yes No

Specify type: _____

Other highest dose (units/kg/min): _____
(units/kg/min)

Day 5

Day 5 Date: _____

Patient received vasoactive agent on Day 5:

 Yes No Discharged

Dopamine:

 Yes No

Dopamine highest dose (mcg/kg/min):

(mcg/kg/min, 1 decimal place)

Epinephrine:

 Yes No

Epinephrine highest dose (mcg/kg/min):

(mcg/kg/min, 2 decimal places)

Norepinephrine:

 Yes No

Norepinephrine highest dose (mcg/kg/min):

(mcg/kg/min, 2 decimal places)

Milrinone:

 Yes No

Milrinone highest dose (mcg/kg/min):

(mcg/kg/min, 2 decimal places)

Vasopressin:

 Yes No

Vasopressin highest dose (units/kg/min):

(units/kg/min, 4 decimal places)

Other:

 Yes No

Specify type: _____

Other highest dose (units/kg/min):

(units/kg/min)

Day 6

Day 6 Date: _____

Patient received vasoactive agent on Day 6:

 Yes No Discharged

Dopamine:

 Yes No

Dopamine highest dose (mcg/kg/min):

(mcg/kg/min, 1 decimal place)

Epinephrine:

 Yes No

Epinephrine highest dose (mcg/kg/min):

(mcg/kg/min, 2 decimal places)

Norepinephrine:

 Yes No

Norepinephrine highest dose (mcg/kg/min):

(mcg/kg/min, 2 decimal places)

Milrinone:

 Yes No

Milrinone highest dose (mcg/kg/min):

(mcg/kg/min, 2 decimal places)

Vasopressin: Yes No

Vasopressin highest dose (units/kg/min): _____
(units/kg/min, 4 decimal places)

Other: Yes No

Specify type: _____

Other highest dose (units/kg/min): _____
(units/kg/min)

Day 7

Day 7 Date: _____

Patient received vasoactive agent on Day 7: Yes No Discharged

Dopamine: Yes No

Dopamine highest dose (mcg/kg/min): _____
(mcg/kg/min, 1 decimal place)

Epinephrine: Yes No

Epinephrine highest dose (mcg/kg/min): _____
(mcg/kg/min, 2 decimal places)

Norepinephrine: Yes No

Norepinephrine highest dose (mcg/kg/min): _____
(mcg/kg/min, 2 decimal places)

Milrinone: Yes No

Milrinone highest dose (mcg/kg/min): _____
(mcg/kg/min, 2 decimal places)

Vasopressin: Yes No

Vasopressin highest dose (units/kg/min): _____
(units/kg/min, 4 decimal places)

Other: Yes No

Specify type: _____

Other highest dose (units/kg/min): _____
(units/kg/min)

Day 8

Day 8 Date: _____

Patient received vasoactive agent on Day 8: Yes No Discharged

Dopamine: Yes No

Dopamine highest dose (mcg/kg/min): _____
(mcg/kg/min, 1 decimal place)

Epinephrine: Yes No

Epinephrine highest dose (mcg/kg/min):

(mcg/kg/min, 2 decimal places)

Norepinephrine:

Yes No

Norepinephrine highest dose (mcg/kg/min):

(mcg/kg/min, 2 decimal places)

Milrinone:

Yes No

Milrinone highest dose (mcg/kg/min):

(mcg/kg/min, 2 decimal places)

Vasopressin:

Yes No

Vasopressin highest dose (units/kg/min):

(units/kg/min, 4 decimal places)

Other:

Yes No

Specify type:

Other highest dose (units/kg/min):

(units/kg/min)

7. Fluid Bolus and Intake/Output

A. Total Fluid Received Prior to Enrolment

Please record the total fluid received in mls prior to enrolment. Record any fluid received from 6 hours prior to the start of the first vasoactive infusion up until the time of enrolment (i.e. randomization). Record all IV fluid received including maintenance, antibiotics, other medications, and blood products.

If the patient did not receive a given fluid, please enter "0" mL

Is information on fluid intake prior to enrolment available?

- Yes
 No

Normal Saline - Amount of Fluid received (mls)

_____ (mls)

5% Albumin - Amount of Fluid received (mls)

_____ (mls)

FFP - Amount of Fluid received (mls)

_____ (mls)

pRBC - Amount of Fluid received (mls)

_____ (mls)

Platelets - Amount of Fluid received (mls)

_____ (mls)

3% Saline - Amount of Fluid received (mls)

_____ (mls)

Medications - Amount of Fluid received (mls)

_____ (mls)

Other - Amount of fluid received (mls)

_____ (mls)

Specify type of other fluid:

B. Total Intake/Output and Fluid Bolus

Please record the total intake and output of fluid (in mls) given for Day 1 - 7 (or until PICU discharge if discharged before Day 7). Please use the 24 hour schedule in use at your institution. Day 1 starts at the time of enrolment into the study.

DAY 1

Fluid I/O - Day 1 date:

Total Day 1 intake (mL): _____
(mL)

Total Day 1 output (mL): _____
(mL)

DAY 2

Day 2 - Fluid intake & output available? Yes No

Fluid I/O Day 2 date: _____

Total Day 2 intake (mL): _____
(mL)

Total Day 2 output (mL): _____
(mL)

DAY 3

Day 3 - Fluid intake & output available? Yes No

Fluid I/O Day 3 date: _____

Total Day 3 intake (mL): _____
(mL)

Total Day 3 output (mL): _____
(mL)

DAY 4

Day 4 - Fluid intake & output available? Yes No

Fluid I/O Day 4 date: _____

Total Day 4 intake (mL): _____
(mL)

Total Day 4 output (mL): _____
(mL)

DAY 5

Day 5 - Fluid intake & output available? Yes No

Fluid I/O Day 5 date: _____

Total Day 5 intake (mL): _____
(mL)

Total Day 5 output (mL): _____
(mL)

DAY 6

Day 6 - Fluid intake & output available?

Yes No

Fluid I/O Day 6 date:

Total Day 6 intake (mL):

(mL)

Total Day 6 output (mL):

(mL)

DAY 7

Day 7 - Fluid intake & output available?

Yes No

Fluid I/O Day 7 date:

(mL)

Total Day 7 intake (mL):

(mL)

Total Day 7 output (mL):

(mL)

8. Mechanical Ventilation

Daily Mechanical Ventilation

Record whether the patient was mechanically ventilated at any time during Day 1 to Day 28 of PICU admission. Day 1 is the day of patient enrollment. Record the INITIAL start time and the FINAL stop time of mechanical ventilation. Indicate if the patient was extubated and re-intubated during this time, and record the date and time of each extubation & re-intubation.

Mechanical ventilation includes any form of INVASIVE ventilation. Do not include non-invasive ventilation (i.e. CPAP, BiPAP).

If the patient did not receive mechanical ventilation at any time during PICU admission, please check "N/A" and proceed to Section 9.

Patient was mechanically ventilated between Day 1 to Day 28 of PICU admission

- Yes
 Not applicable
 (If N/A, proceed to Section 9)

Initial Start Date and Time

Mechanical Ventilation - INITIAL Start Date: _____

Mechanical Ventilation - INITIAL Start Time: _____

Final Stop Date and Time

Mechanical Ventilation - FINAL Stop Date: _____

Mechanical Ventilation - FINAL Stop Time: _____

Was the patient extubated and re-intubated during the above time period (i.e. between the INITIAL start date and time and the FINAL stop date and time)?

- Yes No

Extubation and Re-Intubation 1

Date of Extubation (1): _____

Time of Extubation (1): _____

Date of Re-Intubation (1): _____

Time of Re-Intubation (1): _____

Additional extubation & re-intubation applicable? Yes No

Extubation and Re-Intubation 2

Date of Extubation (2): _____

Time of Extubation (2): _____

Date of Re-Intubation (2): _____

Time of Re-Intubation (2): _____

Additional Extubation and Re-Intubation applicable? Yes No

Extubation and Re-Intubation 3

Date of Extubation (3): _____

Time of Extubation (3): _____

Date of Re-Intubation (3): _____

Time of Re-Intubation (3): _____

9. Acute CPAP or BiPAP Ventilation

Daily Acute CPAP or BiPAP Ventilation

Record whether the patient had non-invasive ventilation (CPAP or BiPAP) at any time during Day 1 to Day 28 of PICU admission. Day 1 is the day of patient enrollment. If yes, record the INITIAL start date & time and the FINAL stop date & time for non-invasive ventilation.

If CPAP/BiPAP was stopped and re-started >6 hours later between the initial start date & time and final stop date & time, please indicate the stop and re-start times.

If the patient did not receive CPAP or BiPAP, please check "N/A" and proceed to Section 10.

Patient received Acute CPAP or BiPAP between Day 1 and Day 28 of PICU admission

- Yes
 Not applicable
 (If N/A, proceed to Section 10)

CPAP/ BiPAP Initial Start Date and Time

CPAP/BiPAP - INITIAL Start Date: _____

CPAP/BiPAP - INITIAL Start Time: _____

CPAP/BiPAP Final Stop Date and Time

CPAP/BiPAP - FINAL Stop Date: _____

CPAP/BiPAP - FINAL Stop Time: _____

Was CPAP/BiPAP stopped and re-started >6 hours later during the above timeframe (i.e. between the initial start time and final stop time)

- Yes No

CPAP/BiPAP Stop and Re-Start Date & Time (1)

CPAP/BiPAP Stop Date (1) _____

CPAP/BiPAP Stop Time (1) _____

CPAP/BiPAP Re-Start Date (1) _____

CPAP/BiPAP Re-Start Time (1) _____

Additional CPAP/BiPAP Stop & Re-Start applicable? Yes No

CPAP/BiPAP Stop and Re-Start Date & Time (2)

CPAP/BiPAP Stop Date (2) _____

CPAP/BiPAP Stop Time (2) _____

CPAP/BiPAP Re-Start Date (2) _____

CPAP/BiPAP Re-Start Time (2) _____

Additional CPAP/BiPAP Stop and Re-Start applicable? Yes No

CPAP/BiPAP Stop and Re-Start Date and Time (3)

CPAP/BiPAP Stop Date (3) _____

CPAP/BiPAP Stop Time (3) _____

CPAP/BiPAP Re-Start Date (3) _____

CPAP/BiPAP Re-Start Time (3) _____

10. Research Blood Sampling & Adrenal Testing

Research Blood Sampling

Did the patient have a research blood sample collected? Yes No

Date of research blood sample collection: _____

Time of research blood sample collection: _____

Was the patient on study drug when the research blood sample was collected? Yes No

Clinically-Indicated Blood Sample: Total Cortisol

Did the patient have a total cortisol level done as part of clinical care? Yes No

Date of cortisol level: _____

Time of cortisol level: _____

Total cortisol level (nmol/l): _____
(nmol/l, 1 decimal place)

Additional cortisol level done as part of clinical care? Yes No

Date of cortisol level (2): _____

Time of cortisol level (2): _____

Total cortisol level (nmol/l) (2): _____
(nmol/l, 1 decimal place)

Additional cortisol level done as part of clinical care? Yes No

Date of cortisol level (3): _____

Time of cortisol level (3): _____

Total cortisol level (nmol/l) (3): _____
(nmol/l, 1 decimal place)

ACTH Stimulation Test

Did the patient have an ACTH stimulation test? Yes No

When was the ACTH stimulation test done? _____

Total cortisol level post-ACTH (nmol/l): _____
(nmol/l, 1 decimal place)

Time of post-ACTH cortisol level: _____

11. Use of Ranitidine, Pantoprazole or Lanzoprazole

Use of Ranitidine, Pantoprazole or Lanzoprazole

Record if patient received ranitidine, pantoprazole or lanzoprazole prior to admission, at any time during PICU admission, and if the patient received any of these medications while on study drug.

Record the initial start date and time and the final stop date and time of any medications administered. If any of the above medications are started and stopped during the PICU course, please use the first date/time that the medication was started as the start date/time, and the final date/time that the medication was stopped as the stop date/time.

If the patient is discharged home while still on the medication, use the date and time of hospital discharge as the stop date/time.

Ranitidine

Was the patient on Ranitidine prior to enrolment? Yes No Unknown

Did the patient receive Ranitidine at any time during PICU admission? Yes No

Did the patient receive ranitidine while on study drug? Yes No

Initial Start Date for Ranitidine available? Yes No

Initial Start Time for Ranitidine available? Yes No

Indicate the FIRST Start Date for Ranitidine: _____

Indicate the FIRST Start Time for Ranitidine: _____

Final Stop Date for Ranitidine available? Yes No
Includes date or discharge/death if patient was still on Ranitidine at discharge/death

Final Stop Time for Ranitidine available? Yes No
Includes date or discharge/death if patient was still on Ranitidine at discharge/death

Indicate the FINAL Stop Date Ranitidine: _____

Indicate the FINAL Stop Time for Ranitidine: _____

Pantoprazole/Lanzoprazole

Was the patient on Pantoprazole/Lanzoprazole prior to enrolment?

Yes No Unknown

Did the patient receive Pantoprazole/Lanzoprazole at any time during PICU admission?

Yes No

Did the patient receive pantoprazole/lanzoprazole while on study drug?

Yes No

Initial Start Date for Pantoprazole/Lanzoprazole available?

Yes No

Initial Start Time for Pantoprazole/Lanzoprazole available?

Yes No

Indicate the FIRST Start Date for Pantoprazole/Lanzoprazole:

Indicate the FIRST Start Time for Pantoprazole/Lanzoprazole:

Final Stop Date for Pantoprazole/Lanzoprazole available? **Includes date or discharge/death if patient was still on Ranitidine at discharge/death**

Yes No

Final Stop Time for Pantoprazole/Lanzoprazole available? **Includes date or discharge/death if patient was still on Ranitidine at discharge/death**

Yes No

Indicate the FINAL Stop Date for Pantoprazole/Lanzoprazole :

Indicate the FINAL Stop Time for Pantoprazole/Lanzoprazole :

12. Red Blood Cell Transfusions and Hemoglobin

Red Blood Cell Transfusions and Hemoglobin

Record if the patient was given a red blood cell transfusion for Days 1 - 8 of PICU admission. For Days 1-8, indicate "Yes" if a transfusion was given, "No" if no transfusion was given and the patient is still on study drug, or "Study drug stopped/discharged" if the patient is no longer on study drug or has been discharged. Please use midnight to midnight as the 24 hour schedule.

For Days 1-8, indicate the lowest hemoglobin value recorded that day (if available).

Day 1 is the day of patient enrollment.

Day 1

Day 1 Date: _____

Was a red blood cell transfusion given on Day 1?

Yes No

Day 1 hemoglobin available?

Yes No

Lowest hemoglobin value on Day 1 (g/dL): _____

(g/dL)

Day 2

Day 2 Date: _____

Was a red blood cell transfusion given on Day 2?

Yes No Study drug stopped/Discharged

Day 2 hemoglobin available?

Yes No

Lowest hemoglobin value on Day 2 (g/dL): _____

(g/dL)

Day 3

Day 3 Date: _____

Was a red blood cell transfusion given on Day 3?

Yes No Study drug stopped/Discharged

Day 3 hemoglobin available?

