A multicentre Observational study of critically ill patients with Hospital-acquired Blood Stream Infection.

Case report form

V 1.08
19/09/2019

INCLUSION CRITERIA

☐ Age > 18 Years

☐ Hospital acquired Blood Stream Infection (BSI).
  • Positive blood culture (BC) sampled after 48 hours following hospital admission.
  • For CNS (coagulase-negative staphylococci) and other typical contaminants (Corynebacterium species, Bacillus species, Propionibacterium species, Micrococcus species), 2 blood cultures with the same antimicrobial susceptibility profile are mandatory or strong clinical grounds that it is not a contaminant. One example is infected material proven as a source for the HA-BSI.

☐ Treated in the ICU
  • ☐ BC has been sampled in the ICU (ICU-Acquired BSI)

OR
  • ☐ BC sampled in the ward AND the patient has been transferred to the ICU for the treatment of the BSI. (HOSPITAL-Acquired BSI)

EXCLUSION CRITERIA

☐ Previous inclusion in the study.

☐ BSI that does not meet the inclusion criteria
Section 2  –  Demographics

Patient ID: ____________
(the patient ID consists out of: site number + rank number within the site)

Age (years) ____________
Gender: □ Male □ Female
Weight (kg): ____________
Height (m): ____________

Use measured values if available, else enter estimated values. (tick □ if estimated)

Section 3  –  Admission data

3.1. Date of hospital admission (day/month/year): ____________
3.2. Date of ICU admission (day/month/year): ____________
3.3 Admission source
□ Other hospital
□ Emergency department
□ Operating Room/recovery
□ Hospital ward/ floor
□ Other, please specify ______________________
3.4. Type of admission, one possible answer only (see appendix for definitions):
□ medical □ surgical □ elective □ emergency

5.2 ICU Admission diagnosis

Primary ICU admission diagnosis (reason for ICU admission) ____________

See list in appendix and enter the code – Post operative admissions other than cardiac arrest should have an operative code as primary diagnosis

e-crf should show dropdown lists appropriate to the type of patient and ease data capture
Section 4 – Blood culture data

4.1 Timing of the first positive blood culture sampling (study infection, it is time zero of the study):
- date (day / month / year): ____________
- time (24h clock; e.g. 23:59): ____________

4.2 Time to positivity _____ hours – or tick ☐ if unknown/ not reported.

4.3 Presumed source of the bloodstream infection:
(presumed source of the bloodstream infection as determined by the treating clinician.
Please indicate the most likely source. If more than one, please number in the order of likelihood)
This is a surgical site infection ☐
(please tick if an infection of the surgical site from a previous intervention)

☐ Primary (no clear portal of entry identified)

☐ Catheter-related

Respiratory tract
☐ Pneumonia
☐ Pleural, empyema
☐ Tracheobronchitis

Intra-abdominal
☐ Peritonitis
☐ Biliary source
☐ Other intra-abdominal

☐ Urinary tract

Bone or soft tissues
☐ Necrotizing fasciitis
☐ Other soft tissue
☐ Joint or bone
☐ Spine

☐ Endocarditis
☐ Mediastinitis

☐ Central Nervous System

☐ Other, please describe _______ (free text comment box)
4.4 Causative micro-organism and susceptibility

This section to come immediately following the inclusion criteria to avoid data capture in ineligible patients

Dependent on the species that is selected in the eCRF a susceptibility pattern checklist will pop-up.
Possibility to enter multiple pathogens.

Causative micro-organism table 1: Aerotolerant Gram-positive
Causative micro-organism table 2: Aerotolerant Gram-negative
Causative micro-organism table 3: Strict anaerobe
Causative micro-organism table 4: Fungi

Will ask for specific MICs, mechanisms of resistance, and selected enzymes ONLY in centres that report the capability in the centre questionnaire.

