UHL Neonatal Guideline: Probiotic administration in preterm infants

University Hospitals of Leicester NHS Trust

Trust ref: C47/2018

1. Introduction and Who Guideline applies to

This guideline is aimed at all Health care professionals involved in the care of infants within the Neonatal Service.

Aims:

- To outline the process for prescription and administration of a probiotic preparation. Current evidence suggests that probiotics may reduce the incidence of severe necrotising enterocolitis.

Key Points:

- Neonates < 32^{+0} gestation and <1500 grams are eligible for probiotics
- The probiotic formulation (Labinic) contains live bacteria. Standard infection control measures apply for its preparation and administration.
- Each probiotic bottle should be discarded 30 days after opening.
- The probiotic drops should be withheld if nil by mouth.
- Blood culture growth of *Lactobacillus acidophilus/ Bifidobacterum bifidum/ Bifidobacterium infantis* is uncommon and should be discussed with the consultant neonatologist and microbiologist.
- Labinic should be discontinued when an infant reaches 34 weeks corrected gestational age.

Related UHL documents:

Feeding Babies of Less than 30 Weeks Gestation UHL Neonatal Guideline Trust ref: C105/2005

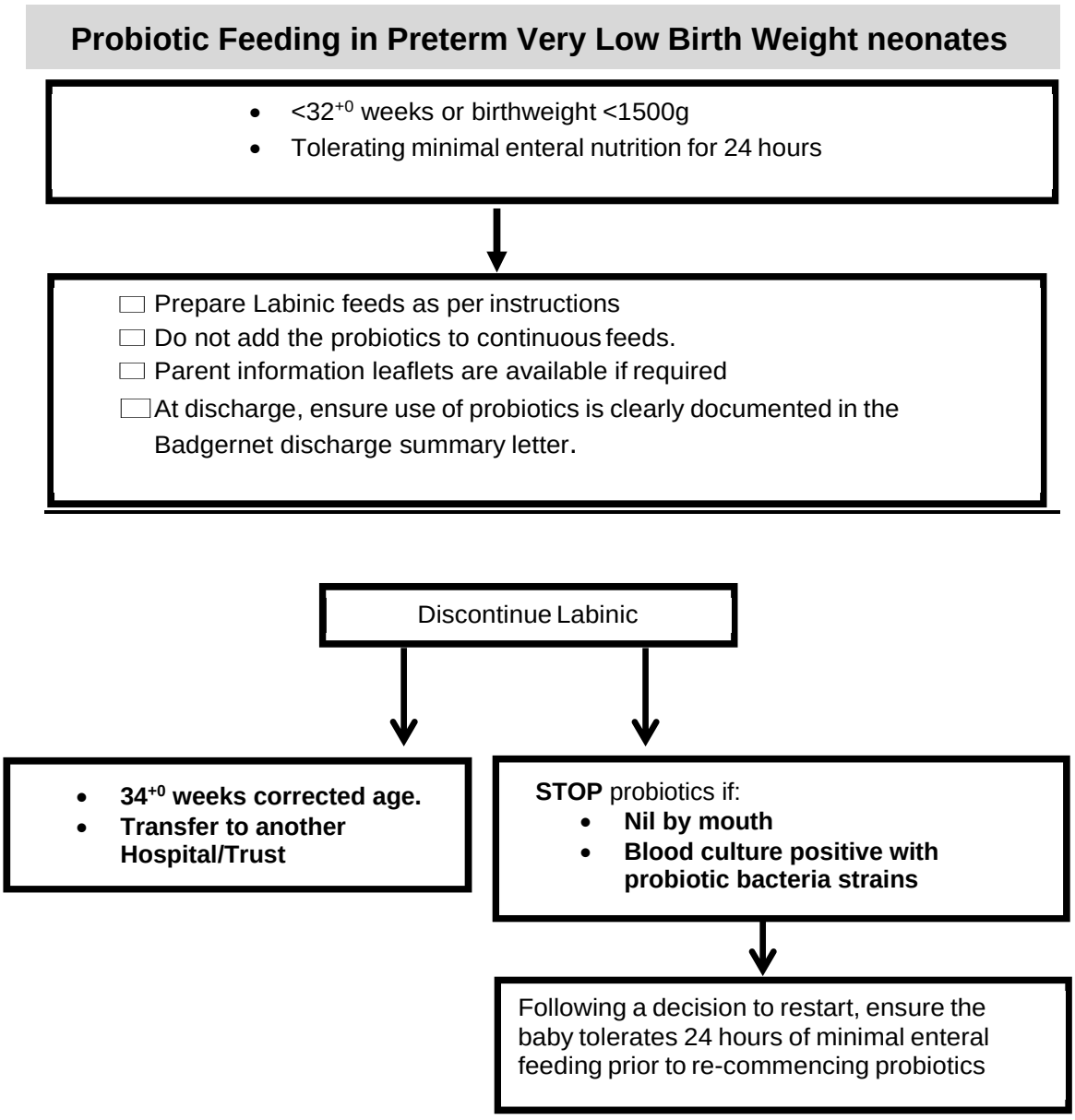
Background;