Yes No

Lowest hemoglobin value on Day 3 (g/dL): _____

(g/dL)

Day 4

Day 4 Date: _____

Was a red blood cell transfusion given on Day 4? Yes No Study drug stopped/DischargedDay 4 hemoglobin available? Yes NoLowest hemoglobin value on Day 4 (g/dL): _____
(g/dL)

Day 5

Day 5 Date: _____

Was a red blood cell transfusion given on Day 5? Yes No Study drug stopped/DischargedDay 5 hemoglobin available? Yes NoLowest hemoglobin value on Day 5 (g/dL): _____
(g/dL)

Day 6

Day 6 Date: _____

Was a red blood cell transfusion given on Day 6? Yes No Study drug stopped/DischargedDay 6 hemoglobin available? Yes NoLowest hemoglobin value on Day 6 (g/dL): _____
(g/dL)

Day 7

Day 7 Date: _____

Was a red blood cell transfusion given on Day 7? Yes No Study drug stopped/DischargedDay 7 hemoglobin available? Yes NoLowest hemoglobin value on Day 7(g/dL): _____
(g/dL)

Day 8

Day 8 Date:

Was a red blood cell transfusion given on Day 8?

Yes No Study drug
stopped/Discharged

Day 8 hemoglobin available?

Yes No

Lowest hemoglobin value on Day 8(g/dL):

(g/dL)

13. Gastrointestinal Bleeding

Gastrointestinal Bleeding

Record any form of GI bleeding that occurred during each day of PICU admission up to 28 days or discharge, whichever occurs first. For Days 1-28, indicate "Yes" for each day when GI bleeding was documented, "No" if the patient was in the PICU and GI bleeding was not documented that day, or "Discharged" once the patient has been discharged from the PICU. Use midnight to midnight as the 24 hour schedule.

GI bleeding is any of the following as documented in the nurse's notes or other progress notes, including: coffee ground emesis, coffee grounds in nasogastric tube, melena stools, blood in diaper etc.

Day 1 is the day of enrolment (i.e. the day that the patient first met eligibility criteria for the study).

If there was no documentation of GI bleeding during Day 1 to Day 28, please check "N/A" and proceed to Section 14.

The patient had GI bleeding during Day 1 to Day 28 of PICU admission

- Yes
 Not applicable
 (If N/A, proceed to Section 14)

Day 1

GI Bleeding - Day 1: Yes No

Day 1 Date: _____

Day 2

GI Bleeding - Day 2: Yes No Discharged

Day 2 Date: _____

Day 3

GI Bleeding - Day 3: Yes No Discharged

Day 3 Date: _____

Day 4

GI Bleeding - Day 4:

Yes No Discharged

Day 4 Date:

Day 5

GI Bleeding - Day 5:

Yes No Discharged

Day 5 Date:

Day 6

GI Bleeding - Day 6:

Yes No Discharged

Day 6 Date:

Day 7

GI Bleeding - Day 7:

Yes No Discharged

Day 7 Date:

Day 8

GI Bleeding - Day 8:

Yes No Discharged

Day 8 Date:

Day 9

GI Bleeding - Day 9:

Yes No Discharged

Day 9 Date:

Day 10

GI Bleeding - Day 10:

Yes No Discharged

Day 10 Date:

Day 11

GI Bleeding - Day 11:

Yes No Discharged

Day 11 Date:

Day 12

GI Bleeding - Day 12:

Yes No Discharged

Day 12 Date:

Day 13

GI Bleeding - Day 13:

Yes No Discharged

Day 13 Date:

Day 14

GI Bleeding - Day 14:

Yes No Discharged

Day 14 Date:

Day 15

GI Bleeding - Day 15:

Yes No Discharged

Day 15 Date:

Day 16

GI Bleeding - Day 16:

Yes No Discharged

Day 16 Date:

Day 17

GI Bleeding - Day 17:

Yes No Discharged

Day 17 Date:

Day 18

GI Bleeding - Day 18:

Yes No Discharged

Day 18 Date:

Day 19

GI Bleeding - Day 19:

Yes No Discharged

Day 19 Date:

Day 20

GI Bleeding - Day 20:

Yes No Discharged

Day 20 Date:

Day 21

GI Bleeding - Day 21:

Yes No Discharged

Day 21 Date:

Day 22

GI Bleeding - Day 22:

Yes No Discharged

Day 22 Date:

Day 23

GI Bleeding - Day 23:

Yes No Discharged

Day 23 Date:

Day 24

GI Bleeding - Day 24:

Yes No Discharged

Day 24 Date:

Day 25

GI Bleeding - Day 25:

Yes No Discharged

Day 25 Date:

Day 26

GI Bleeding - Day 26:

Yes No Discharged

Day 26 Date:

Day 27

GI Bleeding - Day 27:

Yes No Discharged

Day 27 Date:

Day 28

GI Bleeding - Day 28:

Yes No Discharged

Day 28 Date:

14. Daily Insulin Infusion

Daily Insulin Infusion

Record if the patient was on an insulin infusion for each day that the patient is on study drug. For Days 1-8, indicate "Yes" if patient was on an insulin infusion + study drug, "No" if the patient was on study drug and did not receive an insulin infusion that day, or "Study drug stopped" if the patient is no longer receiving study drug that day. Use midnight to midnight as the 24 hour schedule.

Start and Stop Time: Record the start and stop time of each insulin infusion administered on a given day. If multiple insulin infusions were given that day, record the start & stop time of the first two infusions. If the patient was on an insulin infusion for the entire day, record 0:00 as the start time and 23:59 as the stop time.

Day 1 is the day of patient enrolment (i.e. the day that the patient first met eligibility criteria for the study).

If there was no documentation of insulin infusion while the patient was on study drug, please check "N/A" and proceed to Section 15.

Was the patient given an insulin infusion on any day while the patient was on study drug?

Yes No
(If No, proceed to Section 15)

Day 1

Day 1 Date: _____

Insulin Infusion: Yes No

Day 1 Insulin Infusion Start Time (1): _____

Day 1 Insulin Infusion Stop Time (1): _____

Additional Start/Stop required times for Day 1?: Yes No

Day 1 Insulin Infusion Start Time (2): _____

Day 1 Insulin Infusion Stop Time (2): _____

Day 2

Day 2 Date: _____

Insulin Infusion: Yes No Study drug stopped

Day 2 Insulin Infusion Start Time (1): _____

Day 2 Insulin Infusion Stop Time (1): _____

Additional Start/Stop required times for Day 2?: Yes No
Day 2 Insulin Infusion Start Time (2): _____
Day 2 Insulin Infusion Stop Time (2): _____

Day 3

Day 3 Date: _____
Insulin Infusion: Yes No Study drug stopped
Day 3 Insulin Infusion Start Time (1): _____
Day 3 Insulin Infusion Stop Time (1): _____
Additional Start/Stop required times for Day 3?: Yes No
Day 3 Insulin Infusion Start Time (2): _____
Day 3 Insulin Infusion Stop Time (2): _____

Day 4

Day 4 Date: _____
Insulin Infusion: Yes No Study drug stopped
Day 4 Insulin Infusion Start Time (1): _____
Day 4 Insulin Infusion Stop Time (1): _____
Additional Start/Stop required times for Day 4?: Yes No
Day 4 Insulin Infusion Start Time (2): _____
Day 4 Insulin Infusion Stop Time (2): _____

Day 5

Day 5 Date: _____
Insulin Infusion: Yes No Study drug stopped
Day 5 Insulin Infusion Start Time (1): _____
Day 5 Insulin Infusion Stop Time (1): _____
Additional Start/Stop required times for Day 5?: Yes No
Day 5 Insulin Infusion Start Time (2): _____
Day 5 Insulin Infusion Stop Time (2): _____

Day 6

Day 6 Date: _____

Insulin Infusion: Yes No Study drug stopped

Day 6 Insulin Infusion Start Time (1): _____

Day 6 Insulin Infusion Stop Time (1): _____

Additional Start/Stop required times for Day 6?: Yes No

Day 6 Insulin Infusion Start Time (2): _____

Day 6 Insulin Infusion Stop Time (2): _____

Day 7

Day 7 Date: _____

Insulin Infusion: Yes No Study drug stopped

Day 7 Insulin Infusion Start Time (1): _____

Day 7 Insulin Infusion Stop Time (1): _____

Additional Start/Stop required times for Day 7?: Yes No

Day 7 Insulin Infusion Start Time (2): _____

Day 7 Insulin Infusion Stop Time (2): _____

Day 8

Day 8 Date: _____

Insulin Infusion: Yes No Study drug stopped

Day 8 Insulin Infusion Start Time (1): _____

Day 8 Insulin Infusion Stop Time (1): _____

Additional Start/Stop required times for Day 8?: Yes No

Day 8 Insulin Infusion Start Time (2): _____

Day 8 Insulin Infusion Stop Time (2): _____

15. Lab Results

Lab Results - Section 1

Please record the following lab results at Baseline (prior to enrolment) and for 72 hours after patient enrolment (Test #1 up to Test #30)

Baseline - use the lab results closest to the time of patient enrolment (but **PRIOR** to patient enrolment). You may use lab results prior to PICU admission (i.e. Emergency or the ward) if the patient met the criteria either on admission, or just prior to admission to PICU. If no lab results were available for the time specified, please check "No".

Calcium (Ca⁺) - use ionized calcium, adjusted to pH if available.

WBC - White blood cell.

GLU - Glucose, random.

Baseline Test

Baseline lab results available for WBC, GLU, and/or Ca⁺?

Yes No

Baseline Test - Date :

Baseline Test - Time:

Results available for (check all that apply):

- WBC
 GLU
 Ca⁺

Baseline WBC (X 10⁹/L, 1 decimal place):

_____ (1 decimal place, (X 10⁹/L))

Baseline GLU (mmol/L, 1 decimal place):

_____ (mmol/L, 1 decimal place)

Baseline Ca⁺ (mmol/L, 2 decimal places):

_____ (mmol/L, 2 decimal places)

Test #1 - Date:

Test #1 - Time:

Test#1 - Results available for:

- WBC
 GLU
 Ca⁺

Test #1 - WBC (X 10⁹/L, 1 decimal place):

_____ (1 decimal place (X 10⁹/L))

Test #1 - GLU (mmol/L, 1 decimal place): _____
(mmol/L, 1 decimal place)

Test #1 - Ca+ (mmol/L, 2 decimal places): _____
(mmol/L, 2 decimal places)

Additional lab results available for the first 72 hours post-enrollment? Yes No

Test #2 - Date : _____

Test #2 - Time: _____

Test#2 - Results available for: WBC
 GLU
 Ca+

Test #2 - WBC (X 109/L, 1 decimal place): _____
(1 decimal place (X 109/L))

Test #2 - GLU (mmol/L, 1 decimal place): _____
(mmol/L, 1 decimal place)

Test #2 - Ca+ (mmol/L, 2 decimal places): _____
(mmol/L, 2 decimal places)

Additional lab results available for the first 72 hours post-enrollment? Yes No

Test #3 - Date: _____

Test #3 - Time: _____

Test#3 - Results available for: WBC
 GLU
 Ca+

Test #3 - WBC (X 109/L, 1 decimal place): _____
(1 decimal place (X 109/L))

Test #3 - GLU (mmol/L, 1 decimal place): _____
(mmol/L, 1 decimal place)

Test #3 - Ca+ (mmol/L, 2 decimal places): _____
(mmol/L, 2 decimal places)

Additional lab results available for the first 72 hours post-enrollment? Yes No

Test #4 - Date: _____

Test #4 - Time: _____

Test#4 - Results available for: WBC
 GLU
 Ca+

Test #4 - WBC (X 109/L, 1 decimal place): _____
(1 decimal place (X 109/L))

Test #4 - GLU (mmol/L, 1 decimal place): _____
(mmol/L, 1 decimal place)

Test #4 - Ca+ (mmol/L, 2 decimal places): _____
(mmol/L, 2 decimal places)

Additional lab results available for the first 72 hours post-enrollment? Yes No

Test #5 - Date: _____

Test #5 - Time: _____

Test#5 - Results available for: WBC
 GLU
 Ca+

Test #5 - WBC (X 109/L, 1 decimal place): _____
(1 decimal place (X 109/L))

Test #5 - GLU (mmol/L, 1 decimal place): _____
(mmol/L, 1 decimal place)

Test #5 - Ca+ (mmol/L, 2 decimal places): _____
(mmol/L, 2 decimal places)

Additional lab results available for the first 72 hours post-enrollment? Yes No

Test #6 - Date : _____

Test #6 - Time: _____

Test#6 - Results available for: WBC
 GLU
 Ca+

Test #6 - WBC (X 109/L, 1 decimal place): _____
(1 decimal place (X 109/L))

Test #6 - GLU (mmol/L, 1 decimal place): _____
(mmol/L, 1 decimal place)

Test #6 - Ca+ (mmol/L, 2 decimal places):

_____ (mmol/L, 2 decimal places)

Additional lab results available for the first 72 hours post-enrollment?

Yes No

Test #7 - Date :

Test #7 - Time:

Test#7 - Results available for:

- WBC
- GLU
- Ca+

Test #7 - WBC (X 109/L, 1 decimal place):

_____ (1 decimal place (X 109/L))

Test #7 - GLU (mmol/L, 1 decimal place):

_____ (mmol/L, 1 decimal place)

Test #7 - Ca+ (mmol/L, 2 decimal places):

_____ (mmol/L, 2 decimal places)

Additional lab results available for the first 72 hours post-enrollment?

Yes No

Test #8 - Date:

Test #8 - Time:

Test#8 - Results available for:

- WBC
- GLU
- Ca+

Test #8 - WBC (X 109/L, 1 decimal place):

_____ (1 decimal place (X 109/L))

Test #8 - GLU (mmol/L, 1 decimal place):

_____ (mmol/L, 1 decimal place)

Test #8 - Ca+ (mmol/L, 2 decimal places):

_____ (mmol/L, 2 decimal places)

Additional lab results available for the first 72 hours post-enrollment?

Yes No

Test #9 - Date:

Test #9 - Time:

Test#9 - Results available for:

- WBC
- GLU
- Ca+

Test #9 - WBC (X 109/L, 1 decimal place):

(1 decimal place (X 109/L))

Test #9 - GLU (mmol/L, 1 decimal place):

(mmol/L, 1 decimal place)

Test #9 - Ca+ (mmol/L, 2 decimal places):

(mmol/L, 2 decimal places)

Additional lab results available for the first 72 hours post-enrollment?

Yes No

Test #10 - Date :

Test #10 - Time:

Test#10 - Results available for:

WBC
 GLU
 Ca+

Test #10 - WBC (X 109/L, 1 decimal place):

(1 decimal place (X 109/L))

Test #10 - GLU (mmol/L, 1 decimal place):

(mmol/L, 1 decimal place)

Test #10 - Ca+ (mmol/L, 2 decimal places):

(mmol/L, 2 decimal places)

Additional lab results available for the first 72 hours post-enrollment?

Yes No

Test #11 - Date:

Test #11 - Time:

Test#11 - Results available for:

WBC
 GLU
 Ca+

Test #11 - WBC (X 109/L, 1 decimal place):

(1 decimal place (X 109/L))

Test #11 - GLU (mmol/L, 1 decimal place):

(mmol/L, 1 decimal place)

Test #11 - Ca+ (mmol/L, 2 decimal places):

(mmol/L, 2 decimal places)

Additional lab results available for the first 72 hours post-enrollment?