Tables for pathogen specific antibiogram provided

If Coagulase Negative Staphylococcus (or other common contaminants) is selected: please confirm there have been at least 2 positive blood cultures with the same pathogen (species and susceptibility profile) or infected material with the same pathogen and strong clinical suspicion of the blood culture not being a contaminant.
Section 5  –  Co-morbidities

5.1 Presence of chronic illnesses and co-morbid conditions
(check all present, see definitions)

<table>
<thead>
<tr>
<th>Category</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory</td>
<td>COPD / Chronic Pulmonary Disease Moderate, COPD / Chronic Pulmonary Disease Severe*</td>
</tr>
<tr>
<td>Cardio-Vascular</td>
<td>Heart Failure (NYHA 3), Heart Failure (NYHA 4), Previous Myocardial infarction, Peripheral vascular disease</td>
</tr>
<tr>
<td>Neurological</td>
<td>Cerebro-vascular disease, Dementia, Hemiplegia</td>
</tr>
<tr>
<td>Metabolic</td>
<td>Diabetes without end organ damage, Diabetes with end organ damage, Renal disease, moderate, Renal disease, receiving chronic dialysis, Connective tissue disease</td>
</tr>
<tr>
<td>Gastro-intestinal</td>
<td>Ulcer disease (gastro-duodenal), Liver disease, mild to moderate, Liver disease, severe*</td>
</tr>
<tr>
<td>Immunosuppression</td>
<td>Steroids &gt; 20 mg/day for at least 4 weeks or recent high dose steroids, Chemotherapy /radiotherapy within 6 months, Organ transplant, AIDS (not only HIV pos.), Immunosuppression Other, Targeted Cancer Therapy (ongoing)</td>
</tr>
<tr>
<td>Malignancy</td>
<td>Malignancy – solid tumours (active only and without metastasis), Malignancy – solid tumours (Proven metastasis), Head and Neck, Lung, Gastro-intestinal, Gynaecological</td>
</tr>
</tbody>
</table>
Breast
Prostate
Solid Tumour, other
Haematological malignancy (Leukaemia or lymphoma)
Acute lymphocytic leukaemia
Acute myeloid leukaemia
Chronic Lymphocytic Leukaemia
Chronic Myelogenous Leukaemia
Non-Hodgkin lymphoma
Hodgkin lymphoma
Haematological malignancy Other

In e-CRF subtypes of haematological malignancy and cancer only pop-up (dropdown) if the parent condition is ticked.
Immunosuppression other opens a textbox to describe.

*Liver disease, severe = Biopsy-proven cirrhosis with portal hypertension; episodes of past upper GI bleeding attributed to portal hypertension; or prior episodes of of hepatic failure, encephalopathy, or coma

*COPD / Chronic Pulmonary Disease Severe = Chronic restrictive, obstructive or vascular disease resulting in severe exercise limitation (eg unable to climb stairs or perform household duties) or documented chronic hypoxia, hypercapnia, secondary polycythemia, severe pulmonary hypertension (>40 mmHg) or home oxygen or NIV.

Previous Health status
A = Prior good health; no functional limitation
B = Mild to moderate limitation of activity because of a chronic medical problem
C = Chronic disease producing serious but not incapacitation restriction of activity.
D = severe restriction of activity due to disease; includes persons bedridden or institutionalized due to illness
If the first positive Blood culture was taken in the ward, prior to ICU admission, please go to

**SEVERITY – SCORING FOR HOSPITAL ACQUIRED INFECTIONS**

If the first positive Blood culture was taken in the ICU, please go to

**SEVERITY – SCORING FOR ICU DIAGNOSED OR ICU ACQUIRED INFECTIONS**
6 - SEVERITY – SCORING FOR HOSPITAL ACQUIRED INFECTIONS

Section shown only for patients with a Hospital-acquired BSI, prior to ICU admission

6.1 Severity, Organ dysfunctions and septic shock on ICU admission

Please enter worse values of the first 24H following ICU admission.
(to obtain organ dysfunctions present on ICU admission, SAPS 2, SOFA SCORE, qSOFA and calculate sepsis 3)

All data from ICU

Was there an infection (proven or suspected) on ICU admission  Yes □ No □
(this will be automatically coded Yes as there is the index BSI)

Cardiac arrest in the 48 hours preceding or the 24 hours following BC sampling  Yes □ No □

Adrenaline  Yes □ No □
Noradrenaline Yes □ No □
(if yes pops the question:)
Maximum dose of Adrenaline or Noradrenaline on the day of Blood Culture sampling ______
Unit selector (mg/h or mcg/min or mcg/kg/min)

Dopamine □
Dobutamine □
Levosimendan □
Vasopressin □
Terlipressin □

Ventilation status:

Invasive Mechanical Ventilation □
Non-Invasive Mechanical Ventilation or CPAP □
High Flow Oxygen Nasal Canula □
Low flow Oxygen or no oxygen □

