Study number:						
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Late-onset infections and gut signs form

To be used at continuing care sites only

Name of hospital (where this form is completed):

Use this form if any of the following are satisfied:

- If a baby has an episode of microbiologically-confirmed or clinically-suspected late-onset (blood or CSF) infection (72 hours or more after birth)
- If a baby has received <u>at least 5 days</u> of antibiotic or antifungal <u>treatment</u> for suspected or proven late-onset infection (not prophylaxis)
- If they are transferred to another unit with presumed late-onset infection
- If they have died from suspected or proven late-onset infection
- If they have received <u>at least 5 days</u> of treatment for gut signs
- If they are transferred to another unit with gut signs
- · If they have surgery for gut signs
- · If they have died with gut signs

This form should be used to report an episode of infection and/or gut signs (as these often go together), but please use a separate form for each new episode of late-onset infection and/or gut signs.

Which type of signs are you reporting on this form? (please choose all that apply)	
Late-onset infection	Gut signs

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Microbiologically-confirmed late-onset infection

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 diphtheroids, micrococci, propionibacteria or a mixed flora)
- Fungi

AND

Treatment for 5 or more days with intravenous antibiotics or antifungals after the above investigation was undertaken. If the baby died, was discharged home, or was transferred to another unit prior to the completion of 5 days of intravenous antibiotics/antifungals, this condition would still be met if the intention was to treat for 5 or more days.

DO NOT report urinary tract infection unless there is also a positive blood culture.

Clinically-suspected late-onset infection

Either:

- · Absence of positive microbiological culture, OR
- Culture of a mixed microbial flora or of likely skin contaminants (diphtheroids, micrococci, propionibacteria) only

AND

Clinician intent to administer antibiotic treatment or intravenous antifungals for 5 or more days (excluding antimicrobial prophylaxis) for a baby who demonstrates 3 or more <u>clinical or laboratory</u> features of infection (to be reported below).

Date episode started:	DD/MM/YY
Date episode ended:	DD/MM/YY
Tick here if the baby was transferred out of your hospital during the episod (leave the end date blank)	
If you are reporting signs of infection:	
Which type of late-onset infection are you reporting?	
Microbiologically-confirmed	
Clinically-suspected	

Study number:					
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Section 1: Signs present	
If you are reporting clinically-suspected infection and/or gut signs:	
Please specify which of the following signs are present (choose all that app	oly):
Clinical or laboratory features of infection:	
Increase in oxygen requirement or ventilatory support	
Increase in frequency of episodes of bradycardia, desaturations, or apno-	ea
Temperature instability	
lleus or enteral feeds intolerance and/or abdominal distension	
Reduced urine output to <1 ml/kg/hour	
Impaired peripheral perfusion (e.g. capillary refill time >3 seconds, skin mottling or core peripheral temperature gap >2°C)	
Hypotension (treated with volume or inotrope support)	
Irritability, lethargy or hypotonia (clinician-defined)	
Increase in serum C-reactive protein levels to >15 mg/l or procalcitonin ≥2	
White blood cells count <4 or >20 × 10 ⁹ cells/l	
Platelet count < 100 × 10 ⁹ /l	
Glucose intolerance: blood glucose <40 mg/dl [2.2 mmol/l] or >180 mg/dl	[10 mmol/l]
Metabolic acidosis: base excess (BE) <-10 mmol/l or lactate >2 mmol/l .	
Additional systemic signs:	_
pH <7.2	
Disseminated intravascular coagulation	
Neutropenia <1.0	
Other systemic signs (please specify):	
If you are reporting signs of infection: Details of samples showing positive culture:	
Site (blood or CSF) Name of organism	Date sample taken
tick if no positive blood or cerebrospinal fluid (CSF) culture	
☐ Blood ☐ CSF	DD/MM/YY
Blood CSF	DD/MM/YY
Blood CSF	DD/MM/YY
Blood CSF	DD/MM/YY
☐ Blood ☐ CSF	DD/MM/YY

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If you are reporting gut signs:	
Please specify which gastrointestinal symptoms are present (choose all t	that annly):
Abdominal distension	
Abdominal tenderness	
Blood in stool.	
Abdominal wall oedema	
Abdominal wall erythema	
Abdominal wall induration	
Green/bile-stained aspirates or vomit	
Generalised peritonitis	
Other abdominal/gastrointestinal signs of NEC(please specify):	
If you are reporting gut signs:	
Please specify which radiological signs are present (choose all that apply):
Pneumatosis intestinalis	
Portal venous gas	
Pneumoperitoneum	
Ascites	
Other radiological signs (please specify):	
If any radiological signs are present:	
Were these signs seen on (choose all that apply):	
X-ray	
Ultrasound	
Section 2: Treatment given	
For how many consecutive days was the baby treated with antibiotics fo	or this episode?
Did the baby die during this treatment course?	Yes No
If you are reporting signs of infection: For how many consecutive days was the baby treated with antifungals for the continuity (Do not include prophylactic doses)	or this episode?
Did the baby die during this treatment course?	Yes No
If you are reporting signs of infection, there are no further questions to a	
Please sign and date the form on the last page.	<u> </u>

If you are reporting gut signs, please complete the remaining questions:

Did the baby have abdominal surgery in association with this episode?

No

Yes

	a) maniferenced (along a cilitizat angle).
If Yes: Please specify which procedure(s	
·	
If a laparotomy was performed: Please s	
Final diagnosis (choose all that apply):	
·	
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· ·	
How was this diagnosis made? (choose all that	
·	
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_	
If diagnosis was made via surgery: Date	
What was seen at surgery? (choose all th	
•	
• •	
Isolated perforation(s) only	
Other (please specify):	
Was histology of the gut performed?	Yes No
If Yes: Did this confirm the presence of NEC?	Yes No

Details of person completing form:	
Name:	
Role:	
Signature:	
Date:	DD/MM/YY
Principal Investigator signature:	
Date:	DD/MM/YY

When this form has been completed:

Please scan and return to the baby's recruiting site via secure email.

neoGASTRIC Study Team

NPEU Clinical Trials Unit, University of Oxford, Old Road Campus, Headington, Oxford, OX3 7LF.
• 01865 617927

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Imperial College London



Study number:

