



neoGASTRIC

Training Package for Continuing Care Sites



- neoGASTRIC Key Staff
- Background
- neoGASTRIC trial
- Role of Continuing Care Sites
- Supporting Documents
- Key contacts



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neoGASTRIC background

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The neoGASTRIC Trial

Avoiding routine gastric residual volume measurements in neonatal critical care.

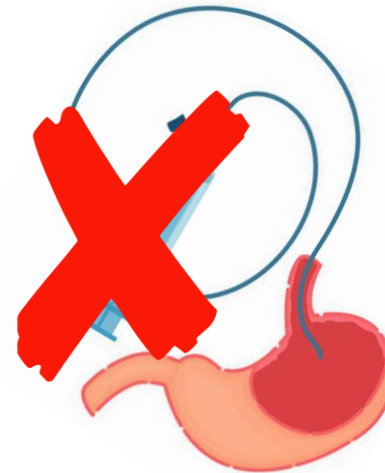
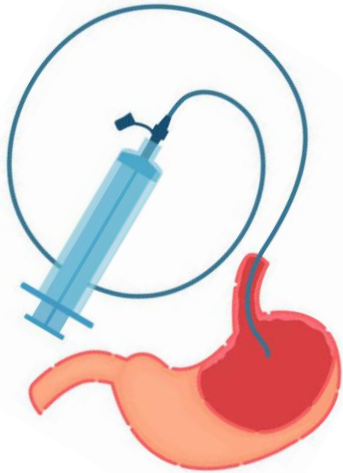
A multi-centre, pragmatic, unblinded, 2-arm, parallel group, opt-out, randomised controlled trial, with an internal pilot (and embedded process evaluation), and an integrated health economic analysis.



The Intervention

**Routine Measurement of
Gastric Residual Volume**

**No Routine measurement
of Gastric Residual Volume**



Studies have shown GRV can be unreliable...

- Aspirating stomach contents (measuring GRV) is not an accurate or reliable indicator of gastric volume - *gastric enzymes also contribute to total fluid volume* - and does not guarantee gastric emptiness
- The amount obtained is dependent on the aspiration technique, gastric tube size, the consistency of the stomach contents, patient's position and/or tube position in stomach



The neoGASTRIC Trial

- Population = preterm infants <34+0 weeks
- Sample Size = 7,040 babies
- Duration = 50 months (Aug 2022 – Oct 2026)
- Recruitment = 36 months (Mar 2023 – Mar 2026)
- Sites = 40-50 across UK and Australia.



Babies already recruited to neoGASTRIC

Inclusion criteria

- ✓ <34 weeks gestation
- ✓ Nasogastric or orogastric tube in place

Exclusion criteria

- × Infant has received more than 15 ml/kg/day of milk for more than 24 hours
- × Gastrointestinal surgical condition
- × Major congenital abnormalities
- × No realistic prospect of survival
- × Parent opted out



The routine measurement of gastric residual volume (GRV) is to:

- Aspirate the whole stomach content
- Routine measuring of this stomach content every 4-6 hours to guide enteral feeding

IT IS NOT.....

- **Aspirating a small amount (e.g. 0.5ml) to confirm feeding tube position, and testing pH**

Please still check tube position – it is a clinical requirement!





The Role of Continuing Care Sites

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Roles of Continuing Care Sites

1. **Continue with the allocated intervention** until the infant is discharged home or reaches 44+0 gestational weeks +days (whichever is sooner)



Roles of Continuing Care Sites

2. **Complete the Daily Feed Log** for all infants regardless of intervention until infant reaches 14 days since randomisation.
- If the baby completes day 14 and has not been on full feeds for **three consecutive days** then move onto Day 15+ feed log.
 - Feed logs only stop once baby completes 14 days since randomisation and reaches full feeds for three consecutive days.
 - If the baby reaches full feeds before they complete 14 days since randomisation, the feed logs should not be stopped and should be carried on until they reach day 14.