Please enter the highest level of ventilation that the patient has received for those 24H
(Invasive > non-invasive>high>low flow oxygen)

Renal replacement therapy: Intermittent Haemodialysis □
Renal replacement therapy: Continuous Veno-Venous Hemo(dia)Filtration □
Renal replacement therapy: SLEDD □

ECMO : Veno-Venous □
ECMO : Veno-Arterial □
Heart rate   ____ (min)   ____ (max)

Systolic Blood Pressure   ____ (min)   ____ (max)

Mean Arterial Pressure   ____ (min)   ____ (max)

Respiratory Rate   ____ (min)   ____ (max)

Glasgow Coma Scale   _____ / 15 *

*For non-sedated patients, enter the lowest GCS during the 24 hours. For patients sedated, enter the GCS at the time of/just prior to sedation. If not available, please enter an estimated GCS score as it would be if the patient was not receiving sedation.*

**Current neurological status**

- [ ] Conscious and normal neurological status
- [ ] Hyporeactive delirium
- [ ] Mixed delirium
- [ ] Hyperreactive delirium
- [ ] Comatose / unconscious, with ongoing sedation
- [ ] Comatose / unconscious, without ongoing sedation

Temperature   _____ (min)   _____ (max)

Unit selector (C or F)

urine output   _____ ml/24h

PaO2   _______     Unit selector (mmHg, kPa)

FiO2   _______ %     (please enter paired PaO2/FiO2 for the worse value of the 24h)

pH   _____

Lactate   _______ (max) mmol/l

BUN or serum Urea (max value)   _______

Unit selector (mg/dL, mmol/L)

Creatinine   _____ (max)

Unit selector (mg/dL, µmol/L)
<table>
<thead>
<tr>
<th>Parameter</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium (mmol/l)</td>
<td>____</td>
<td>____</td>
</tr>
<tr>
<td>Potassium (mmol/L)</td>
<td>____</td>
<td>____</td>
</tr>
<tr>
<td>Bicarbonate (mmol/L)</td>
<td>____</td>
<td>____</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>____</td>
<td></td>
</tr>
<tr>
<td>Haematocrit</td>
<td>______  %</td>
<td></td>
</tr>
<tr>
<td>Platelet count</td>
<td>____</td>
<td>____</td>
</tr>
<tr>
<td>White Blood Cell count</td>
<td>____</td>
<td>____</td>
</tr>
<tr>
<td>Neutrophil count</td>
<td>____</td>
<td></td>
</tr>
<tr>
<td>Lymphocyte count</td>
<td>____</td>
<td></td>
</tr>
<tr>
<td>CRP</td>
<td>______  (max) mg/L</td>
<td></td>
</tr>
<tr>
<td>Procalcitonin</td>
<td>______  (max) ng/mL</td>
<td></td>
</tr>
</tbody>
</table>
6 SEVERITY - SCORING FOR ICU DIAGNOSED OR ICU ACQUIRED INFECTIONS

For ICU acquired infections there is a data point on ICU admission to collect data for SAPS2 and a 2nd data point at the time of BSI to collect SOFA score, Sepsis3, qSOFA and INCREMENT)

6.1 Severity scoring on ICU Admission (SAPS2 and septic shock)

Cardiac arrest in the 24 hours preceding or during the 1st 24 hours of ICU admission
Yes ☐ No ☐

Was there an infection (proven or suspected) Yes ☐ No ☐

Ventilation status:
☐ Invasive Mechanical Ventilation
☐ Non-Invasive Mechanical Ventilation or CPAP
☐ High Flow Oxygen Nasal Canula
☐ Low flow Oxygen or no oxygen

Please enter the highest level of ventilation that the patient has received for those 24H (Invasive > non-invasive>high>low flow oxygen)

Adrenaline ☐ or Noradrenaline ☐ (if yes pops the question:)
Maximum dose of Adrenaline or Noradrenaline _____
(mg/h or mcg/min or mcg/kg/min)

Heart rate _____ (min) _____ (max)
Systolic Blood Pressure _____ (min) _____ (max)
Mean Arterial Pressure _____ (min) _____ (max)
Glasgow Coma Scale _____ / 15 *
For non-sedated patients, enter the lowest GCS during the 24 hours. For patients sedated, enter the GCS at the time of/just prior to sedation. If not available, please enter an estimated GCS score as it would be if the patient was not receiving sedation.

