

# **Specialist Milk Provision on the Neonatal Unit Standard Operating Procedure**

**V1.0**

**July 2025**

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### **Data Protection Act 2018 (UK General Data Protection Regulation – GDPR) Legislation.**

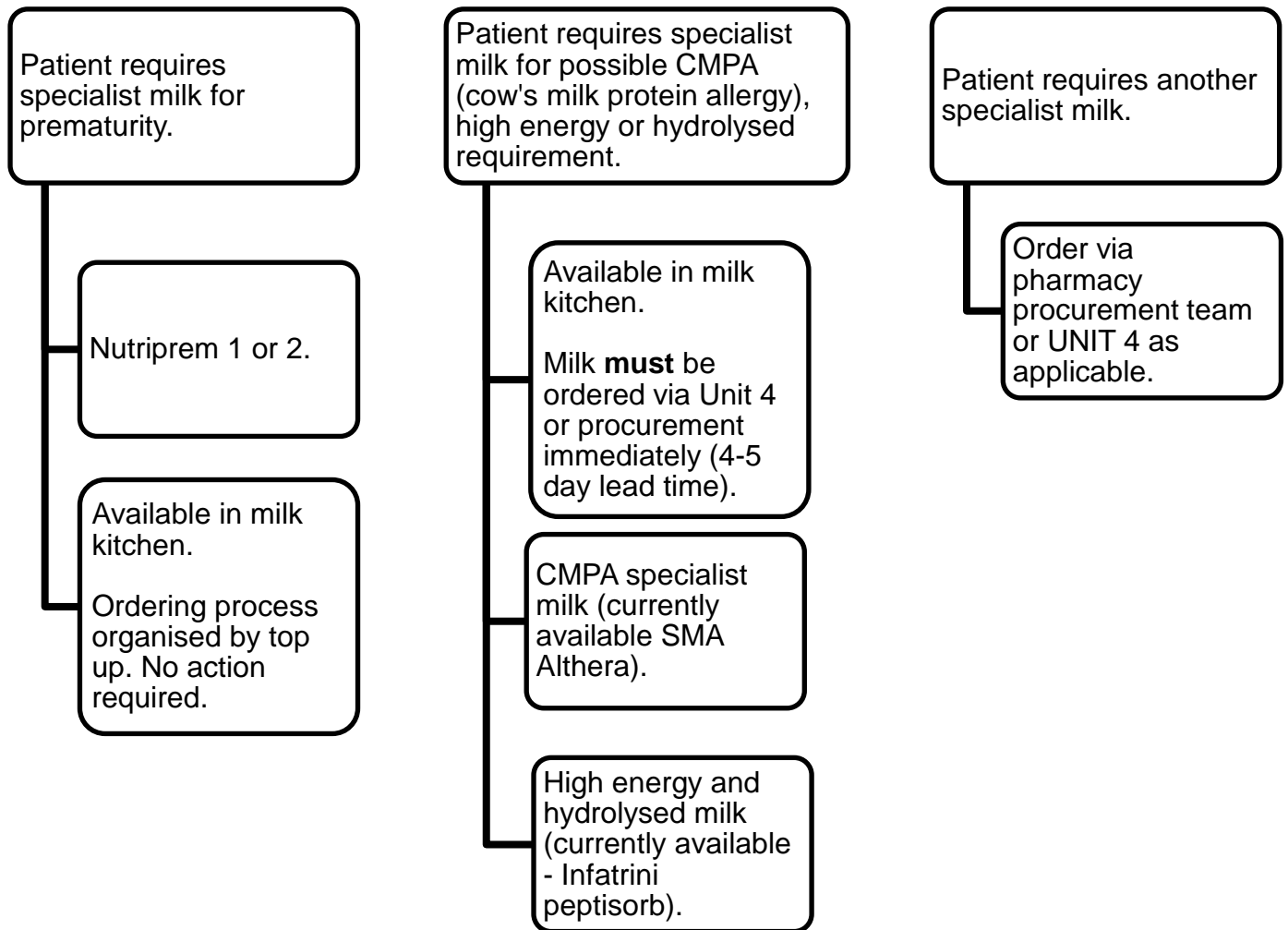
The Trust has a duty under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 please see the Information Use Framework Policy or contact the Information Governance Team.

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## Summary Flowchart



## 1. Introduction

This document gives information on the procurement routes for different specialist infant formula milks supplied on the neonatal unit.

## 2. Purpose of this Standard Operating Procedure

The Royal Cornwall Hospitals NHS Trust is committed to ensuring that its procurement practices comply with the WHO International Code of Marketing of Breastmilk Substitutes. More information on the requirements of health workers working within the International Code of Marketing of Breastmilk Substitutes can be found here: [A guide for health workers to working within the Code - Baby Friendly Initiative \(unicef.org.uk\)](https://www.unicef.org.uk/infant-friendly-initiative). Changes made in the procurement of specialist milks within the Neonatal unit is reflected in this standard operating procedure.

