



Registration for Part 1

The registration form must be faxed to the Data Centre within 72 hours of presentation of an episode of fever*

⁺ Or other vascular access device such as a port.

***Fever defined** as T >38°C for more than four hours, or on two occasions >4hours apart within a 24 hour period, or >38.5°C on one occasion.

Patient identifier: [_S_]M I_ (1 st 3 letters of surname) J_ O (1 st 2 letters of first name)		Male <input checked="" type="checkbox"/> Female <input type="checkbox"/>	Trial Number [_1]2[_3]4 (to be completed by the data centre)
Date of birth: 1_ 3_ . 1_ 0_ . 1_ 9 9_ 9_ (dd mm yyyy)		Diagnosis...ALL..... Date of diagnosis: _ 0_ 1 _ 0_ 1 _ 2 0 0_ 5	
Hospital Number: 7890.....			
Responsible Clinician: John Mitchell			

Check of eligibility criteria

- Patient undergoing treatment for cancer/leukaemia or are immunosuppressed with a severe haematological disorder at a collaborating UKCCSG centre Yes No
- Aged 0 – 18 years inclusive Yes No
- The patient has a tunnelled single, double or triple lumen CVC or implanted vascular port Yes No
- Patient has been afebrile and has not received intravenous antimicrobial therapy in the preceding 2 weeks Yes No
- Written informed consent by parent(s) / patient Yes No
- Blood samples for 16S rDNA analysis (EDTA anticoagulated)** to be collected (with blood cultures) within 72 hours of presentation from each lumen of the vascular access device(s) Yes No

All answers should be 'Yes' for patient to be eligible for the study.

Hospital/Centre: General Hospital.....

Responsible clinician: John Mitchell.....

Signature: Date: 19/08/2005

Please fax completed form to UKCCSG Data Centre.

**This can be an initial sample aspirated from the lumen(s) of the device which would otherwise be discarded. Please use the Vacuette tubes provided – K3E. Samples can be stored frozen at -20 °C or below for collection as a batch or sent directly by post to *Molecular Study (CVC), Department of Microbiology, Pathology Block, Barts Hospital, Smithfield, London, E1 1BB.*



Baseline Infection Form

Complete and return form to the Data Centre within 72 hours of presentation of an episode of fever*

* Or other vascular access device (VAD) such as a port.

*Fever defined as T >38°C for more than four hours, or on two occasions >4 hours apart within a 24 hour period, or >38.5°C on one occasion.

Table with 2 columns: Symptom description, and an empty box for recording.

Date fever confirmed [][]/[][]/[][][][][] (dd mm yyyy) (please copy this date to page 1 of form 3)

Time confirmed 24hr clock _ _ / _ _

Patient identifier: [][][] (1st 3 letters of surname) [][] (1st 2 letters of first name)
Date of birth: [][]/[][]/[][][][][] (dd mm yyyy) Trial Number [][][][][]
Please fill trial number onto form 3

Target date for filling in form 3 (4 weeks from date of fever presentation) [][]/[][]/[][][][] (ddmm yyyy) Copy date to form 3

Date blood cultures collected [][]/[][]/[][][][] (dd mm yyyy) [][]/[][]/[][][][] (dd mm yyyy)

Date blood samples collected for 16S rDNA analysis [][]/[][]/[][][][] (dd mm yyyy) Please use screw cap Vacuette K3E 2ml tubes provided for this study- samples may be stored in a fridge for up to 24 hours and/or in a freezer at 20°C or below for extended periods

Date vascular access device inserted: [][]/[][]/[][][][] (dd mm yyyy)

- Vascular access device => External [], Implanted port [], Other []
Number of lumens => Single [], Double [], Triple []

Method of access of vascular access device (please circle)

Smart site Click lock Direct / open Other

Oral antibiotics at the time of sampling and within 2 weeks before presentation Yes [] No []

Please specify.....

CRP available Yes [] No []
If Yes result.....

Procalcitonin available Yes [] No []
If Yes result.....

Please fill in page 2 and staple to this page



Baseline Infection Form
Completed form to be sent to the Data Centre within 72 hours of presentation of an episode of fever*

Patient identifier: [][][] (1st 3 letters of surname) [][] (1st 2 letters of first name) Trial Number [][][][]
Date of birth: [][]/[][]/[][][][] (dd mm yyyy)

Symptoms or signs (clinical or radiological) of infection – please tick and give details

Table with 3 columns: Symptom/Sign, Description, and a tick box. Rows include: Fever only, Respiratory, Gastrointestinal, Central nervous system (CNS), Cardiac signs, Vascular access device related, Skin, Urinary tract, Septic shock, Other.

1Vascular access device related infection

- Chills/fever/rigors or hypotension associated with access device manipulations? Yes [] No []
Exit site inflammation Yes [] No []
Inflammation along the tunnel
If YES then please specify extent of inflammation from exit site in cms cms

Hospital/Centre:
Clinician responsible for clinical care:
Signature: Date:
Phone: Fax:

To be sent to the UKCCSG Data Centre, University of Leicester, 3rd Floor, Hearts of Oak House, 9 Princess Road West, Leicester LE1 6TH



Infection Summary Form

Complete and return form to the data centre 4 weeks after presentation of an episode of fever*

+ Or other vascular access device (VAD) such as a port.

Please enclose copies of positive microbiology, virology and mycology reports with this form

Form with fields for Patient identifier, Date of birth, Date fever confirmed, Target form return date, and Date form filled in.

Date blood samples sent to Barts [] (dd mm yyyy)

Blood cultures collected within 72 hours of presentation Please specify below dates and time for each lumen of VAD and result

Space is provided for a 1st and a 2nd set of blood cultures collected within the first 72 hours

Table with 4 columns: 1st set, Date, Time, Result (name of isolate only). Rows include Yellow, Red, Blue, Other for both 1st and 2nd sets.

* Please use CoNS as code for Staphylococcus epidermidis/ spp., Coagulase Negative Staph

Additional blood cultures collected in the 72 hrs - 4 weeks after presentation Yes [] No [] If yes, then please add information on positive results to back of this form

Antibiotics prescribed at the time of presentation with fever ? Yes [] No []

Please specify for the four weeks after presentation - the antibiotic, route of administration, duration of treatment

Table with 5 columns: Antibiotic, Start date, Stop date, Dose, Route of administration. Multiple empty rows for data entry.

(Please continue on back of page if insufficient space)

Please also fill in pages 2 and 3 and staple to this page



Infection Summary Form Complete and return form to the date centre 4 weeks after presentation of an episode of fever*

Patient identifier: [][][] (1st 3 letters of surname) [][] (1st 2 letters of first name) Trial Number [][][][] Date of birth: [][].[][].[][][][] (dd mm yyyy)

Date fever abated (<37.5°C f or 24 hour) [][].[][].[][][][] (dd mm yyyy)

Duration of fever (days)

Was the patient treated for Vascular Access Device (VAD) associated infection?* Yes [] No []

(* Requires that all of the lumens of the CVC exposed to antibiotic therapy or VAD removed for suspected infection)

If YES to previous question then -

Did the patient respond to treatment specific for VAD associated infection? ** Yes [] No []

(** Requires resolution of fever within 5 days of the initiation of treatment (all lumens of CVC exposed to antibiotic t or VAD removal) and no recurrence within 5 days of discontinuation of antibiotic treatment or VAD removal)

Did fever recur within 5 days of stopping antibiotic therapy or removal of VAD? Yes [] No []

Vascular Access Device removed for suspected infection Yes [] No []

If Yes then please specify reason for suspecting infection

Were antibiotics locked in to all lumens of the the Vascular Access Device? Yes [] No []

Were antibiotics given by prolonged infusion (>1 h) in to all lumens of the VAD? Yes [] No []

Were all lumens of the Vascular Access Device exposed to antibiotic treatment? Yes [] No []

Vascular Access Device removed within four weeks of presentation Yes [] No []

If yes, date of removal [][].[][].[][][][] (dd mm yyyy)

(all vascular access tips irrespective of reason for removal to go for culture)

Table with 2 columns: Date, Vascular Access Device tip culture results (name of isolate and number of colonies)

Source of infection suspected other than VAD (GI, Resp, CNS) Yes [] No []

If Yes please give details.....

Source of infection identified Yes [] No []

If Yes please give details.....

Specific agent of infection identified Yes [] No []

If Yes please give name of agent

Please also fill in page 3 and staple to this page

Infection Summary Form
Complete and return form to the date centre 4 weeks after presentation of an episode of fever*

Patient identifier: _ _ _ _ (1 st 3 letters of surname) _ _ _ (1 st 2 letters of first name)	Trial Number _ _ _ _
Date of birth: _ _ _ · _ _ · _ _ _ _ _ (dd mm yyyy)	

Positive Microbiology/Virology/Mycology/Parasitology results
 (Please enclose copies of positive microbiology, virology and mycology reports with this form)

Date	Sample	Results

Clinician responsible for clinical care

Impression of clinician responsible for clinical care of the aetiology of febrile episode (explanation for fever)(such as pneumonia, drug/blood reaction, virus infection)	
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How likely do you think that this episode was an episode of vascular access device associated infection?

Probable / Possible / Unlikely / Not possible to say (please circle)

Hospital/Centre:

Signature:Date:

Phone:Fax:

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Hearts of Oak House, 9 Princess Road West, Leicester LE1 6TH**