**There is a Daily Feed Log for days 1 – 14 and another for days 15+*

Full feeds: defined as tolerating 150 ml/kg/day (at least 145 ml/kg/day) including breastfeeding where total milk is considered equivalent to full enteral feeds



Role of Continuing Care Sites

3. If the baby moves to another unit, or when baby goes home, please complete the paper transfer and discharge form. Please **inform the recruiting site** accordingly
4. If required, **complete relevant reporting forms** e.g. Infection & Gut Signs Form, Incident Form, SAE Form.
5. **Securely return all completed data collection forms** to the recruiting site via secure email for data entry - see the Parent Information Sheet (PIS) for contact details. You can also contact the neogastric team via email to obtain this information



Key Paper Data Entry Forms

Daily Feed Log (Days 1 – 14)

Hospital & Transfer Discharge form

Log number:

Study number:

neoGASTRIC

Daily Feed Log (Days 1 - 14)

Baby's date of birth:

Baby's date of randomisation:

Name of hospital (where this form is completed): _____

How to use this form:

The Daily Feed Log must be completed each consecutive day in 11

- The baby has reached full feeds for three consecutive days
- Or the baby no longer requires a gastric feeding tube
- Or the baby is 44th gestational weeks¹⁴⁻¹⁶

Complete this feed log for 14 complete days from randomisation criteria are met, please complete a **Daily Feed Log (Day 15)**

Complete the feeding log for each calendar day (24 hours)

Complete the question on the last page when the baby has

Definitions

Serious clinical concerns: abdominal tenderness, deterioration, bilious/bloody vomiting

Full feeds: defined as tolerating 150 ml/kg/day (7 where total milk is considered equivalent to full)

Allocation No routine measurement of gastric residual volumes
 Routine measurement of gastric residual volumes

| | Day 0 | Day 1 | Day 2 | Day 3 | Day 4 | Day 5 | Day 6 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 1. Date (dd/mm) | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 2. Weight (g) used to calculate the volume of full feeds given | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 3. Has the baby reached full feeds today? (see definition) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Does the baby have a gastric tube in situ today? This includes days where a baby has a gastric tube in place for any part of the day | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Total milk feed volume received per day (ml) today? | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 6. Was the baby breastfed (sucking at the breast) today? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Were the baby's feeds withheld for any length of time on this day? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. If withheld: How long were feeds withheld today (in hours)? e.g. if a baby is on 2-hourly equates to feeds withheld for 1 hour, this | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 9. If withheld: Were the baby's feeds withheld due to vomiting on this day? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. If withheld: Was this around transfusion as part of the WHEAT trial? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. Were antibiotics (suspected and proven infection) or antituberculars given on this day following row 10? or if this baby died from suspected late-onset infection. Please review guidance and consider completing a Late-Onset Infection and Gut Signs Form if 2 consecutive boxes are ticked in the following row. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 12. Was the baby nil by mouth at any point today with the intention that this was for 4 or more hours? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 13. How many times were gastric residual volumes measured today? | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 14. Were any of these measured for serious clinical concerns (see definition)? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 15. If any were measured for serious clinical concerns, please state how many: | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| 16. If the baby is on the routine measurements arm and has had <4 GRV measurements today: Is the baby establishing oral feeds today (e.g. breastfeeding or bottle feeding as well)? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 17. Initial here if you have completed any of the log for this day | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Page 2 of 4

v3.0, 26-Jul-2023

Study number:

neoGASTRIC

Hospital Transfer/Discharge Form

To be used at completion in the

Use this form if a baby:

- Is discharged home
- Has transferred to another hospital
- Has died
- Is still an inpatient at your hospital

Please answer

Section 1: Details of stay

1.1 Name of this hospital: _____

1.2 Date of admission to this hospital:

1.3 From this hospital, the baby (choose one only):
 Was discharged home:
 Was transferred to another hospital:
 Died:
 Reached 44th gestational weeks¹⁴⁻¹⁶:

If this baby was discharged home:
 1.3.1 Date of discharge from this hospital:

If this baby was transferred:
 1.3.1 Name of hospital baby is being transferred to:

If this baby died:
 1.3.1 Date of death:

1.4 Has the baby been randomised to the FEED1 allocation?
 Full feeds from Day 1:
 Gradual advancement of feeds:

Section 2: Clinical outcomes

2.1 Were any of the following diagnosed during the baby's stay in this hospital (prior to discharge or the baby reaching 44th gestational weeks¹⁴⁻¹⁶)?
 Intraventricular haemorrhage (Grade 3 or Grade 4, Papile):
 If Yes, please specify grade (choose all that apply):
 Grade 3 Intraventricular haemorrhage:
 Grade 4 Intraventricular haemorrhage:
 Cystic periventricular leukomalacia:
 Microbiologically-confirmed or clinically-suspected late-onset infection:
 If the answer is Yes, Please complete a Late-onset Infection and Gut Signs form. If one was not already completed for this instance of infection.
 Necrotising enterocolitis (NEC):
 If the answer is Yes, Please complete a Late-onset Infection and Gut Signs form. If one was not already completed for this instance of NEC.

Page 2 of 4

v1.0, 2023-05-23

Continuation of care & adhering to the trial arm



GCP, CVs & Delegation Log

- These are not required as data entry will be carried out by the recruiting site.
- Continuing care sites only enter data on the paper version and individuals entering data are not required have GCP.

Principal Investigator

- PI is not required to be a doctor, an experience research nurse can be assigned as PI. However, a doctor is required to assess SAEs and to make any relevant clinical decisions.



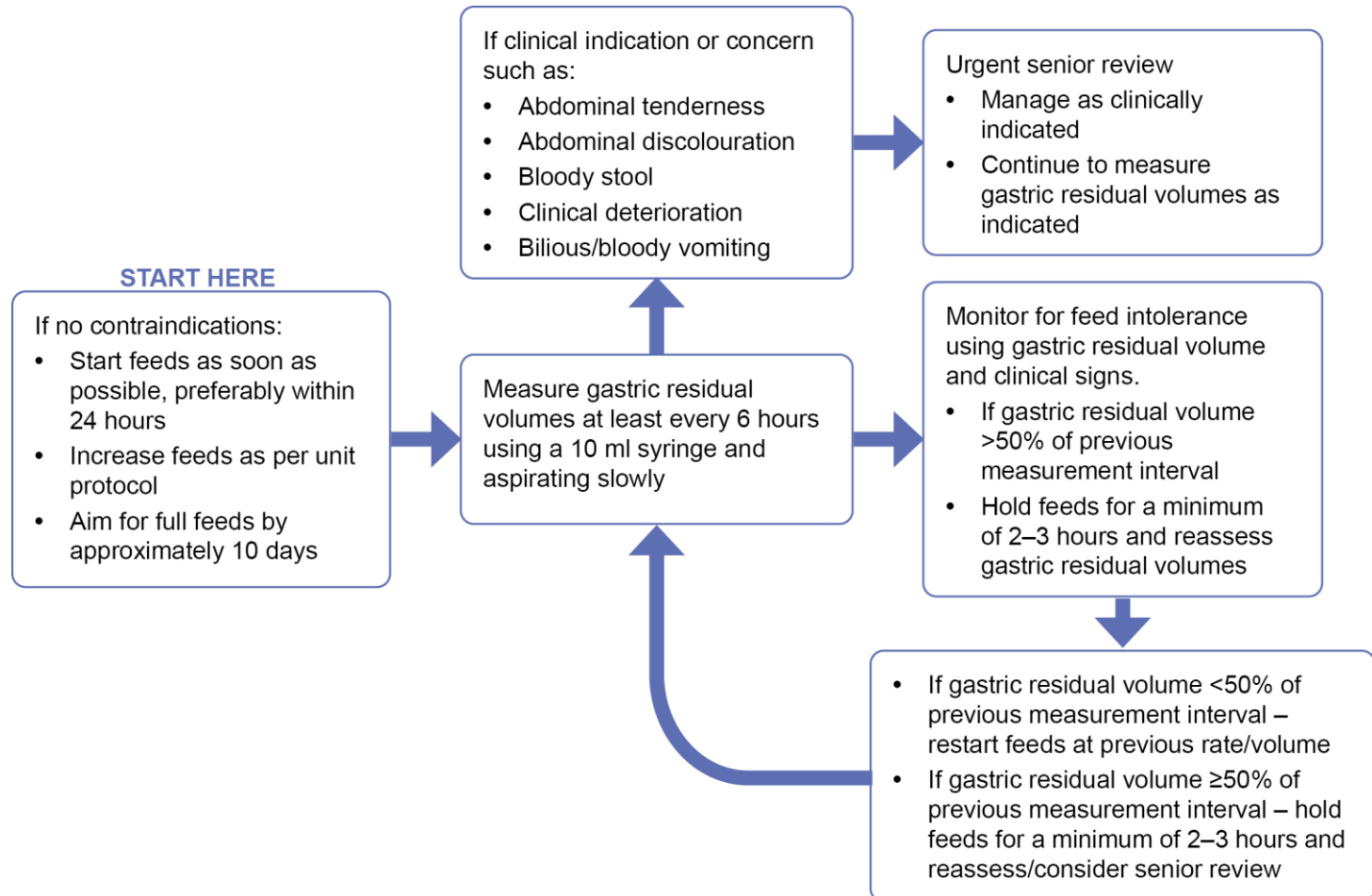
If the infant is on the Routine GRV Measurement Arm

- GRV should ideally be routinely measured 4-6 hourly to guide enteral feeding.
- Use local guideline for management if available.

If serious clinical concerns -> urgent senior review



Suggested management within the Routine, up to 6 hourly, measurement of gastric residual volumes pathway



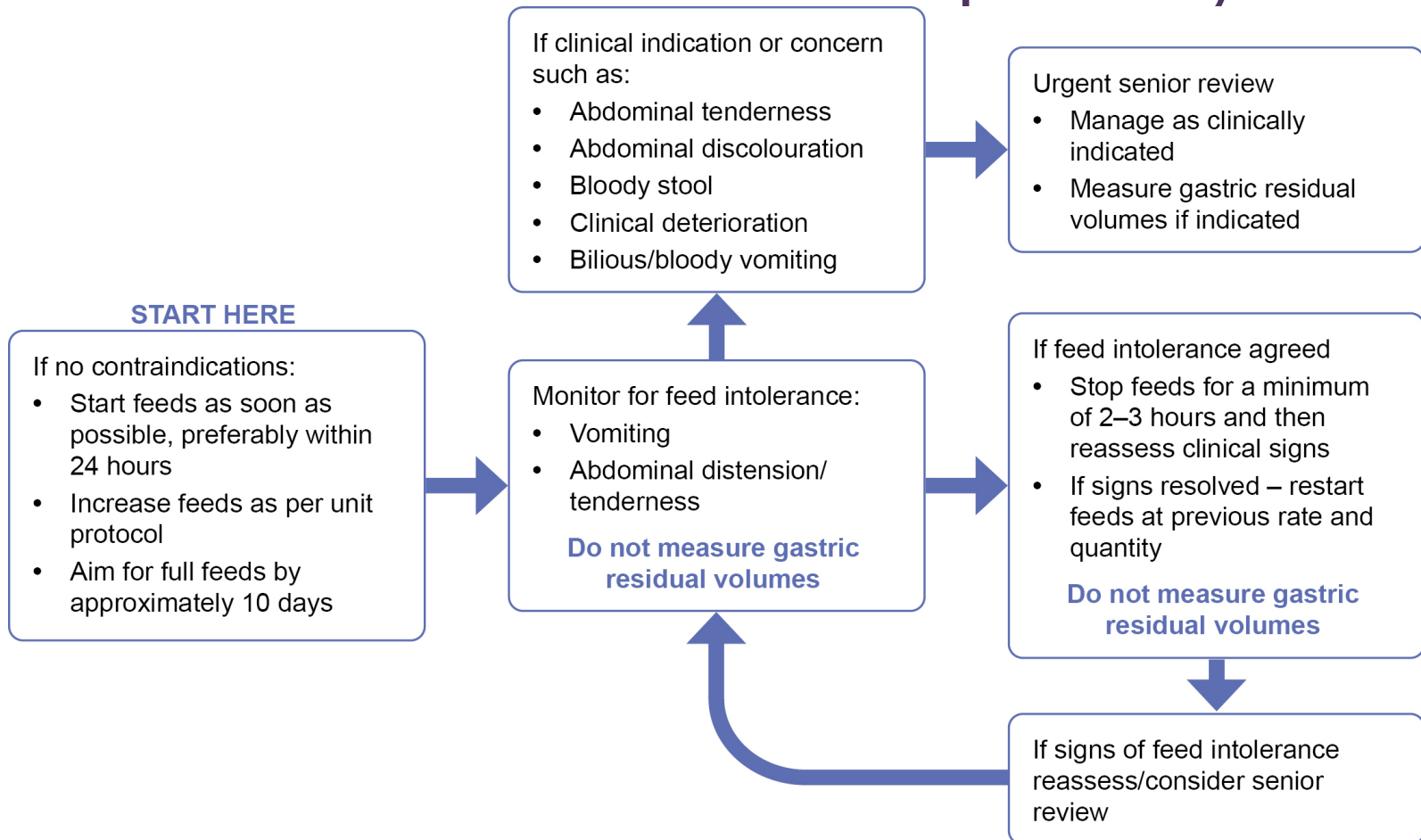
If the infant is on the No GRV Measurement Arm