Yes No

Test #12 - Date: _____

Test #12 - Time: _____

Test#12 - Results available for: WBC
 GLU
 Ca+

Test #12 - WBC (X 109/L, 1 decimal place): _____
(1 decimal place (X 109/L))

Test #12 - GLU (mmol/L, 1 decimal place): _____
(mmol/L, 1 decimal place)

Test #12 - Ca+ (mmol/L, 2 decimal places): _____
(mmol/L, 2 decimal places)

Additional lab results available for the first 72 hours post-enrollment? Yes No

Test #13 - Date: _____

Test #13 - Time: _____

Test#13 - Results available for: WBC
 GLU
 Ca+

Test #13 - WBC (X 109/L, 1 decimal place): _____
(1 decimal place (X 109/L))

Test #13 - GLU (mmol/L, 1 decimal place): _____
(mmol/L, 1 decimal place)

Test #13 - Ca+ (mmol/L, 2 decimal places): _____
(mmol/L, 2 decimal places)

Additional lab results available for the first 72 hours post-enrollment? Yes No

Test #14 - Date: _____

Test #14 - Time: _____

Test#14 - Results available for: WBC
 GLU
 Ca+

Test #14 - WBC (X 109/L, 1 decimal place): _____
(1 decimal place (X 109/L))

Test #14 - GLU (mmol/L, 1 decimal place): _____
(mmol/L, 1 decimal place)

Test #14 - Ca+ (mmol/L, 2 decimal places):

_____ (mmol/L, 2 decimal places)

Additional lab results available for the first 72 hours post-enrollment?

Yes No

Test #15 - Date:

Test #15 - Time:

Test#15 - Results available for:

- WBC
- GLU
- Ca+

Test #15 - WBC (X 109/L, 1 decimal place):

_____ (1 decimal place (X 109/L))

Test #15 - GLU (mmol/L, 1 decimal place):

_____ (mmol/L, 1 decimal place)

Test #15 - Ca+ (mmol/L, 2 decimal places):

_____ (mmol/L, 2 decimal places)

Additional lab results available for the first 72 hours post-enrollment?

Yes No

Test #16 - Date:

Test #16 - Time:

Test#16 - Results available for:

- WBC
- GLU
- Ca+

Test #16 - WBC (X 109/L, 1 decimal place):

_____ (1 decimal place (X 109/L))

Test #16 - GLU (mmol/L, 1 decimal place):

_____ (mmol/L, 1 decimal place)

Test #16 - Ca+ (mmol/L, 2 decimal places):

_____ (mmol/L, 2 decimal places)

Additional lab results available for the first 72 hours post-enrollment?

Yes No

Test #17 - Date :

Test #17 - Time:

Test#17 - Results available for:

- WBC
- GLU
- Ca+

Test #17 - WBC (X 109/L, 1 decimal place):

(1 decimal place (X 109/L))

Test #17 - GLU (mmol/L, 1 decimal place):

(mmol/L, 1 decimal place)

Test #17 - Ca+ (mmol/L, 2 decimal places):

(mmol/L, 2 decimal places)

Additional lab results available for the first 72 hours post-enrollment?

Yes No

Test #18 - Date :

Test #18 - Time:

Test#18 - Results available for:

WBC
 GLU
 Ca+

Test #18 - WBC (X 109/L, 1 decimal place):

(1 decimal place (X 109/L))

Test #18 - GLU (mmol/L, 1 decimal place):

(mmol/L, 1 decimal place)

Test #18 - Ca+ (mmol/L, 2 decimal places):

(mmol/L, 2 decimal places)

Additional lab results available for the first 72 hours post-enrollment?

Yes
 No

Test #19 - Date:

Test #19 - Time:

Test #19 - Results available for:

WBC
 GLU
 Ca+

Test #19 - WBC (X 109/L, 1 decimal place):

(1 decimal place, (X 109/L))

Test #19 - GLU (mmol/L, 1 decimal place):

(mmol/L, 1 decimal place)

Test #19 - Ca+ (mmol/L, 2 decimal places)

(mmol/L, 2 decimal places)

Additional lab results available for the first 72 hours post-enrolment?

Yes
 No

Test #20 - Date: _____

Test #20 - Time: _____

Test #20 - Results available for: WBC
 GLU
 Ca+

Test #20 - WBC (X 109/L, 1 decimal place): _____
(1 decimal place (X 109/L))

Test #20 - GLU (mmol/L, 1 decimal place) _____
(mmol/L, 1 decimal place)

Test #20 - Ca+ (mmol/L, 1 decimal place): _____
(mmol/L, 2 decimal place)

Additional lab results available for the first 72 hours post-enrolment? Yes
 No

Test #21 - Date: _____

Test #21 - Time: _____

Test #21 - Results available for: WBC
 GLU
 Ca+

Test #21 - WBC (X 109/L, 1 decimal place): _____
(1 decimal place (X 109/L))

Test #21 - GLU (mmol/L, 1 decimal place) _____
(mmol/L, 1 decimal place)

Test #21 - Ca+ (mmol/L, 2 decimal places) _____
(mmol/L, 2 decimal places)

Additional lab results available for the first 72 hours post-enrolment? Yes
 No

Test #22 - Date _____

Test #22 - Time: _____

Test #22 - Results available for: WBC
 GLU
 Ca+

Test #22 - WBC (X 109/L, 1 decimal place): _____
(1 decimal place (X 109/L))

Test #22 - GLU (mmol/L, 1 decimal place): _____
(mmol/L, 1 decimal place)

Test #22 - Ca+ (mmol/L, 2 decimal places): _____
(mmol/L, 2 decimal places)

Additional lab results available for the first 72 hours post-enrolment? Yes No

Test #23 - Date: _____

Test #23 - Time: _____

Test #23 - Results available for: WBC GLU Ca+

Test #23 - WBC (X 109/L, 1 decimal place): _____
(1 decimal place (X 109/L))

Test #23 - GLU (mmol/L, 1 decimal place): _____
(mmol/L, 1 decimal place)

Test #23 - Ca+ (mmol/L, 2 decimal places): _____
(mmol/L, 2 decimal places)

Additional lab results available for the first 72 hours post-enrolment? Yes No

Test #24 - Date: _____

Test #24 - Time: _____

Test #24 - Results available for: WBC GLU Ca+

Test #24 - WBC (X 109/L, 1 decimal place): _____
(1 decimal place (X 109/L))

Test #24 - GLU (1 mmol/L, 1 decimal place): _____
(mmol/L, 1 decimal place)

Test #24 - Ca+ (1 mmol/L, 2 decimal places): _____
(mmol/L, 2 decimal places)

Additional lab results available for the first 72 hours post-enrolment? Yes No

Test #25 - Date: _____

Test #25 - Time: _____

Test #25 - Results available for: WBC GLU Ca+

Test #25 - WBC (X 109/L, 1 decimal place)

(1 decimal place (X 109/L))

Test #25 - GLU (mmol/L, 1 decimal place)

(mmol/L, 1 decimal place)

Test #25 - Ca+ (mmol/L, 2 decimal places)

(mmol/L, 2 decimal places)

Additional lab results available for the first 72 hours post-enrolment?

- Yes
 No
-
-

Test #26 - Date:

Test #26 - Time:

Test #26 - Results available for:

- WBC
 GLU
 Ca+

Test #26 - WBC (X 109/L, 1 decimal place)

(1 decimal place (X 109/L))

Test #26 - GLU (mmol/L, 1 decimal place)

(mmol/L, 1 decimal place)

Test #26 - Ca+ (mmol/L, 2 decimal places)

(mmol/L, 2 decimal places)

Additional lab results available for the first 72 hours post-enrolment?

- Yes
 No
-
-

Test #27 - Date:

Test #27 - Time:

Test #27 - Results available for:

- WBC
 GLU
 Ca+

Test #27 - WBC (X 109/L, 1 decimal place):

(1 decimal place (X 109/L))

Test #27 - GLU (mmol/L, 1 decimal place):

(mmol/L, 1 decimal place)

Test #27 - Ca+ (mmol/L, 2 decimal places)

(mmol/L, 2 decimal places)

Additional lab results available for the first 72 hours post-enrolment?

- Yes
 No

Test #28 - Date: _____

Test #28 - Time: _____

Test #28 - Results available for: WBC
 GLU
 Ca+

Test #28 - WBC (X 109/L, 1 decimal place) _____
(1 decimal place (X 109/L))

Test #28 - GLU (mmol/L, 1 decimal place) _____
(mmol/L, 1 decimal place)

Test #28 - Ca+ (mmol/L, 2 decimal places) _____
(mmol/L, 2 decimal places)

Additional lab results available for the first 72 hours post-enrolment? Yes
 No

Test #29 - Date: _____

Test #29 - Time: _____

Test #29 - Results available for: WBC
 GLU
 Ca+

Test #29 - WBC (X 109/L, 1 decimal place) _____
(1 decimal place (X 109/L))

Test #29 - GLU (mmol/L, 1 decimal place) _____
(mmol/L, 1 decimal place)

Test #29 - Ca+ (mmol/L, 2 decimal places): _____
(mmol/L, 2 decimal places)

Additional lab results available for the first 72 hours post-enrolment? Yes
 No

Test #30 - Date: _____

Test #30 - Time: _____

Test #30 - Results available for: WBC
 GLU
 Ca+

Test #30 - WBC (X 109/L, 1 decimal place) _____
(1 decimal place (X 109/L))

Test #30 - GLU (mmol/L, 1 decimal place) _____
(mmol/L, 1 decimal place)

Test #30 - Ca+ (mmol/L, 2 decimal places)

(mmol/L, 2 decimal places)

Lab Results - Section 2

Record albumin, BUN, and creatinine results at baseline and for the first 7 days following enrolment (or until hospital discharge if discharged from hospital before Day 7). Day 1 is the day the patient was enrolled into the study (i.e. the day the patient first met the study eligibility criteria). Use midnight to midnight as the 24 hour schedule. If results are not available for a given day, please indicate "No".

If multiple albumin, BUN or creatinine results are available for a given day:

Record the lowest albumin value for that day

Record the highest BUN value for that day

Record the highest creatinine value for that day

Baseline - use the lab results closest to the time of patient enrolment (but PRIOR to patient enrolment). You may use lab results prior to PICU admission (i.e. Emergency or the ward) if the patient met the criteria either on admission, or just prior to admission to PICU. If no lab results were available for the time specified, please check "No".

Baseline Albumin?

 Yes No

Baseline - Albumin Date of Test:

Baseline - Albumin Time of Test:

Baseline - Albumin (g/L)

(g/L)

Baseline BUN?

 Yes No

Baseline - BUN Date of Test:

Baseline - BUN Time of Test:

Baseline - BUN (mmol/L)

(mmol/L, 1 decimal place)

Baseline Creatinine?

 Yes No

Baseline - Creatinine Date of Test:

Baseline - Creatinine Time of Test:

Baseline - Creatinine (umol/L)

(umol/L)

Day 1

Day 1 - Date of Lab Results

Day 1 Albumin?

 Yes No

Day 1 - Albumin Time of Test:

Day 1 - Albumin (g/L)

(g/L)

Day 1 BUN?

 Yes No

Day 1 - BUN Time of Test:

Day 1 - BUN (mmol/L)

(mmol/L, 1 decimal place)

Day 1 Creatinine?

 Yes No

Day 1 - Creatinine Time of Test:

Day 1 - Creatinine (umol/L)

(umol/L)

Day 2

Day 2 - Date of Lab Results

Day 2 Albumin?

 Yes No

Day 2 - Albumin Time of Test:

Day 2 - Albumin (g/L)

(g/L)

Day 2 BUN?

 Yes No

Day 2 - BUN Time of Test:

Day 2 - BUN (mmol/L)

(mmol/L, 1 decimal place)

Day 2 Creatinine?

 Yes No

Day 2 - Creatinine Time of Test:

Day 2 - Creatinine (umol/L)

(umol/L)

Day 3

Day 3 - Date of Lab Results

Day 3 Albumin?

 Yes No

Day 3 - Albumin Time of Test:

Day 3 - Albumin (g/L)

(g/L)

Day 3 BUN? Yes No

Day 3 - BUN Time of Test: _____

Day 3 - BUN (mmol/L) _____
(mmol/L, 1 decimal place)

Day 3 Creatinine? Yes No

Day 3 - Creatinine Time of Test: _____

Day 3 - Creatinine (umol/L) _____
(umol/L)

Day 4

Day 4 - Date of Lab Results _____

Day 4 Albumin? Yes No

Day 4 - Albumin Time of Test: _____

Day 4 - Albumin (g/L) _____
(g/L)

Day 4 BUN? Yes No

Day 4 - BUN Time of Test: _____

Day 4 - BUN (mmol/L) _____
(mmol/L, 1 decimal place)

Day 4 Creatinine? Yes No

Day 4 - Creatinine Time of Test: _____

Day 4 - Creatinine (umol/L) _____
(umol/L)

Day 5

Day 5 - Date of Lab Results _____

Day 5 Albumin? Yes No

Day 5 - Albumin Time of Test: _____

Day 5 - Albumin (g/L) _____
(g/L)

Day 5 BUN? Yes No

Day 5 - BUN Time of Test: _____

Day 5 - BUN (mmol/L) _____
(mmol/L, 1 decimal place)

Day 5 Creatinine? Yes No

Day 5 - Creatinine Time of Test: _____

Day 5 - Creatinine (umol/L) _____
(umol/L)

Day 6

Day 6 - Date of Lab Results

Day 6 Albumin?

 Yes No

Day 6 - Albumin Time of Test:

Day 6 - Albumin (g/L)

(g/L)

Day 6 BUN?

 Yes No

Day 6 - BUN Time of Test:

Day 6 - BUN (mmol/L)

(mmol/L, 1 decimal place)

Day 6 Creatinine?

 Yes No

Day 6 - Creatinine Time of Test:

Day 6 - Creatinine (umol/L)

(umol/L)

Day 7

Day 7 - Date of Lab Results

Day 7 Albumin?

 Yes No

Day 7 - Albumin Time of Test:

Day 7 - Albumin (g/L)

(g/L)

Day 7 BUN?

 Yes No

Day 7 - BUN Time of Test:

Day 7 - BUN (mmol/L)

(mmol/L, 1 decimal place)

Day 7 Creatinine?

 Yes No

Day 7 - Creatinine Time of Test:

Day 7 - Creatinine (umol/L)

(umol/L)

16. Cultures & Antibiotics

Cultures & Antibiotics

Record if cultures were sent and if the patient was on antibiotics for each day of PICU admission up to Day 28 or hospital discharge, whichever occurs first. Record the site where cultures were taken and the organism grown at each site. Please indicate for each day what antibiotics (if applicable) the patient was administered. If the patient was not on antibiotics, please check "No". Use midnight to midnight as the 24 hour schedule.

Day 1 is the day of patient enrolment (i.e. the day that the patient first met eligibility criteria for the study).

Please also indicate if antibiotics were administered in the ER, or in hospital prior to PICU admission, and list the type of antibiotics given.

Was the patient administered antibiotics in the ER OR in hospital prior to PICU admission?

