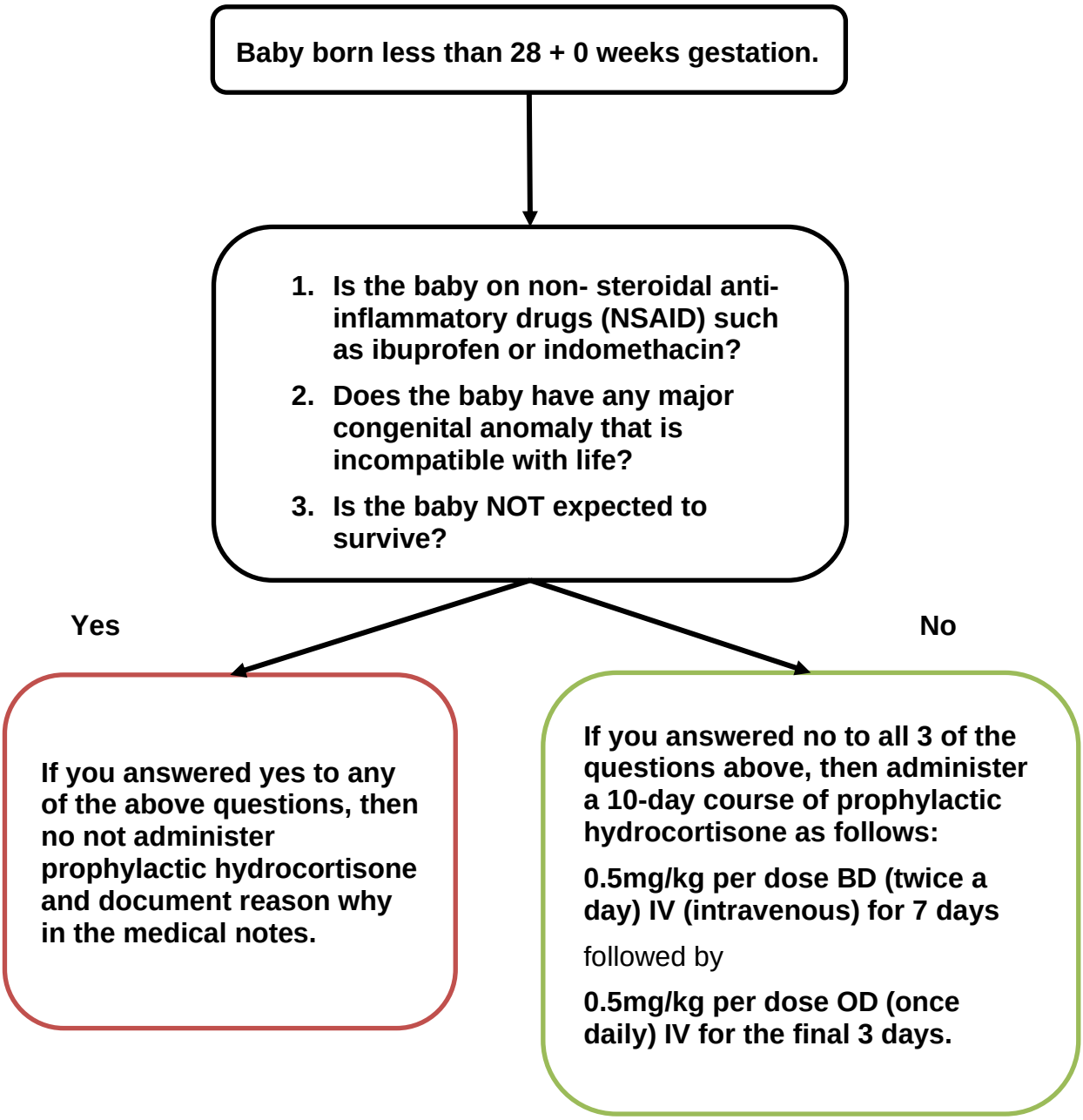
Royal Cornwall Hospitals
NHS Trust

Prophylactic Hydrocortisone Low Dose Treatment for Babies Born Before 28 Weeks Gestation Neonatal Clinical Guideline

V2.0

May 2024

Summary


Baby born less than 28 + 0 weeks gestation.
1. Is the baby on non- steroidal anti-inflammatory drugs (NSAID) such as ibuprofen or indomethacin?
2. Does the baby have any major congenital anomaly that is incompatible with life?
3. Is the baby NOT expected to survive?
Yes
No
If you answered yes to any of the above questions, then no not administer prophylactic hydrocortisone and document reason why in the medical notes.
If you answered no to all 3 of the questions above, then administer a 10-day course of prophylactic hydrocortisone as follows:
0.5mg/kg per dose BD (twice a day) IV (intravenous) for 7 days
followed by
0.5mg/kg per dose OD (once daily) IV for the final 3 days.

