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1. Introduction and who this guideline applies to:

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

Vaccinations are an important defence against infectious diseases. These guidelines have been produced to inform staff working within University Hospitals Leicester Neonatal service about the most up to date recommendations for the timing of infant immunisations. Immunisations are given as per the routine childhood immunisation schedule.

Key Points

- The guidance given below is applicable to infants of ALL GESTATIONS¹ (additional immunisations for preterm infants below a certain gestation are no longer advocated and the previous advice no longer applies.)¹

In all cases vaccinations should be administered unless specifically contraindicated e.g. live vaccines in immune-compromised babies, or those babies who haven't yet received a 'SCID not suspected' outcome after newborn screening.

Vaccinations are given at the infant's postnatal age, not at their corrected gestational age

A summary of the UK immunisation schedule² can be found at

<https://www.gov.uk/government/publications/routine-childhood-immunisation-schedule>

Related documents:

[Newborn Screening for Severe Combined Immune Deficiency \(SCID\) UHL Neonatal Guideline](#)

[Influenza Vaccination in Primary Immune Deficiency Patients UHL Childrens Hospital Guideline](#)

[Hepatitis B and Syphilis Screening in Pregnancy UHL Obstetric Guideline](#)

[Hepatitis C Screening in Pregnancy UHL Obstetric Guideline](#)

2. When to immunise - What vaccine is given? How is it given?

Detailed information about the current routine immunisation schedule is available in the Green book: <https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>

Technique & site

The anterior aspect of the thigh(s) is the best site for vaccinations in the neonate. All vaccinations (except BCG and oral rotavirus) should be given by deep subcutaneous or intramuscular injection. In infants a size 23 or 25G needle should be used. Remember:

- Individual sites will be needed for the various injections; document which sites have been used for which injections.
- Sites to be used include anterior aspect of thigh, and deltoid if both thighs have been used.

Notes:

1. Prematurity - All infants should be immunised according to their chronological age, irrespective of gestation. The incidence of apnoeas following vaccination is increased in infants who were born very prematurely^{3,4,5,6}.

- Infants with **all** of these factors should have heart rate and saturation monitoring for 48-72 hours:
 - born at <29⁺⁰ weeks
 - receiving their immunisation on NNU
 - having desaturations / bradycardias in the 72 hours pre-immunisation
- Additionally, babies in supplemental oxygen receiving their first immunisation in hospital should be monitored for 48-72 hours.
- Babies that have been discharged from NNU prior to receiving their first immunisation can be immunised in the community in the usual way.

If any baby has apnoea, bradycardia or desaturations following immunisation in hospital or at home subsequent immunisation in hospital should be considered and this decision informed by their response to previous immunisation. Adverse reactions need to be documented (see point 12).

3. Impact of SCID newborn screening

Babies screened locally have newborn screening for SCID and should not receive live vaccines until their screening outcome is known. There are 3 possible screening outcomes:

- **‘SCID is not suspected’**: can received the standard immunisation schedule including live vaccines
- **Intermediate result**: needs repeat screening at 37 weeks or discharge, whichever is sooner. This outcome is more common among preterm babies. Until the repeat screen outcome is known they should not receive live vaccines, but this should not delay the receipt of other vaccines.
- **‘SCID suspected’** either at initial or repeat screening; blood needs to go to immunology for flow cytometry, which may need to be repeated at a later date. These babies should only receive live vaccines once Immunology have confirmed it is safe for them to do so; some babies may be able to receive rotavirus but not BCG.

[Newborn Screening for Severe Combined Immune Deficiency \(SCID\) UHL Neonatal Guideline](#)

4. Meningitis B

(<https://www.gov.uk/government/publications/meningococcal-the-green-book-chapter-22>) all infants given this vaccine should receive 3 doses of post immunisation paracetamol following the dosage guidelines in the neonatal formulary.

5. Polio

(<https://www.gov.uk/government/publications/polio-the-green-book-chapter-26>)

The polio vaccine is now given in the inactivated form (IPV), as a component of the 6 in 1 vaccine on NNU. This inactivated vaccine is not excreted in a transmissible form and there is no risk to other infants.