Yes No

Number of different antibiotic types administered in ER or in hospital prior to PICU admission:

1
 2
 3
 4
 5
 6

Type of antibiotics given in ER/hospital prior to PICU admission (1):

Type of antibiotics given in ER/hospital prior to PICU admission (2):

Type of antibiotics given in ER/hospital prior to PICU admission (3):

Type of antibiotics given in ER/hospital prior to PICU admission (4):

Type of antibiotics given in ER/hospital prior to PICU admission (5):

Type of antibiotics given in ER/hospital prior to PICU admission (6):

Cultures and Antibiotics during PICU Admission

The patient had cultures done and/or received antibiotics during Day 1 to Day 28 of PICU admission

Yes
 Not applicable
 (If N/A, proceed to Section 17)

Day 1

Cultures sent on Day 1? Yes No

Day 1 Date: _____

Positive Culture on Day 1? Yes No

Total number of positive culture sites on Day 1:
 1
 2
 3

Day 1 - Site 1:
 Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 1 - Site 1 - Specify other: _____

Day 1 - Organism grown (Site 1): _____

Day 1 - Site 2:
 Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 1 - Site 2 - Specify other: _____

Day 1 - Organism grown (Site 2): _____

Day 1 - Site 3:
 Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 1 - Site 3 - Specify other: _____

Day 1 - Organism grown (Site 3): _____

Day 1 - Currently on antibiotics? Yes No

How many types of antibiotics is the patient on today (Day 1)?
 1
 2
 3
 4
 5
 6

Day 1 - Antibiotics currently on (1): _____

Day 1 - Antibiotics currently on (2): _____

Day 1 - Antibiotics currently on (3): _____

Day 1 - Antibiotics currently on (4): _____

Day 1 - Antibiotics currently on (5): _____

Day 1 - Antibiotics currently on (6): _____

Day 2

Cultures sent on Day 2?

- Yes No Discharged

Day 2 Date:

Positive Culture on Day 2?

- Yes No

Total number of positive culture sites on Day 2:

- 1
 2
 3

Day 2 - Site 1:

- Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 2 - Site 1 - Specify other:

Day 2 - Organism grown (Site 1):

Day 2 - Site 2:

- Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 2 - Site 2 - Specify other:

Day 2 - Organism grown (Site 2):

Day 2 - Site 3:

- Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 2 - Site 3 - Specify other:

Day 2 - Organism grown (Site 3):

Day 2 - Currently on antibiotics?

- Yes No

How many types of antibiotics is the patient on today (Day 2)?

- 1
 2
 3
 4
 5
 6

Day 2 - Antibiotics currently on (1):

Day 2 - Antibiotics currently on (2):

Day 2 - Antibiotics currently on (3):

Day 2 - Antibiotics currently on (4):

Day 2 - Antibiotics currently on (5):

Day 2 - Antibiotics currently on (6):

Day 3

Cultures sent on Day 3?

- Yes No Discharged

Day 3 Date:

Positive Culture on Day 3?

- Yes No

Total number of positive culture sites on Day 3:

- 1
 2
 3

Day 3 - Site 1:

- Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 3 - Site 1 - Specify other:

Day 3 - Organism grown (Site 1):

Day 3 - Site 2:

- Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 3 - Site 2 - Specify other:

Day 3 - Organism grown (Site 2):

Day 3 - Site 3:

- Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 3 - Site 3 - Specify other:

Day 3 - Organism grown (Site 3):

Day 3 - Currently on antibiotics?

- Yes No

How many types of antibiotics is the patient on today (Day 3)?

- 1
 2
 3
 4
 5
 6

Day 3 - Antibiotics currently on (1):

Day 3 - Antibiotics currently on (2):

Day 3 - Antibiotics currently on (3):

Day 3 - Antibiotics currently on (4):

Day 3 - Antibiotics currently on (5):

Day 3 - Antibiotics currently on (6):

Day 4

Cultures sent on Day 4?

- Yes No Discharged

Day 4 Date:

Positive Culture on Day 4?

- Yes No

Total number of positive culture sites on Day 4:

- 1
 2
 3

Day 4 - Site 1:

- Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 4 - Site 1 - Specify other:

Day 4 - Organism grown (Site 1):

Day 4 - Site 2:

- Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 4 - Site 2 - Specify other:

Day 4 - Organism grown (Site 2):

Day 4 - Site 3:

- Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 4 - Site 3 - Specify other:

Day 4 - Organism grown (Site 3):

Day 4 - Currently on antibiotics?

- Yes No

How many types of antibiotics is the patient on today (Day 4)?

- 1
 2
 3
 4
 5
 6

Day 4 - Antibiotics currently on (1):

Day 4 - Antibiotics currently on (2):

Day 4 - Antibiotics currently on (3):

Day 4 - Antibiotics currently on (4):

Day 4 - Antibiotics currently on (5):

Day 4 - Antibiotics currently on (6):

Day 5

Cultures sent on Day 5?

- Yes
- No
- Discharged

Day 5 Date:

Positive Culture on Day 5?

- Yes
- No

Total number of positive culture sites on Day 5:

- 1
- 2
- 3

Day 5 - Site 1:

- Skin
- Respiratory/ETT
- Blood
- Urine
- Other

Day 5 - Site 1 - Specify other:

Day 5 - Organism grown (Site 1):

Day 5 - Site 2:

- Skin
- Respiratory/ETT
- Blood
- Urine
- Other

Day 5 - Site 2 - Specify other:

Day 5 - Organism grown (Site 2):

Day 5 - Site 3:

- Skin
- Respiratory/ETT
- Blood
- Urine
- Other

Day 5 - Site 3 - Specify other:

Day 5 - Organism grown (Site 3):

Day 5 - Currently on antibiotics?

- Yes
- No

How many types of antibiotics is the patient on today (Day 5)?

- 1
- 2
- 3
- 4
- 5
- 6

Day 5 - Antibiotics currently on (1):

Day 5 - Antibiotics currently on (2):

Day 5 - Antibiotics currently on (3):

Day 5 - Antibiotics currently on (4):

Day 5 - Antibiotics currently on (5):

Day 5 - Antibiotics currently on (6):

Day 6

Cultures sent on Day 6

- Yes
- No
- Discharged

Day 6 Date:

Positive Culture on Day 6

- Yes
- No

Total number of positive culture sites on Day 6:

- 1
- 2
- 3

Day 6 - Site 1:

- Skin
- Respiratory/ETT
- Blood
- Urine
- Other

Day 6 - Site 1 - Specify other:

Day 6 - Organism grown (Site 1):

Day 6 - Site 2:

- Skin
- Respiratory/ETT
- Blood
- Urine
- Other

Day 6 - Site 2 - Specify other:

Day 6 - Organism grown (Site 2):

Day 6 - Site 3:

- Skin
- Respiratory/ETT
- Blood
- Urine
- Other

Day 6 - Site 3 - Specify other:

Day 6 - Organism grown (Site 3):

Day 6 - Currently on antibiotics?

- Yes
- No

How many types of antibiotics is the patient on today (Day 6)?

- 1
- 2
- 3
- 4
- 5
- 6

Day 6 - Antibiotics currently on (1):

Day 6 - Antibiotics currently on (2):

Day 6 - Antibiotics currently on (3):

Day 6 - Antibiotics currently on (4):

Day 6 - Antibiotics currently on (5):

Day 6 - Antibiotics currently on (6):

Day 7

Cultures sent on Day 7

- Yes
- No
- Discharged

Day 7 Date:

Positive Culture on Day 7

- Yes
- No

Total number of positive culture sites on Day 7:

- 1
- 2
- 3

Day 7 - Site 1:

- Skin
- Respiratory/ETT
- Blood
- Urine
- Other

Day 7 - Site 1 - Specify other:

Day 7 - Organism grown (Site 1):

Day 7 - Site 2:

- Skin
- Respiratory/ETT
- Blood
- Urine
- Other

Day 7 - Site 2 - Specify other:

Day 7 - Organism grown (Site 2):

Day 7 - Site 3:

- Skin
- Respiratory/ETT
- Blood
- Urine
- Other

Day 7 - Site 3 - Specify other:

Day 7 - Organism grown (Site 3):

Day 7 - Currently on antibiotics?

- Yes
- No

How many types of antibiotics is the patient on today (Day 7)?

- 1
- 2
- 3
- 4
- 5
- 6

Day 7 - Antibiotics currently on (1):

Day 7 - Antibiotics currently on (2):

Day 7 - Antibiotics currently on (3):

Day 7 - Antibiotics currently on (4):

Day 7 - Antibiotics currently on (5):

Day 7 - Antibiotics currently on (6):

Day 8

Cultures sent on Day 8

- Yes
- No
- Discharged

Day 8 Date:

Positive Culture on Day 8

- Yes
- No

Total number of positive culture sites on Day 8:

- 1
- 2
- 3

Day 8 - Site 1:

- Skin
- Respiratory/ETT
- Blood
- Urine
- Other

Day 8 - Site 1 - Specify other:

Day 8 - Organism grown (Site 1):

Day 8 - Site 2:

- Skin
- Respiratory/ETT
- Blood
- Urine
- Other

Day 8- Site 2 - Specify other:

Day 8 - Organism grown (Site 2):

Day 8 - Site 3:

- Skin
- Respiratory/ETT
- Blood
- Urine
- Other

Day 8 - Site 3 - Specify other:

Day 8 - Organism grown (Site 3):

Day 8 - Currently on antibiotics?

- Yes
- No

How many types of antibiotics is the patient on today (Day 8)?

- 1
- 2
- 3
- 4
- 5
- 6

Day 8 - Antibiotics currently on (1):

Day 8 - Antibiotics currently on (2):

Day 8 - Antibiotics currently on (3):

Day 8 - Antibiotics currently on (4):

Day 8 - Antibiotics currently on (5):

Day 8 - Antibiotics currently on (6):

Day 9

Cultures sent on Day 9

Yes No Discharged

Day 9 Date:

Positive Culture on Day 9

Yes No

Total number of positive culture sites on Day 9:

1
 2
 3

Day 9 - Site 1:

Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 9 - Site 1 - Specify other:

Day 9 - Organism grown (Site 1):

Day 9 - Site 2:

Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 9 - Site 2 - Specify other:

Day 9 - Organism grown (Site 2):

Day 9 - Site 3:

Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 9 - Site 3 - Specify other:

Day 9 - Organism grown (Site 3):

Day 9 - Currently on antibiotics?

Yes No

How many types of antibiotics is the patient on today (Day 9)?

1
 2
 3
 4
 5
 6

Day 9 - Antibiotics currently on (1):

Day 9 - Antibiotics currently on (2):

Day 9 - Antibiotics currently on (3):

Day 9 - Antibiotics currently on (4):

Day 9 - Antibiotics currently on (5):

Day 9 - Antibiotics currently on (6):

Day 10

Cultures sent on Day 10?

- Yes
- No
- Discharged

Day 10 Date:

Positive Culture on Day 10?

- Yes
- No

Total number of positive culture sites on Day 10:

- 1
- 2
- 3

Day 10 - Site 1:

- Skin
- Respiratory/ETT
- Blood
- Urine
- Other

Day 10 - Site 1 - Specify other:

Day 10 - Organism grown (Site 1):

Day 10 - Site 2:

- Skin
- Respiratory/ETT
- Blood
- Urine
- Other

Day 10- Site 2 - Specify other:

Day 10 - Organism grown (Site 2):

Day 10 - Site 3:

- Skin
- Respiratory/ETT
- Blood
- Urine
- Other

Day 10 - Site 3 - Specify other:

Day 10 - Organism grown (Site 3):

Day 10 - Currently on antibiotics?

- Yes
- No

How many types of antibiotics is the patient on today (Day 10)?

- 1
- 2
- 3
- 4
- 5
- 6

Day 10 - Antibiotics currently on (1):

Day 10 - Antibiotics currently on (2):

Day 10 - Antibiotics currently on (3):

Day 10 - Antibiotics currently on (4):

Day 10 - Antibiotics currently on (5):

Day 10 - Antibiotics currently on (6):

Day 11

Cultures sent on Day 11?

- Yes
- No
- Discharged

Day 11 Date:

Positive Culture on Day 11?

- Yes
- No

Total number of positive culture sites on Day 11:

- 1
- 2
- 3

Day 1 - Site 1:

- Skin
- Respiratory/ETT
- Blood
- Urine
- Other

Day 11 - Site 1 - Specify other:

Day 11 - Organism grown (Site 1):

Day 11 - Site 2:

- Skin
- Respiratory/ETT
- Blood
- Urine
- Other

Day 11 - Site 2 - Specify other:

Day 11 - Organism grown (Site 2):

Day 11 - Site 3:

- Skin
- Respiratory/ETT
- Blood
- Urine
- Other

Day 11 - Site 3 - Specify other:

Day 11 - Organism grown (Site 3):

Day 11 - Currently on antibiotics?

- Yes
- No

How many types of antibiotics is the patient on today (Day 11)?

- 1
- 2
- 3
- 4
- 5
- 6

Day 11 - Antibiotics currently on (1):

Day 11 - Antibiotics currently on (2):

Day 11 - Antibiotics currently on (3):

Day 11 - Antibiotics currently on (4):

Day 11 - Antibiotics currently on (5):

Day 11 - Antibiotics currently on (6):

Day 12

Cultures sent on Day 12?

- Yes
- No
- Discharged

Day 12 Date:

Positive Culture on Day 12?

- Yes
- No

Total number of positive culture sites on Day 12:

- 1
- 2
- 3

Day 2 - Site 1:

- Skin
- Respiratory/ETT
- Blood
- Urine
- Other

Day 12 - Site 1 - Specify other:

Day 12 - Organism grown (Site 1):

Day 12 - Site 2:

- Skin
- Respiratory/ETT
- Blood
- Urine
- Other

Day 12 - Site 2 - Specify other:

Day 12 - Organism grown (Site 2):

Day 12 - Site 3:

- Skin
- Respiratory/ETT
- Blood
- Urine
- Other

Day 12 - Site 3 - Specify other:

Day 12 - Organism grown (Site 3):

Day 12 - Currently on antibiotics?

- Yes
- No

How many types of antibiotics is the patient on today (Day 12)?

- 1
- 2
- 3
- 4
- 5
- 6

Day 12 - Antibiotics currently on (1):

Day 12 - Antibiotics currently on (2):

Day 12 - Antibiotics currently on (3):

Day 12 - Antibiotics currently on (4):

Day 12 - Antibiotics currently on (5):

Day 12 - Antibiotics currently on (6):

Day 13

Cultures sent on Day 13?

- Yes
- No
- Discharged

Day 13 Date:

Positive Culture on Day 13?

- Yes
- No

Total number of positive culture sites on Day 13:

- 1
- 2
- 3

Day 13 - Site 1:

- Skin
- Respiratory/ETT
- Blood
- Urine
- Other

Day 13 - Site 1 - Specify other:

Day 13 - Organism grown (Site 1):

Day 13 - Site 2:

- Skin
- Respiratory/ETT
- Blood
- Urine
- Other

Day 13 - Site 2 - Specify other:

Day 13 - Organism grown (Site 2):

Day 13 - Site 3:

- Skin
- Respiratory/ETT
- Blood
- Urine
- Other

Day 13 - Site 3 - Specify other:

Day 13 - Organism grown (Site 3):

Day 13 - Currently on antibiotics?

- Yes
- No

How many types of antibiotics is the patient on today (Day 13)?

