

GAinS Country Code **UK** Centre ID Study No. Pt. Initials

Clinical Report Form

Genomic Advances in Sepsis (GAinS)

A multi-centre collaborative study of the genetic factors predisposing to sepsis and influencing its progression and outcome

From: UK Critical Care Genomics
(UKCCG)



Guidelines:

- Apply inclusion and exclusion criteria on page 5
- Obtain consent from patient or next of kin - page 5
- Time clock begins from date/time of ICU admission
- Stick CRF bar-code label onto indicated space on page 5 and page 24
- Try to obtain Day 1 blood sample for plasma and a urine sample during 1st 24 hr of ICU admission (selected centres only).
If patients are admitted at night, samples could be taken on the morning of the next day. This is OK. Subsequent samples will be taken at 24 hr intervals thereafter
- Blood for DNA and cell lines can be taken any time during hospital/ICU admission - put in pre-addressed box and mail (all centres) - Pg 6
- Complete Ethnicity Questionnaire - Pg 7
- Complete clinical data sheets for days 1, 2, 3, 5 and 7
- Complete Diagnostic & Microbiological data - Pg 10
- Complete Charleson and Infection Risk Factor Index when possible from patient or next of kin - Pg 11
- Antibiotic Prescription - Pg 20 and 21
- Additional infection audit - Pg 22
- ICU Outcome data (end of Pt 1 of form) - Pg 23
- Final outcome (hospital and 6 months, Pt 2) - Pg 24

Checklist: tick box when complete

ICU Day	Day 1 (1st 24 Hr)	Day 2	Day 3	Day 5	Day 7
Clinical Data <i>All centres</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comorbidity/ Risk Factors <i>All centres (once, any day)</i>	<input type="checkbox"/>				
DNA blood <i>All centres (once, any day)</i>	<input type="checkbox"/>				
Plasma <i>Selected GAInS centres</i>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	
Urine <i>Selected GAInS centres</i>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	
Cell line blood <i>Selected GAInS centres (once, any day)</i>	<input type="checkbox"/>				

Part 1

ICU Admission Days

When the patient is discharged from ICU retain photocopy of Part 1 on-site. Send original Part 1 to the GAInS Coordinator, Oxford in the pre-paid, pre-addressed envelope

Blood Sample for DNA should be mailed to the William Harvey Research Institute, London in the pre-paid, pre-addressed box as soon as possible after the sample has been drawn

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CLINICAL DEFINITIONS and GUIDELINES

FAECAL PERITONITIS

Inflammation of the serosal membrane that lines the abdominal cavity secondary to contamination by faeces as diagnosed at laparotomy. Usually associated with colonic perforation, disruption or anastomotic breakdown. Excludes peritonitis due to **gastric or upper GI-tract perforation** e.g. gastric or duodenal ulcer perforation, terminal ileum perforation.

COMMUNITY ACQUIRED PNEUMONIA

Febrile illness, associated with cough, sputum production, breathlessness, leukocytosis and radiological features of pneumonia acquired in the community (or within less than 2 days of hospital admission).

IMMUNOCOMPROMISE

- known regular systemic corticosteroid therapy (exceeding 7mg/kg/day of hydrocortisone or equivalent) within three months of admission and prior to acute episode.
- known regular therapy with other immunosuppressive agents (e.g. azathioprine).
- known to be HIV positive or have acquired immunodeficiency syndrome as defined by the Centre for Disease Control.
- neutrophil count less than 1000 mm⁻³ due to any cause including metastatic disease and haematological malignancies or chemotherapy, but excluding severe sepsis.
- an organ or bone marrow transplant receiving immuno-suppressive therapy.

GLASGOW COMA SCORE

EYE (4 max)	Open spontaneously - 4, Eye opening to verbal command - 3, Eye opening to pain - 2, No response - 1
MOTOR (6 max)	Obeys verbal commands - 6, Localises to pain - 5, Withdraws from pain - 4, Flexion to pain - 3, Extension to pain - 2, No response - 1
VERBAL (5 max)	Oriented and converses - 5, Confused - 4, Inappropriate words - 3, Incomprehensible sounds - 2, No response - 1

If patient is sedated make best estimate of underlying coma score e.g. pre-sedation score

PREQUALIFYING CRITERIA and CONSENT

Apply CRF bar-code label here

INCLUSION CRITERIA (✓one for each)