Temperature _____ (min) _____ (max)
Unit selector (C or F)
urine output  

PaO2  
FiO2  (please enter paired PaO2/FiO2 for the worse value of the 24h)

BUN or serum Urea (max value)  
Creatinine  
Sodium (mmol/l)  
Potassium (mmol/L)  
Bicarbonate (mmol/L)  
pH  
Lactate  
Bilirubin  
White Blood Cell count  
CRP  
Procalcitonin
6.2 Severity assessment and scoring at the time of BSI

Please note worse values in the 24h following BC sampling (the day where the first positive blood culture was taken).

☐ Cardiac arrest in the 48 hours preceding or the 24 hours following BC sampling

Ventilation status:
- □ Invasive Mechanical Ventilation
- □ Non-Invasive Mechanical Ventilation or CPAP
- □ High Flow Oxygen Nasal Canula
- □ Low flow Oxygen or no oxygen

Please enter the highest level of ventilation that the patient has received for those 24H (Invasive > non-invasive>high>low flow oxygen)

☐ Renal replacement therapy: Intermittent Haemodialysis
☐ Renal replacement therapy: Continuous Veno-Venous Hemo(dia)Filtration
☐ Renal replacement therapy: SLEDD

☐ ECMO : Veno-Venous
☐ ECMO : Veno-Arterial

Adrenaline
Noradrenaline (if yes pops the question:)

Maximum dose of Adrenaline or Noradrenaline on the day of Blood Culture sampling _____
Unit selector (mg/h or mcg/min or mcg/kg/min)

Dopamine
Dobutamine
Levosimendan
Vasopressin
Terlipressin

Systolic Blood Pressure _____ (min) _____ (max)
Mean Arterial Pressure _____ (min) _____ (max)
Heart rate _____ (min) _____ (max)
Respiratory rate _____ (min) _____ (max)

Temperature _____ (min) _____ (max)
Unit selector (C or F)
urine output ______ ml/24h

Glasgow Coma Scale ____ / 15 *  
For non-sedated patients, enter the lowest GCS during the 24 hours. For patients sedated, enter the GCS at the time of / just prior to sedation. If not available, please enter an estimated GCS score as it would be if the patient was not receiving sedation.

Current neurological status

☐ Conscious and normal neurological status
☐ Hyporeactive delirium
☐ Mixed delirium
☐ Hyperreactive delirium
☐ Comatose / unconscious, with ongoing sedation
☐ Comatose / unconscious, without ongoing sedation

PaO2 ______ Unit selector (mmHg, kPa)  
FiO2 ______ % (please enter paired PaO2/FiO2 for the worse value of the 24h)  

Lactate ______ (max) mmol/l  

Creatinine ______ (max) Unit selector (mg/dL, µmol/L)  

White Blood Cell count ______ (min) ______ (max)  
Unit selector (x 10^3/mm^3, 10^3/µL, cells/mm3).  

Neutrophil count ______ (min)  
Unit selector (x 10^3/mm^3, 10^3/µL, cells/mm3)  

Lymphocyte count ______ (min)  
Unit selector (x 10^3/mm^3, 10^3/µL, cells/mm3)  

Platelet count ______ (min)  
Unit selector (x 10^3/mm^3, 10^3/µL, cells/mm3)  

Bilirubin ______ (max)  
Unit selector mg/dL (µmol/L)  

CRP ______ (max) mg/L  

Procalcitonin ______ (max) ng/mL
Section 7: Previous antibiotics and colonisation

7.1 Multidrug resistant colonisation
Was there any know Multidrug Resistant colonisation prior to the BSI

☐ YES ☐ NO

If yes tick all present:
☐ MRSA (Staphylococcus aureus isolates resistant to methicillin)
☐ VRE (of Enterococcus spp. isolates resistant to vancomycin)
☐ ESBL (Enterobacteriaceae isolates producing extended-spectrum β-lactamase)
☐ Carbapenemase producing Enterobacteriaceae

7.2 Previous antimicrobial therapy

Did the patient receive any antimicrobials in the 7 days prior to the blood stream infection (other than those started for the episode and that will be entered in section 7)

☐ YES ☐ NO

If yes,
Name of the antimicrobial            ________________ (dropdown list)
Name of the antimicrobial            ________________ (dropdown list)
Name of the antimicrobial            ________________ (dropdown list)
Name of the antimicrobial            ________________ (dropdown list)

