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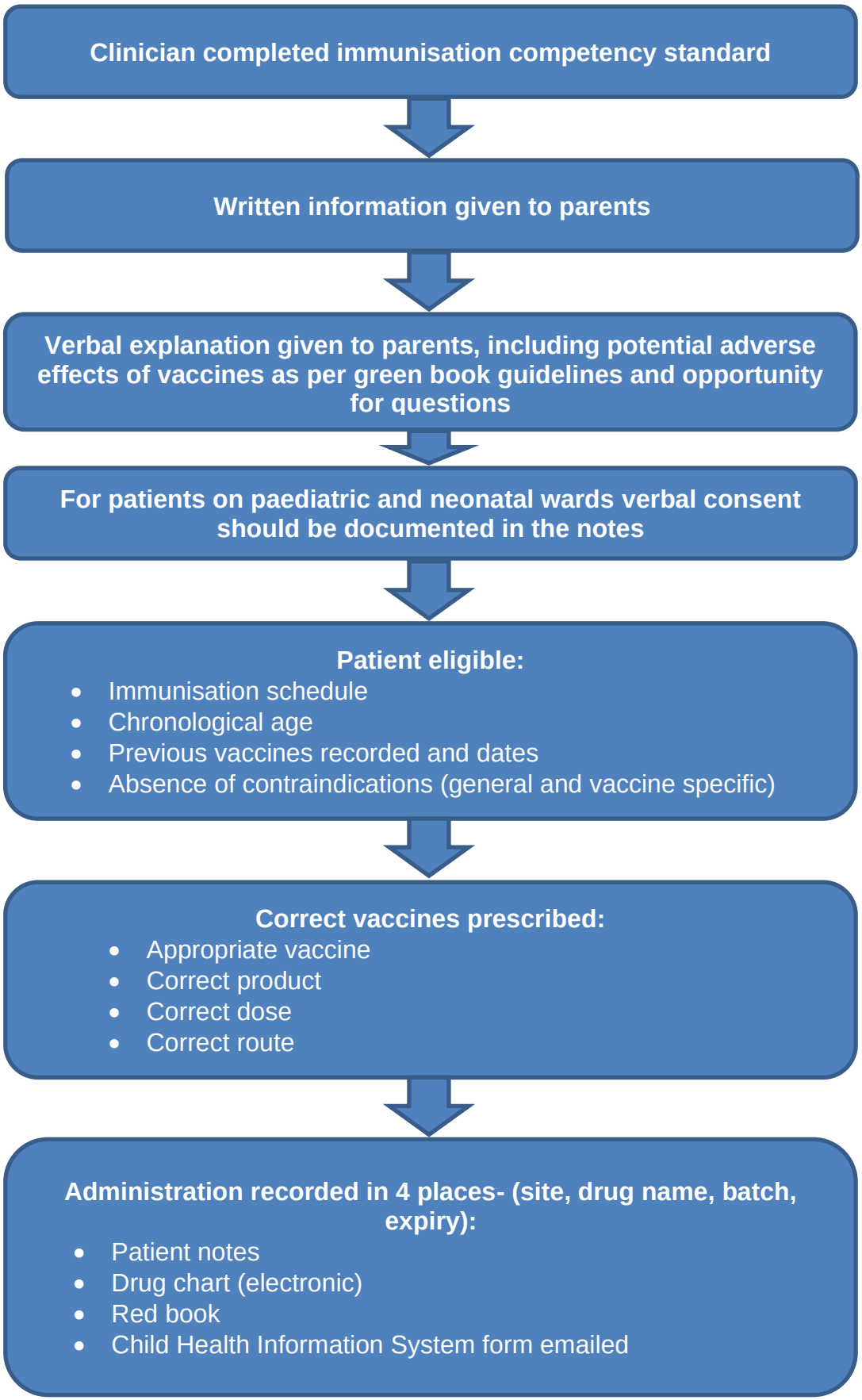
Royal Cornwall Hospitals NHS Trust

