

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

## Case report form

V 1.08	
V 1.00	
19/09/2019	
15/05/2015	

### **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:		
Age (years)		
Gender: Dale 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):		
<ul> <li>3.3 Admission source</li> <li>Other hospital</li> <li>Emergency department</li> <li>Operating Room/recovery</li> <li>Hospital ward/ floor</li> <li>Other, please specify</li> </ul>		
3.4. Type of admission, one possible answer only (see appendix for definitions):		
<ul> <li>medical</li> <li>surgical</li> <li>elective</li> <li>emergency</li> </ul>		
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

(center code/patient no.): ...... / .....

Section 4 – Blood culture data
<ul> <li>4.1 Timing of the first positive blood culture sampling (study infection, it is time zero of the study):</li> <li>date (day / month / year):</li> <li>time (24h clock; e.g. 23:59):</li> </ul>
<b>4.2 Time to positivity</b> hours – or tick 🗌 if unknown/ not reported.
<b>4.3 Presumed source of the bloodstream infection:</b> (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 ( <i>free text comment box</i> )

(center code/patient no.): ...... / .....

### 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 <u>and</u> 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)

Respiratory	
COPD / Chronic Pulmonary Disease Moderate	
COPD / Chronic Pulmonary Disease Severe*	
Cardio-Vascular	
Heart Failure (NYHA 3)	
Heart Failure (NYHA 4)	
Previous Myocardial infarction	
Peripheral vascular disease	
Neurological	
Cerebro-vascular disease	
Dementia	
Hemiplegia	
Metabolic	
Diabetes without end organ damage	
Diabetes with end organ damage	
Renal disease, moderate	
Renal disease, receiving chronic dialysis	
Connective tissue disease	
Gastro-intestinal	
Ulcer disease (gastro-duodenal)	
Liver disease, mild to moderate	
Liver disease, severe*	
Immunosuppression	
Steroids > 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)	
Malignancy	
Malignancy – solid tumours (active only and without	
metastasis)	
Malignancy – solid tumours (Proven metastasis)	
Head and Neck	
Lung	
Gastro-intestinal	
Gynaecological	

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
<ul> <li>6.1 Severity, Organ dysfunctions and septic shock on ICU admission</li> <li>Please enter worse values of the first 24H following ICU admission.</li> <li>(to obtain organ dysfunctions present on ICU admission, SAPS 2, SOFA SCORE, qSOFA and calculate sepsis 3)</li> <li>All data from ICU</li> </ul>
Was there an infection (proven or suspected) on ICU admission Yes (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)
<ul> <li>Renal replacement therapy: Intermittent Haemodialysis</li> <li>Renal replacement therapy: Continuous Veno-Venous Hemo(dia)Filtration</li> <li>Renal replacement therapy: SLEDD</li> </ul>
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 FiO2	Unit selector (mmHg, kPa) % (please enter paired PaO2/FiO2 for the worse value of the 24h)
рН	
Lactate _	(max) mmol/l
BUN or serum	Urea (max value) Unit selector (mg/dL, mmol/L)
Creatinine	(max) Unit selector (mg/dL, μmol/L)

EUROBACT II Case	Report Form	Center/Patient ID	
		(center code/patient no.):/	
Sodium (mmol/l)	(min)		
Potassium (mmol/L)	(min) _	(max)	
Bicarbonate (mmol/l	.) (min) _	(max)	
Bilirubin	(max) Unit selector mg/dL	(μmol/L)	
Haematocrit	%		
Platelet count	(min)	Unit selector (x 10 <sup>3</sup> /mm <sup>3</sup> , 10 <sup>3</sup> /µL, cells/mm3)	
White Blood Cell count (min) (max) Unit selector (x 10³/mm³, 10³/µL, cells/mm3)			
Neutrophil count	(min) Unit selector (x 10 <sup>3</sup> /	mm³, 10³/μL, cells/mm3)	
Lymphocyte count	· · ·	mm³, 10³/μL ,cells/mm3).	
CRP	(max) mg/	′L	
Procalcitonin	(max) ng	/mL	

## 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 2<sup>nd</sup> 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 duri	ng the 1 <sup>st</sup> 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 ( <i>if yes pops the question:</i> )
Maximum do	ose 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)

EUROBACT II Case Report Form	Center/Patient ID
	(center code/patient no.): /
urine output ml/2	4h
PaO2 Unit selector ( FiO2% (please enter p	mmHg, kPa) aired PaO2/FiO2 for the worse value of the 24h)
BUN or serum Urea (max value) Unit selector (mg/dL, mmo	ol/L)
Creatinine (max) Unit selector (mg/dl	., μmol/L)
Sodium (mmol/l) (min) _	(max)
Potassium (mmol/L) (min)	(max)
Bicarbonate (mmol/L) (min) _	(max)
рН	
Lactate (max) mmol/l	
Bilirubin (max) Unit selector mg/dL	(μmol/L)
White Blood Cell count (min) Unit selector (x 10 <sup>3</sup> /	(max) mm <sup>3</sup> , 10 <sup>3</sup> /μL, cells/mm3)
CRP(max) mg/	Έ
Procalcitonin(max) ng	/mL

(center code/patient no.): ...... / .....