Allow for up to 4 previous antimicrobials in the eCRF
Section 8: Management of blood stream infection

8.1 Antimicrobial therapy

Please enter all antimicrobials that were administered starting the 2 days before the BSI to document probabilistic treatments and breakthrough infections (eCRF to show this date). Document any antimicrobials used in ICU after the infection. (this table is printed several times at the end of the CRF to help research coordinators with data capture where required)

**Antimicrobial 1** (possibility to increment other antimicrobials in the e-crf)

Name of the antimicrobial  ________________ (dropdown list)

Date and time of the first dose  ________________dd/mm/yyyy , hh:mm

Date of the last dose  ________________ dd/mm/yyyy

Route

- ☐ Intra-Venous
- ☐ Once daily dose
- ☐ Intermittent infusion
- ☐ extended infusion (duration > 3 hours)
- ☐ continuous infusion
- ☐ Oral
- ☐ Aerosolized
- ☐ Intra-Muscular

Was a loading dose administered?  ☐ yes  ☐ No

If yes, how much ________ (gram/milligram/unit)

Total dose on the first 24 hours of therapy (NOT including loading dose) ________

(gram/milligram/unit)

(Please indicate the total dosing administered for 24hours, regardless of the time of the day it is started and/or if it crosses calendar days)
Reason for prescription (one from dropdown list)
- Empirical therapy for sepsis
- Targeted therapy for BSI based on rapid diagnostic testing (please comment)
- Targeted therapy for blood stream infection based on positive blood culture
- Targeted therapy for blood stream infection based on antibiogram results
- De-escalation based on antibiogram results (study infection)
- Escalation based on antibiogram results (study infection)
- 2nd antibiotic for combination therapy (study infection)
- Treatment of a different infection than the study infection
- To treat the BSI, reason not recorded
- Allergic reaction to another antimicrobial, please specify _____________
- Adverse event attributed to another antimicrobial, please specify _____________
- Other, please specify _____________

Reason for stopping the antibiotic (one from dropdown list)
- Patient cured
- Duration of treatment completed
- Change to a different antibiotic, escalation
- Change to a different antibiotic or stopping an antibiotic, de-escalation
- Allergic reaction to the antimicrobial.
- Adverse event attributed to the antimicrobial, please specify _____________
- Withdrawing treatment or life sustaining therapy.
- Other, please specify

If therapeutic drug monitoring / antibiotics level were measured please enter
Level _____ / unit (mg/L or other) _____ day of sampling: dd/mm/yyyy,
was it a
- Random level
- Steady state level for continuous infusion
- through / pre-dose level
- peak / post dose level

If dosing was modified following TDM and/or multiple levels were taken, please enter the
first one after the BSI and provide detail in comments
8.2 Source control

Was source control was
- Not required
- Required, Completed.
- Source control REQUIRED but NOT achieved

*If source controlled was required, please complete the table below for each intervention that was required and/or completed.*

For each group of interventions that was performed, the intervention was:
- Completed and effective.
- Attempted but partially effective.
- Attempted but ineffective.
- Not attempted (patient too sick).
- Not attempted (decision to withhold or withdraw LST)
- Not attempted (service unavailable)

Date and time of the intervention ________  dd/mm/yyyy , hh:mm

Was a specimen taken for microbiology?
- No
- yes and negative microbiology
- yes and positive with the same pathogen as the BSI
- yes and positive with different pathogen(s)

---

**Catheter Related**
- [ ] Catheter removal
- [ ] Surgical vascular procedure (ligature)

**Respiratory tract (Pulmonary, Pleural, empyema)**
- [ ] Surgical Thoracic
- [ ] Percutaneous Thoracic (including Chest drain)
- [ ] Percutaneous mediastinal

**Vascular**
- [ ] Surgical Vascular
- [ ] Percutaneous Vascular
- [ ] other Vascular

**Cardiac and mediastinal**
- [ ] Surgical cardiac
- [ ] Surgical mediastinal
- [ ] Percutaneous mediastinal
- [ ] other cardiac or mediastinal
Intra-abdominal
- [ ] Surgical Abdominal
- [ ] Percutaneous Abdominal
- [ ] Surgical other (mediastinal, pleural, ...)
- [ ] Percutaneous other (mediastinal, pleural, ...)