6. Rotavirus vaccine

(<https://www.gov.uk/government/publications/rotavirus-the-green-book-chapter-27b>) is a live, attenuated vaccine given orally. Two doses are required. The first is given between 6⁺⁰ weeks and 14⁺⁶ weeks post-delivery, the second must be given by 23⁺⁶ weeks. The two doses must be given at least 4 weeks apart. The weakened virus is excreted in stools and there is a low risk of transmission to people changing the nappy. Good hand washing following nappy changes should prevent transmission.

- Rotavirus vaccine can be given at the usual time to babies who are still inpatients on NNU
- Try to coordinate with 8 week vaccinations if possible
- Contra-indicated in babies with SCID (severe combined immunodeficiency) or awaiting SCID screening outcome – see SCID screening section.
- Contraindicated in babies who have had or are at high risk of getting intussusception. If baby has had abdominal surgery discuss with neonatal consultant prior to immunisation with rotavirus vaccine
- Contra-indicated in immunosuppressed infants (e.g. SCID, maternal anti-TNF α treatment in pregnancy where the infant is currently < 6months old, maternal Tocilizumab (used as a Covid treatment) or other immunosuppressant biologics)

7. Influenza

(<https://www.gov.uk/government/publications/influenza-the-green-book-chapter-19>) can be given as an intramuscular inactivated quadrivalent vaccine or as a live attenuated intranasal influenza vaccine.

Children aged six months to less than two years of age in clinical risk groups (Table 1) should be offered inactivated quadrivalent influenza vaccine. Prematurity on its own is not a qualifying risk factor. Those who have not received influenza vaccine previously should be offered a second dose of vaccine, at least four weeks later. The inactivated influenza vaccines are interchangeable.

The first dose is licensed to be given after 6 months chronological age and a 0.5ml dose is given. Please advise GPs of the need to do this in the immunisations section of the Badger discharge letter. Currently the live attenuated intranasal influenza vaccine is not recommended for infants under 2 years old¹.

Table 1: Influenza vaccination eligibility		
Age	Eligibility	Vaccine available
6 months to <2 years*	CLD / BPD Congenital heart disease Liver disease Kidney disease Immunosuppressed	Quadrivalent inactivated flu vaccine
2 years to <18 years	Everyone***	Live attenuated intranasal vaccine (LAIV) (Fluenz™ Tetra)**
<p>*Repeat quadrivalent inactivated flu vaccine after at least 4 weeks</p> <p>**if LAIV medically contraindicated give quadrivalent inactivated flu vaccine</p> <p>*** See annual flu letters for England and the Devolved Administrations for the cohorts of children not in clinical risk groups that are eligible for influenza vaccination for the coming/current season.</p>		

Household contacts of babies with risk factors listed in Table 1 should be advised to have an influenza immunisation as soon as possible.

8. Steroids

Infants who have received a standard 10 day 'DART' steroid regime or a Premilock steroid regime can receive the usual vaccination schedule. For babies that have received prolonged (>10 days) or multiple courses of steroids please refer to the neonatal pharmacist so that the total steroid exposure can be calculated. This will inform decisions as to whether live vaccination (e.g. BCG) needs to be delayed for 3 months after the cessation of steroids in accordance with the 'green book'¹. In practice infants receiving prolonged courses of steroid are unlikely to receive the rotavirus vaccine because of the time frame in which it needs to be given.

**Please seek public health advice for discussion of any special cases-
Health Protection Agency East Midlands South Health Protection Unit-**

9. BCG vaccination

(<https://www.gov.uk/government/publications/tuberculosis-the-green-book-chapter-32>) mothers whose infants will need BCG vaccination are informed of this during their antenatal care and the BCG immunisation is given by St. Peters Health Centre or by their GP. Community BCG vaccination is organised by the TB nurse.

High risk patients are those with ethnic origin outside North America, Europe and Australia/NZ, and those with a family history of TB. If current family members have been on treatment for TB for <2 weeks then baby may need preventive treatment – discuss with TB nurses.

Contraindications to BCG vaccination are

known immunodeficiency e.g.

SCID,

Chronic Granulomatous Disease)

Maternal anti-TNF α treatment in pregnancy where the infant is currently < 6months old, maternal Tocilizumab (used as a Covid treatment) or other immunosuppressant biologics).

Where infant is awaiting SCID screening outcome – see SCID screening section. If unclear discuss with neonatal consultant.

10. Hepatitis B vaccination

(<https://www.gov.uk/government/publications/hepatitis-b-the-green-book-chapter-18>)

- All pregnant women are offered antenatal screening for hepatitis B. The hepatitis B virus has three major structural antigens: surface antigen (HBsAg), core antigen (HBcAg), and e antigen (HBeAg). All mothers who are HBsAg+ve are infectious.