- 1. Patient, or legal representative are able to give informed consent Yes
- 2. Male or female of 18 yrs or more Yes
- 3. Patient admitted to ICU/HDU with FAECAL PERITONITIS or COMMUNITY ACQUIRED PNEUMONIA - see definitions Pg 4 Yes

Only enter the patient to the study if all inclusion criteria answered YES

EXCLUSION CRITERIA (✓one for each)

- 1. Patient or legal representative is unwilling to consent No
- 2. Patient is under the age of 18 yrs No
- 3. Patient is already enrolled in an interventional study No
- 4. Patient is immunocompromised - see definitions Pg 4 No
- 5. Patient is pregnant No
- 6. An advance directive to withhold or withdraw life-sustaining treatment or admitted for palliative care only No

Only enter patient to the study if all exclusion criteria answered NO

CONSENT

Written consent obtained from patient, or legal representative (tick box). Yes

Consent obtained by (Insert name)

Signed Date

Surviving patients must confirm consent when deemed competent (see pages 23 and 24)

BLOOD AND URINE SAMPLING LOG

For all participating ICU/HDUs - Any day during ICU/HDU admission

Date format e.g. 16 AUG 05

20 ml whole blood in EDTA for DNA Yes Date taken

DNA sample drawn as 2 X 10 ml whole-blood samples in EDTA tubes. Return as soon as possible to coordinating centre in pre-addressed, Royal Mail package. Do not freeze.

For selected ICU/HDUs - On specified days

DAY 1 (insert date sample taken) Date format e.g. 16 AUG 05

10 ml EDTA for plasma Yes . Time (24 hr clock)

20 ml urine sample Yes . Time (24 hr clock)

DAY 3 (insert date sample taken) Date format e.g. 16 AUG 05

10 ml EDTA for plasma Yes . Time (24 hr clock)

20 ml urine sample Yes . Time (24 hr clock)

DAY 5 (insert date sample taken) Date format e.g. 16 AUG 05

10 ml EDTA for plasma Yes . Time (24 hr clock)

20 ml urine sample Yes . Time (24 hr clock)

For selected ICU/HDUs - On any ICU day

Date format e.g. 16 AUG 05

8.5 ml blood in ACD for cell line Yes Date taken

Plasma samples- from 10 ml EDTA whole blood, chill centrifuge at 1600 RCG for 10 min, pipette 500 microlitre plasma into 8 X 2 ml cryotubes. Store at minus 20°C to minus 80°C. For transfer to coordinating centre on dry-ice by pre-arranged courier.

Urine samples - 20 ml aliquotted to 2 X 10 ml cryotubes, Store at minus 20°C to minus 80°C. For transfer to coordinating centre on dry-ice by pre-arranged courier.

Cell line preservation 10 ml whole blood into ACD tube. Return as soon as possible to coordinating centre in pre-addressed, Royal Mail package. Do NOT freeze.

Ethnicity Questionnaire (✓one for each group)

	Patient			
White/Caucasian	<input type="checkbox"/>			
Black	<input type="checkbox"/>			
Hispanic	<input type="checkbox"/>			
Asian	<input type="checkbox"/>			
Mediterranean	<input type="checkbox"/>			
Chinese	<input type="checkbox"/>			
Mixed	<input type="checkbox"/>			
Not Known	<input type="checkbox"/>			

	Patient's Mother		Patient's Father	
White/Caucasian	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Black	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hispanic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Asian	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Mediterranean	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Chinese	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Mixed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Not Known	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Mother's Mother		Mother's Father		Father's Mother		Father's Father	
White/Caucasian	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Black	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Hispanic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Asian	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Mediterranean	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Chinese	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Mixed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Not Known	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

DAY 1 ICU - FIRST 24 HR

PATIENT AGE **YEARS**

Date format e.g. 16 AUG 05

DATE OF HOSPITAL ADMISSION

DATE OF ICU ADMISSION

TIME OF ICU ADMISSION

. (24 hr clock)

Temperature (°C)	Highest	<input type="text"/> <input type="text"/> . <input type="text"/>	Lowest	<input type="text"/> <input type="text"/> . <input type="text"/>
White blood cell count (cells/mm ³)	Highest	<input type="text"/> <input type="text"/> . <input type="text"/>	Lowest	<input type="text"/> <input type="text"/> . <input type="text"/>
>10% immature neutrophils (if known)	Yes	<input type="checkbox"/>	Not available	<input type="checkbox"/>
Haematocrit (%)	Highest	<input type="text"/> <input type="text"/>	Lowest	<input type="text"/> <input type="text"/>
Platelet Count (10 ³ /mm ³)			Lowest	<input type="text"/> <input type="text"/> <input type="text"/>
D-dimer (µg/L)	Highest	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		

