

The Use of Probiotics in Preterm Babies

Main Author(s):	David Bartle, Paediatrician (RDE) Chris Knight, Paediatrician (TST) Pam Cairns, Neonatologist (UHB)
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<i>The South West Neonatal Network comprises of NHS Trust Neonatal Units in the following locations: Southmead (Bristol), St Michael's (Bristol), Yeovil, Gloucester, Bath, Barnstaple, Plymouth, Torbay, Truro, Exeter, Taunton, Swindon.</i>	

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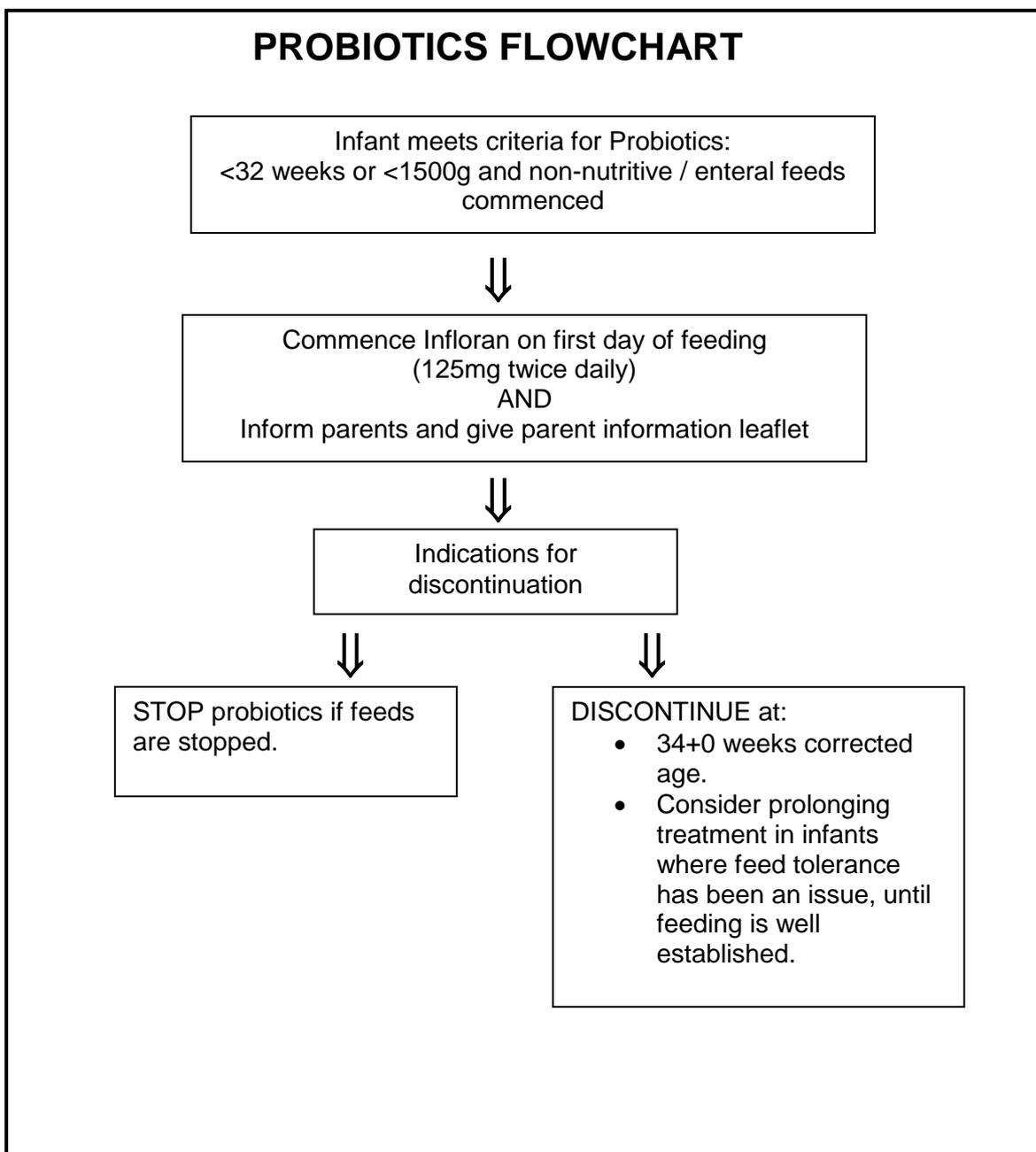
1. Scope of the Guideline

The Guideline applies to all Units within the South West Neonatal Network who care for babies <32 weeks gestation or birthweight <1500g.

2. Definition of Terms

NEC	Necrotising Enterocolitis
EBM	Expressed Breast Milk
NGT	Nasogastric Tube

3. Overview – USE OF PROBIOTICS IN PRETERM BABIES



4. Guideline- Use of Probiotics in Preterm Babies

The aetiological basis for Necrotising Enterocolitis (NEC) remains poorly understood but the nature of the bacterial colonisation of a baby's gut is felt to be a significant factor. Probiotics are gram positive non-pathogenic and non-toxicogenic live microbes which, when administered enterally, have been shown to successfully colonise the gut of preterm infants¹. Probiotic products such as Infloran contain lactobacilli and bifidobacteria, the predominant organisms found in the GI tract of healthy breastfed infants. Colonisation with these organisms is thought to protect the gut from colonisation by more pathogenic species.

Product

Infloran capsules (250mg/capsule)

Contents: *Lactobacillus acidophilus* and *Bifidobacterium Bifidum*.

Each capsule contains at least 10⁹ colony forming units.