Urinary tract
- [ ] Surgical urinary (JJ stent)
- [ ] Surgical urinary (Nephrectomy or other)
- [ ] Percutaneous urinary (nephrostomy)
- [ ] Other Urinary ________

Bone or soft tissues
- [ ] Surgical skin
- [ ] Surgical bone
- [ ] Other bone or soft tissue

Other
- [ ] Percutaneous Other, please describe ________
- [ ] Surgical Other, please describe ________
- [ ] Other, please describe ________

Was source control effective:
- [ ] Yes, completely
- [ ] No or Incompletely

- did the patient receive any further intervention Yes [ ] No [ ]
- Additional surgical intervention Yes [ ] No [ ]
- Additional percutaneous intervention Yes [ ] No [ ]
- Total number of procedures ___
- Date of the last procedure
- Was source control effective after the last procedure:
  - [ ] Yes, completely
  - [ ] No or incompletely

Comments or details __________________________________ (Free text Box)

If patient required ongoing or continuous intervention while in the ICU (e.g. irrigation) or the intervention was unusually complex, please provide detail in comments.
8.3 Investigations performed to investigate source or septic metastasis
Enter any investigations done between day 1 and 7 that were performed to investigate the source or the complications of the BSI.

CT SCANNER: □ Abdomen/Pelvis □ Thorax □ Head □ Neck □ Limbs □ Spine □ Other

MRI: □ Abdomen/Pelvis □ Thorax □ Head □ Neck □ Limbs □ Spine □ Other

PET-Scan □ Abdomen/Pelvis □ Thorax □ Head □ Neck □ Limbs □ Spine □ Other

ULTRASOUND: □ Abdomen/Pelvis □ Thorax □ Head □ Neck □ Limbs □ Other

CARDIAC ECHOGRAPHY □ Transthoracic □ Transoesophageal

Bronchoscopy □

Fundoscopy □

8.4 Other treatments received between day1 and day7 (eCRF to display dates)
(Y/N for corticosteroids, others tick only)

Did the patient receive Steroids for sepsis or septic shock Yes □ No □
If ticked YES eCRF to display dropdown with 1 to 7 days
If yes, number of days ____

Did the patient receive G-CSF or GM-CSF □
If ticked YES eCRF to display dropdown with 1 to 7 days
If yes, number of days ____

Did the patient receive IFN-γ □
If ticked YES eCRF to display dropdown with 1 to 7 days
If yes, number of days ____

Did the patient receive Blood Purification Techniques □
If ticked YES eCRF to display
- Dropdown of possible choices (oXiris, CytoSorb, Toraymyxin, other please specify _______)
- Dropdown with 1 to 7 days
Section 9: Status at day 7

9.1 Severity assessment and scoring at day 7

Please record worse values within the calendar day

Only for patients alive and still in the ICU at day 7

Day 7 is the ___/___/____ (calculated by the e-CRF)

Adrenaline Yes [ ] No [ ]
Noradrenaline Yes [ ] No [ ]
(if yes pops the question:)
Maximum dose of Adrenaline or Noradrenaline on the day of Blood Culture sampling _____

Unit selector (mg/h or mcg/min or mcg/kg/min)

Dopamine [ ]
Dobutamine [ ]
Levosimendan [ ]
Vasopressin [ ]
Terlipressin [ ]

Ventilation status:

[ ] Invasive Mechanical Ventilation
[ ] Non-Invasive Mechanical Ventilation or CPAP
[ ] High Flow Oxygen Nasal Canula
[ ] Low flow Oxygen or no oxygen

Please enter the highest level of ventilation that the patient has received for those 24H
(Invasive > non-invasive>high>low flow oxygen)

[ ] Renal replacement therapy: Intermittent Haemodialysis
[ ] Renal replacement therapy: Continuous Veno-Venous Hemo(dia)Filtration
[ ] Renal replacement therapy: SLEDD

[ ] ECMO : Veno-Venous
[ ] ECMO : Veno-Arterial

Mean Arterial Pressure _____ (min) _____(max)

Temperature _____ (min) _____ (max)
Unit selector (C or F)

urine output _____ ml/24h
Glasgow Coma Scale   ____ / 15 *
For non-sedated patients, enter the lowest GCS during the 24 hours. For patients sedated, enter the GCS at the time of/just prior to sedation. If not available, please enter an estimated GCS score as it would be if the patient was not receiving sedation.