## 3. Ownership and Responsibilities

All staff working within the Neonatal Unit are responsible for complying with this standard operating procedure.

## 4. Standards and Practice

- 4.1. The procurement of the majority of formula milks on the Neonatal unit are organised via either the Pharmacy Department or via top up and the procurement service. As the current pharmacy contract is non-compliant with the International Code of Marketing of Breastmilk Substitutes, the Neonatal unit has changed the way in which it procures the following specialist milks:
  - 4.1.1. SMA Althera.
  - 4.1.2. Infatrini Peptisorb.
- 4.2. Both SMA Althera and Infatrini Peptisorb will be kept in small amounts (2 x 400g tubs of SMA Althera, and 1x tray of 24 Infatrini Peptisorb) on the neonatal unit and will be procured via the NHS supply chain and UNIT 4 ordering system. This will ensure that the NHS supply chain price is paid by the neonatal unit.
- 4.3. Staff will be required to order either specialist formula on Unit 4 or via procurement as soon as a patient is commenced on the product as this system has a lead time of 4-5 days. The Neonatal Equipment Manager will be able to support the ordering process.
- 4.4. If, in the immediate short term, additional milk to what is in stock on NNU is needed until milk arrives via UNIT 4, then it can be ordered via pharmacy to avoid there being a gap in patient provision. However, this should be a **last resort** and as much as possible avoided, due to the aforementioned non-code compliance.

## 5. Dissemination and Implementation

This standard operating procedure will be disseminated to all staff working within the Neonatal unit. These products are always used under the supervision of the dietetic team.

## 6. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	All usage of the two specialist milks will be monitored to ensure compliance with the standard operating procedure.
Lead	Dellen Prescott - Neonatal Infant feeding Lead.
Tool	An audit of the amount of either SMA Althera or Infatrini Peptisorb used and purchased for each patient will be conducted.
Frequency	Audit will be conducted when the product is used. These products are infrequently used by the Neonatal unit.
Reporting arrangements	The results of the audit will be reported to the Neonatal infant feeding strategy group and to the Joint RCHT infant feeding strategy group. Both of which run every 2 months. Any discrepancies in procedure compliance will be incident reported and investigated to ensure causality is identified and discussed in the steering committees to decide actions taken.
Acting on recommendations and Lead(s)	Neonatal Infant Feeding Strategy Group.
Change in practice and lessons to be shared	Required changes to practice will be identified and actioned within 2 months. A lead member of the team will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders.

## 7. Updating and Review

This Standard operating procedure should be reviewed following the renegotiation of the pharmacy procurement contract which is expected in 2026.

## 8. Equality and Diversity

8.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the [Equality Diversity And Inclusion Policy](#) or the [Equality and Diversity website](#).

8.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

## Appendix 1. Governance Information

Information Category	Detailed Information
<b>Document Title:</b>	Specialist Milk Provision on the Neonatal Unit Standard Operating Procedure V1.0
<b>This document replaces (exact title of previous version):</b>	New Document
<b>Date Issued/Approved:</b>	July 2025
<b>Date Valid From:</b>	July 2025
<b>Date Valid To:</b>	July 2028
<b>Author/Owner:</b>	Dellen Prescott, Neonatal Infant Feeding Lead
<b>Contact details:</b>	<a href="mailto:rcht.neonatalinfantfeedingteam@nhs.net">rcht.neonatalinfantfeedingteam@nhs.net</a>
<b>Brief summary of contents:</b>	This SOP guides the procedure for procurement of specialist formula milks on the neonatal unit.
<b>Suggested Keywords:</b>	CMPA, cow's milk protein allergy, hydrolysed, infant formula, high energy formula, international code of marketing, the code.
<b>Target Audience:</b>	<b>RCHT:</b> Yes <b>CFT:</b> No <b>CIOB ICB:</b> No
<b>Executive Director responsible for Policy:</b>	Chief Medical Officer
<b>Approval route for consultation and ratification:</b>	Neonatal Audit and Guidelines Group
<b>Manager confirming approval processes:</b>	Caroline Chappell
<b>Name of Governance Lead confirming consultation and ratification:</b>	Michael Cross
<b>Links to key external standards:</b>	WHO International Code of Marketing of Breastmilk Substitutes: <a href="https://www.who.int/publications/m/item/international-code-of-marketing-of-breast-milk-substitutes">International Code of Marketing of Breast-Milk Substitutes (who.int)</a> . UNICEF Baby Friendly Initiative: <a href="https://www.unicef.org/uk/baby-friendly-initiative">A guide for health workers to working within the Code - Baby Friendly Initiative (unicef.org.uk)</a> .