- 1
- 2
- 3
- 4
- 5
- 6

Day 13 - Antibiotics currently on (1):

Day 13 - Antibiotics currently on (2):

Day 13 - Antibiotics currently on (3):

Day 13 - Antibiotics currently on (4):

Day 13 - Antibiotics currently on (5):

Day 13 - Antibiotics currently on (6):

Day 14

Cultures sent on Day 14? Yes No Discharged

Day 14 Date: _____

Positive Culture on Day 14? Yes No

Total number of positive culture sites on Day 14:
 1
 2
 3

Day 14 - Site 1:
 Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 14 - Site 1 - Specify other: _____

Day 14 - Organism grown (Site 1): _____

Day 14 - Site 2:
 Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 14 - Site 2 - Specify other: _____

Day 14 - Organism grown (Site 2): _____

Day 14 - Site 3:
 Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 14 - Site 3 - Specify other: _____

Day 14 - Organism grown (Site 3): _____

Day 14 - Currently on antibiotics? Yes No

How many types of antibiotics is the patient on today (Day 14)?
 1
 2
 3
 4
 5
 6

Day 14 - Antibiotics currently on (1): _____

Day 14 - Antibiotics currently on (2): _____

Day 14 - Antibiotics currently on (3): _____

Day 14 - Antibiotics currently on (4): _____

Day 14 - Antibiotics currently on (5): _____

Day 14 - Antibiotics currently on (6): _____

Day 15

Cultures sent on Day 15?

- Yes No Discharged

Day 15 Date:

Positive Culture on Day 15?

- Yes No

Total number of positive culture sites on Day 15:

- 1
 2
 3

Day 15 - Site 1:

- Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 15 - Site 1 - Specify other:

Day 15 - Organism grown (Site 1):

Day 15 - Site 2:

- Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 15 - Site 2 - Specify other:

Day 15 - Organism grown (Site 2):

Day 15 - Site 3:

- Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 15 - Site 3 - Specify other:

Day 15 - Organism grown (Site 3):

Day 15 - Currently on antibiotics?

- Yes No

How many types of antibiotics is the patient on today (Day 15)?

- 1
 2
 3
 4
 5
 6

Day 15 - Antibiotics currently on (1):

Day 15 - Antibiotics currently on (2):

Day 15 - Antibiotics currently on (3):

Day 15 - Antibiotics currently on (4):

Day 15 - Antibiotics currently on (5):

Day 15 - Antibiotics currently on (6):

Day 16

Cultures sent on Day 16

Yes No Discharged

Day 16 Date:

Positive Culture on Day 16

Yes No

Total number of positive culture sites on Day 16:

1
 2
 3

Day 16 - Site 1:

Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 16 - Site 1 - Specify other:

Day 16 - Organism grown (Site 1):

Day 16 - Site 2:

Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 16 - Site 2 - Specify other:

Day 16 - Organism grown (Site 2):

Day 16 - Site 3:

Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 16 - Site 3 - Specify other:

Day 16 - Organism grown (Site 3):

Day 16 - Currently on antibiotics?

Yes No

How many types of antibiotics is the patient on today (Day 16)?

1
 2
 3
 4
 5
 6

Day 16 - Antibiotics currently on (1):

Day 16 - Antibiotics currently on (2):

Day 16 - Antibiotics currently on (3):

Day 16 - Antibiotics currently on (4):

Day 16 - Antibiotics currently on (5):

Day 16 - Antibiotics currently on (6):

Day 17

Cultures sent on Day 17

Yes No Discharged

Day 17 Date:

Positive Culture on Day 17

Yes No

Total number of positive culture sites on Day 17:

1
 2
 3

Day 17 - Site 1:

Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 17 - Site 1 - Specify other:

Day 17 - Organism grown (Site 1):

Day 17 - Site 2:

Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 17- Site 2 - Specify other:

Day 17 - Organism grown (Site 2):

Day 17 - Site 3:

Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 17 - Site 3 - Specify other:

Day 17 - Organism grown (Site 3):

Day 17 - Currently on antibiotics?

Yes No

How many types of antibiotics is the patient on today (Day 17)?

1
 2
 3
 4
 5
 6

Day 17 - Antibiotics currently on (1):

Day 17 - Antibiotics currently on (2):

Day 17 - Antibiotics currently on (3):

Day 17 - Antibiotics currently on (4):

Day 17 - Antibiotics currently on (5):

Day 17 - Antibiotics currently on (6):

Day 18

Cultures sent on Day 18

Yes No Discharged

Day 18 Date:

Positive Culture on Day 18

Yes No

Total number of positive culture sites on Day 18:

1
 2
 3

Day 18 - Site 1:

Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 18 - Site 1 - Specify other:

Day 18 - Organism grown (Site 1):

Day 18 - Site 2:

Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 18- Site 2 - Specify other:

Day 18 - Organism grown (Site 2):

Day 18 - Site 3:

Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 18 - Site 3 - Specify other:

Day 18 - Organism grown (Site 3):

Day 18 - Currently on antibiotics?

Yes No

How many types of antibiotics is the patient on today (Day 18)?

1
 2
 3
 4
 5
 6

Day 18 - Antibiotics currently on (1):

Day 18 - Antibiotics currently on (2):

Day 18 - Antibiotics currently on (3):

Day 18 - Antibiotics currently on (4):

Day 18 - Antibiotics currently on (5):

Day 18 - Antibiotics currently on (6):

Day 19

Cultures sent on Day 19

Yes No Discharged

Day 19 Date:

Positive Culture on Day 19

Yes No

Total number of positive culture sites on Day 19:

1
 2
 3

Day 19 - Site 1:

Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 19 - Site 1 - Specify other:

Day 19 - Organism grown (Site 1):

Day 19 - Site 2:

Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 19- Site 2 - Specify other:

Day 19 - Organism grown (Site 2):

Day 19 - Site 3:

Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 19 - Site 3 - Specify other:

Day 19 - Organism grown (Site 3):

Day 19 - Currently on antibiotics?

Yes No

How many types of antibiotics is the patient on today (Day 19)?

1
 2
 3
 4
 5
 6

Day 19 - Antibiotics currently on (1):

Day 19 - Antibiotics currently on (2):

Day 19 - Antibiotics currently on (3):

Day 19 - Antibiotics currently on (4):

Day 19 - Antibiotics currently on (5):

Day 19 - Antibiotics currently on (6):

Day 20

Cultures sent on Day 20? Yes No Discharged

Day 20 Date: _____

Positive Culture on Day 20? Yes No

Total number of positive culture sites on Day 20:
 1
 2
 3

Day 20 - Site 1:
 Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 20 - Site 1 - Specify other: _____

Day 20 - Organism grown (Site 1): _____

Day 20 - Site 2:
 Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 20- Site 2 - Specify other: _____

Day 20 - Organism grown (Site 2): _____

Day 20 - Site 3:
 Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 20 - Site 3 - Specify other: _____

Day 20 - Organism grown (Site 3): _____

Day 20 - Currently on antibiotics? Yes No

How many types of antibiotics is the patient on today (Day 20)?
 1
 2
 3
 4
 5
 6

Day 20 - Antibiotics currently on (1): _____

Day 20 - Antibiotics currently on (2): _____

Day 20 - Antibiotics currently on (3): _____

Day 20 - Antibiotics currently on (4): _____

Day 20 - Antibiotics currently on (5): _____

Day 20 - Antibiotics currently on (6): _____

Day 21

Cultures sent on Day 21?

- Yes
- No
- Discharged

Day 21 Date:

Positive Culture on Day 21?

- Yes
- No

Total number of positive culture sites on Day 21:

- 1
- 2
- 3

Day 21 - Site 1:

- Skin
- Respiratory/ETT
- Blood
- Urine
- Other

Day 21 - Site 1 - Specify other:

Day 21 - Organism grown (Site 1):

Day 21 - Site 2:

- Skin
- Respiratory/ETT
- Blood
- Urine
- Other

Day 21 - Site 2 - Specify other:

Day 21 - Organism grown (Site 2):

Day 21 - Site 3:

- Skin
- Respiratory/ETT
- Blood
- Urine
- Other

Day 21 - Site 3 - Specify other:

Day 21 - Organism grown (Site 3):

Day 21 - Currently on antibiotics?

- Yes
- No

How many types of antibiotics is the patient on today (Day 21)?

- 1
- 2
- 3
- 4
- 5
- 6

Day 21 - Antibiotics currently on (1):

Day 21 - Antibiotics currently on (2):

Day 21 - Antibiotics currently on (3):

Day 21 - Antibiotics currently on (4):

Day 21 - Antibiotics currently on (5):

Day 21 - Antibiotics currently on (6):

Day 22

Cultures sent on Day 22? Yes No Discharged

Day 22 Date: _____

Positive Culture on Day 22? Yes No

Total number of positive culture sites on Day 22:
 1
 2
 3

Day 22 - Site 1:
 Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 22 - Site 1 - Specify other: _____

Day 22 - Organism grown (Site 1): _____

Day 22 - Site 2:
 Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 22 - Site 2 - Specify other: _____

Day 22 - Organism grown (Site 2): _____

Day 22 - Site 3:
 Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 22 - Site 3 - Specify other: _____

Day 22 - Organism grown (Site 3): _____

Day 22 - Currently on antibiotics? Yes No

How many types of antibiotics is the patient on today (Day 22)?
 1
 2
 3
 4
 5
 6

Day 22 - Antibiotics currently on (1): _____

Day 22 - Antibiotics currently on (2): _____

Day 22 - Antibiotics currently on (3): _____

Day 22 - Antibiotics currently on (4): _____

Day 22 - Antibiotics currently on (5): _____

Day 22 - Antibiotics currently on (6): _____

Day 23

Cultures sent on Day 23?

- Yes
- No
- Discharged

Day 23 Date:

Positive Culture on Day 23?

- Yes
- No

Total number of positive culture sites on Day 23:

- 1
- 2
- 3

Day 23 - Site 1:

- Skin
- Respiratory/ETT
- Blood
- Urine
- Other

Day 23 - Site 1 - Specify other:

Day 23 - Organism grown (Site 1):

Day 23 - Site 2:

- Skin
- Respiratory/ETT
- Blood
- Urine
- Other

Day 23 - Site 2 - Specify other:

Day 23 - Organism grown (Site 2):

Day 23 - Site 3:

- Skin
- Respiratory/ETT
- Blood
- Urine
- Other

Day 23 - Site 3 - Specify other:

Day 23 - Organism grown (Site 3):

Day 23 - Currently on antibiotics?

- Yes
- No

How many types of antibiotics is the patient on today (Day 23)?

- 1
- 2
- 3
- 4
- 5
- 6

Day 23 - Antibiotics currently on (1):

Day 23 - Antibiotics currently on (2):

Day 23 - Antibiotics currently on (3):

Day 23 - Antibiotics currently on (4):

Day 23 - Antibiotics currently on (5):

Day 23 - Antibiotics currently on (6):

Day 24

Cultures sent on Day 24?

- Yes
- No
- Discharged

Day 24 Date:

Positive Culture on Day 24?

- Yes
- No

Total number of positive culture sites on Day 24:

- 1
- 2
- 3

Day 24 - Site 1:

- Skin
- Respiratory/ETT
- Blood
- Urine
- Other

Day 24 - Site 1 - Specify other:

Day 24 - Organism grown (Site 1):

Day 24 - Site 2:

- Skin
- Respiratory/ETT
- Blood
- Urine
- Other

Day 24 - Site 2 - Specify other:

Day 24 - Organism grown (Site 2):

Day 24 - Site 3:

- Skin
- Respiratory/ETT
- Blood
- Urine
- Other

Day 24 - Site 3 - Specify other:

Day 24 - Organism grown (Site 3):

Day 24 - Currently on antibiotics?

- Yes
- No

How many types of antibiotics is the patient on today (Day 24)?

- 1
- 2
- 3
- 4
- 5
- 6

Day 24 - Antibiotics currently on (1):

Day 24 - Antibiotics currently on (2):

Day 24 - Antibiotics currently on (3):

Day 24 - Antibiotics currently on (4):

Day 24 - Antibiotics currently on (5):

Day 24 - Antibiotics currently on (6):

Day 25

Cultures sent on Day 25? Yes No Discharged

Day 25 Date: _____

Positive Culture on Day 25? Yes No

Total number of positive culture sites on Day 25:
 1
 2
 3

Day 25 - Site 1:
 Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 25 - Site 1 - Specify other: _____

Day 25 - Organism grown (Site 1): _____

Day 25 - Site 2:
 Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 25 - Site 2 - Specify other: _____

Day 25 - Organism grown (Site 2): _____

Day 25 - Site 3:
 Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 25 - Site 3 - Specify other: _____

Day 25 - Organism grown (Site 3): _____

Day 25 - Currently on antibiotics? Yes No

How many types of antibiotics is the patient on today (Day 25)?
 1
 2
 3
 4
 5
 6

Day 25 - Antibiotics currently on (1): _____

Day 25 - Antibiotics currently on (2): _____

Day 25 - Antibiotics currently on (3): _____

Day 25 - Antibiotics currently on (4): _____

Day 25 - Antibiotics currently on (5): _____

Day 25 - Antibiotics currently on (6): _____

Day 26

Cultures sent on Day 26

Yes No Discharged

Day 26 Date:

Positive Culture on Day 26

Yes No

Total number of positive culture sites on Day 26:

1
 2
 3

Day 26 - Site 1:

Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 26 - Site 1 - Specify other:

Day 26 - Organism grown (Site 1):

Day 26 - Site 2:

Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 26 - Site 2 - Specify other:

Day 26 - Organism grown (Site 2):

Day 26 - Site 3:

Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 26 - Site 3 - Specify other:

Day 26 - Organism grown (Site 3):

Day 26 - Currently on antibiotics?

Yes No

How many types of antibiotics is the patient on today (Day 26)?

1
 2
 3
 4
 5
 6

Day 26 - Antibiotics currently on (1):

Day 26 - Antibiotics currently on (2):

Day 26 - Antibiotics currently on (3):

Day 26 - Antibiotics currently on (4):

Day 26 - Antibiotics currently on (5):

Day 26 - Antibiotics currently on (6):

Day 27

Cultures sent on Day 27

Yes No Discharged

Day 27 Date:

Positive Culture on Day 27

Yes No

Total number of positive culture sites on Day 27:

1
 2
 3

Day 27 - Site 1:

Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 27 - Site 1 - Specify other:

Day 27 - Organism grown (Site 1):

Day 27 - Site 2:

Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 27 - Site 2 - Specify other:

Day 27 - Organism grown (Site 2):

Day 27 - Site 3:

Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 27 - Site 3 - Specify other:

Day 27 - Organism grown (Site 3):

Day 27 - Currently on antibiotics?

Yes No

How many types of antibiotics is the patient on today (Day 27)?

1
 2
 3
 4
 5
 6

Day 27 - Antibiotics currently on (1):

Day 27 - Antibiotics currently on (2):

Day 27 - Antibiotics currently on (3):

Day 27 - Antibiotics currently on (4):

Day 27 - Antibiotics currently on (5):

Day 27 - Antibiotics currently on (6):

Day 28

Cultures sent on Day 28

Yes No Discharged

Day 28 Date:

Positive Culture on Day 28

Yes No

Total number of positive culture sites on Day 28:

1
 2
 3

Day 28 - Site 1:

Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 28 - Site 1 - Specify other:

Day 28 - Organism grown (Site 1):

Day 28 - Site 2:

Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 28- Site 2 - Specify other:

Day 28 - Organism grown (Site 2):

Day 28 - Site 3:

Skin
 Respiratory/ETT
 Blood
 Urine
 Other

Day 28 - Site 3 - Specify other:

Day 28 - Organism grown (Site 3):

Day 28 - Currently on antibiotics?

Yes No

How many types of antibiotics is the patient on today (Day 28)?