CVS

Heart rate (b/min)	Highest	<input type="text"/> <input type="text"/> <input type="text"/>	Lowest	<input type="text"/> <input type="text"/> <input type="text"/>
Mean BP (mmHg)	Highest	<input type="text"/> <input type="text"/> <input type="text"/>	Lowest	<input type="text"/> <input type="text"/> <input type="text"/>
Systolic BP (mmHg)	High	<input type="text"/> <input type="text"/> <input type="text"/>	Lowest	<input type="text"/> <input type="text"/> <input type="text"/>
"Adequate" fluid resuscitation	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Dobutamine (any dose)	Yes	<input type="checkbox"/>		
Dopamine		<input type="text"/> . <input type="text"/> <input type="text"/> (Highest dose µg/Kg/min)		
Epinephrine		<input type="text"/> . <input type="text"/> <input type="text"/> (Highest dose µg/Kg/min)		
Norepinephrine		<input type="text"/> . <input type="text"/> <input type="text"/> (Highest dose µg/Kg/min)		
Other Pressor/Inotrope (specify)	Yes	<input type="checkbox"/>		

RS/Acid-Base

Respiratory rate (spont or MV, resp/min)	Highest	<input type="text"/> <input type="text"/>	Lowest	<input type="text"/> <input type="text"/>
PaO ₂ (kPa)			Lowest	<input type="text"/> <input type="text"/> . <input type="text"/>
Associated PaCO ₂ (kPa)		<input type="text"/> <input type="text"/> . <input type="text"/>		
Associated FiO ₂		<input type="text"/> . <input type="text"/> <input type="text"/>		
With Respiratory Support**	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Arterial pH	Highest	<input type="text"/> . <input type="text"/> <input type="text"/>	Lowest	<input type="text"/> . <input type="text"/> <input type="text"/>
Base excess/deficit	Highest plus	<input type="text"/> <input type="text"/> . <input type="text"/>	Lowest minus	<input type="text"/> <input type="text"/> . <input type="text"/>
Blood Lactate (mmol/l)	Highest	<input type="text"/> <input type="text"/> . <input type="text"/>		

** Respiratory support includes positive pressure ventilation or CPAP via mask, LMA, ET tube or tracheotomy tube

DAY 1 ICU - FIRST 24 hr - continued

LIVER

Bilirubin (mcmol/l) Highest
 AST or ALT (either variable, IU/L) Highest AST ALT
 INR (ratio) or PT (sec) Highest . INR or . PT
 Systemic anti-coagulation Yes No

CNS

Glasgow Coma Score (out of 15) Best - pre-sedation/intubation value

RENAL

Creatinine (mmol/l) Highest
 Urine Output (ml/24 hr) Total
 Is this acute renal failure? Yes No
 Renal support given? Yes No

* Includes CVVHF, haemodialysis, PD

SERUM ELECTROLYTES

Sodium (mmol/l) Highest Lowest
 Potassium (mmol/l) Highest . Lowest .

OPERATIVE STATUS

Emergency Postoperative Yes No
 Elective Postoperative Yes No

***CHRONIC HEALTH POINTS** (✓one) Yes No

For chronic health points, organ insufficiency or immunocompromised state must have preceded the current admission: Immunocompromised if: (1) receiving therapy reducing host defenses (immuno-suppression, Chemotherapy, radiation therapy, long term steroid use high dose steroid therapy) or (2) has a disease severe enough to interfere with immune function such as malignant lymphoma, leukemia or AIDS.

*Liver insufficiency if: (1) biopsy proven cirrhosis (2) portal hypertension (3) episodes of upper GI bleeding due to portal hypertension (4) prior episodes of hepatic failure, coma or encephalopathy.