Immunisation reduces the risk that an infant born to a mother who is hepatitis B +ve will develop chronic active hepatitis or hepatocellular carcinoma as a young adult. Higher risk infants receive 250 international units Hepatitis B immunoglobulin IM within 24 hours of birth (see table below). Prior to vaccination +/- immunoglobulin blood samples from the baby should be sent to virology for hepatitis serology and PCR.

Table 2: Which babies need HB vaccination +/- HB immunoglobulin

Hepatitis B status of mother	Baby should receive	
	Hepatitis B vaccine	HBIG
Mother is HBsAg positive and HBeAg positive	Yes	Yes
Mother is HBsAg positive, HBeAg negative and anti-HBe negative	Yes	Yes
Mother had acute hepatitis B during pregnancy	Yes	Yes
Mother is HBsAg positive and anti-HBe positive	Yes	No
Mother is HBsAg positive and known to have an HBV DNA level equal or above 1x10 ⁶ IUs/ml in any antenatal sample during this pregnancy (regardless of HBeAg and anti-HBe status)	Yes	Yes
Mother is HBsAg positive and baby weighs 1500g or less	Yes	Yes

Hepatitis B vaccination of pre-term babies

Response to Hepatitis B vaccine is lower in pre-term, low-birth weight babies so it is important that premature infants receive the full paediatric dose of hepatitis B vaccine on schedule. Babies born to mothers infected with hepatitis B, with a birthweight of 1500g or less, should receive HBIG in addition to the vaccine, regardless of the e-antigen status or viral load of the mother. As the benefit of

vaccination is high in this group of infants, vaccination should not be withheld or delayed.

For all babies born to Hepatitis B +ve mothers

- Complete formatted referral letter to Consultant Paediatrician (Ext 15525) (Appendix A)
- Inform Hepatitis B Specialist Nurse on ext 15990
- NNU follow up is not needed unless there are additional neonatal problems.
- At NIPE check please write clearly on the immunisation, all the relevant details related to giving the vaccine.

Other Hepatitis B Risk Factors

Check that there are no other concerns with mum (Hepatitis C / HIV / IV drug use)

- If either mum or dad are Hepatitis C +ve, HIV +ve or IV drug users then the baby should receive Hepatitis B immunisation (but immunoglobulin only if they qualify as per Table 2)

Post-exposure schedule and follow-up for the selective neonatal Hepatitis B programme

Babies born to hepatitis B infected mothers should be vaccinated using an accelerated immunisation schedule with a dose of hepatitis-B containing vaccine at birth, 4 weeks and 8 weeks of age. As the routine childhood immunisation programme includes hepatitis B, these infants will receive monovalent vaccine at birth and 4 weeks, but hexavalent hepatitis B-containing vaccine instead of monovalent vaccine at 8 weeks. They should then receive additional hexavalent vaccine doses at 12 and 16 weeks.

A further dose of monovalent HB vaccine is given at one year of age, alongside a test for HBsAg. Testing at one year of age is important to identify babies who have become chronically infected with hepatitis B despite vaccination, and will allow prompt referral for further management. This testing can be carried out at the same time as the dose at one year of age is given, or soon after.

A further dose of hepatitis B-containing vaccine at 3 years and 4 months is no longer recommended for those children who have completed their routine primary immunisations with the hexavalent hepatitis B-containing vaccine.

Maternal treatment – some mothers may require treatment for Hepatitis B, this will be dealt with by the obstetric team, further details can be found in the [Hepatitis B and Syphilis Screening in Pregnancy UHL Obstetric Guideline](#) Hepatitis B & Syphilis Screening in Pregnancy; [Hepatitis C Screening in Pregnancy UHL Obstetric Guideline](#) available on insite.

11. Coronavirus vaccinations

Multiple vaccines against SARS-COV-2 were developed in 2020 and started to be administered in 2021 with prioritisation according to risk profiles. Fortunately, initial

concerns that SARS-COV-2 infection might be more severe in preterm babies were not realised, with no deaths attributable to SARS-CoV-2 reported in neonates in the UK between March and April, 2020⁸.

The situation around coronavirus vaccination is liable to change and up to date information from JCVI or government websites should be sought.