Information Category	Detailed Information
Related Documents:	None required
Training Need Identified:	No
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
Document Library Folder/Sub Folder:	Clinical/Neonatal

### Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
July 2025	V1.0	Initial issue.	Dellen Prescott; Neonatal Infant Feeding Lead.

**All or part of this document can be released under the Freedom of Information Act 2000.**

**All Policies, Strategies and Operating Procedures, including Business Plans, are to be kept for the lifetime of the organisation plus 6 years.**

**This document is only valid on the day of printing.**

### Controlled Document.

This document has been created following the Royal Cornwall Hospitals NHS Trust [The Policy on Policies \(Development and Management of Knowledge Procedural and Web Documents Policy\)](#). It should not be altered in any way without the express permission of the author or their Line Manager.

## Appendix 2. Equality Impact Assessment

### Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity, and Inclusion Team  
[rcht.inclusion@nhs.net](mailto:rcht.inclusion@nhs.net)

Information Category	Detailed Information
<b>Name of the strategy/policy/proposal/service function to be assessed:</b>	Specialist Milk Provision on the Neonatal Unit Standard Operating Procedure V1.0
<b>Department and Service Area:</b>	Neonatal
<b>Is this a new or existing document?</b>	New
<b>Name of individual completing EIA</b> (Should be completed by an individual with a good understanding of the Service/Policy):	Dellen Prescott, Neonatal Infant Feeding Lead
<b>Contact details:</b>	01872 252667

Information Category	Detailed Information
<b>1. Policy Aim - Who is the Policy aimed at?</b>  (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	All staff working within the Neonatal unit, this includes allied health professionals.
<b>2. Policy Objectives</b>	To ensure clear routes for procurement of specialist formula milks on the neonatal unit.  To ensure compliance of the Neonatal unit with the International Code of Marketing of Breastmilk substitutes.
<b>3. Policy Intended Outcomes</b>	Clear guidance for staff as to procurement routes.  SMA Althera and Infatrini Peptisorb not purchased via pharmacy procurement route.
<b>4. How will you measure each outcome?</b>	All usage of either SMA Althera or Infatrini will be audited to ensure purchasing route is via UNIT 4 and NHS supply chain.



Information Category	Detailed Information
<b>5. Who is intended to benefit from the policy?</b>	Staff.
<b>6a. Who did you consult with?</b> (Please select Yes or No for each category)	<ul style="list-style-type: none"> <li>Workforce: Yes</li> <li>Patients/visitors: No</li> <li>Local groups/system partners: Yes</li> <li>External organisations: Yes</li> <li>Other: No</li> </ul>
<b>6b. Please list the individuals/groups who have been consulted about this policy.</b>	<b>Please record specific names of individuals/groups:</b> Neonatal Dietician - Holly Byatt. Lead Consultant for the Neonatal Unit – Christopher Bell. Director of Nursing and AHPs – Louise Dickinson. Matron for Neonatal and Transitional Care – Helen Greenhill. UNICEF Baby Friendly Initiative Professional Lead for Neonatal Standards – Karen Read.
<b>6c. What was the outcome of the consultation?</b>	Agreed.
<b>6d. Have you used any of the following to assist your assessment?</b>	<b>National or local statistics, audits, activity reports, process maps, complaints, staff, or patient surveys:</b> No.

## 7. The Impact

Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
<b>Age</b>	No	
<b>Sex</b> (male or female)	No	
<b>Gender reassignment</b> (Transgender, non-binary, gender fluid etc.)	No	

Protected Characteristic	(Yes or No)	Rationale
<b>Race</b>	No	Any information provided should be in an accessible format for the parent/ carer/ patient's needs- i.e., available in different languages if required/ access to an interpreter if required.
<b>Disability</b> (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	Those parent/ carer/ patients with any identified additional needs will be referred for additional support as appropriate- i.e., to the Liaison Team or for specialised equipment.  Written information will be provided in a format to meet the family's needs e.g., easy read, audio etc.
<b>Religion or belief</b>	No	All staff should be aware of any beliefs that may impact on the decision to treat and should respond accordingly.
<b>Marriage and civil partnership</b>	No	All staff should be aware of any marital arrangements that may have an impact on care (for example: separated parents, domestic abuse).
<b>Pregnancy and maternity</b>	No	
<b>Sexual orientation</b> (e.g. gay, straight, bisexual, lesbian etc.)	No	

**A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.**

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment: Dellen Prescott.

**If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:**  
[Section 2. Full Equality Analysis](#)