1
 2
 3
 4
 5
 6

Day 28 - Antibiotics currently on (1):

Day 28 - Antibiotics currently on (2):

Day 28 - Antibiotics currently on (3):

Day 28 - Antibiotics currently on (4):

Day 28 - Antibiotics currently on (5):

Day 28 - Antibiotics currently on (6):

17. Outcome Information

PICU Length of Stay

Date of discharge from PICU:

Time of discharge from PICU:

Survival Status at PICU Discharge:

Alive Dead

Hospital Length of Stay

Date of discharge from hospital:

Time of discharge from hospital:

Survival Status at hospital discharge

Alive Dead

18. Study Drug

Study Drug

Record the date, dosing frequency, and number of doses for each day of study drug administration. Use midnight to midnight as the 24 hour schedule. If the patient is no longer on study drug, indicate No for the remaining days.

Day 1 is the day of patient enrolment (i.e. the day that the patient first met eligibility criteria for the study).

If the patient did not receive study drug, please indicate "No" and the reason study drug was not received, then proceed to Section 19.

The patient was administered the study drug: Yes No

Start date of study drug administration: _____

Start time of study drug administration: _____

FINAL stop date of study drug administration: _____
(If study drug was stopped and restarted, indicate the final stop date)

FINAL stop time of study drug administration: _____
(If study drug was stopped and restarted, indicate the final stop time)

Was study drug stopped and restarted within the above 7 days (i.e. were intoropes restarted) Yes No

Date study drug was initially stopped (prior to being restarted): _____

Time study drug was initially stopped (prior to being restarted): _____

Date study drug was restarted: _____

Time study drug was restarted: _____

Reason study drug was not administered: _____
(Indicate reason, then proceed to Section 19)

Did the patient receive all doses of study drug that they should have received according to the study protocol? Yes No

If no, please explain why study drug was stopped early/doses were missed:

(If applicable, document as a protocol deviation/violation. Consult with the Study Coordinating Centre if you are unsure.)

Day 1

Date - Day 1 of study drug _____

Type of dose given on Day 1:

-
- Bolus (2mg/kg)
-
-
- q6h (1mg/kg)
-
-
- q8h (1mg/kg)

Number of doses given at q6h on Day 1:

(Number of doses on Day 1 at q6h)

Number of doses given at q8h on Day 1:

(Number of doses on Day 1 at q8h)

Day 2

Day 2 on study drug applicable?

 Yes No

Date - Day 2 of study drug _____

Type of dose given on Day 2:

-
- q6h (1mg/kg)
-
-
- q8h (1mg/kg)

Number of doses given at q6h on Day 2:

(Number of doses on Day 2 at q6h)

Number of doses given at q8h on Day 2:

(Number of doses on Day 2 at q8h)

Day 3

Day 3 on study drug applicable?

 Yes No

Date - Day 3 of study drug _____

Type of dose given on Day 3:

-
- q6h (1mg/kg)
-
-
- q8h (1mg/kg)

Number of doses given at q6h on Day 3:

(Number of doses on Day 3 at q6h)

Number of doses given at q8h on Day 3:

(Number of doses on Day 3 at q8h)

Day 4

Day 4 on study drug applicable?

 Yes No

Date - Day 4 of study drug _____

Type of dose given on Day 4:

-
- q6h (1mg/kg)
-
-
- q8h (1mg/kg)

Number of doses given at q6h on Day 4:

(Number of doses on Day 4 at q6h)

Number of doses given at q8h on Day 4:

(Number of doses on Day 4 at q8h)

Day 5Day 5 on study drug applicable? Yes No

Date - Day 5 of study drug _____

Type of dose given on Day 5:
 q6h (1mg/kg)
 q8h (1mg/kg)Number of doses given at q6h on Day 5: _____
(Number of doses on Day 5 at q6h)Number of doses given at q8h on Day 5: _____
(Number of doses on Day 5 at q8h)

Day 6Day 6 on study drug applicable? Yes No

Date - Day 6 of study drug _____

Type of dose given on Day 6:
 q6h (1mg/kg)
 q8h (1mg/kg)Number of doses given at q6h on Day 6: _____
(Number of doses on Day 6 at q6h)Number of doses given at q8h on Day 6: _____
(Number of doses on Day 6 at q8h)

Day 7Day 7 on study drug applicable? Yes No

Date - Day 7 of study drug _____

Type of dose given on Day 7:
 q6h (1mg/kg)
 q8h (1mg/kg)Number of doses given at q6h on Day 7: _____
(Number of doses on Day 7 at q6h)Number of doses given at q8h on Day 7: _____
(Number of doses on Day 7 at q8h)

Day 8Day 8 on study drug applicable? Yes No

Date - Day 8 of study drug _____

Type of dose given on Day 8:
 q6h (1mg/kg)
 q8h (1mg/kg)Number of doses given at q6h on Day 8: _____
(Number of doses on Day 8 at q6h)Number of doses given at q8h on Day 8: _____
(Number of doses on Day 8 at q8h)

19. Unblinding and Open-Label Steroid Use

Open Label Steroid Use During PICU Admission

Record if the patient received open-label hydrocortisone at any time during PICU admission. For each open-label dose given, please record the specified clinical information as close to, but prior to, administration of the dose.

Did the treating physician choose to administer open label hydrocortisone during PICU admission? Yes No

Hydrocortisone (open label) - Total number of doses received: _____
(Total number of doses)

Open-Label Hydrocortisone - Dose 1

Record date & time of dose, and the following information about the patient's status at the time of open label hydrocortisone use

Hydrocortisone (open label) - Date of dose 1: _____

Hydrocortisone (open label) - Time of dose 1: _____

Blood pressure information available at time of open label hydrocortisone use (Dose #1)? Yes No

Systolic blood pressure at time of open label hydrocortisone use (Dose #1): _____
(Systolic)

Diastolic blood pressure at time of open label hydrocortisone use (Dose #1): _____
(Diastolic)

Heart rate information available at time of open label hydrocortisone use (Dose #1)? Yes No

Heart rate at time of open label hydrocortisone use (Dose #1): _____
(beats per minute)

Capillary refill information available at time of open label hydrocortisone use (Dose #1)? Yes No

Capillary refill time (in seconds) at time of open label hydrocortisone use (Dose #1): _____
(seconds)

Mental status (GCS) information available at time of open label hydrocortisone use (Dose #1)? Yes No

Mental status at time of open label hydrocortisone use (Dose #1):

Not applicable

3

4

5

6

7

8

9

10

11

12

13

14

15

(Glasgow Coma Scale)

Oxygen saturation information available at time of open label hydrocortisone use (Dose #1)?

Yes No

Oxygen saturation (%) at time of open label hydrocortisone use (Dose #1):

_____ (percent (%) oxygen saturation)

Additional open-label hydrocortisone dose given?

Yes No

Open-Label Hydrocortisone - Dose 2

Record date & time of dose, and the following information about the patient's status at the time of open label hydrocortisone use

Hydrocortisone (open label) - Date of dose 2:

Hydrocortisone (open label) - Time of dose 2:

Blood pressure information available at time of open label hydrocortisone use (Dose #2)?

Yes No

Systolic blood pressure at time of open label hydrocortisone use (Dose #2):

_____ (Systolic)

Diastolic blood pressure at time of open label hydrocortisone use (Dose #2):

_____ (Diastolic)

Heart rate information available at time of open label hydrocortisone use (Dose #2)?

Yes No

Heart rate at time of open label hydrocortisone use (Dose #2):

_____ (beats per minute)

Capillary refill information available at time of open label hydrocortisone use (Dose #2)?

Yes No

Capillary refill time (in seconds) at time of open label hydrocortisone use (Dose #2):

_____ (seconds)

Oxygen saturation information available at time of open label hydrocortisone use (Dose #2)?

Yes No

Mental status (GCS) information available at time of open label hydrocortisone use (Dose #2)?

Yes No

Mental status at time of open label hydrocortisone use (Dose #2):

- Not applicable
 - 3
 - 4
 - 5
 - 6
 - 7
 - 8
 - 9
 - 10
 - 11
 - 12
 - 13
 - 14
 - 15
- (Glasgow Coma Scale)

Oxygen saturation (%) at time of open label hydrocortisone use (Dose #2):

_____ (percent (%) oxygen saturation)

Additional open-label hydrocortisone dose given?

- Yes No

Open-Label Hydrocortisone - Dose 3

Record date & time of dose, and the following information about the patient's status at the time of open label hydrocortisone use

Hydrocortisone (open label) - Date of dose 3:

Hydrocortisone (open label) - Time of dose 3:

Blood pressure information available at time of open label hydrocortisone use (Dose #3)?

- Yes No

Systolic blood pressure at time of open label hydrocortisone use (Dose #3):

_____ (Systolic)

Diastolic blood pressure at time of open label hydrocortisone use (Dose #3):

_____ (Diastolic)

Heart rate information available at time of open label hydrocortisone use (Dose #3)?

- Yes No

Heart rate at time of open label hydrocortisone use (Dose #3):

_____ (beats per minute)

Capillary refill information available at time of open label hydrocortisone use (Dose #3)?

- Yes No

Capillary refill time (in seconds) at time of open label hydrocortisone use (Dose #3):

_____ (seconds)

Oxygen saturation information available at time of open label hydrocortisone use (Dose #3)?

- Yes No

Mental status (GCS) information available at time of open label hydrocortisone use (Dose #3)?

- Yes No

Mental status at time of open label hydrocortisone use (Dose #3):

- Not applicable
 - 3
 - 4
 - 5
 - 6
 - 7
 - 8
 - 9
 - 10
 - 11
 - 12
 - 13
 - 14
 - 15
- (Glasgow Coma Scale)

Oxygen saturation (%) at time of open label hydrocortisone use (Dose #3):

_____ (percent (%) oxygen saturation)

Additional open-label hydrocortisone dose given?

- Yes No

Open-Label Hydrocortisone - Dose 4

Record date & time of dose, and the following information about the patient's status at the time of open label hydrocortisone use

Hydrocortisone (open label) - Date of dose 4:

Hydrocortisone (open label) - Time of dose 4:

Blood pressure information available at time of open label hydrocortisone use (Dose #4)?

- Yes No

Systolic blood pressure at time of open label hydrocortisone use (Dose #4):

_____ (Systolic)

Diastolic blood pressure at time of open label hydrocortisone use (Dose #4):

_____ (Diastolic)

Heart rate information available at time of open label hydrocortisone use (Dose #4)?

- Yes No

Heart rate at time of open label hydrocortisone use (Dose #4):

_____ (beats per minute)

Capillary refill information available at time of open label hydrocortisone use (Dose #4)?

- Yes No

Capillary refill time (in seconds) at time of open label hydrocortisone use (Dose #4):

_____ (seconds)

Mental status (GCS) information available at time of open label hydrocortisone use (Dose #4)?

- Yes No

Mental status at time of open label hydrocortisone use (Dose #4):

- Not applicable
 - 3
 - 4
 - 5
 - 6
 - 7
 - 8
 - 9
 - 10
 - 11
 - 12
 - 13
 - 14
 - 15
- (Glasgow Coma Scale)

Oxygen saturation information available at time of open label hydrocortisone use (Dose #4)?

- Yes
- No

Oxygen saturation (%) at time of open label hydrocortisone use (Dose #4):

_____ (percent (%) oxygen saturation)

Additional open-label hydrocortisone dose given?

- Yes
- No

Open-Label Hydrocortisone - Dose 5

Record date & time of dose, and the following information about the patient's status at the time of open label hydrocortisone use

Hydrocortisone (open label) - Date of dose 5:

Hydrocortisone (open label) - Time of dose 5:

Blood pressure information available at time of open label hydrocortisone use (Dose #5)?

- Yes
- No

Systolic blood pressure at time of open label hydrocortisone use (Dose #5):

_____ (Systolic)

Diastolic blood pressure at time of open label hydrocortisone use (Dose #5):

_____ (Diastolic)

Heart rate information available at time of open label hydrocortisone use (Dose #5)?

- Yes
- No

Heart rate at time of open label hydrocortisone use (Dose #5):

_____ (beats per minute)

Capillary refill information available at time of open label hydrocortisone use (Dose #5)?

- Yes
- No

Capillary refill time (in seconds) at time of open label hydrocortisone use (Dose #5):

_____ (seconds)

Mental status (GCS) information available at time of open label hydrocortisone use (Dose #5)?

- Yes
- No

Mental status at time of open label hydrocortisone use (Dose #5):

- Not applicable
 3
 4
 5
 6
 7
 8
 9
 10
 11
 12
 13
 14
 15
 (Glasgow Coma Scale)

Oxygen saturation information available at time of open label hydrocortisone use (Dose #5)?

- Yes No

Oxygen saturation (%) at time of open label hydrocortisone use (Dose #5):

_____ (percent (%) oxygen saturation)

Additional open-label hydrocortisone dose given?

- Yes No

Open-Label Hydrocortisone - Dose 6

Record date & time of dose, and the following information about the patient's status at the time of open label hydrocortisone use

Hydrocortisone (open label) - Date of dose 6:

Hydrocortisone (open label) - Time of dose 6:

Blood pressure information available at time of open label hydrocortisone use (Dose #6)?

- Yes No

Systolic blood pressure at time of open label hydrocortisone use (Dose #6):

_____ (Systolic)

Diastolic blood pressure at time of open label hydrocortisone use (Dose #6):

_____ (Diastolic)

Heart rate information available at time of open label hydrocortisone use (Dose #6)?

- Yes No

Heart rate at time of open label hydrocortisone use (Dose #6):

_____ (beats per minute)

Capillary refill information available at time of open label hydrocortisone use (Dose #6)?

- Yes No

Capillary refill time (in seconds) at time of open label hydrocortisone use (Dose #6):

_____ (seconds)

Mental status (GCS) information available at time of open label hydrocortisone use (Dose #6)?

- Yes No

Mental status at time of open label hydrocortisone use (Dose #6):

- Not applicable
 3
 4
 5
 6
 7
 8
 9
 10
 11
 12
 13
 14
 15
 (Glasgow Coma Scale)

Oxygen saturation information available at time of open label hydrocortisone use (Dose #6)?

- Yes No

Oxygen saturation (%) at time of open label hydrocortisone use (Dose #6):

_____ (percent (%) oxygen saturation)

Additional open-label hydrocortisone dose given?

- Yes No

Open-Label Hydrocortisone - Dose 7

Record date & time of dose, and the following information about the patient's status at the time of open label hydrocortisone use

Hydrocortisone (open label) - Date of dose 7:

Hydrocortisone (open label) - Time of dose 7:

Blood pressure information available at time of open label hydrocortisone use (Dose #7)?

- Yes No

Systolic blood pressure at time of open label hydrocortisone use (Dose #7):

_____ (Systolic)

Diastolic blood pressure at time of open label hydrocortisone use (Dose #7):

_____ (Diastolic)

Heart rate information available at time of open label hydrocortisone use (Dose #7)?

- Yes No

Heart rate at time of open label hydrocortisone use (Dose #7):

_____ (beats per minute)

Capillary refill information available at time of open label hydrocortisone use (Dose #7)?

- Yes No

Capillary refill time (in seconds) at time of open label hydrocortisone use (Dose #7):

_____ (seconds)

Mental status (GCS) information available at time of open label hydrocortisone use (Dose #7)?