Current neurological status
- Conscious and normal neurological status
- Hyporeactive delirium
- Mixed delirium
- Hyperreactive delirium
- Comatose / unconscious, with ongoing sedation
- Comatose / unconscious, without ongoing sedation

PaO2     ______           Unit selector (mmHg, kPa)
FiO2     ______ %       (please enter paired PaO2/FiO2 for the worse value of the 24h)

Lactate   ______ (max)   mmol/l

Creatinine    ______ (max)
               Unit selector (mg/dL, µmol/L)

Bilirubin    ______ (max)
               Unit selector mg/dL (µmol/L)

White Blood Cell count   ______ (min) ______ (max)
               Unit selector (x 10\(^3\)/mm\(^3\), 10\(^3\)/µL, cells/mm\(^3\)).

Neutrophil count   ______ (min)
               Unit selector (x 10\(^3\)/mm\(^3\), 10\(^3\)/µL, cells/mm\(^3\)).

Lymphocyte count   ______ (min)
               Unit selector (x 10\(^3\)/mm\(^3\), 10\(^3\)/µL, cells/mm\(^3\)).

Platelet count   ______ (min)
               Unit selector (x 10\(^3\)/mm\(^3\), 10\(^3\)/µL, cells/mm\(^3\)).

CRP              ______ (max)   mg/L

Procalcitonin      ______ (max)   ng/mL
9.4 Clinical response on day 7
Please check the clinical response of the patient for the initial infection under study (as estimated by treating physician).

☐ Resolution (= clinical cure)
(disappearance of all signs and symptoms related to the BSI and its source)

☐ Improvement (incomplete reduction in the signs and symptoms of the BSI)

☐ Clinical failure with: *(multiple possible answers)*
  ☐ Persistence or progression of signs of infection or sepsis.
  ☐ Septic metastasis.
  ☐ Persisting infection at the source.
  ☐ As defined by clinician (No details given)

☐ Indeterminate (no evaluation possible, for any reason)
Section 10 : Day 28 follow-up

(day 1 = day of onset bloodstream infection)

10.1 Microbiological response on day 7
(this table is printed several times at the end of the CRF to help research coordinators with data capture where required)

Where there any other blood cultures taken between the first positive BC and day 7.

☐ NO  ☐ Yes       If yes, please enter:
Day of subsequent blood culture sampling: (day / month / year):  ______________

Was it positive?  ☐ Negative  ☐ Positive
If Positive:
☐ Same Bacteria
☐ Other Bacteria (this opens selection of bacteria, same as initial one)
Time to positivity _____ hours

10.2 Subsequent bacteraemia (d7-d28)
Was there any other positive blood culture between day 7 and day 28.

☐ Yes  ☐ NO

If yes, please enter details

Date of positivity _____ / _____ / ______

☐ Same Bacteria
☐ Other Bacteria (this opens selection of bacteria, same as initial one)
10.3 Supportive therapy after the occurrence of blood stream infection

Please enter the number of days on the therapy from the day of the blood stream infection to day 28 – It has to be administered as at least 1 hour / day to be considered on.

- Vasoactive medications (inotropic or vasopressor) _______ days
- Invasive mechanical ventilation _______ days
- Non-Invasive mechanical ventilation _______ days
- renal replacement therapy _______ days
- ECMO _______ days

10.4 28-day status

☐ Alive in the ICU
☐ Alive in the Hospital
☐ Death in the ICU
☐ Death in the Hospital
☐ Discharged from the Hospital

_Dates to pop up according to status._

Date of ICU discharge (day / month / year): ______________
Date of Hospital discharge (day / month / year): ______________
Date of death (day / month / year): ______________

☐ Death was preceded by a decision to withhold or withdraw life-sustaining treatment. (Ethical decision to change goal of treatment from life-prolonging to palliative. It should only be entered if organ supportive therapy was stopped or not started when it would otherwise have been indicated)
Definitions

**Type of admission**: Surgical - defined as having surgery within 7 days of ICU admission. Elective surgery is defined as surgery scheduled > 24 hours in advance and emergency surgery as that scheduled within 24 hours of operation. All other admissions are considered medical.