Immunisations in Infants and Children Neonatal Clinical Guideline

V3.0

May 2023

Summary


Clinician completed immunisation competency standard
Written information given to parents
Verbal explanation given to parents, including potential adverse effects of vaccines as per green book guidelines and opportunity for questions
For patients on paediatric and neonatal wards verbal consent should be documented in the notes
Patient eligible:
Immunisation schedule
Chronological age
Previous vaccines recorded and dates
Absence of contraindications (general and vaccine specific)
Correct vaccines prescribed:
Appropriate vaccine
Correct product
Correct dose
Correct route
Administration recorded in 4 places- (site, drug name, batch, expiry):
Patient notes
Drug chart (electronic)
Red book
Child Health Information System form emailed

1. Aim/ Purpose of this Guideline

1.1. This guideline is designed to support clinical staff, both medical and nursing, involved in immunisation programs.

1.2. This version supersedes any previous versions of this document.

Data Protection Act 2018 (General Data Protection Regulation – GDPR) Legislation

The Trust has a duty under the Data Protection Act 2018 and 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 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 General Data Protection Regulations 2016/679 please see the Information Use Framework Policy or contact the Information Governance Team

Royal Cornwall Hospital Trust rch-tr.infogov@nhs.net

2. The Guidance

2.1. **Introduction**:

Throughout this guidance, reference is made to Public Health England's Immunisation against infectious disease "Green Book" Guidance (GBG), see:

https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book

The current immunisation schedule can be found at:

https://www.gov.uk/government/publications/the-complete-routine-immunisation-schedule

2.2. **Immunisation Competency Standard**

This is a competency standard which should be completed and achieved in order for a member of qualified clinical staff to independently immunise patients on the neonatal or paediatric wards.

Clinical staff wishing to independently immunise patients should have completed the sections below:

- Be familiar with the local SOP for immunisations and also have read and understand the Green Book Guidance on immunisations – particularly sections:

- Immunity and how vaccines work: the green book, chapter 1.
- Immunisation procedures: the green book, chapter 4.
- UK immunisation schedule: the green book, chapter 11.

- Be familiar with the immunisation checklist.
- Observe, on at least one occasion, a colleague (who is competent in the immunisation procedure) administer immunisations, as per section 6 of SOP - immunisation procedure.
- Be observed by a colleague (who is competent in the immunisation procedure), to administer immunisations competently as per section 6 of SOP - immunisation procedure.

Once the observing colleague is satisfied that the member of staff has demonstrated competence with the immunisation procedure, they can perform this procedure independently.

There is no need for formal record of competence, but it is suggested that a DOPs assessment is completed, where applicable.

2.3. **Pre- Immunisation administration:**

2.3.1. Ensure immunisation checklist completed (see Appendix 3)

- **Immunisation Schedule**

  https://www.gov.uk/government/publications/the-complete-routine-immunisation-schedule

  It is important to ensure you are referring to the correct schedule according to the date of birth of the child.

- **Consent**:

  Please refer to chapter 2 of the Green book:

  https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book

NOTE For pre-term infant's immunisations should be administered according to chronological age, regardless of prematurity.

2.3.2. Individuals, or those giving consent on their behalf, must be given information about the process, benefits and risks of the immunisation(s), including awareness of possible adverse reactions (ADRs) and how to treat them.

2.3.3. Written or verbal information should be available in a form that can be easily understood by the individual who will be giving the consent.

2.3.4. Consent for those unable to give consent themselves, can be given

by a person with parental responsibility. Where this person brings the baby/child in response to an invitation for immunisation and, following an appropriate consultation, presents the child for that immunisation, these actions may be considered evidence of consent. However, if the baby/child is already an inpatient, either on the neonatal unit or paediatric ward, then consent cannot be assumed in this way and should be obtained in written form.

