neoGASTRIC

FAQS FOR SITES

DURING THE STUDY

1. **How is the daily feed log completed? Is the daily feed log (Day 0-14) for the full 14 days or we stop once baby reaches full feeds?**

   If baby reaches full feeds during the first 14 days post randomisation, the whole feed log should still be completed for the 14 days.

   If baby has not reached full feeds for 3 consecutive days, move onto the 15 days onwards daily feed log and continue to complete until baby has reached full feeds over 3 consecutive days.

2. **On the withheld feeds section of the Daily feed log its asked 'for how long were feeds held', are we capturing only withheld feeds due to vomiting?**

   We want to know how long feeds were held for any reason (including for aspirates), but specifically we want to know about feeds withheld for vomiting as it is a separate outcome (in the first 14 days only).

3. **What is a continuing care site?**

   A continuing care site (CCS) is a site that an infant is being transferred to from one of the neoGASTRIC named recruiting sites. A CCS will receive a Transfer Pack with information about the neoGASTRIC trial including any instructions on the data collection that is required in order to continue the infant's participation in the trial.

   To continue this participation, the CCS's Research and Development team will be contacted by the neoGASTRIC Coordinating Centre (NPEU). Data cannot be collected at CCS until regulatory approvals are in place for this site.

   If a baby is transferred to a neoGASTRIC recruitment site, then this is OK to collect data.

4. **Will continuing care sites be set up routinely?**

   Yes, but it can take some time to set up continuing care sites so please do inform the neoGASTRIC trial team of units that you commonly send babies back to so we can start this process early.

5. **Will delegation log be required for data entry?**

   Yes, this will be required but the trial is collecting only minimal data.

6. **Are we monitoring that the patient information documents have been given to parents, or do we just document this in the notes/EPR?**

   No further monitoring will be required however you can record that the parents have been given the trial information in their notes, but this is not required on the CRF

7. **How do we report incidents and Serious Adverse Events (SAEs)?**

   Please refer to Guidance Sheet 8 Safety & Incident Reporting.

8. **What are the procedures around hospital transfer?**

   Please refer to Guidance Sheet 6 (a) and (b) Transfer of Infants and the Continuing Care sites Guidance sheet for further details. Please notify the neoGASTRIC coordinating centre of any planned or completed infant transfers as soon as possible.