Systematic reviews (including meta-analyses) of studies employing different probiotic preparations and feeding regimens concluded that preterm and low birth weight infants benefit from probiotics to prevent severe necrotising enterocolitis and death [1-9]. The probiotic preparation Labinic is the preferred probiotic of choice on the UHL neonatal units due to shelf-life and ease of preparation [10].

2. Guidance:

2.1 Labinic: Composition and Characteristics

- Each 0.2 ml Labinic liquid drops contains approx. 2 billion bacteria (Lactobacillus acidophilus, Bifidobacterum bifidum and Bifidobacterium infantis)
- Other constituents: EU-approved food additive & medium chain triglyceride oil.
- Labinic is not licensed as a medicine; it is categorised as a food product.
- Storage is at room temperature (max 25°C)
- Labinic is lactose, dairy, gluten, soya and animal product free.



2.2 Probiotic (Labinic) Prescription

- Prescribe on drug chart as follows:
- **Labinic 0.16 ml (4 drops) once daily; given PO/NG with milk**.
- This needs to be checked prior to administration as with any medication.

2.3 When to stop Labinic

- Stop at 34 weeks corrected gestation
- If baby is nil by mouth for any reason.
- If baby develops blood culture positive with the probiotic bacteria strains.
- If being transferred to another hospital, the probiotic may be given on the day of transfer if due, but will not normally be continued in the receiving hospital unless they also have a policy of giving probiotics.

2.4 Probiotic (Labinic) Preparation and precautions (Appendix)

- The Labinic vials will be shared between patients. Labinic feeds should be prepared by strict adherence to aseptic non-touch technique in the drug preparation area.
- Use clean gloves and **do not touch the rim / inside of cap**.
- Shake the bottle well prior to first use and allow it to stand for 30 seconds. The bottle needs to be gently swirled for 5-10 seconds prior to subsequent uses.
- Ensure the bottle is dated when opened as the probiotics can only be used for 30 days. The bottle must be discarded after this.
- When opening a new bottle remove the stopper using clean gloves and discard it. Replace this with a small bung.
- Using a medical straw and sterile 1 ml oral (purple) syringe, aspirate 0.16 ml from the bottle.
- Please take care not to spill the excess medication around the sides of the bottle. If there is a spillage, use clean gloves and sterile gauze to wipe it.

2.5 Labinic administration

- Labinic is drawn directly from the bottle and given without further dilution either orally or via NGT.

- Start by giving the probiotic first. Following this, milk should be given to 'flush' the dose through the NGT. This will prevent blockage of the NGT.

3. Education & training:

None identified

4. Audit standards:

1. All eligible babies <32^{+0} weeks or < 1500 grams should receive probiotics drops with feeds (100%).
2. The probiotic drops should be discontinued at 34 weeks corrected gestation or when nil by mouth.

5. Supporting References:

1. Sawh SC et al. Prevention of necrotising enterocolitis with probiotics: a systematic review and meta-analysis. PeerJ 2016: 2429

2. Balain M, Oddie S, Banait N, et al. PC.99 PINC UK (Probiotics in Neonatal Collaboration in UK). Archives of Disease in Childhood Fetal and Neonatal Edition 2014;99:A70

3. AlFaleh K, Anabrees J. Probiotics for prevention of necrotizing enterocolitis in preterm infants. Cochrane Database of Systematic Reviews 2014, Issue 4. Art. No.: CD005496. DOI: 10.1002/14651858.CD005496.pub4

4. Shane AL, Deshpande GC, Merenstein D. Improved Neonatal Outcomes with Probiotics. JAMA Pediatr. 2013;167(10):885-886

5. Thomas JP, Raine T, Reddy S, Belteki G. Probiotics for the prevention of necrotising enterocolitis in very low-birth-weight infants: a meta-analysis and systematic review. Acta Paediatr 2017; 106: 1729–41.