- Yes No

Mental status at time of open label hydrocortisone use (Dose #7):

- Not applicable
 3
 4
 5
 6
 7
 8
 9
 10
 11
 12
 13
 14
 15
 (Glasgow Coma Scale)

Oxygen saturation information available at time of open label hydrocortisone use (Dose #7)?

- Yes No

Oxygen saturation (%) at time of open label hydrocortisone use (Dose #7):

_____ (percent (%) oxygen saturation)

Additional open-label hydrocortisone dose given?

- Yes No

Open-Label Hydrocortisone - Dose 8

Record date & time of dose, and the following information about the patient's status at the time of open label hydrocortisone use

Hydrocortisone (open label) - Date of dose 8:

Hydrocortisone (open label) - Time of dose 8:

Blood pressure information available at time of open label hydrocortisone use (Dose #8)?

- Yes No

Systolic blood pressure at time of open label hydrocortisone use (Dose #8):

_____ (Systolic)

Diastolic blood pressure at time of open label hydrocortisone use (Dose #8):

_____ (Diastolic)

Heart rate information available at time of open label hydrocortisone use (Dose #8)?

- Yes No

Heart rate at time of open label hydrocortisone use (Dose #8):

_____ (beats per minute)

Capillary refill information available at time of open label hydrocortisone use (Dose #8)?

- Yes No

Capillary refill time (in seconds) at time of open label hydrocortisone use (Dose #8):

_____ (seconds)

Mental status (GCS) information available at time of open label hydrocortisone use (Dose #8)?

- Yes No

Mental status at time of open label hydrocortisone use (Dose #8):

- Not applicable
 3
 4
 5
 6
 7
 8
 9
 10
 11
 12
 13
 14
 15
 (Glasgow Coma Scale)

Oxygen saturation information available at time of open label hydrocortisone use (Dose #8)?

- Yes No

Oxygen saturation (%) at time of open label hydrocortisone use (Dose #8):

_____ (percent (%) oxygen saturation)

Additional open-label hydrocortisone dose given?

- Yes No

Open-Label Hydrocortisone - Dose 9

Record date & time of dose, and the following information about the patient's status at the time of open label hydrocortisone use

Hydrocortisone (open label) - Date of dose 9:

Hydrocortisone (open label) - Time of dose 9:

Blood pressure information available at time of open label hydrocortisone use (Dose #9)?

- Yes No

Systolic blood pressure at time of open label hydrocortisone use (Dose #9):

_____ (Systolic)

Diastolic blood pressure at time of open label hydrocortisone use (Dose #9):

_____ (Diastolic)

Heart rate information available at time of open label hydrocortisone use (Dose #9)?

- Yes No

Heart rate at time of open label hydrocortisone use (Dose #9):

_____ (beats per minute)

Capillary refill information available at time of open label hydrocortisone use (Dose #9)?

- Yes No

Capillary refill time (in seconds) at time of open label hydrocortisone use (Dose #9):

_____ (seconds)

Mental status (GCS) information available at time of open label hydrocortisone use (Dose #9)?

- Yes No

Mental status at time of open label hydrocortisone use (Dose #9):

- Not applicable
 3
 4
 5
 6
 7
 8
 9
 10
 11
 12
 13
 14
 15
 (Glasgow Coma Scale)

Oxygen saturation information available at time of open label hydrocortisone use (Dose #9)?

- Yes No

Oxygen saturation (%) at time of open label hydrocortisone use (Dose #9):

_____ (percent (%) oxygen saturation)

Additional open-label hydrocortisone dose given?

- Yes No

Open-Label Hydrocortisone - Dose 10

Record date & time of dose, and the following information about the patient's status at the time of open label hydrocortisone use

Hydrocortisone (open label) - Date of dose 10:

Hydrocortisone (open label) - Time of dose 10:

Blood pressure information available at time of open label hydrocortisone use (Dose #10)?

- Yes No

Systolic blood pressure at time of open label hydrocortisone use (Dose #10):

_____ (Systolic)

Diastolic blood pressure at time of open label hydrocortisone use (Dose #10):

_____ (Diastolic)

Heart rate information available at time of open label hydrocortisone use (Dose #10)?

- Yes No

Heart rate at time of open label hydrocortisone use (Dose #10):

_____ (beats per minute)

Capillary refill information available at time of open label hydrocortisone use (Dose #10)?

- Yes No

Capillary refill time (in seconds) at time of open label hydrocortisone use (Dose #10):

_____ (seconds)

Mental status (GCS) information available at time of open label hydrocortisone use (Dose #10)?

- Yes No

Mental status at time of open label hydrocortisone use (Dose #10):

Not applicable

3

4

5

6

7

8

9

10

11

12

13

14

15

(Glasgow Coma Scale)

Oxygen saturation information available at time of open label hydrocortisone use (Dose #10)?

Yes No

Oxygen saturation (%) at time of open label hydrocortisone use (Dose #10):

_____ (percent (%) oxygen saturation)

Additional open-label hydrocortisone given?

Yes No

Open-Label Hydrocortisone - Dose 11

Record date & time of dose, and the following information about the patient's status at the time of open label hydrocortisone use

Hydrocortisone (open label) - Date of dose 11:

Hydrocortisone (open label) - Time of dose 11:

Blood pressure information available at time of open label hydrocortisone use (Dose #11)?

Yes No

Systolic blood pressure at time of open label hydrocortisone use (Dose #11):

_____ (Systolic)

Diastolic blood pressure at time of open label hydrocortisone use (Dose #11):

_____ (Diastolic)

Heart rate information available at time of open label hydrocortisone use (Dose #11)?

Yes No

Heart rate at time of open label hydrocortisone use (Dose #11):

_____ (beats per minute)

Capillary refill information available at time of open label hydrocortisone use (Dose #11)?

Yes No

Capillary refill time (in seconds) at time of open label hydrocortisone use (Dose #11):

_____ (seconds)

Mental status (GCS) information available at time of open label hydrocortisone use (Dose #11)?

Yes No

Mental status at time of open label hydrocortisone use (Dose #11):

- Not applicable
 3
 4
 5
 6
 7
 8
 9
 10
 11
 12
 13
 14
 15
 (Glasgow Coma Scale)

Oxygen saturation information available at time of open label hydrocortisone use (Dose #11)?

- Yes No

Oxygen saturation (%) at time of open label hydrocortisone use (Dose #11):

_____ (percent (%) oxygen saturation)

Additional open-label hydrocortisone given?

- Yes No

Open-Label Hydrocortisone - Dose 12

Record date & time of dose, and the following information about the patient's status at the time of open label hydrocortisone use

Hydrocortisone (open label) - Date of dose 12:

Hydrocortisone (open label) - Time of dose 12:

Blood pressure information available at time of open label hydrocortisone use (Dose #12)?

- Yes No

Systolic blood pressure at time of open label hydrocortisone use (Dose #12):

_____ (Systolic)

Diastolic blood pressure at time of open label hydrocortisone use (Dose #12):

_____ (Diastolic)

Heart rate information available at time of open label hydrocortisone use (Dose #12)?

- Yes No

Heart rate at time of open label hydrocortisone use (Dose #12):

_____ (beats per minute)

Capillary refill information available at time of open label hydrocortisone use (Dose #12)?

- Yes No

Capillary refill time (in seconds) at time of open label hydrocortisone use (Dose #12):

_____ (seconds)

Mental status (GCS) information available at time of open label hydrocortisone use (Dose #12)?

- Yes No

Mental status at time of open label hydrocortisone use (Dose #12):

Not applicable

3

4

5

6

7

8

9

10

11

12

13

14

15

(Glasgow Coma Scale)

Oxygen saturation information available at time of open label hydrocortisone use (Dose #12)?

Yes No

Oxygen saturation (%) at time of open label hydrocortisone use (Dose #12):

_____ (percent (%) oxygen saturation)

Additional open-label hydrocortisone given?

Yes No

Open-Label Hydrocortisone - Dose 13

Record date & time of dose, and the following information about the patient's status at the time of open label hydrocortisone use

Hydrocortisone (open label) - Date of dose 13:

Hydrocortisone (open label) - Time of dose 13:

Blood pressure information available at time of open label hydrocortisone use (Dose #13)?

Yes No

Systolic blood pressure at time of open label hydrocortisone use (Dose #13):

_____ (Systolic)

Diastolic blood pressure at time of open label hydrocortisone use (Dose #13):

_____ (Diastolic)

Heart rate information available at time of open label hydrocortisone use (Dose #13)?

Yes No

Heart rate at time of open label hydrocortisone use (Dose #13):

_____ (beats per minute)

Capillary refill information available at time of open label hydrocortisone use (Dose #13)?

Yes No

Capillary refill time (in seconds) at time of open label hydrocortisone use (Dose #13):

_____ (seconds)

Mental status (GCS) information available at time of open label hydrocortisone use (Dose #13)?

Yes No

Mental status at time of open label hydrocortisone use (Dose #13):

Not applicable

3

4

5

6

7

8

9

10

11

12

13

14

15

(Glasgow Coma Scale)

Oxygen saturation information available at time of open label hydrocortisone use (Dose #13)?

Yes No

Oxygen saturation (%) at time of open label hydrocortisone use (Dose #13):

_____ (percent (%) oxygen saturation)

Additional open-label hydrocortisone given?

Yes No

Open-Label Hydrocortisone - Dose 14

Record date & time of dose, and the following information about the patient's status at the time of open label hydrocortisone use

Hydrocortisone (open label) - Date of dose 14:

Hydrocortisone (open label) - Time of dose 14:

Blood pressure information available at time of open label hydrocortisone use (Dose #14)?

Yes No

Systolic blood pressure at time of open label hydrocortisone use (Dose #14):

_____ (Systolic)

Diastolic blood pressure at time of open label hydrocortisone use (Dose #14):

_____ (Diastolic)

Heart rate information available at time of open label hydrocortisone use (Dose #14)?

Yes No

Heart rate at time of open label hydrocortisone use (Dose #14):

_____ (beats per minute)

Capillary refill information available at time of open label hydrocortisone use (Dose #14)?

Yes No

Capillary refill time (in seconds) at time of open label hydrocortisone use (Dose #14):

_____ (seconds)

Mental status (GCS) information available at time of open label hydrocortisone use (Dose #14)?

Yes No

Mental status at time of open label hydrocortisone use (Dose #14):

- Not applicable
 3
 4
 5
 6
 7
 8
 9
 10
 11
 12
 13
 14
 15
 (Glasgow Coma Scale)

Oxygen saturation information available at time of open label hydrocortisone use (Dose #14)?

- Yes No

Oxygen saturation (%) at time of open label hydrocortisone use (Dose #14):

_____ (percent (%) oxygen saturation)

Additional open-label hydrocortisone given?

- Yes No

Open-Label Hydrocortisone - Dose 15

Record date & time of dose, and the following information about the patient's status at the time of open label hydrocortisone use

Hydrocortisone (open label) - Date of dose 15:

Hydrocortisone (open label) - Time of dose 15:

Blood pressure information available at time of open label hydrocortisone use (Dose #15)?

- Yes No

Systolic blood pressure at time of open label hydrocortisone use (Dose #15):

_____ (Systolic)

Diastolic blood pressure at time of open label hydrocortisone use (Dose #15):

_____ (Diastolic)

Heart rate information available at time of open label hydrocortisone use (Dose #15)?

- Yes No

Heart rate at time of open label hydrocortisone use (Dose #15):

_____ (beats per minute)

Capillary refill information available at time of open label hydrocortisone use (Dose #15)?

- Yes No

Capillary refill time (in seconds) at time of open label hydrocortisone use (Dose #15):

_____ (seconds)

Mental status (GCS) information available at time of open label hydrocortisone use (Dose #15)?

- Yes No

Mental status at time of open label hydrocortisone use (Dose #15):

- Not applicable
 3
 4
 5
 6
 7
 8
 9
 10
 11
 12
 13
 14
 15
 (Glasgow Coma Scale)

Oxygen saturation information available at time of open label hydrocortisone use (Dose #15)?

- Yes No

Oxygen saturation (%) at time of open label hydrocortisone use (Dose #15):

_____ (percent (%) oxygen saturation)

Additional open-label hydrocortisone given?

- Yes No

Open-Label Hydrocortisone - Dose 16

Record date & time of dose, and the following information about the patient's status at the time of open label hydrocortisone use

Hydrocortisone (open label) - Date of dose 16:

Hydrocortisone (open label) - Time of dose 16:

Blood pressure information available at time of open label hydrocortisone use (Dose #16)?

- Yes No

Systolic blood pressure at time of open label hydrocortisone use (Dose #16):

_____ (Systolic)

Diastolic blood pressure at time of open label hydrocortisone use (Dose #16):

_____ (Diastolic)

Heart rate information available at time of open label hydrocortisone use (Dose #16)?

- Yes No

Heart rate at time of open label hydrocortisone use (Dose #16):

_____ (beats per minute)

Capillary refill information available at time of open label hydrocortisone use (Dose #16)?

- Yes No

Capillary refill time (in seconds) at time of open label hydrocortisone use (Dose #16):

_____ (seconds)

Mental status (GCS) information available at time of open label hydrocortisone use (Dose #16)?

- Yes No

Mental status at time of open label hydrocortisone use (Dose #16):

- Not applicable
 - 3
 - 4
 - 5
 - 6
 - 7
 - 8
 - 9
 - 10
 - 11
 - 12
 - 13
 - 14
 - 15
- (Glasgow Coma Scale)

Oxygen saturation information available at time of open label hydrocortisone use (Dose #16)?

- Yes
- No

Oxygen saturation (%) at time of open label hydrocortisone use (Dose #16):

_____ (percent (%) oxygen saturation)

Unblinding

Did the treating physician request unblinding?

- Yes
- No

Was the patient unblinded?

- Yes
- No

Date patient was unblinded:

Reason(s) for unblinding:

Other Steroid Use during PICU Admission

Please indicate if any of the following other types of steroids were used while the patient was admitted to PICU (check all that apply):

- Dexamethasone
- Methylprednisolone
- Prednisolone
- Prednisone
- No other steroids administered during PICU admission

Dexamethasone - Date of dose:

Dexamethasone - Time of dose:

Dexamethasone - Number of doses:

Methylprednisolone - Date of dose:

Methylprednisolone - Time of dose:

Methylprednisolone - Number of doses:

Prednisolone - Date of dose:

Prednisolone - Time of dose:

Prednisolone - Number of doses:

Prednisone - Date of dose:

Prednisone - Time of dose:

Prednisone - Number of doses:

Why did the treating physician chose to start open-label steroids?

20. Economic Variables

Therapy/Interventions - Please indicate if the patient used the following resources during PICU admission.

	Yes	No
Nitric oxide	<input type="radio"/>	<input type="radio"/>
CVVH	<input type="radio"/>	<input type="radio"/>
ECMO	<input type="radio"/>	<input type="radio"/>

Time on intervention - Nitric Oxide (total hours): _____
(Total Hours)

Time on intervention - CVVH (Total hours): _____
(Total hours)

Time on intervention - ECMO (Total hours): _____
(Total hours)

Please indicate the services consulted during PICU admission (e.g. nursing, RT, social work, psychology):

Number of services consulted during PICU admission: 1
 2
 3
 4
 5
 6
 7
 8

Service consulted - #1: _____

Service consulted - #2: _____

Service consulted - #3: _____

Service consulted - #4: _____

Service consulted - #5: _____

Service consulted - #6: _____

Service consulted - #7: _____

Service consulted - #8: _____

Caregiver Information

Is information on where the patient's family/caregiver is staying while patient is in hospital available?