*Cardiovascular insufficiency if: New York Heart Association Class IV

*Respiratory insufficiency if: (1) severe exercise restriction due to chronic restrictive, obstructive or vascular disease (2) documented chronic hypoxia, hypercapnia, secondary polycythaemia, severe pulmonary hypertension (3) respirator Dependency. Renal insufficiency if: on chronic dialysis

CHEST RADIOGRAPH - Date taken (Date format e.g. 16 AUG 05)

Lung infiltrates Yes No
 - Lobar
 - Localised
 - Diffuse Bilateral
 Cardiogenic pulmonary oedema? Yes No

DIAGNOSTIC & MICROBIOLOGICAL DATA

Estimated Day of Onset of Faecal Peritonitis or Community Acquired Pneumonia prior to ICU admission day days

If onset occurred on ICU admission day indicate 0 days (zero days)

Cause of faecal peritonitis (underlying pathology) (✓one for each)

- Surgical colonic anastomosis breakdown
- Colonic perforation due to malignancy
- Colonic perforation due to diverticular disease
- Colonic perforation due to trauma
- Colonic perforation due to other (state cause)

Diagnosis confirmed by 2nd experienced clinician Yes

Cause of Community Acquired Pneumonia (organism) (✓one for each)

- Streptococcus pneumoniae*
- Haemophilus influenzae*
- Mycoplasma pneumoniae*
- Legionella spp.*
- Chlamydia pneumoniae*
- Staphylococcus aureus*
- Pseudomonas aeruginosa*
- Mixed organisms
- Not known
- Virus (state type if known)
- Other (state organism)

Lung organism identification based on: (✓one for each)

- Culture of lung fluid
- Blood Culture
- Serology
- Other technique (state type)

Diagnosis confirmed by 2nd experienced clinician Yes

CHARLESON COMORBIDITY AND INFECTION RISK FACTORS

Childhood illnesses (NAME unusually severe, prolonged or recurrent)

- 1.
- 2.
- 3.
- 4.

(✓one for each)

(✓one for each)

Heart disease/Vascular disease

Malignant or Immune Disease*

- Angina
- Arrhythmia
- Valvular
- Myocardial infarction
- Congestive Heart failure
- Peripheral vascular disease
- Other (state.....)

- Tumour
- Lymphoma
- Leukaemia
- Metastatic disease
- Rheumatoid arthritis
- SLE
- Other (state.....)

* If ✓ to any of these criteria please review exclusion criteria

Respiratory disease

Diabetes mellitus

- COPD
- Asthma
- Cystic fibrosis
- Home oxygen or ventilation
- Other (state.....)
- Never smoked

- Diabetes (insulin dependent)
- Diabetes (non-insulin dep.)
- Diabetes with organ damage

Neurologic Disease

Serious infections

- Stroke or hemiplegia
- Dementia
- Other (state.....)

- Unusually Severe
- Unusually Recurrent
- Unusually Prolonged

Gastrointestinal disease

Other illnesses

- Moderate or severe Liver disease
- GI bleeding
- Inflammatory bowel disease
- Other (state.....)

- Major surgery
- ICU admissions for any reason
- Other (state.....)
- Other (state.....)
- Other (state.....)

Renal disease

- Moderate or severe renal disease
- Other (state.....)

DAY 2 ICU - 2nd 24 hour period

Date format e.g. 16 AUG 05

STARTING DATE AND TIME of 2nd 24 HR PERIOD

(See time of admission on day 1) (24 hr clock)

Temperature (°C) Highest Lowest

White blood cell count (cells/mm³) Highest Lowest

>10% immature neutrophils (if known) Yes N/A

Platelet count (10³/mm³) Lowest

D-dimer (µg/L) Highest

CVS

Heart rate (b/min) Highest Lowest

Mean BP (mmHg) Highest Lowest

Systolic BP (mmHg) Highest Lowest

“Adequate” fluid resuscitation Yes No

Dobutamine (any dose) Yes

Dopamine (Highest dose µg/Kg/min)

Epinephrine (Highest dose µg/Kg/min)

Norepinephrine (Highest dose µg/Kg/min)

Other Pressor/Inotrope (specify) Yes

RS/Acid-Base

Resp. rate (spont or MV, resp/min) Highest Lowest

PaO₂ (kPa) Lowest

Associated FiO₂

With Respiratory Support** Yes No

Arterial pH Highest Lowest

Base excess/deficit Highest plus Lowest minus

Blood Lactate (mmol/l) Highest

** Respiratory support includes positive pressure ventilation or CPAP via mask, LMA, ET tube or tracheotomy tube

DAY 2 ICU - 2nd 24 hr period - continued

LIVER

Bilirubin (mcmol/l) Highest
 AST or ALT (either variable, IU/L) Highest AST ALT
 INR or PT Highest . INR or . PT sec
 Systemic anti-coagulation* Yes No