6. Dermyshi E, Wang Y, Yan C, Hong W, Qiu G, Gong X, Zhang T. The "Golden Age" of Probiotics: A Systematic Review and Meta-Analysis of Randomized and Observational Studies in Preterm Infants. Neonatology. 2017;112:9-23. doi: 10.1159/000454668

7. Rees CM, Hall NJ, Fleming P, Eaton S. Probiotics for the prevention of surgical necrotising enterocolitis: systematic review and metaanalysis. BMJ Paediatrics Open 2017;1:e000066. doi:10.1136/bmjpo-2017-000066

8. Deshpande GC, Rao SC, Keil AD,Sanjay, K Patole SK. Evidence-based guidelines for use of probiotics in preterm neonates. BMC Medicine 2011;9:92

9. Abrahamsson TR. Using probiotics to prevent necrotising enterocolitis. Acta Paediatr 2017;106: 1718-1719

10. https://biofloratech.com/EU_page_Labinic_Drops.html

11. Neu J, Walker WA. Necrotizing enterocolitis. N Engl J Med 2011; 364: 255–64.

6. Key Words

Bifidobacterum bifidum, Bifidobacterium infantis, Feed, Lactobacillus acidophilus, Low birth weight,

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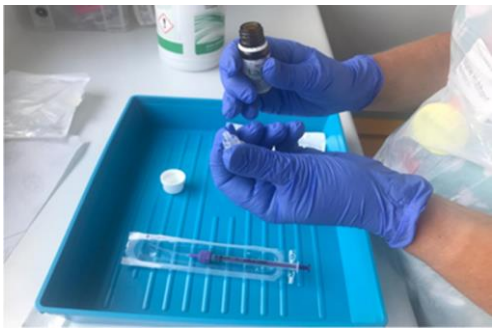
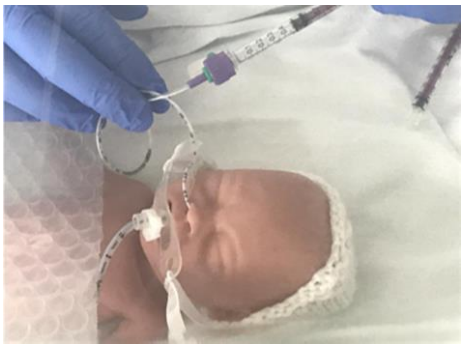
The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.
As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

CONTACT AND REVIEW DETAILS			
Guideline Lead (Name and Title) **Original authors:**Dr Deepa Panjwani – Consultant Neonatologist Somayya Giga – Senior Specialist Dietitian Dr Venkatesh Kairamkonda – Consultant Neonatologist **Guidelines Lead:** Sumit Mittal Consultant clinical guidelines lead			**Executive Lead** **Chief Medical Officer**
Details of Changes made during review:			
Date	**Issue Number**	**Reviewed By**	**Description Of Changes (If Any)**
Sept 2018	**1**	Neonatal Guidelines Meeting – New Guideline Neonatal Governance Meeting	(amendments recommended)
May 2021	**2**	Neonatal Guidelines Meeting Neonatal Governance Meeting	(Approved no changes)
April 2024	**3**	Neonatal Guidelines Meeting Neonatal Governance Meeting	Approved no changes I year review date requested as awaiting decision regarding new product

Appendix 1: Probiotic Administration

1. Preparation of Tray	
	Ensure ANTT technique has been followed for preparation of the tray. In the clean tray, you will require: • 1 ml oral syringe • medicines straw • small bung
2. Preparation of Probiotic	
	Use clean gloves Do not touch the dropper or rim.
	When opening a new bottle, shake well prior to use. Following this, remove the stopper using clean gloves and discard it. Ensure the bottle is dated when opened as once opened, the probiotics can only be used for 30 days and the bottle must be discarded after this.
	Replace the stopper with a small bung

	Using a medical straw, draw up 0.16 ml of probiotic into the syringe.
3. Administration to Baby	
	Start the feed by giving the 0.16 ml of probiotic via the nasogastric or orogastric tube.
	This should be followed immediately by a milk feed for the baby. Please follow the NG feeding guidance for this.

*Brief explanation of purpose of guideline **and users**, i.e. does it cover all staff, specific*