Study number: ☐☐☐☐☐

neoGASTRIC

Late-onset infections and gut signs form

To be used at continuing care sites only

Baby's date of birth: D D / M M / Y Y

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 at least 5 days of antibiotic or antifungal treatment 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 at least 5 days 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 late-onset 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 ☐

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 clinical or laboratory features of infection (to be reported below) that commenced more than 72 hours after birth.

Date episode started: D D / M M / Y Y

Date episode ended: D D / M M / Y Y

Tick here if the baby was transferred out of your hospital during the episode
(leave the end date blank) . . . . . .Ongoing ☐

If you are reporting signs of late-onset infection:

Which type of late-onset infection are you reporting?

Microbiologically-confirmed . . . . . ☐

Clinically-suspected . . . . . ☐

Section 1: Signs present

If you are reporting clinically-suspected late-onset infection and/or gut signs:

Clinical or laboratory features of infection:

- Increase in oxygen requirement or ventilatory support ☐
- Increase in frequency of episodes of bradycardia, desaturations, or apnoea ☐
- Temperature instability ☐
- Ileus 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 ng/ml ☐
- 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 ☐

If this is a case of clinically-suspected late-onset infection and you have reported fewer than 3 signs in the list above:

☐ **I confirm that there were fewer than 3 signs in the list above present in this case of clinically-suspected late-onset infection**

Please add any further relevant information here:

_____

_____

Additional systemic signs:

- pH <7.2 ☐
- Disseminated intravascular coagulation ☐
- Neutropenia <1.0 ☐
- Other systemic signs *(please specify)*: _____

If you are reporting signs of late-onset 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		D D / M M / Y Y
☐ Blood ☐ CSF		D D / M M / Y Y
☐ Blood ☐ CSF		D D / M M / Y Y
☐ Blood ☐ CSF		D D / M M / Y Y
☐ Blood ☐ CSF		D D / M M / Y Y

If you are reporting gut signs:

Please specify which gastrointestinal symptoms are present *(choose all that apply)*:

- 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 ☐

If you are reporting gut signs:

On the calendar day before the baby had their first gut sign, did they have gastric residual volumes measured routinely (approximately 3 or more times)? Yes ☐ No ☐

Section 2: Treatment given

For how many consecutive days was the baby treated with antibiotics for this episode? ☐☐☐

If number of days is more than 0: **Did the baby die during this treatment course?** Yes ☐ No ☐

If you are reporting signs of late-onset infection:
For how many consecutive days was the baby treated with antifungals for this episode?
(Do not include prophylactic doses) ☐☐☐

If number of days is more than 0: **Did the baby die during this treatment course?** Yes ☐ No ☐

If you are reporting signs of late-onset infection, there are no further questions to answer. Please sign and date the form on the last page.

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

Did the baby have abdominal surgery or an abdominal procedure in association with this episode? Yes ☐ No ☐

If Yes: Please specify which procedure(s) performed *(choose all that apply)*:

- Peritoneal drain or paracentesis ☐
- Laparotomy ☐
- Other *(please specify)*: _____

If a laparotomy was performed: Please specify laparotomy type:

- Bowel resection ☐
- Stoma ☐
- Other *(please specify)*: _____

Final diagnosis *(choose all that apply)*:

- Dysmotility, meconium, or milk plug ☐
- Septic ileus ☐
- Focal intestinal perforation (no NEC) ☐
- Necrotising enterocolitis ☐
- Other diagnosis *(please specify)*: _____

How was this diagnosis made? *(choose all that apply)*

- Clinically and radiologically ☐
- Surgery ☐
- Post-mortem ☐

If diagnosis was made via surgery: Date of surgery: D D / M M / Y Y

What was seen at surgery? *(choose all that apply)*

- No bowel abnormality ☐
- Pneumatosis intestinalis ☐
- Inflamed intestine ☐
- Necrotic / gangrenous intestine ☐
- Perforation due to NEC ☐
- 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 ☐

What did the histology show?

_____

_____

_____

_____

_____

_____

_____

Details of person completing form:

Name: _____

Role: _____

Signature: _____

Date: D D / M M / Y Y

Principal Investigator signature: _____

Date: D D / M M / Y Y

When this form has been completed:

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

neoGASTRIC Study Team

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