*(Warfarin or heparin in anticoagulant doses)

CNS

Glasgow Coma Score (out of 15) Best - best pre-sedation/intubation value

RENAL

Creatinine (mmol/l) Highest
 Urine Output (ml/24 hr) Total
 Renal support given?* Yes No

* Includes CVVHF, haemodialysis, Peritoneal Dialysis

CHEST RADIOGRAPH - if there is no new CXR on Day 2 please leave blank

Date taken (Date format e.g. 16 AUG 05)

Lung infiltrates Yes No
 - Lobar
 - Localised
 - Diffuse Bilateral

Cardiogenic pulmonary oedema? Yes No

Comments (please print):

DAY 3 ICU - 3rd 24 hour period

Date format e.g. 16 AUG 05

STARTING DATE AND TIME of 3rd 24 HR PERIOD

(See time of admission on day 1)

. (24 hr clock)

Temperature (°C)	Highest	<input type="text"/> <input type="text"/> . <input type="text"/>	Lowest	<input type="text"/> <input type="text"/> . <input type="text"/>
White blood cell count (cells/mm ³)	Highest	<input type="text"/> <input type="text"/> . <input type="text"/>	Lowest	<input type="text"/> <input type="text"/> . <input type="text"/>
>10% immature neutrophils (if known)	Yes	<input type="checkbox"/>	N/A	<input type="checkbox"/>
Platelet count (10 ³ /mm ³)			Lowest	<input type="text"/> <input type="text"/> <input type="text"/>
D-dimer (µg/L)	Highest	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		

CVS

Heart rate (b/min)	Highest	<input type="text"/> <input type="text"/> <input type="text"/>	Lowest	<input type="text"/> <input type="text"/> <input type="text"/>
Mean BP (mmHg)	Highest	<input type="text"/> <input type="text"/> <input type="text"/>	Lowest	<input type="text"/> <input type="text"/> <input type="text"/>
Systolic BP (mmHg)	Highest	<input type="text"/> <input type="text"/> <input type="text"/>	Lowest	<input type="text"/> <input type="text"/> <input type="text"/>
“Adequate” fluid resuscitation	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Dobutamine (any dose)	Yes	<input type="checkbox"/>		
Dopamine		<input type="text"/> . <input type="text"/> <input type="text"/> (Highest dose µg/Kg/min)		
Epinephrine		<input type="text"/> . <input type="text"/> <input type="text"/> (Highest dose µg/Kg/min)		
Norepinephrine		<input type="text"/> . <input type="text"/> <input type="text"/> (Highest dose µg/Kg/min)		
Other Pressor/Inotrope (specify)	Yes	<input type="checkbox"/>	

RS/Acid-Base

Respiratory rate (spont or MV, resp/min)	Highest	<input type="text"/> <input type="text"/> <input type="text"/>	Lowest	<input type="text"/> <input type="text"/> <input type="text"/>
PaO ₂ (kPa)	Lowest	<input type="text"/> <input type="text"/> . <input type="text"/>		
Associated FiO ₂		<input type="text"/> . <input type="text"/> <input type="text"/>		
With Respiratory Support**	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Arterial pH	Highest	<input type="text"/> . <input type="text"/> <input type="text"/>	Lowest	<input type="text"/> . <input type="text"/> <input type="text"/>
Base excess/deficit	Highest plus	<input type="text"/> <input type="text"/> . <input type="text"/>	Lowest minus	<input type="text"/> <input type="text"/> . <input type="text"/>
Serum Lactate (mmol/l)	Highest	<input type="text"/> <input type="text"/> . <input type="text"/>		

** Respiratory support includes positive pressure ventilation or CPAP via mask, LMA, ET tube or tracheotomy tube

DAY 3 ICU - 3rd 24 hr period - continued

LIVER

Bilirubin (mcmol/l) Highest
 AST or ALT (either variable, IU/L) Highest AST ALT
 INR or PT Highest . INR or . PT sec
 Systemic anti-coagulation* Yes No

*(Warfarin or heparin in full anticoagulant doses)

CNS

Glasgow Coma Score (out of 15) Best - best pre-sedation/intubation value

RENAL

Creatinine (mmol/l) Highest
 Urine Output (ml/24 hr) Total
 Renal support given?* Yes No

* Includes CVVHF, haemodialysis, Peritoneal Dialysis

CHEST RADIOGRAPH - if there is no new CXR on Day 3 please leave blank

Date taken (Date format e.g. 16 AUG 05)

Lung infiltrates Yes No
 - Lobar
 - Localised
 - Diffuse Bilateral

Cardiogenic pulmonary oedema? Yes No

Comments (please print):

DAY 5 ICU - 5th 24 hour period

Date format e.g. 16 AUG 05

STARTING DATE AND TIME of 5th 24 HR PERIOD

(See time of admission on day 1)

. (24 hr clock)

Temperature (°C)	Highest	<input type="text"/> <input type="text"/> . <input type="text"/>	Lowest	<input type="text"/> <input type="text"/> . <input type="text"/>
White blood cell count (cells/mm ³)	Highest	<input type="text"/> <input type="text"/> . <input type="text"/>	Lowest	<input type="text"/> <input type="text"/> . <input type="text"/>
>10% immature neutrophils (if known)	Yes	<input type="checkbox"/>	N/A	<input type="checkbox"/>
Platelet count (10 ³ /mm ³)			Lowest	<input type="text"/> <input type="text"/> <input type="text"/>
D-dimer (µg/L)	Highest	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		

CVS

Heart rate (b/min)	Highest	<input type="text"/> <input type="text"/> <input type="text"/>	Lowest	<input type="text"/> <input type="text"/> <input type="text"/>
Mean BP (mmHg)	Highest	<input type="text"/> <input type="text"/> <input type="text"/>	Lowest	<input type="text"/> <input type="text"/> <input type="text"/>
Systolic BP (mmHg)	Highest	<input type="text"/> <input type="text"/> <input type="text"/>	Lowest	<input type="text"/> <input type="text"/> <input type="text"/>
“Adequate” fluid resuscitation	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Dobutamine (any dose)	Yes	<input type="checkbox"/>		
Dopamine		<input type="text"/> . <input type="text"/> <input type="text"/> (Highest dose µg/Kg/min)		
Epinephrine		<input type="text"/> . <input type="text"/> <input type="text"/> (Highest dose µg/Kg/min)		
Norepinephrine		<input type="text"/> . <input type="text"/> <input type="text"/> (Highest dose µg/Kg/min)		
Other Pressor/Inotrope (specify)	Yes	<input type="checkbox"/>	

RS/Acid-Base

Respiratory rate (spont or MV, resp/min)	Highest	<input type="text"/> <input type="text"/> <input type="text"/>	Lowest	<input type="text"/> <input type="text"/> <input type="text"/>
PaO ₂ (kPa)	Lowest	<input type="text"/> <input type="text"/> . <input type="text"/>		
Associated FiO ₂		<input type="text"/> . <input type="text"/> <input type="text"/>		
With Respiratory Support**	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Arterial pH	Highest	<input type="text"/> . <input type="text"/> <input type="text"/>	Lowest	<input type="text"/> . <input type="text"/> <input type="text"/>
Base excess/deficit	Highest plus	<input type="text"/> <input type="text"/> . <input type="text"/>	Lowest minus	<input type="text"/> <input type="text"/> . <input type="text"/>
Blood Lactate (mmol/l)	Highest	<input type="text"/> <input type="text"/> . <input type="text"/>		

** Respiratory support includes positive pressure ventilation or CPAP via mask, LMA, ET tube or tracheotomy tube

DAY 5 ICU - 5th 24 hr period - continued

LIVER

Bilirubin (mcmol/l) Highest
 AST or ALT (either variable, IU/L) Highest AST ALT
 INR or PT Highest . INR or . PT sec
 Systemic anti-coagulation* Yes No

*(Warfarin or heparin in anticoagulant doses)

CNS

Glasgow Coma Score (out of 15) Best - best pre-sedation/intubation value

RENAL

Creatinine (mmol/l) Highest
 Urine Output (ml/24 hr) Total
 Renal support given?* Yes No

* Includes CVVHF, haemodialysis, Peritoneal Dialysis

CHEST RADIOGRAPH - if there is no new CXR on Day 4 or 5 please leave blank

Date taken (Date format e.g. 16 AUG 05)

Lung infiltrates Yes No
 - Lobar
 - Localised
 - Diffuse Bilateral

Cardiogenic pulmonary oedema? Yes No

Comments (please print):