- **DO NOT** routinely measure GRV
- Confirm feeding tube position using pH paper and NGT length – **DO NOT** aspirate the whole stomach contents
- If clinical signs of **feed intolerance** do occur and other causes are ruled out:
 - Discuss this with a senior clinical colleague before a decision is made.

!! In acute deterioration urgent aspiration of stomach contents should be done if indicated !!



Suggested management within the *No routine measurement of gastric residual volumes* pathway





Supporting Documents

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Transfer Packs

Study Number:

NeoGASTRIC Infant Transfer Pack

Complete this cover page if a NeoGASTRIC baby is being transferred to another hospital:

Baby Name:

Date of Birth: / /

Name of Transferring Hospital:

Name of Receiving Hospital:

Has the infant reached full milk feeds? Yes No

**Please note: Full milk feeds refers to 3 consecutive days of the infant being fed more than 145ml/kg/day from NGT/OG tube*

If Yes, please remove the feeding logs from this pack

If No, please state the date / / and last completed day on feeding log Day

RECRUITING SITE TO ADD WHERE RELEVANT BEFORE SENDING:

Photocopy of current Daily Feed Log

OR print out of the Daily Feed Log just from the last 5 days

One Thank you Card for parents if this has not been provided to them yet

Ongoing SAE forms

Transfer documentation prepared by:

Contact number:

Email:

Secure email for sending data:

NeoGASTRIC Study Team: NPEU CTU, Oxford Population Health University of Oxford, Old Road Campus, Headington, Oxford, OX3 7LF.
T: 01865 617778 E: neoGASTRIC@npeu.ox.ac.uk



Trial ARM
 DO NOT Measure GRV

Study Number:

NeoGASTRIC Infant Transfer Pack

Complete this cover page if a NeoGASTRIC baby is being transferred to another hospital:

Baby Name:

Date of Birth: / /

Name of Transferring Hospital:

Name of Receiving Hospital:

Has the infant reached full milk feeds? Yes No

**Please note: Full milk feeds refers to 3 consecutive days of the infant being fed more than 145ml/kg/day from NGT/OG tube*

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T: 01865 617778 E: neoGASTRIC@npeu.ox.ac.uk

Supporting Documents

(Provided within Transfer Pack)

- Parent Information Sheet (PIS)
- neoGASTRIC Protocol Summary
- Data Collection Forms
- Guidance Sheets
- Cot Cards and trial stickers
- SAE and Incident Forms
- Key Contacts



Data Collection Forms

All data collection forms will be provided.

These will include:

- Feed Log, main data collection form
 - Days 1 – 14
 - Days 15+
- Transfer/Discharge form
- Infection & Gut Signs form (if necessary)
- Withdrawal & Discontinuation form

Please note that you may be required to complete feed log 3 (72 days +) if the infant has not reached full feeds by day 72. Only, a few babies are likely to still not have reached full feeds after 72 days.

**Please see Guidance Sheet 11. For Continuing Care Sites –
provided in the Transfer Pack**



Guidance Sheets

All the necessary Guidance Sheets will be provided.