1. Aim/Purpose of this Guideline

1.1. As part of the Perinatal Excellence to Reduce Injury in Preterm Birth Bundle (PERIPrem) being delivered in the South West of England Region by all Neonatal Units in the South West Neonatal Network (SWNN), recommendations have been made that eligible babies born earlier than 28 weeks receive low dose hydrocortisone, and is supported by the SWNN and the South West Academic Health Science Network (SWAHSN), the Health Innovation Network (HIN) and the British Association of Perinatal Medicine (BAPM). This also supports the ongoing work on the NHS Long Term Plan to reduce stillbirth, maternal mortality and serious brain injury by 50% by 2025.

1.2. Bronchopulmonary dysplasia (BPD) is the leading cause of mortality as well as short-term and long-term respiratory morbidity in extremely premature infants born between 23+0 and 27+6 weeks gestation and is strongly associated with adverse neurodevelopmental outcomes.

1.3. This guideline aims to provide guidance for treating babies born at less than 28+0 weeks gestation with prophylactic hydrocortisone to reduce the risk of bronchopulmonary dysplasia (BPD), neurodevelopmental impairment and mortality.

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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2. The Guidance

2.1. Preterm infants born earlier than 28 weeks of gestation are eligible to receive low dose hydrocortisone except:

- Preterm infants who are not expected to survive.
- Major congenital anomalies that are incompatible with life.
- Preterm infants receiving NSAID such are ibuprofen or indomethacin, since this will significantly increase the risk of spontaneous intestinal perforation.

2.2. Infection, such as neonatal sepsis or chorioamnionitis, is not a contraindication to the low/physiologic dose hydrocortisone therapy.

2.3. **Dosing Regime**

- A 10-day intravenous (IV) course starting within 24 hours of birth consisting of:
  - 0.5mg/kg per dose BD IV for 7 days followed by
  - 0.5mg/kg per dose OD IV for 3 days
- The prophylactic hydrocortisone dosing regime is included in the EPMA (Electronic Prescribing and Medicines Administration System) bundle: “NEONATAL <28/40 care bundle protocol”.
- There is also a standalone prophylactic hydrocortisone EPMA bundle available: “NEONATAL PROPHYLACTIC HYDROCORT”.

2.4. **Administration**

- The ward stocks Hydrocortisone Sodium Succinate. Please reconstitute vial of Hydrocortisone Sodium Succinate with 1.9mL of water for injection to give a concentration of 50mg in 1mL. This will need further diluting with sodium chloride as below.
- Draw up 20mg (0.4mL) hydrocortisone sodium succinate and dilute up to 20mLs with 0.9% Sodium Chloride to give 20mg in 20mL (1mg in 1mL).
- Draw up dose required from this 1mg in 1mL solution.
- Administer dose required via slow push over at least 3 minutes.

2.5. **Potential side effect**

Intestinal perforation if used simultaneously with indomethacin. No evidence available to extrapolate about simultaneous use with ibuprofen.

Increase prevalence of late onset sepsis reported, however this finding all-cause mortality was substantially reduced, and neurodevelopmental outcomes not adversely affected.

All though short-term neurodevelopmental outcomes at 2 years of age were not negatively impacted, longer term follow up is required to be able to assess the impact on children’s neurodevelopmental and neurosensory outcomes after 2 years of age.

2.6. **Potential Benefit**

Early low dose hydrocortisone treatment can improve survival without BPD (bronchopulmonary dysplasia) (NNT (number needed to treat) 12), showed a

reduction in frequency for PDA (patent ductus arteriosus) ligation and an increased proportion of infants not requiring oxygen at 36 weeks of postmenstrual age. It can increase the incidence of extubation by the end of the dosing regimen for all gestations and in babies born between 26+0-27+6, hydrocortisone also significantly reduced the risk of neonatal death before discharge.