**Delirium**: Delirium is defined as an acute or fluctuating mental state (which represents a change from the patient’s normal baseline) and is characterized by inattention with altered level of consciousness, agitation or disorganized thought processes. It can be diagnosed by standardized assessment tools such as (but not limited to) the Confusion Assessment Method for ICU (CAM-ICU)

- **Hyperactive delirium** is characterized by agitation, restlessness, and attempts to remove tubes and lines.
- **Hypoactive delirium** is characterized by withdrawal, flat affect, apathy, lethargy, and decreased responsiveness.
- **Mixed delirium** is when patients fluctuate between the two.

**Glasgow Coma Scale** (GCS): if non-sedated, please enter lowest GCS of the 24 hours, if sedated enter the GCS just prior to sedation. If unable to enter one of those two, please enter current GCS and tick the box GCS assessed with ongoing sedation.

□ **Admission source**: refers to where was the patient prior to admission to the ICU.

□ **Primary diagnosis**: The main reason for admission to the ICU. Only one primary diagnosis should be entered (see codes). If surgical admission should enter the site of surgery as primary diagnosis.

□ **Comorbidities**: Chronic diseases present prior to ICU admission. More than one can be chosen according to the following definitions:

- **Metastatic cancer**: Metastases proven by surgery, computed tomography or magnetic resonance scan, or any other method.
- **Hematologic cancer**: Lymphoma, Leukaemia.
- **AIDS** HIV positive patients with clinical complications such as *Pneumocystis carinii* pneumonia, Kaposi’s sarcoma, lymphoma, tuberculosis, or toxoplasma infection.
- **Chronic renal failure**: Defined as either chronic dialysis dependent renal failure or history of chronic renal insufficiency with a serum creatinine > 3.6 g/dL (300 µmol/L).
- **Immunosuppression**: Administration within the 6 months prior to ICU admission of corticosteroid treatment (at least 0.3 mg/kg/day prednisolone for at least one month) or other immunosuppressant drugs, severe malnutrition, congenital immune-humoral or cellular immune deficiency state.
- **Chemotherapy/radiotherapy**: If within 6 months prior to ICU admission.
List of admission diagnosis
Codes and coefficients corresponding to Apache II and ROD calculations.

Medical admissions
Respiratory
-2.108 Asthma/allergy
-0.367 COPD
-0.251 Pulmonary edema (non-cardiogenic)
-0.168 Postrespiratory arrest
-0.142 Aspiration/poisoning/toxic
-0.128 Pulmonary embolus
0 Infection
0.891 Neoplasm

Cardiovascular
-1.798 Hypertension
-1.368 Rhythm disturbance
-0.424 Congestive heart failure
0.493 Hemorrhagic shock/hypovolemia
-0.191 Coronary artery disease
0.113 Sepsis
0.393 Postcardiac arrest
-0.259 Cardiogenic shock
0.731 Dissecting thoracic/abdominal aneurysm

Trauma (non-surgical)
-1.228 Multiple trauma
-0.517 Head trauma

Neurologic (non-surgical)
-0.584 Seizure disorder
0.723 Intracerebral, Subdural or Subarachnoid Haemorrhage

Other
-3.353 Drug overdose
-1.507 Diabetic ketoacidosis
0.334 GI bleeding

Non-surgical (not otherwise specified)
-0.885 Metabolic/renal
-0.890 Respiratory
-0.759 Neurologic
0.47 Cardiovascular
0.501 Gastrointestinal

Postoperative admissions
0.113 Post-op sepsis
0.393 Post-op post cardiac arrest
-1.684 Multiple trauma
-1.376 Chronic cardiovascular disease
-1.315 Peripheral vascular surgery
-1.261 Cardiac surgery
-1.245 Craniotomy for neoplasm
-1.204 Renal surgery for neoplasm
-1.042 Renal transplant
-0.955 Head trauma
-0.802 Thoracic surgery for neoplasm
-0.788 Craniotomy for Intracerebral, Subdural or Subarachnoid Haemorrhage
-0.699 Laminectomy and other spinal surgery
-0.682 Haemorrhagic shock
-0.617 GI bleeding
-0.248 GI surgery for neoplasm
-0.14 Respiratory insufficiency after OR
0.060 GI perforation/obstruction

Postoperative (not otherwise specified)
-1.150 Neurologic
-0.797 Cardiovascular
-0.610 Respiratory
-0.613 Gastrointestinal
-0.196 Metabolic/renal