DAY 7 ICU - 7th 24 hour period

Date format e.g. 16 AUG 05

STARTING DATE AND TIME of 7th 24 HR PERIOD

(See time of admission on day 1)

. (24 hr clock)

Temperature (°C)	Highest	<input type="text"/> <input type="text"/> . <input type="text"/>	Lowest	<input type="text"/> <input type="text"/> . <input type="text"/>
White blood cell count (cells/mm ³)	Highest	<input type="text"/> <input type="text"/> . <input type="text"/>	Lowest	<input type="text"/> <input type="text"/> . <input type="text"/>
>10% immature neutrophils (if known)	Yes	<input type="checkbox"/>	N/A	<input type="checkbox"/>
Platelet count (10 ³ /mm ³)			Lowest	<input type="text"/> <input type="text"/> <input type="text"/>
D-dimer (µg/L)	Highest	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		

CVS

Heart rate (b/min)	Highest	<input type="text"/> <input type="text"/> <input type="text"/>	Lowest	<input type="text"/> <input type="text"/> <input type="text"/>
Mean BP (mmHg)	Highest	<input type="text"/> <input type="text"/> <input type="text"/>	Lowest	<input type="text"/> <input type="text"/> <input type="text"/>
Systolic BP (mmHg)	Highest	<input type="text"/> <input type="text"/> <input type="text"/>	Lowest	<input type="text"/> <input type="text"/> <input type="text"/>
“Adequate” fluid resuscitation	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Dobutamine (any dose)	Yes	<input type="checkbox"/>		
Dopamine		<input type="text"/> . <input type="text"/> <input type="text"/>	(Highest dose µg/Kg/min)	
Epinephrine		<input type="text"/> . <input type="text"/> <input type="text"/>	(Highest dose µg/Kg/min)	
Norepinephrine		<input type="text"/> . <input type="text"/> <input type="text"/>	(Highest dose µg/Kg/min)	
Other Pressor/Inotrope (specify)	Yes	<input type="checkbox"/>	

RS/Acid-Base

Respiratory rate (spont or MV, resp/min)	Highest	<input type="text"/> <input type="text"/> <input type="text"/>	Lowest	<input type="text"/> <input type="text"/> <input type="text"/>
PaO ₂ (kPa)	Lowest	<input type="text"/> <input type="text"/> . <input type="text"/>		
Associated FiO ₂		<input type="text"/> . <input type="text"/> <input type="text"/>		
With Respiratory Support**	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Arterial pH	Highest	<input type="text"/> . <input type="text"/> <input type="text"/>	Lowest	<input type="text"/> . <input type="text"/> <input type="text"/>
Base excess/deficit	Highest plus	<input type="text"/> <input type="text"/> . <input type="text"/>	or Lowest minus	<input type="text"/> <input type="text"/> . <input type="text"/>
Blood Lactate (mmol/l)	Highest	<input type="text"/> <input type="text"/> . <input type="text"/>		

** Respiratory support includes positive pressure ventilation or CPAP via mask, ET tube or tracheotomy tube

DAY 7 ICU - 7th 24 hr period - continued

LIVER

Bilirubin (mcmol/l) Highest
 AST or ALT (either variable, IU/L) Highest AST ALT
 INR or PT Highest . INR or . PT sec
 Systemic anti-coagulation* Yes No

*(Warfarin or heparin in anticoagulant doses)

CNS

Glasgow Coma Score (out of 15) Best - best pre-sedation/intubation value

RENAL

Creatinine (mmol/l) Highest
 Urine Output (ml/24 hr) Total
 Renal support given?* Yes No

* Includes CVVHF, haemodialysis, Peritoneal Dialysis

CHEST RADIOGRAPH - if there is no new CXR on Day 6 or 7 please leave blank

Date taken (Date format e.g. 16 AUG 05)

Lung infiltrates Yes No
 - Lobar
 - Localised
 - Diffuse Bilateral

Cardiogenic pulmonary oedema? Yes No

Comments (please print):

ANTIBIOTICS PRESCRIBED (in 1st 7 ICU days for CAP or FP)

