

Frequently Asked Questions

1. Is it safe for a preterm baby to have their feeds stopped for this study?

There are lots of reasons a preterm baby may have their enteral feeds stopped during their stay at the NICU. Feeds are being stopped around the time of blood transfusions (max 12 hrs.) for some study babies in order to determine if stopping their feeds at this particular time will minimize their risk of NEC. Some health centres across Canada/internationally feel it puts the baby at higher risk for NEC if feeds are continued around their blood transfusions, however we don't have enough evidence to prove if this is true or not. This study will give us the evidence needed to determine the safest/best approach to continuing/stopping feeds during blood transfusions.

2. When can a participating baby be randomized?

A participating baby can be randomized any time before 34⁺⁶ weeks.

3. What if a baby has already had a blood transfusion prior to consenting/randomizing - are they still eligible to participate in the study?

A baby can participate in the study as long as they haven't received a previous blood transfusion while being fed (> 15ml/kg) enterally.

4. How long is a participating baby enrolled in the study?

A participating baby is enrolled in their assigned study arm until 34⁺⁶ weeks gestation. Once the baby reaches 35⁺⁰ weeks feeds surrounding a blood transfusion should no longer be dictated by their study arm and should revert to typical unit care. Data will continue to be collected on participating babies until time of discharge or 40 weeks gestation (whichever comes first).

5. How do I know if the baby I'm caring for has opted into the WHEAT study?

Babies that are opted into the study will have a study indicator card at the bedside, as well as a cot card both inside and outside of their room, to alert unit staff of their involvement. A copy of their Study Review form will also be kept in their chart.

6. The WHEAT baby I'm caring for isn't randomized into a study arm but they have a transfusion coming up, what should I do?

Contact your local NICU Research team right away if you know that a WHEAT baby has an upcoming blood transfusion and hasn't been randomized yet.

7. Are all feeds for this WHEAT baby dictated by their randomized study arm?

Only the feeds around the time of a blood transfusions (4 hours before, during, and 4 hours after) are impacted by a baby's study involvement. All other feeds should be based on typical unit care.

Once the baby reaches **35⁺⁰ weeks** they are no longer in the study and feeds surrounding a blood transfusion should revert to typical unit care.

8. Is a 2nd IV required for babies that have their feeds withheld?

A 2nd IV should not be used for the purpose of this study. A PICC line can be used for IV fluid if one is already in place. If one is not in place the same IV line used for the blood transfusion can be used for IV fluid pre/post transfusion. IV fluid would then be stopped for the duration of the blood transfusion and restarted after.

9. If we stop IV fluid during the time of blood transfusion will the baby be at risk for hypoglycemia?

If there is a concern of hypoglycemia in a participating baby the blood transfusion can take place over a 2-hour period allowing IV fluid to only be stopped for a 2-hour timeframe which would be in line with a typical 2-3 hour feeding schedule.

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10. What if a baby is breastfeeding and in the Withhold Feeds group, would the mother need to stop breastfeeding their baby?

We do not anticipate that any of the babies involved in this study will be actively breastfeeding babies based on their age/health status. In the event that a baby is breastfeeding they should not be made to stop breastfeeding for the purpose of the study. Instead, we would document through our data collection processes whether they followed their allotted study arm or not.

11. What happens if a baby is accidentally fed around the time of their blood transfusion when they shouldn't have been or vice versa?

If a baby is mistakenly fed around the time of a blood transfusion when they're in the Withhold Feeds study arm (or not fed when in the Continued Feeds study arm) the NICU Research team should be notified and they will identify this as a study deviation. The baby will remain in the study and every effort should be made to ensure that all other feeds around the time of blood transfusions are dictated by their study arm.

12. What happens if a study baby is transferred to another hospital?

If a baby is transferred to another unit (non-CNN site) a data release form should be signed by the parent/guardian allowing the research team to access the required outcome data. This data will then need to be entered into a REDCap form.

13. Is Oral Immune Therapy or OIT considered a feed? Should it be stopped when in the withhold feeds arm?

OIT is not considered a feed for the purpose of this trial and can be continued for babies that have their feeds withheld.

14. Is Minimal Enteral Nutrition or MEN feeds considered a feed? Should it be stopped when in the withhold feeds arm?

MEN feeds would generally involve more volume than OIT so they should be stopped for babies in the withhold feeds group. However, if a baby has only received MEN feeds (up to 15 ml/kg) during a previous blood transfusion, they would still be eligible to take part.

15. If a baby hasn't been fed in the first few days of life other than OIT (not due to NEC or congenital anomaly) should they still be randomized prior to their first blood transfusion, even if they haven't been fed yet?

If a baby is NPO in the first seven days at the time of transfusion (e.g. a baby with septic shock on inotropes), then, in this case, do not randomize during the first transfusion and randomize during the subsequent transfusion. If the baby does get randomized during this first transfusion by error, and the patient is in continued feeds arm, the initial transfusion would be considered a protocol deviation if the baby is NPO. Every effort should be made to continue feeds through any subsequent transfusions.

16. If a several week-old baby is NPO for something that is not considered an exclusion criteria (e.g. septic shock) should they still be randomized if their first blood transfusion takes place while NPO?

In this scenario, we shouldn't randomize this baby as we would be unable to provide the baby with the study intervention if allocated to the continued feeds arm. However, if it is a 2nd or 3rd transfusion, and the baby is already allocated to a continued feeds arm, then this transfusion would be considered a protocol deviation.