Dosage and Administration

- Speak to parents, offer them written information (Appendix 1).
- Commence Infloran in any baby born <32 weeks or <1500g on the day non-nutritive feeds are started.
- Prescribe 125mg Infloran twice daily (half capsule) on drug chart to be administered via nasogastric tube or by mouth.
- Mix with 0.5-1ml expressed breast milk (EBM) (or sterile water) and give as bolus via NGT
- Do not add to continuous feeds.
- It is safe to provide this extra bolus twice daily even in babies only on 0.5ml/2 hourly.
- Stop probiotics in any baby if feeds are stopped.
- Probiotic use should not influence decisions regarding the rate of increase of enteral feeding. This remains as per protocol or as directed by the consultant in charge.

Preparation

- Preparation of probiotics should be carried out in the milk kitchen and disposal of any excess product should be carried out in to designated sharp bins and should not be tipped in to sinks.
- Storage: +2°C - +8°C (ie in drug fridge).

Duration and Indications for Stopping Infloran

- Continue until 34+0 weeks corrected age or until discharge, whichever is sooner. Consider prolonging treatment in infants where feed tolerance has been an issue, until feeding is well established.
- Only give Infloran to babies tolerating milk. It is safe to give even if feed volumes are as low as 0.5ml/2 hourly, provided feeds are tolerated. If feeds are stopped for whatever reason, this is also an indication for stopping Infloran.

Side Effects

No significant side effects have been reported.

No drug interactions have been reported.

5. Monitoring Effectiveness

Clinical Audit Standards and Governance

- Key outcomes (incidence of NEC, sepsis etc.) will be routinely recorded for infants that receive probiotics through Badger and the Vermont Oxford Network (<30/40 and <1500g). These audit figures will be presented yearly to the Mortality and Morbidity Meeting, and at any Neonatal / Paediatric Audit Meetings.
- In theory there is a small risk of infection to the patient from the organisms in the probiotics. It is also known that the risk of gut translocation of bacteria increases when babies are unwell. However, this possibility is considered unlikely as there were no infections secondary to probiotic organisms detected in over 2000 babies studied as part of probiotic research.

6. Associated Documents

Local Antibiotic / Septicaemia Guideline.
Use of Donor Breast Milk in Preterm Infants.

7. References

1. Deshpande G, Rao S, Patole S, Bulsara M. Updated meta-analysis of probiotics for preventing NEC in preterm neonates. *Pediatrics* 2010;125(5):921-30.
2. Wang Q, Dong J, Zhu Y. Probiotic supplement reduces risk of necrotizing enterocolitis and mortality in preterm very low-birth-weight infants: an updated meta-analysis of 20 randomized, controlled trials. *J Pediatr Surg* 2012; 47(1):241-248.
3. Deshpande GC, Rao SC, Keil AD, Patole SK. Evidence-based guidelines for use of probiotics in preterm neonates. *BMC Med.* 2011 Aug 2;9:92.
4. Lin H-C, Hsu C-H, Chen H-L, et al. Oral probiotics prevent necrotizing enterocolitis in very low birth weight preterm infants: A multicenter, randomized, controlled trial. *Pediatrics* 2008; 122; 693-700.
5. Lin H-C, Su B-H, Chen A-C, et al. Oral probiotics reduce the incidence and severity of necrotizing enterocolitis in very low birth weight infants. *Pediatrics* 2005; 115; 1-4.
6. Hey E, editor. *Probiotics in Neonatal Formulary 5. Drug use in pregnancy and the first year of life.* Oxford: Blackwell Publishing Ltd. Electronic version, 2008. Accessed via www.blackwellpublishing.com/medicine/bmj/nnf5/pdfs/new/probiotics.pdf

APPENDIX 1: PARENT INFORMATION LEAFLET

Probiotics in preterm infants

This leaflet provides information for the parents of babies born prematurely about the use of regular probiotic treatment.

What is the medication called and what is it used for?

It is called Infloran and is a probiotic treatment that contains the friendly bacteria that would usually be found in the intestine of breast-fed babies born at term. It is similar to drinking live yoghurt products. The bacteria are obtained by purifying a yoghurt type liquid so that your baby doesn't receive the milk part of the yoghurt.

How is it taken?

The product is contained in a capsule and is mixed with milk before being given.

How often should it be taken?

It is given twice a day until your baby reaches 34 weeks corrected age, or may be continued if there are difficulties with tolerating milk feeds.

What are the benefits?

Preterm babies frequently have unusual bacteria in their intestines, often as a result of other treatments we need to use, such as antibiotics. These unusual bacteria can increase the risks of serious diseases such as Necrotising Enterocolitis (NEC), which is a severe inflammatory disease of the bowel. Probiotics work by replacing these with normal bacteria, and by strengthening your baby's immune response to infection.

There is good research evidence that probiotics protect babies, reducing NEC by 30%, and improving babies' ability to tolerate milk feeds.

What are the side effects?

Research has shown probiotics to be safe. There are no known risks or side effects to taking probiotics. The treatment may be temporarily stopped if your baby becomes unwell or feeds are stopped for any reason.

What are the alternatives?

There are none.

Who to contact if you have any more questions

Please feel free to discuss this with the nurse caring for your baby or the consultant on duty, who will be happy to answer any queries you might have.

Reference: Deshpande G et al: Pediatrics 2010; 125; 921-930

Author: Enter author / name of Clinician

APPENDIX 2: AUDIT TOOL

Auditable Standard		No of Eligible Babies	No of Babies Received	% of Eligible Babies
1	Have eligible infants received probiotics when indicated?			
2	Are probiotics appropriately ceased as per indications for discontinuation?			
3	Did parents receive a Parent Information Leaflet?			
4	Has long-term monitoring of incidence of NEC been reported through Vermont-Oxford Network and Badger Data?			
5	Have any cases of possible sepsis from organisms introduced through probiotic use been reported to the Network Governance Group?			