Antibiotics appropriate*

Antibiotic - Enter all	Start time 24 hr clock	Start day e.g. 16 AUG 05	End day e.g. 16 AUG 05	Yes	No	Not known
Amoxicillin	<input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ampicillin	<input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Amphotericin	<input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ben Penicillin	<input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cefotaxime	<input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ceftazidime	<input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ceftriaxone	<input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cefuroxime	<input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ciprofloxacin	<input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Clarithromycin	<input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cotrimoxazole	<input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Flucloxacillin	<input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Fluconazole	<input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Gentamicin	<input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Imipenem	<input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Meropenem	<input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Metronidazole	<input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Netilmicin	<input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Piperacillin	<input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Piperacillin/ Tazobactam	<input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Teicoplanin	<input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Vancomycin	<input type="text"/> . <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

More than one course of same antibiotic given? See over page and enter name of antibiotic with prescription details

*i.e. organisms sensitive to antibiotic used based on lab sensitivities or clinical response

ANTIBIOTICS PRESCRIBED but not listed on prior page or given in repeat courses - (in 1st 7 ICU days for CAP or FP)

Antibiotics appropriate*

Antibiotic - Enter all	Start time 24 hr clock	Start day e.g. 16 AUG 05	End day e.g. 16 AUG 05	Yes	No	Not known
Other (state)	<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other (state)	<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other (state)	<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other (state)	<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other (state)	<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other (state)	<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other (state)	<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other (state)	<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other (state)	<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other (state)	<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Antibiotics continued after ICU discharge? Yes

*i.e. organisms sensitive to antibiotic used based on lab sensitivities or clinical response

Comments (please print):

Additional Infection Audit (following CAP or FP)

Other ICU acquired infection? Yes No
(any time during this ICU admission)

If Yes, what was the nature of this infection? (✓one for each)

- Ventilator associated pneumonia (VAP)
- Lower respiratory infection (not VAP)
- Bacteraemia
- Line related infection
- Wound infection
- Urinary tract infection
- Other (describe)
- Other (describe)

Other specific “Sepsis Therapies” used during this admission? Yes No

If Yes, what was the nature of this therapy? (✓one for each)

- Activated protein C (Xigris)
- Corticosteroids
- Early goal-directed resuscitation
- Tight Glycaemic control
- Other (describe)
- Other (describe)

Duration of organ support (estimate cumulative total)

- Number of days of mechanical respiratory support (includes NIV, mask CPAP) days
- Number of days of renal support (includes haemofiltration, diafiltration, dialysis) days
- Number of days of inotrope/pressor support days

Comments (please print):

GAInS Country Code **UK** Centre ID Study No. Pt. Initials

ICU Discharge and Outcome Data

At ICU discharge (tick box) Alive
Dead

Date of ICU discharge or death Date format e.g. 16 AUG 05

What was deemed to be the mode of death? (tick box)

- intractable "sepsis-related" cardiovascular failure
- failure to resolve "sepsis-related" organ(s) failure
- persistent or recurrent sepsis
- limitation of therapy
- unrelated cardiac/pulmonary event
- other unrelated cause

(describe)

Was consent to participate confirmed by patient (if originally obtained from legal representative) Yes No N/A

Now detach Part 1 (Pgs 1-23 covering period of ICU admission) and photocopy. Return original in pre-addressed envelope to GAInS Coordinator, Oxford

Retain photocopy of Part 1 with consent form locally

Retain Part 2 in your files for post ICU follow-up if patient discharged alive from ICU

GAInS Country Code **UK** Centre ID Study No. Pt. Initials

Apply CRF bar-code label
here

Part 2 - Final discharge and outcome data

Retain locally until 6-month follow up completed (unless patient died in ICU or hospital)

At Hospital discharge (tick box) Alive
Dead

Date of hospital discharge or death Date format e.g. 16 AUG 05

What was deemed to be the mode of death? (tick box)

- intractable "sepsis-related" cardiovascular failure
- failure to resolve "sepsis-related" organ(s) failure
- persistent or recurrent sepsis
- limitation of therapy
- unrelated cardiac/pulmonary event
- other unrelated cause (describe)

(describe)

At 6 month post-ICU admission (tick box) Alive
Dead

Date of death (if known) Date format e.g. 16 AUG 05

Still in ICU or hospital at 6 months

Was consent to participate confirmed by patient (if originally obtained from legal representative) Yes No N/A
- ignore if already confirmed during ICU admission

When 6 month data complete return Part 2 original copy in pre-addressed envelope to GAInS coordinator, Oxford.

Please retain photocopy of Part 2 together with photocopy of Part 1 and Consent Form locally in your files.