Early low dose hydrocortisone is not associated with a statistically significant difference in neurodevelopmental outcomes at 2 years of age for babies born before 28+0 weeks of gestation and infant neurodevelopmental outcomes are improved with low dose hydrocortisone treatment, particularly in infants born at less than 26+0 weeks gestation.

3. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	Compliance with guideline.
Lead	Charlotte Lea, Neonatal Guidelines Lead.
Tool	Adherence to guideline will be monitored as part of the ongoing audit process within the neonatal unit on a Word or Excel template.
Frequency	As dictated by audit findings.
Reporting arrangements	Neonatal Guidelines Group. PERI Prem Team.
Acting on recommendations and Lead(s)	PERI PREM recommendation for SWNN guideline.
Change in practice and lessons to be shared	Required changes to practice will be identified and actioned within 3 months, immediately if required. 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.

4. Equality and Diversity

4.1. 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.

4.2. Equality Impact Assessment

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

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	Prophylactic Hydrocortisone Low Dose Treatment for Babies Born Before 28 weeks Gestation Neonatal Clinical Guideline V2.0
This document replaces (exact title of previous version):	Prophylactic Hydrocortisone Low Dose Treatment for Babies Born Before 28 weeks Gestation Neonatal Clinical Guideline V1.0
Date Issued/Approved:	May 2024
Date Valid From:	May 2024
Date Valid To:	May 2027
Directorate / Department responsible (author/owner):	Rachel Bailey; Neonatal Sister
Contact details:	01872 252667
Brief summary of contents:	This guideline applies to Neonatal Unit medical and nursing staff for babies born at less than 28 weeks gestation who should receive prophylactic hydrocortisone.
Suggested Keywords:	Neonate, neonatal, prophylactic hydrocortisone, CLD, BPD, bronchopulmonary dysplasia, chronic lung disease.
Target Audience:	**RCHT:** Yes **CFT:** No **CIOS ICB:** No
Executive Director responsible for Policy:	Chief Medical officer
Approval route for consultation and ratification:	Neonatal Audit and Guidelines Group
Manager confirming approval processes:	Caroline Chappell
Name of Governance Lead confirming consultation and ratification:	Tamara Thirlby
Links to key external standards:	None required

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
February 2021	V1.0	Initial issue.	Andrew Collinson, Consultant Paediatrician and Neonatologist.
May 2024	V2.0	Sections 2.2 updated to confirm chorioamnionitis not a contraindication. Dosing regime updated in section 2.3. Administration guidance updated in section 2.4	Rachel Bailey; Neonatal Sister. Sabrina Tierney: Paediatric Pharmacist.

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

Information Category	Detailed Information
Name of the strategy / policy / proposal / service function to be assessed:	Prophylactic Hydrocortisone Low Dose Treatment for Babies Born Before 28 weeks Gestation Neonatal Clinical Guideline V2.0
Directorate and service area:	Neonatal
Is this a new or existing Policy?	Existing
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Neonatal Audit and Guidelines Group
Contact details:	01872 252667

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	This guideline aims to provide guidance for treating babies born at less than 28+0 weeks gestation with prophylactic hydrocortisone to reduce the risk of bronchopulmonary dysplasia (BPD), neurodevelopmental impairment and mortality.
2. Policy Objectives	As above.
3. Policy Intended Outcomes	To improve the well-being of patients by offering the appropriate management of patients.
4. How will you measure each outcome?	Audit/ Multidisciplinary team weekly discussion/ incidents/ risk management.
5. Who is intended to benefit from the policy?	Patients and their families.

Information Category	Detailed Information
6a. Who did you consult with? (Please select Yes or No for each category)	• Workforce: Yes • Patients/ visitors: No • Local groups/ system partners: No • External organisations: No • Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	**Please record specific names of individuals/ groups:** Neonatal Audit and Guidelines Group.
6c. What was the outcome of the consultation?	Approved.
6d. Have you used any of the following to assist your assessment?	**National or local statistics, audits, activity reports, process maps, complaints, staff, or patient surveys:** 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
Age	No	
Sex (male or female)	No	
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	
Race	No	Any information provided should be in an accessible format for the parent/ carer needs- i.e., available in different languages if required/ access to an interpreter if required.

Protected Characteristic	(Yes or No)	Rationale
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	Those parent/ carer 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.
Religion or belief	No	
Marriage and civil partnership	No	
Pregnancy and maternity	No	
Sexual orientation (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: Neonatal Audit and Guidelines Group.

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