2.3.5. Parents should be directed to www.nhs.uk/vaccination which contains extensive information for parents on immunisation, and the leaflet 'A quick guide to childhood immunisation for the parents of premature babies', which can be found at:

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/849306/PHE_11490_premature_quickguide_Jan2020.pdf

2.3.6. General contraindications

See Chapter 6 of the green book for further information.

2.3.6.1. Also be aware of vaccine specific contra-indications. See GBG part 2 (chapter 13 onwards): https://www.gov.uk/government/collections/immunisation-against-infectious-disease- the-green-book

2.3.6.2. Occasionally you will need to seek additional advice about specific precautions to immunisation, i.e.:

- Bleeding Disorders.
- Immune-compromised patient - either the result of medication or illness.
- Past vaccine reactions.
- (Pregnancy).

2.3.6.3. All vaccines are contraindicated in those who have had a confirmed anaphylactic reaction to a previous dose of a vaccine containing the same antigens. Live vaccines may be temporarily contraindicated in individuals who are immunosuppressed or pregnant. Individuals with a confirmed anaphylactic reaction to egg should not receive yellow fever vaccine. Individuals who have egg allergy may be at increased risk of reaction to some influenza vaccines - refer to Chapter 8 GBG.

2.3.6.4. All children with egg allergy should receive the MMR vaccination as a routine procedure in primary care.

Recent data suggests that anaphylactic reactions to MMR vaccine are not associated with hypersensitivity to egg antigens but to other components of the vaccine (such as

gelatin) (Fox and Lack, 2003). In three large studies with a combined total of over 1000 patients with egg allergy, no severe cardiorespiratory reactions were reported after MMR vaccination (Fasano et al,1992; Freigang et al, 1994; Aickin et al, 1994; Khakoo and Lack, 2000). Children who have had documented anaphylaxis to the vaccine itself should be seen by an allergist.

2.3.7. Adverse effects following immunisation:

See Chapter 8 of the Green book:

https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book

2.3.7.1. Be aware of vaccine specific adverse effects (AEs) – GBG part 2 (Chapter 13 onwards).

2.3.7.2. All healthcare professionals administering vaccines must have received specific training regarding the recognition and treatment of anaphylaxis.

2.3.7.3. Common AEs include local reactions that generally start within a few hours of the injection and are usually mild and self-limiting – i.e., pain, swelling or redness at the site of injection.

2.3.7.4. Fevers over 37.5oC are common in children and are usually mild. Advice on the use and appropriate dose of paracetamol or ibuprofen to treat a fever should be given at the time of immunisation. For patients receiving the meningitis B vaccine it is advised that patients receive 3 doses of prophylactic paracetamol, starting at the time of the immunisation. These doses are prescribed as part of the relevant immunisation protocols on EPMA.

2.3.7.5. Other self-limiting systemic AEs include malaise, myalgia, irritability, headache, and loss of appetite.

2.3.7.6. Although one study in preterm babies found that cardiorespiratory events were as likely to decrease as to increase after immunisation (A Kent et al. Abstract at ESPID 2014. EudraCT number: 2007-007535-23), the likelihood of apnoea following vaccination is especially increased in infants who were born very prematurely. Infants born less than 29 completed weeks gestation who are vaccinated in hospital should have respiratory monitoring for 48-72 hrs when given the first dose. If the infant has apnoea, bradycardia, or desaturations after the first immunisation, the second immunisation should also be given in hospital, with respiratory monitoring for 48-72 hrs (Department of Health Green Book Chapter 7).