## 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

Venti	lation	status

<ul> <li>Invasive Mechanical Ventilation</li> <li>Non-Invasive Mechanical Ventilation or CPAP</li> <li>High Flow Oxygen Nasal Canula</li> <li>Low flow Oxygen or no oxygen</li> <li>Please enter the highest level of ventilation that the patient has received for those 24H</li> <li>(Invasive &gt; non-invasive&gt;high&gt;low flow oxygen)</li> </ul>		
·	by: Intermittent Haemodialysis by: Continuous Veno-Venous Hemo(dia)Filtration by: SLEDD	
ECMO : Veno-Venous		
	e or Noradrenaline on the day of Blood Culture sampling elector (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.

Hyporeactiv	nd normal neurological status e delirium um
PaO2 FiO2	<ul> <li>Unit selector (mmHg, kPa)</li> <li>% (please enter paired PaO2/FiO2 for the worse value of the 24h)</li> </ul>
Lactate	_ (max) mmol/l
Creatinine	(max) Unit selector (mg/dL, μmol/L)
White Blood Cell cour	nt (min) (max) Unit selector (x 10³/mm³, 10³/μL ,cells/mm3).
Neutrophil count	(min) Unit selector (x 10³/mm³, 10³/μL, cells/mm3)
Lymphocyte count	(min) Unit selector (x 10³/mm³, 10³/μL ,cells/mm3).
Platelet count	(min) Unit selector (x 10³/mm³, 10³/μL, cells/mm3)
Bilirubin	(max) Unit selector mg/dL (μmol/L)
CRP	(max) mg/L
Procalcitonin	(max) ng/mL

#### (center code/patient no.): ...... / .....

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

(center code/patient no.): ...... / .....

#### Section 8: Management of blood stream infection

#### 8.1 Antimicrobial therapy

Please enter all antimicrobials that were administered starting the <u>2 days before</u> 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 Date of the last dose	dd/mm/yyyy , hh:mm dd/mm/yyyy
Inte	er daily dose ermittent infusion ended infusion (duration > 3 hours) tinuous infusion erosolized Intra-Muscular
Was a loading dose administered? If yes, how mu	yes No ch (gram/milligram/unit)
Total dose on the first 24 hours of th	erapy (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)		
	2 <sup>nd</sup> 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		
Re	ason 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 / antibiotic	s 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

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

(center code/patient no.): ...... / .....

### 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 <u>Steroids</u> 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 <u>G-CSF</u> or GM-CSF 🗌
If ticked YES eCRF to display dropdown with 1 to 7 days
If yes, number of days

Did the patient receive <u>IFN-γ</u>
If ticked YES eCRF to display dropdown with 1 to 7 days
If yes, number of days

Did the patient receive <u>Blood Purification Techniques</u> 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 b	v the e-CRF)
Day / is the		/	curcurated of	<i>y</i> the e end <i>y</i>

Adrenaline	Yes	No	
Noradrenaline	e 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) (n	nax)
---------------------------------	------

Temperature

\_\_\_\_\_ (min) \_\_\_\_\_ (max) Unit selector (C or F)

ml/24h

urine output

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) % (please enter paired PaO2/FiO2 for the worse value of the 24h) FiO2 (max) mmol/l Lactate Creatinine (max) Unit selector (mg/dL,µmol/L) Bilirubin \_\_\_\_\_ (max) Unit selector mg/dL (µmol/L) \_\_\_\_ (min) \_\_\_\_ (max) White Blood Cell count

Unit selector (x  $10^3$ /mm<sup>3</sup>,  $10^3$ /µL ,cells/mm<sup>3</sup>).

Neutrophil count \_\_ (min) Unit selector (x  $10^3$ /mm<sup>3</sup>,  $10^3$ /µL, cells/mm<sup>3</sup>)

(min) Lymphocyte count Unit selector (x  $10^3$ /mm<sup>3</sup>,  $10^3$ /µL ,cells/mm<sup>3</sup>).

Platelet count \_\_\_\_ (min) Unit selector (x 10<sup>3</sup>/mm<sup>3</sup>, 10<sup>3</sup>/µL, cells/mm3)

CRP \_\_\_\_\_ (max) mg/L

(max) ng/mL Procalcitonin

#### 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
<ul> <li><b>10.2 Subsequent bacteraemia (d7-d28)</b></li> <li>Was there any other positive blood culture between day 7 and day 28.</li> <li>Yes NO</li> </ul>
Was there any other positive blood culture between day 7 and day 28.

Same Bacteria
 Other Bacteria (this opens selection of bacteria, same as initial one)

(center code/patient no.): ...... / .....

#### **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)

(center code/patient no.): ...... / .....

#### 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 failureor history of chronic renal insufficiency with a serum creatinine > 3.6 g/dL ( $300 \mu \text{mol/L}$ ).

- 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 aneursym

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

### (center code/patient no.): ...... / .....

- -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