Guidance Sheet 3: Preparation and administration of the Trial Intervention

- The active intervention in this trial is a live probiotic bacterium, *B. breve* BBG. The product is supplied as a freeze dried powder with corn starch. The placebo is freeze dried corn starch alone. A package **must only be used** by the baby for whom it is allocated.

Cross contamination

- In previous trials of probiotics, colonisation of participants with the bacterial strains under investigation has been found in some of the participants of the placebo arm. Cross colonisation of babies undermines the quality of the trial data.

- Cross colonisation may occur during preparation of the intervention or between babies in clinical areas of the ward and it is important that you are vigilant to the possibility of cross contamination. In the PiPS trial we will monitor rates of colonisation of babies. The procedures for the intervention preparation are designed to minimise this possibility.

- Cross contamination is most likely to occur when two or more babies require intervention preparation. It is important to avoid contamination between different babies' preparations of the intervention. Each time you prepare the intervention **you must ensure that**:
  - you **do not work between preparations** i.e. steps 6 - 12 should be completed sequentially for a single baby before another baby's preparation is started
  - you **wash your hands and clean the working surface before and after** each individual preparation (i.e. steps 1 and 13)
  - you **do not work between administrations** i.e. steps 15 - 18 should be completed sequentially for a single baby before another baby's administration
  - **after administration** you discard the bijou bottle and syringe then **wash your hands** before the next baby's administration
  - if you spill the intervention powder or solution that it is **thoroughly cleaned up**
  - when finished you discard the unused 1/8 strength Neocate and wash or sterilise the measuring jug and rack ready for use the next day.

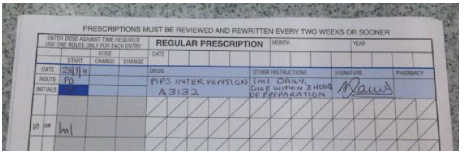
Preparation and administration

If after the intervention has settled it is inconvenient to administer it, it can be left for 2.5 hours and it will remain stable but you must ensure it is given within the **3 hour time limit** by checking the time recorded on the bijou bottle. After this time it should be discarded and a new preparation made. **Each wasted or spoiled** preparation or sachet (due to damage, spillage, expiration or contamination) should be recorded in the **Intervention Wastage Log**.

The box below lists the items needed for the trial intervention preparation (obtained from the PiPS Consumables Box) and overleaf describes the process step-by-step.

For the preparation of the trial intervention you will need:

- The baby's drug chart with the prescription for PiPS trial intervention
- The package of PiPS trial intervention allocated to the baby
- Neocate, at least 240mls of cooled boiled water and a clean jug
- An amber 7ml bijou bottle with screw top
- A fine permanent marker pen
- A 5ml syringe
- A 1ml enteral syringe (not provided)
- A 'vortexing' machine to facilitate mixing (this is not essential)
- A rack in which to stand the bijou bottle



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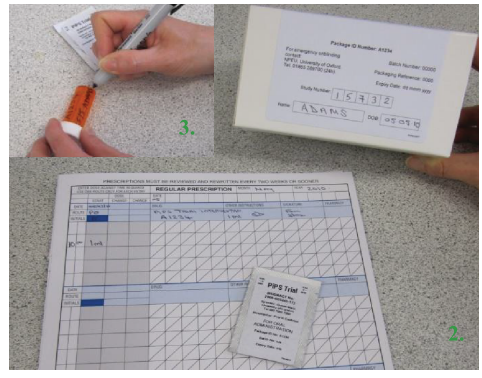
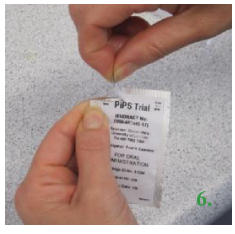
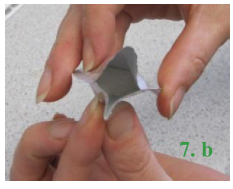
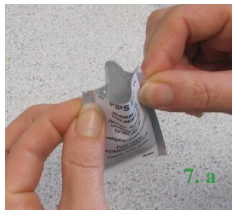
1. Wash your hands and wipe down the working surface with anti-bacterial wipes.
2. Take one foil sachet of intervention from the package checking:
   - that the number on the sachet, on the package and on the prescription are the same
   - that the name and DOB on the prescription and on the outside of the package are the same
3. Mark the outside of the bijou bottle with the **pack ID number**, the **baby's name** and the **time of preparation** using the marker pen.









4. Prepare 1/8 strength Neocate by adding one scoop of Neocate powder to 240mls of cooled boiled water into the clean jug and mix.
5. Using the 5ml syringe, draw up 3ml of 1/8 strength Neocate and inject it into the bijou bottle.
6. Tear across the top of the foil sachet at the point indicated.
7. Push the edges of the sachet together (**a**) and pinch the label to form a 'spout' (**b**).
8. Carefully pour all of the powder in the sachet into the bijou bottle and screw on the lid firmly.

This is most likely to be associated with some spillage and loss of powder. A minor loss is not important.

9. Discard foil sachet and wash your hands.

10. Agitate the bottle using the vortex mixer for 10 seconds to disperse the powder (**a**). If no vortex is available shake for 30 seconds. Check that the powder is dispersed (**b**); if not repeat as necessary.
11. Stand the bottle in the rack for 30 minutes to allow the corn starch to settle.
12. Wash your hands; clean the working surface and the vortex machine with anti-bacterial wipes.

When preparing intervention for more than one baby you can perform steps 1-5 using the same syringe and Neocate solution before opening any foil sachets.

13. After 30 minutes check the solution has settled out being careful not to disturb the corn starch sediment.
14. Carefully withdraw 1ml of supernatant into the syringe taking care not to disturb the sediment.
15. The volume of supernatant may vary, if after 0.8 ml you are anxious that you might disturb the residue stop and that day give just the 0.8ml.
16. Take the syringe with the sealed bijou bottle to the cotside. Check the **name**, **pack ID number** and **time of preparation** on the bottle with the prescription and the baby's ID tags.
17. Administer the supernatant in the syringe to the baby either via the feeding tube or, if the baby no longer has a tube, directly into the mouth.
18. Record the administration on the baby's **drug chart**.