2.4. Injection procedure:

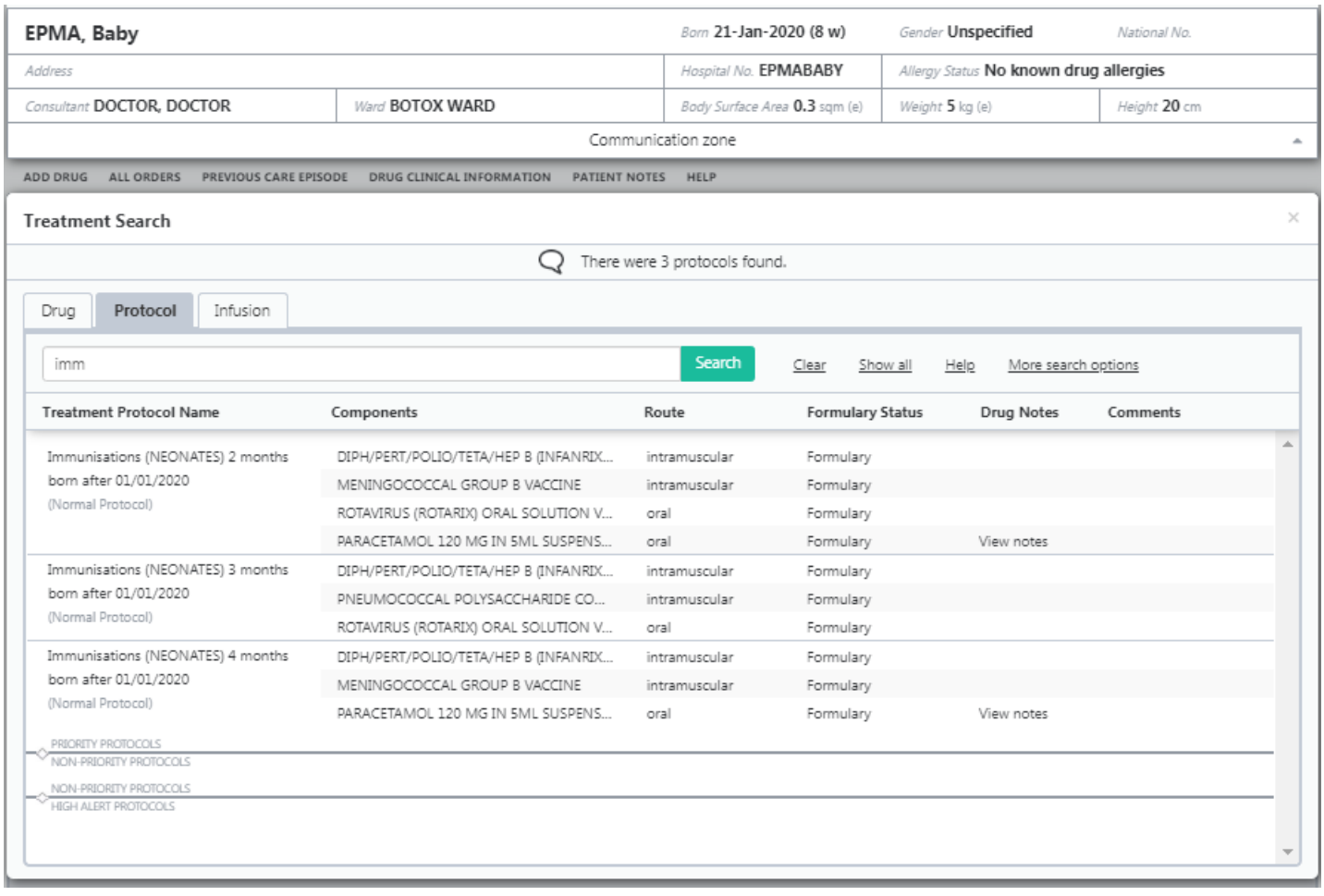
GBG Chapter 4:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/147915/Green-Book-Chapter-4.pdf

Injection technique, choice of needle length and gauge (diameter), and injection site are important considerations, since these factors can affect both the immunogenicity of the vaccine and the risk of local reactions at the injection site.

2.4.1. Prescribing:

When prescribing on EPMA for inpatients the immunisation protocols should be used. Care should be taken to ensure that the correct protocol is selected based on patient's age and date of birth.