These will include:

- 1. neoGASTRIC trial one-page summary
- 5. Daily feed log
- 6a. Transfer of infants
- 7. Withdrawals/Discontinuation
- 11. For Continuing Care Sites
- 8. SAE & Incident Reporting
- 9. Emergency Queries



Supporting Documents at cot side

- Cot cards

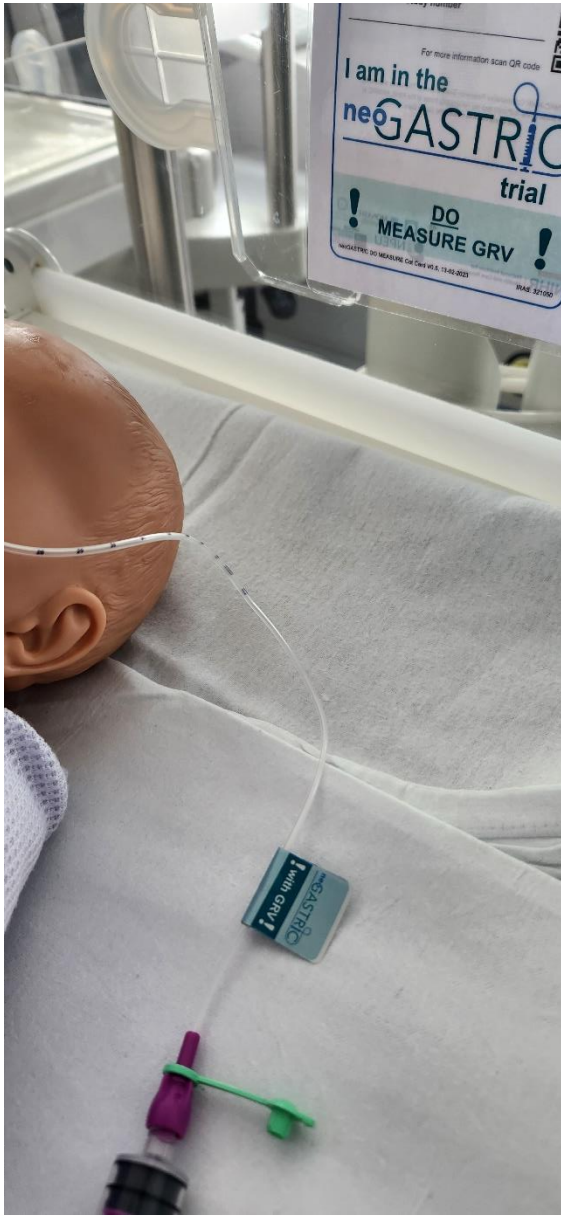


- Tube labels



- Stickers





Safety reporting

- All Serious Adverse Events (SAEs) that are deemed reportable – *see next slides and Protocol* – must be reported as soon as possible.
- For neoGASTRIC only adverse events identified as serious will be recorded.

See Guidance Sheet 11 for full information



Foreseeable SAEs which **do not** require reporting via an SAE form

The following events are expected in the population and will be collected as outcomes, therefore **do not** require reporting as SAEs:

1. Death (unless cause not anticipated in this population)
2. Necrotising enterocolitis or gastrointestinal perforation
3. Bronchopulmonary dysplasia or chronic lung disease
4. Late-onset infection
5. Brain injury on imaging: intraventricular haemorrhage grade 3 or 4 and/or cystic periventricular leukomalacia



Foreseeable SAEs relating to known complication(s) of prematurity

- Any serious event that is deemed by a doctor to be...
 - a known complication of prematurity
 - **at that gestational age**

...should not be reported as an SAE

However do record in the infant's medical notes, as per usual practice.

- ✓ **Only report if considered causally related to the allocated pathway of care**
- ✓ Any other SAEs are classed as unforeseeable SAEs and **must be reported**



Key Contacts & Support

- The recruiting site who transferred the infant should be a key contact
 - See the Transfer Pack for contact details
- The neoGASTRIC Coordinating Centre – **neogastric@npeu.ox.ac.uk**



neoGASTRIC website

<https://www.npeu.ox.ac.uk/neogastric>

The website provides:

- General overview of the study for both parents and clinical staff
- Parent information sheets (PIS)
- Site information
 - Names of key staff





Thank you!

Please feel free to email neogastric@npeu.ox.ac.uk if you have any questions or would like more information.

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