



FEED1
FLUIDS EXCLUSIVELY
ENTERAL FROM DAY 1

eCRF Paper Late Onset Infection form

This additional form is to be used as an aide memoire only, it does not replace the electronic CRF (MACRO).

All paper workbooks and additional forms should be retained in the Investigator Site File as they represent Source Data.

Mother's Initials:

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(If only two initials are given then please separate with a hyphen)

Infant ID:

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Sponsor: University Hospitals of Derby and Burton NHS Foundation Trust

CRF Version: Final Version 1.0

**PLEASE ATTACH THIS COMPLETED FORM TO THE INFANT
WORKBOOK**

Mother's Initials:

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Infant ID:

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Definition of Microbiologically-confirmed Late-onset Invasive Infection (LOS)

A modified version of the UK Neonatal Infection Surveillance Network case-definition will be used:

Microbiological culture from blood or CSF sampled aseptically more than 72 hours after birth of any of the following:

- potentially pathogenic bacteria (including coagulase-negative Staphylococci species but excluding probable skin contaminants such as diptheroids, micrococci, propionibacteria or a mixed flora)
- fungi

AND

Treatment for 5 or more days with intravenous antibiotics after the above investigation was undertaken. If the infant died, was discharged, or was transferred prior to the completion of 5 days of intravenous antibiotics, this condition would still be met if the intention was to treat for 5 or more days. There is no need to report urinary tract infection unless there is also a positive blood culture.

Definition of Clinically Suspected Late-onset Invasive Infection

This is adapted from the European Medicines Agency consensus criteria and the predictive model.

Either – absence of positive microbiological culture OR culture of a mixed microbial flora or of likely skin contaminants (diptheroids, micrococci, propionibacteria) only

AND

Clinician intent to administer intravenous antibiotic treatment for 5 or more days (excluding antimicrobial prophylaxis) for an infant who demonstrates 3 or more of the following clinical or laboratory features of invasive infection:

- Increase in oxygen requirement or ventilatory support
- Increase in frequency of episodes of bradycardia or apnoea
- Temperature instability
- Ileus or enteral feeds intolerance and/or abdominal distention
- Reduced urine output to <1ml/kg/hour
- Impaired peripheral perfusion (impaired capillary refill time >3 seconds, skin mottling or core-peripheral temperature gap >2°C)
- Hypotension (clinician defined as needing volume or inotrope support)
- "irritability, lethargy or hypotonia" (clinician defined)
- Serum C-reactive protein levels to >15 mg/L or procalcitonin ≥2mg/ml
- White blood cells count <4 or >20 X 10⁹ cells/L or platelet count <100X10⁹/L
- Glucose intolerance (blood glucose <2.2 mmol/l or >10 mmol/l)
- Metabolic acidosis (base excess <-10mmol/L or lactate>2mmol/L)

Mother's Initials:

Infant ID: -



Late-onset invasive infection		
Details of samples showing positive culture		
Date of Report (dd-mmm-yyyy)	<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"/>	
Was this episode microbiologically confirmed?	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Site (select one)	Name of Organism	Date of sample (dd-mmm-yyyy)
Blood <input type="checkbox"/> CSF <input type="checkbox"/>		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Blood <input type="checkbox"/> CSF <input type="checkbox"/>		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
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Blood <input type="checkbox"/> CSF <input type="checkbox"/>		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Blood <input type="checkbox"/> CSF <input type="checkbox"/>		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Please specify reasons for antibiotic/ antifungal treatment (tick all boxes that apply)	Increase in oxygen requirement or ventilator support	<input type="checkbox"/>
	Increase in frequency of episodes of bradycardia or apnoea	<input type="checkbox"/>
	Temperature instability	<input type="checkbox"/>
	Ileus or enteral feeds intolerance and/or abdominal distention	<input type="checkbox"/>
	Reduced urine output to <1 ml/kg/hour	<input type="checkbox"/>
	Impaired peripheral perfusion (capillary refill time >3 seconds, skin mottling or core-peripheral temperature gap >2°C)	<input type="checkbox"/>
	Hypotension (clinician defined as needing volume or inotrope support)	<input type="checkbox"/>
	Irritability, lethargy or hypotonia (clinician defined)	<input type="checkbox"/>
	Increase in serum C-reactive protein levels to >15mg/l or procalcitonin ≥2 ng/mL	<input type="checkbox"/>
	White blood cells count <4 or >20 x 10 ⁹ cells/l or platelet count <100 x 10 ⁹ /L	<input type="checkbox"/>
	Glucose intolerance (blood glucose <2.2 mmol/L or >10mmol/L)	<input type="checkbox"/>
	Metabolic acidosis (base excess <-10 mmol/L or lactate >2 mmol/L)	<input type="checkbox"/>

Mother's Initials:

Infant ID: -



Antibiotic Usage: Was this infant treated with antibiotics for this episode?	Yes* <input type="checkbox"/>	No <input type="checkbox"/>
*If yes, please complete the Antibiotic details form (page 5 of this form)		
Antifungal Usage: Was this infant treated with antifungals for this episode?	Yes* <input type="checkbox"/>	No <input type="checkbox"/>
*If yes, please complete the Antifungal details form (page 6 of this form)		

Please note the PI will be required to login to Macro database to assess and sign off each Late-onset Infection episode reported.

Mother's Initials:

Infant ID: -



Late-onset invasive infection: Antibiotic details	
Details of samples showing positive culture	
How many days was this infant treated with antibiotics for this episode? (<i>please state the intended number of days if this infant died during treatment</i>)	<input type="text"/> <input type="text"/>
Date antibiotics started (dd-mmm-yyyy)	<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"/>
Date antibiotics stopped (dd-mmm-yyyy)	<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"/>
Name of antibiotic	Number of days antibiotic taken
	<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"/>

Mother's Initials:

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Infant ID:

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Late-onset invasive infection: Antifungal details																								
Details of samples showing positive culture																								
*If yes, how many days was this infant treated with antifungals for this episode? <i>(State the intended number of days if this infant died during treatment, do not include prophylactic doses)</i>	<table border="1"><tr><td></td><td></td></tr></table>																							
Date antifungals started (dd-mmm-yyyy)	<table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>																							
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Name of antifungal	Number of days antifungal taken																							
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