2.4.2. Route:

2.4.2.1. All injections intramuscular except:

- Japanese encephalitis & Varicella (deep subcutaneous injection).
- Cholera (oral).

- Bacillus Calmette-Guthrin (BCG) (intradermal).

2.4.2.2. Intramuscular injections (IM) are less likely to cause local reactions than deep subcutaneous. Should be given with the needle at a 90 degree angle to the skin and the skin should be stretched, not bunched.

2.4.2.3. Deep Subcutaneous (SC) injections should be given with the needle at a 45 degree angle to the skin and the skin should be bunched, not stretched.

2.4.2.4. Intradermal injection – Aim to create a raised blanched bleb showing the tips of the hair follicles. Considerable resistance should be felt.

2.4.2.5. Nb: For individuals with a bleeding disorder, vaccines normally given by an IM route should be given by deep sub-cutaneous injection to reduce the risk of bleeding - seek senior/haematology advice.

2.4.3. Site: (See images in GBG Chapter 4)

2.4.3.1. Intra-Muscular (IM), or deep into subcutaneous (SC) tissue.

2.4.3.2. A 23-gauge (blue) or 25-gauge (orange) needle is recommended for IM administration of most vaccines in children and infants respectively.

2.4.3.3. In pre-term or very small infants, a 16mm needle is suitable for IM injection.

2.4.3.4. Intradermal injections should only be administered using a 26G (brown) needle.

2.4.4. Immunisation Procedure

2.4.4.1. The site should be chosen so that the injection avoids major nerves and blood vessels.

2.4.4.2. If two or more vaccines need to be given then use separate sites, preferably in a different limb. If in the same limb, administer injections more than 2.5cm apart.

2.4.4.3. Intramuscular/Subcutaneous – Anterolateral aspect of thigh (preferred in children <1year), or deltoid area of upper arm.

2.4.4.4. Nb: BCG vaccine must be administered intra-dermally, normally into the lateral aspect of the left upper arm – see specific GBG Chapter 4.

2.4.5. Needle size:

For IM and SC injections, the needle needs to be sufficiently long to ensure that the vaccine is injected into the muscle or deep

subcutaneous tissue respectively.

2.4.5.1. Check steps 1-7 of immunisation checklist completed.

2.4.5.2. Check correct patient and correct vaccine(s) according to immunisation schedule. Check correct needle/ syringe, expiry date not passed, and vaccine stored correctly.

2.4.5.3. Wash your hands and wear gloves.

2.4.5.4. If not pre-filled, draw up correct dose/volume.

2.4.5.5. Chose injection site.

2.4.5.6. It is not necessary to disinfect the skin. Only visibly dirty skin needs to be washed with soap and water.

- IM: stretch skin and inject at 90 degrees to skin.
- Deep subcutaneous - bunch skin and give inject at 45 degrees to skin.

2.4.5.7. It is not necessary to aspirate the syringe after the needle is inserted into muscle.

2.4.5.8. Observe for immediate adverse drug reactions ADRs.

2.4.5.9. Record vaccine name, product name, batch number, expiry date, dose administered, site used, date given, name and signature of vaccinator.

2.4.6. Safety for vaccinators

All needles, syringes and vials should be disposed of immediately following use into an approved sharps container.

Spillages and needle-stick injury - be aware of hospital policy on blood and body fluid exposures.

2.5. Post Procedure:

Recipients of any vaccine should be observed for immediate adverse drug reactions (ADRs). There is no evidence to support the practice of keeping patients under longer observation. See PUNs study data in Section 5 of this guideline regarding hospitalised infants. Management of AEs can be found in the GBG Chapter 8: https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book

2.6. Documentation:

2.6.1. Accurate, accessible records of vaccinations given are important for keeping individual clinical records, monitoring immunisation uptake, and facilitating the recall of recipients of vaccines, if required.