- Yes
 No

Please describe where the family/caregiver is staying while patient is in hospital:

Is the patient's caregiver on employment leave due to patient's illness?

- Yes No Unknown

If yes, indicate the type of employment leave:

- Paid leave Unpaid leave
 Unknown

Nurse to Patient Ratio

Indicate the nurse to patient ratio for each day of PICU admission by indicated the number of nurses and the number of patients in the ratio. Use the 24 hour schedule currently in use at your institution.

If the nurse:patient ratio changed within a given day, please record the lowest ratio applicable for the 24 hour period.

If the ratio for a given day is unknown, enter "ND" for no data.

How many days was the patient admitted to the PICU?

- 1
 2
 3
 4
 5
 6
 7
 8
 9
 10
 11
 12
 13
 14
 15
 16
 17
 18
 19
 20
 21
 22
 23
 24
 25
 26
 27
 28

Nurse:patient ratio - # of Nurses - Day 1: _____

Nurse:patient ratio - # of Patients - Day 1: _____

Nurse:patient ratio - # of Nurses - Day 2: _____

Nurse:patient ratio - # of Patients - Day 2: _____

Nurse:patient ratio - # of Nurses - Day 3: _____

Nurse:patient ratio - # of Patients - Day 3: _____

Nurse:patient ratio - # of Nurses - Day 4: _____

Nurse:patient ratio - # of Patients - Day 4: _____

Nurse:patient ratio - # of Nurses - Day 5: _____

Nurse:patient ratio - # of Patients - Day 5: _____

Nurse:patient ratio - # of Nurses - Day 6: _____

Nurse:patient ratio - # of Patients - Day 6: _____

Nurse:patient ratio - # of Nurses - Day 7: _____

Nurse:patient ratio - # of Patients - Day 7: _____

Nurse:patient ratio - # of Nurses - Day 8: _____

Nurse:patient ratio - # of Patients - Day 8: _____

Nurse:patient ratio - # of Nurses - Day 9: _____

Nurse:patient ratio - # of Patients - Day 9: _____

Nurse:patient ratio - # of Nurses - Day 10: _____

Nurse:patient ratio - # of Patients - Day 10: _____

Nurse:patient ratio - # of Nurses - Day 11: _____

Nurse:patient ratio - # of Patients - Day 11: _____

Nurse:patient ratio - # of Nurses - Day 12: _____

Nurse:patient ratio - # of Patients - Day 12: _____

Nurse:patient ratio - # of Nurses - Day 13: _____

Nurse:patient ratio - # of Patients - Day 13: _____

Nurse:patient ratio - # of Nurses - Day 14: _____

Nurse:patient ratio - # of Patients - Day 14: _____

Nurse:patient ratio - # of Nurses - Day 15: _____

Nurse:patient ratio - # of Patients - Day 15: _____

Nurse:patient ratio - # of Nurses - Day 16: _____

Nurse:patient ratio - # of Patients - Day 16: _____

Nurse:patient ratio - # of Nurses - Day 17: _____

Nurse:patient ratio - # of Patients - Day 17: _____

Nurse:patient ratio - # of Nurses - Day 18: _____

Nurse:patient ratio - # of Patients - Day 18: _____

Nurse:patient ratio - # of Nurses - Day 19: _____

Nurse:patient ratio - # of Patients - Day 19: _____

Nurse:patient ratio - # of Nurses - Day 20: _____

Nurse:patient ratio - # of Patients - Day 20: _____

Nurse:patient ratio - # of Nurses - Day 21: _____

Nurse:patient ratio - # of Patients - Day 21: _____

Nurse:patient ratio - # of Nurses - Day 22: _____

Nurse:patient ratio - # of Patients - Day 22: _____

Nurse:patient ratio - # of Nurses - Day 23: _____

Nurse:patient ratio - # of Patients - Day 23: _____

Nurse:patient ratio - # of Nurses - Day 24: _____

Nurse:patient ratio - # of Patients - Day 24: _____

Nurse:patient ratio - # of Nurses - Day 25: _____

Nurse:patient ratio - # of Patients - Day 25: _____

Nurse:patient ratio - # of Nurses - Day 26: _____

Nurse:patient ratio - # of Patients - Day 26: _____

Nurse:patient ratio - # of Nurses - Day 27: _____

Nurse:patient ratio - # of Patients - Day 27: _____

Nurse:patient ratio - # of Nurses - Day 28: _____

Nurse:patient ratio - # of Patients - Day 28: _____

23. Co-Enrolment

Was the patient enrolled in another study while participating in the STRIPES study?

Yes

No

Specify other study(ies):

24. Case Report Sign Off

Case Report Sign Off

All sections of the Case Report Form should be saved as "Completed" by the research assistant once the Case Report Form is complete, and all data has been checked for accuracy. Please confirm that:

	Yes	No
The case report form is complete	<input type="radio"/>	<input type="radio"/>
All data entered in the case report form has been checked for accuracy	<input type="radio"/>	<input type="radio"/>

This Case Report Form was completed on: _____

Please print this page. The person who completed the Case Report Form and the Site Investigator must sign the hard copy of this form where indicated below.

This Case Report Form has been completed by: _____
(Print Name)

Signature of person who completed the Case Report Form: _____
(Signature)

Date of signature: _____
(dd-mmm-yy)

Signature of Site Investigator

I have reviewed the content of the case report form and I hereby confirm that the data contained in the case report form is accurate and complete. Site Investigators Name: _____
(Print Name)

21.a. Protocol Deviation/Violation Report - 01

Are you reporting a protocol deviation or a protocol violation?

Protocol deviation Protocol violation

Study Site where protocol deviation/violation occurred: _____

Please report all protocol deviations/violations to the Study Coordinating Centre

Check with you local REB to determine the REB reporting requirements for your centre

Date protocol deviation/violation occurred: _____

Date protocol deviation/violation was reported to the Study Coordinating Centre: _____

Is the site investigator aware of the protocol deviation/violation?

Yes No

Indicate type of protocol deviation:

- Patient was randomized but did not receive the study drug
- Patient died before receiving study drug
- Study procedures conducted out of sequence, but with no impact on patient safety or welfare
- Other

Indicate type of protocol violation:

- Patient was enrolled > 6 hours after being started on a vasoactive agent
- First dose of study drug was given > 8 hours after being started on a vasoactive agent
- Enrolment of a patient not meeting inclusion criteria
- Study medication dispensing or dosing error
- Study procedure omitted (does not include omitted blood sample)
- Study drug not weaned/stopped when patient met weaning/stopping criteria
- Other

Describe "other" type of protocol deviation/violation: _____

Explain the reason for the protocol deviation/violation: _____

Was the subject withdrawn from the study as a result of the protocol deviation/violation?

Yes No

Date the subject was withdrawn: _____

21.b. Protocol Deviation/Violation Report - 02

Are you reporting a protocol deviation or a protocol violation?

Protocol deviation Protocol violation

Study Site where protocol deviation/violation occurred: _____

Please report all protocol deviations/violations to the Study Coordinating Centre

Check with you local REB to determine the REB reporting requirements for your centre

Date protocol deviation/violation occurred: _____

Date protocol deviation/violation was reported to the Study Coordinating Centre: _____

Is the site investigator aware of the protocol deviation/violation?

Yes No

Indicate type of protocol deviation:

- Patient was randomized but did not receive the study drug
- Patient died before receiving study drug
- Study procedures conducted out of sequence, but with no impact on patient safety or welfare
- Other

Indicate type of protocol violation:

- Patient was enrolled > 6 hours after being started on a vasoactive agent
- First dose of study drug was given > 8 hours after being started on a vasoactive agent
- Enrolment of a patient not meeting inclusion criteria
- Study medication dispensing or dosing error
- Study procedure omitted (does not include omitted blood sample)
- Study drug not weaned/stopped when patient met weaning/stopping criteria
- Other

Describe "other" type of protocol deviation/violation: _____

Explain the reason for the protocol deviation/violation: _____

Was the subject withdrawn from the study as a result of the protocol deviation/violation?

Yes No

Date the subject was withdrawn: _____

21.c. Protocol Deviation/Violation Report - 03

Are you reporting a protocol deviation or a protocol violation?

Protocol deviation Protocol violation

Study Site where protocol deviation/violation occurred: _____

Please report all protocol deviations/violations to the Study Coordinating Centre

Check with you local REB to determine the REB reporting requirements for your centre

Date protocol deviation/violation occurred: _____

Date protocol deviation/violation was reported to the Study Coordinating Centre: _____

Is the site investigator aware of the protocol deviation/violation?

Yes No

Indicate type of protocol deviation:

- Patient was randomized but did not receive the study drug
- Patient died before receiving study drug
- Study procedures conducted out of sequence, but with no impact on patient safety or welfare
- Other

Indicate type of protocol violation:

- Patient was enrolled > 6 hours after being started on a vasoactive agent
- First dose of study drug was given > 8 hours after being started on a vasoactive agent
- Enrolment of a patient not meeting inclusion criteria
- Study medication dispensing or dosing error
- Study procedure omitted (does not include omitted blood sample)
- Study drug not weaned/stopped when patient met weaning/stopping criteria
- Other

Describe "other" type of protocol deviation/violation: _____

Explain the reason for the protocol deviation/violation: _____

Was the subject withdrawn from the study as a result of the protocol deviation/violation?

Yes No

Date the subject was withdrawn: _____

22.a. Serious Adverse Event Report - 01

Instructions

1. Please complete the following SAE report
2. Print the report (chose "option" in top right hand corner) and have the report signed by the Site Investigator
3. Notify the study coordinating centre. Fax the report to 613-738-4287
4. File the original signed report in the participant's study file

Report type:

- Serious adverse event*
 Serious adverse drug reaction
 Serious unexpected adverse drug reaction
 (*Since ICU patients commonly develop complications of critical illness, related or unrelated to the reason for their admission to the ICU (e.g. nosocomial infection, organ failure, myocardial infarction) these often expected events in the course of patients requiring life support will not be reported as SAEs in the STRIPES Pilot Study)

Describe the event:

Seriousness (check all that apply):

- Patient died
 Immediately life threatening
 Requires hospitalization
 Prolongs hospitalization
 Results in persistent or significant disability/incapacity
 May require surgical or medical intervention to prevent one of other outcomes
 ()

Expectedness:

- Expected given the subjects medical condition
 Expected given the type of surgical, anesthetic or medical procedures performed during hospital admission
 Expected given the known side-effects of hydrocortisone
 Unexpected

Relationship of event to hydrocortisone:

- Not related
 Unlikely related
 Possibly related
 Probably related

Severity:

- Mild
 Moderate
 Severe

Date on onset of SAE/SADR/SUADR:

Outcomes (at time of report):

- Complete recovery/return to baseline
 Alive with sequelae
 Death
 SAE persisting
 Unknown/lost to follow up

Date SAE reported:

Actions taken for SAE (check all that apply):

- None
- Uncertain
- Procedure or physical therapy
- Blood or blood products
- Prescription drug therapy
- Non-prescription drug therapy
- IV fluids
- Additional investigation - monitoring
- Additional investigation - imaging
- Additional investigation - blood work
- Other

Describe other actions taken:

Name of Site Investigator:

Signature of Site Investigator:

Date:

22.b. Serious Adverse Event Report - 02

Report type:

- Serious Adverse Event
 Serious Adverse Drug Reaction
 Serious Unexpected Drug Reaction
 (*Since ICU patients commonly develop complications of critical illness, related or unrelated to the reason for their admission to the ICU (e.g. nosocomial infection, organ failure, myocardial infarction) these often expected events in the course of patients requiring life support will not be reported as SAEs in the STRIPES Pilot Study)

Describe the event:

Seriousness (check all that apply):

- Patient died
 Immediately life threatening
 Requires hospitalization
 Prolongs hospitalization
 Results in persistent or significant disability/incapacity
 May require surgical or medical intervention to prevent one of other outcomes

Expectedness:

- Expected given the subjects medical condition
 Expected given the type of surgical, anesthetic or medical procedures performed during hospital admission
 Expected given the known side-effects of hydrocortisone
 Unexpected

Relationship of event to hydrocortisone:

- Not related
 Unlikely related
 Possibly related
 Probably related

Severity:

- Mild
 Moderate
 Severe

Date on onset of SAE/SADR/SUADR:

Outcomes (at time of report):

- Complete recovery/return to baseline
 Alive with sequelae
 Death
 SAE persisting
 Unknown/lost to follow up

Date SAE reported:

Actions taken for SAE (check all that apply):

- None
 Uncertain
 Procedure or physical therapy
 Blood or blood products
 Prescription drug therapy
 Non-prescription drug therapy
 IV fluids
 Additional investigation - monitoring
 Additional investigation - imaging
 Additional investigation - blood work
 Other

Describe other actions taken:

Name of Site Investigator:

Signature of Site Investigator:

Date:

22.c. Serious Adverse Event Report - 03

Report type:

- Serious Adverse Event
 Serious Adverse Drug Reaction
 Serious Unexpected Drug Reaction
 (*Since ICU patients commonly develop complications of critical illness, related or unrelated to the reason for their admission to the ICU (e.g. nosocomial infection, organ failure, myocardial infarction) these often expected events in the course of patients requiring life support will not be reported as SAEs in the STRIPES Pilot Study)

Describe the event:

Seriousness (check all that apply):

- Patient died
 Immediately life threatening
 Requires hospitalization
 Prolongs hospitalization
 Results in persistent or significant disability/incapacity
 May require surgical or medical intervention to prevent one of other outcomes

Expectedness:

- Expected given the subjects medical condition
 Expected given the type of surgical, anesthetic or medical procedures performed during hospital admission
 Expected given the known side-effects of hydrocortisone
 Unexpected

Relationship of event to hydrocortisone:

- Not related
 Unlikely related
 Possibly related
 Probably related

Severity:

- Mild
 Moderate
 Severe

Date on onset of SAE/SADR/SUADR:

Outcomes (at time of report):

- Complete recovery/return to baseline
 Alive with sequelae
 Death
 SAE persisting
 Unknown/lost to follow up

Date SAE reported:

Actions taken for SAE (check all that apply):

- None
 Uncertain
 Procedure or physical therapy
 Blood or blood products
 Prescription drug therapy
 Non-prescription drug therapy
 IV fluids
 Additional investigation - monitoring
 Additional investigation - imaging
 Additional investigation - blood work
 Other

Describe other actions taken:

Name of Site Investigator:

Signature of Site Investigator:

Date:

25. Research Blood Sample Results & Group Assignment

****THIS SECTION WILL BE COMPLETED BY THE SCC****

THIS SECTION WILL BE COMPLETED BY THE STUDY COORDINATING CENTRE

Did the patient have a total cortisol level sent? Yes No

Total cortisol level (nmol/L): _____
(nmol/L)

Did the patient have a free cortisol sent? Yes No

Free cortisol level (nmol/l): _____
(nmol/l)

Did the patient have a 25 hydroxy vitamin D (25OHD) level sent? Yes No

The 25OHD level was (nmol/L): _____
(nmol/L)

Did the patient have a 1,25 OHD level sent? Yes No

The 1,25OHD level was (pmol/L): _____
(pmol/L)

Patient was assigned to: Group A
 Group B