11. For Continuing Care Sites

General Information

The infant being transferred to your hospital is enrolled on the neoGASTRIC study.

neoGASTRIC is a multi-centre, unblinded, 2-arm, opt-out, randomised controlled trial. The aim of the neoGASTRIC trial is to determine whether avoiding the routine measurement of gastric residual volumes in preterm infants less than 34 weeks gestation reduces the time taken for an infant to reach full enteral feeds without increasing harm, up until discharge home or 44^{+0} gestational weeks $^{+days}$.

Infants will have been randomised to either:

No routine measurement of gastric residual volumes	OR	Routine – up to 6 hourly – measurement of gastric residual volumes

For further information about the study visit the study website https://www.npeu.ox.ac.uk/neogastric

This Guidance Sheet provides guidance on the forms contained within the **Transfer Pack.**

In summary:

1. Continue with the allocated care pathway until an infant is discharged home or reaches 44^{+0} gestational weeks $^{+days}$
2. Complete the Daily Feed Log every day until reaching full feeds
3. If required, complete the relevant reporting form(s) – see below
4. Inform the recruiting site when infant is discharged home or transferred
5. Securely return all completed data collection forms to the recruiting site via secure email

All data collection forms are on paper and copies are enclosed. Once completed, please return to the recruiting site via secure email.

Completing the Daily Feed Log

The Daily Feed Log is the primary data that needs to be captured during the neoGASTRIC study.

For guidance related to the Daily Feed Log please refer to Guidance Sheet 5: Daily Feed Log FAQs.

! Please remember to complete the Infection and Gut Signs form when the feed log prompts you.

GUIDANCE SHEET 11

Completing all other reporting forms

Form 4: Transfer/Discharge

The Transfer/Discharge form is completed for infants when they either transfer to another hospital or discharged home. This form is not applicable for any internal transfer that may occur, for example, transfer from NNU to surgical ward.

If an infant is due to be transferred or discharged, you should:

1. Immediately notify the original recruiting site (see contact details on the back of the Parent Information Sheet).
2. Complete the paper Transfer/Discharge Form
3. Return the completed Transfer/Discharge form to the original recruiting site. The recruiting site will then input the transfer/discharge data into OpenClinica.

Form 5: Incident Reporting Form

Deviations from the Protocol, trial specific procedures or Good Clinical Practice must be reported to the neoGASTRIC trial coordinating centre using the Incident form. For guidance on how to report incidents please refer to Guidance Sheet 8. SAE and Incident Reporting.

Form 6: Serious Adverse Event (SAE) Report

All Serious Adverse Event's (SAEs) that are deemed reportable (according to the protocol) must be reported as soon as possible after your site has become aware of the event. For the neoGASTRIC study, only adverse events identified as serious will be recorded. The safety reporting window for this study will from the time the infant is randomised until the end of the study follow-up (discharge home or 44^{+0} gestational weeks^{+days}, whichever is sooner). Any staff member can report an SAE. Causality assessment is required for SAEs.

! Please see Guidance Sheet 8. SAE and Incident Reporting for guidance on how to report an SAE and/or incident.

! To note: This guidance sheet states that individuals must be delegated to complete causality as documented on the neoGASTRIC Site Delegation Log however, for continuing care sites, this can be completed by any medically qualified investigator!

! To remember: Do not delay reporting an SAE whilst waiting for a causality assessment. The SAE can be sent to the neoGASTRIC trial coordinating centre initially without the causality assessment completed. An updated SAE form must then be sent to the recruiting site when the causality assessment is complete.

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Form 7: Withdrawals and Discontinuation

If the infant is being permanently withdrawn from their trial-allocated pathway of care or if the parent(s) express a wish to opt out of neoGASTRIC, please complete this form. Parent(s) have a right to withdraw their infant from the study at any time and do not need to specify reasons for withdrawal. When a withdrawal is to take place please refer to the Guidance Sheet 7: Withdrawals/Discontinuation, for details on the steps that need to be taken, including completing the withdrawal and discontinuation form.

! To note: **the withdrawal and discontinuation form should NOT be used** if an infant allocated to the non-aspirate arm has developed a condition for which regular gastric residual measurement is clinically indicated. When regular gastric residual measurement is no longer clinically indicated the baby should be allocated back to their original trial arm if this is considered clinically appropriate.

Queries

Queries should first be directed to the recruiting site. Please see the Transfer pack for the Recruiting Site Contact Details.

NeoGASTRIC Coordinating Centre Contact Details

If you need to contact the neoGASTRIC Coordinating Centre, you can contact the team via email neoGASTRIC@npeu.ox.ac.uk or via telephone during office hours (i.e. between 09.00 – 17.00 Monday to Friday) on 01865 617927.

Out of hours

If you require any assistance outside of regular hours or have an emergency query, please see the Emergency Queries Guidance Sheet 9.

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