2.6.2. Accurate records should be made in four places:

- Patient notes.
- Drug chart (electronic).
- Red book.
- Email the Notification of Immunisation Form Saved in the folder immunisation on the TR11 Neonatal Drive in the folder Immunisation Form to: scwcsu.dcios.swchis@nhs.net

2.6.3. Record should always include:

- Vaccine name, product name, batch number and expiry date.
- Dose administered.
- Site(s) used – including, clear description of which injection was administered in each site, especially where two injections were administered in the same limb.
- Date immunisation(s) were given.
- Name and signature of vaccinator.

3. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	Key Changes to practice.
Lead	Dr Chris Bell.
Tool	Adherence to guidelines will be monitored as part of the ongoing audit process within the department on a Word or Excel template specific to the topic.
Frequency	As dictated by audit findings.
Reporting arrangements	Child Health Directorate Audit and Consultant led Neonatal clinical Guidelines Group.
Acting on recommendations and Lead(s)	Chris Bell Consultant Paediatrician and Neonatologist.
Change in practice and lessons to be shared	Required changes to practice will be identified and actioned within 3 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.

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:	Immunisations in Infants and Children Neonatal Clinical Guideline V3.0
This document replaces (exact title of previous version):	Immunisations in Infants and Children Neonatal Clinical Guideline V2.1
Date Issued/Approved:	May 2023
Date Valid From:	May 2023
Date Valid To:	May 2026
Directorate / Department responsible (author/owner):	Dr Chris Warren; Consultant Paediatrician
Contact details:	01872 252667
Brief summary of contents:	This guideline outlines the clinical responsibilities of staff involved in the immunisation of an infant or child.
Suggested Keywords:	Children, Infants, Neonates, Immunisation
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 Meeting
General Manager confirming approval processes:	Caroline Chappell
Name of Governance Lead confirming approval by specialty and care group management meetings:	Caroline Amukusana
Links to key external standards:	None Required
Related Documents:	Immunisation against infectious disease - GOV.UK (www.gov.uk)

Information Category	Detailed Information
	A quick guide to childhood immunisations for the parents of premature babies (publishing.service.gov.uk)
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
December 2016	V1.0	Initial issue.	Andrew Collinson. Consultant Paediatrician and Neonatologist
January 2016	V1.0	Approved by Neonatal Clinical Guidelines Group.	Author: Andrew Collinson. Consultant Paediatrician and Neonatologist. Formatter: Kim Smith. Staff Nurse.
November 2016	V1.1	Addition of www.gov.uk parent information leaflet.	Changes made by Andrew Collinson. Consultant Paediatrician and Neonatologist. Neonatal Guidelines group approved
March 2020	V2.0	Full review - updated with an alteration to the recording of immunisation which is a form that gets emailed now, rather than posted. Reviewed, links updated, minor wording alterations	Chris Warren, Consultant Paediatrician Sabrina Tierney, Paediatric pharmacist
October 2020	V2.1	Updated to new Trust format. Appendix 3 amended with updated CHA	WCSH Governance Team

Date	Version Number	Summary of Changes	Changes Made by
February 2023	V3.0	Written consent no longer required (section 2.3.5 removed). Changes to reflect electronic drug chart throughout.	Dr Chris Warren; Paediatric Consultant

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:	Immunisation in Infants and Children Neonatal Clinical Guideline V3.0
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 is aimed at clinical staff responsible for the immunisation of infants and children.
2. Policy Objectives	Safe immunisation.
3. Policy Intended Outcomes	As above.
4. How will you measure each outcome?	Audit.
5. Who is intended to benefit from the policy?	Patients. Medical and nursing staff.

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- 03 May 2023
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/ carers 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	All staff should be aware of any beliefs that may impact on the decision to treat and should respond accordingly.
Marriage and civil partnership	No	All staff should be aware of any marital arrangements that may have an impact on care (for example: separated parents, domestic abuse).
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

Appendix 3. Immunisation Checklist

CHA4315: Immunisation Checklist (cornwall.nhs.uk)