

#### ! IMPORTANT: The daily feed log must be completed for each day the infant is enrolled in the study!

#### When to start and stop completing the Daily Feed Log

All infants must have a Daily Feed Log (Days 0 - 14) completed, covering 14 days after randomisation. After that, continue completing a Daily Feed Log (Day 15 onwards) until:

- the infant has reached full feeds for the last three consecutive days OR
- the infant no longer requires a gastric feeding tube **OR**
- the infant is aged 44<sup>+0</sup> gestational weeks<sup>+days</sup>.

The Daily Feed Log (Days 0 - 14) should be completed for **all** infants on the trial, whichever arm they are allocated to and whether or not they receive the correct intervention on each of those days and regardless of whether they have reached full feeds before completing 14 days after randomisation.

Day 0 is the day of randomisation and will nearly always be a partial day (dependant on time of day randomised).

## **Enteral feeds**

The total milk feed volume per day should include all types of milk received, when the volume is known. For example if the infant is mixed feeding, both expressed breast milk and supplement milk should be included in the daily total.

#### !Complete the feeding log for each calendar day (24 hours from 00:00)!

# Withheld Feeds

If an infant has had their feed withheld due to clinical reasons or vomiting, the clinical reasons <u>do not need to be captured</u>. Just the time, in hours, for how long feeds were withheld should be entered into the form. There is a section on the form to record whether the infant was nil by mouth (with the intention that this was for 4 or more hours). If this occurs for five consecutive days, **consider a Late-onset Infection and Gut Signs Form.** 

# Antibiotic / antifungal treatment

The Daily Feed Log also includes a section to record whether the infant was given antibiotics or antifungals for treatment of suspected or proven infection. If this occurs for five consecutive days, **complete a Late-onset Infection and Gut Signs Form.** 



# <u>Do not</u> answer "Yes" to the question about antibiotics/antifungals if these were given for prophylaxis.

Remember that you will need to complete the Late Onset Infections and Gut Signs form if **any** of the following are satisfied:

- If an infant has an episode of microbiologically-confirmed or clinicallysuspected 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 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 <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

### **Reaching Full feeds**

Full feeds is when an infant has reached about 150 ml/kg/day (at least 145 ml/kg/day) for three consecutive days.

If an infant is being breastfed, in addition to having a gastric tube, and so it is not possible to measure how much milk the infant is receiving it will be up to the clinical staff to decide when a baby has reached full feeds.

If infant has not reached full feeds after 14 days, please continue recording on daily feed log (day 15 onwards) until:

- the infant has reached full feeds for the last three consecutive days **OR**
- the infant no longer requires a gastric feeding tube OR
- the infant is aged 44<sup>+0</sup> gestational weeks<sup>+days</sup> **OR**
- the infant has been discharged.

#### **Enquiries**

For all queries please contact the Trial Coordinating Centre, National Perinatal Epidemiology Unit Clinical Trials Unit (NPEU CTU) via Email: <u>neogastric@npeu.ox.ac.uk</u> or via Telephone: 01865 617927.

For further contact information, please see the Key Contacts Form.

For any urgent queries outside of office hours (9am – 5pm) please see: Guidance Sheet 9: Emergency Queries

London

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