12. Documentation

All immunisations given and reason for any omissions should be written in the 'Child Health Record' (red book) and in the immunisation section on BadgerNet. Clearly document what has been given; how much; site(s) of any injections; who administered the immunisations; and the vaccination batch number and expiry date.

Note: Whenever an immunisation is carried out on NNU output PDF from badger. Attached form to email addressed to lpt.childhealthrecords@nhs.net so details can be entered onto the Child Health Computer.

13. Consent

Consent by someone with legal parental responsibility and capacity **MUST** have given prior to administering any vaccinations. It should be recorded that vaccinations have been discussed and consent given.

14. Information on childhood vaccination

For those with parental responsibility can be found at:

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/851521/PHE_11490_IMM_up_to_one_year_A5_booklet_Dec2019.pdf

15. Adverse Reactions - MUST be documented.

Treatment will depend on the clinical problem. Any child who has a clinically significant adverse event following immunisation (AEFI) in hospital should return to hospital for their second immunisation. A yellow card should be completed online at <https://yellowcard.mhra.gov.uk/>

Form IMM18: Notification of an Adverse Reaction to Immunisation (Appendix B) should be completed and sent to:
The Immunisation Officer, Child Health Services, Bridge Park Plaza, Bridge Park Road, Thurmaston, Leicester, LE4 8PQ

Or emailed to childhealthrecords@leicspart.nhs.uk

16. Education & Training

None

17. References

1. Department of Health. Immunisation against infectious disease. The UK Immunisation programme.
<https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>
2. UK Immunisation Schedules
<https://www.gov.uk/government/publications/routine-childhood-immunisation-schedule>
3. Bonhoeffer, J, Siegrist, C-A and Heath, PT. Immunisation of premature infants. Archives of Disease in Childhood 2006; 91: 929-935.
4. Pfister, RE, Aeschbach, V, Niksic-Stuver, V et al. Safety of DTaP-based combined immunization in very-low-birth-weight premature infants: frequent but mostly benign cardiorespiratory events. Journal of Pediatrics 2004; 145: 58-66.
5. Schulzke, S, Heininger, U, Lucking-Famira, M et al. Apnoea and bradycardia in preterm infants following immunisation with pentavalent or hexavalent vaccine. European Journal of Pediatrics 2005; 164: 432-435.
6. Lee, J, Robinson, JL and Spady, DW. Frequency of apnea, bradycardia and desaturations following first diphtheria-tetanus-pertussis-inactivated polio-Haemophilus influenza type B immunization in hospitalized preterm infants. BMC Pediatrics 2006; 6:20.
7. UHL Insite document library
Hepatitis B & Syphilis Screening in Pregnancy; Maternity Unit Care Pathways for the Management of Positive Results including Hepatitis C
8. Gale C, Quigley MA, Placzek A, Knight M, Ladhani S, Draper ES et al. Characteristics and outcomes of neonatal SARS-CoV-2 in the United Kingdom: a prospective national cohort study using active surveillance. Lancet Child Adolesc Health 2021; 5: 113–21 doi:10.1016/S2352-4642(20)30342-4.
<http://insitetogether.xuhl-tr.nhs.uk/pag/pagdocuments/Hepatitis%20B%20and%20Syphilis%20Screening%20in%20Pregnancy%20UHL%20Obstetric%20Guideline.pdf>

[UHL Newborn Screening for Severe Combined Immune Deficiency \(SCID\) UHL Neonatal Guideline](#)

**[UHL Influenza Vaccination in Primary Immune Deficiency Patients UHL
Childrens Hospital Guideline](#)**

18. Monitoring Compliance

What will be measured to monitor compliance	How will compliance be monitored	Monitoring Lead	Frequency	Reporting arrangements
Appropriate immunisations provided there are no contra-indications and parental consent	Audit			

19. Key Words

Adverse reaction, BCG, Coronavirus, Hepatitis B, Influenza, Meningitis B, Polio, Rotavirus, SCID, Steroids, Vaccination

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) L Stachow - Clinical pharmacist J Fawke - Consultant		Executive Lead Chief Medical Officer	
Details of Changes made during review:			
Date	Issue Number	Reviewed By	Description Of Changes (If Any)
6/2/2007	1	Dr S Ghosh, Dr P Monk	Original document
2/2/2010	2	Clinical guidelines coordinator (EMB)	
2/7/2013 - 15/10/2013	3	Neonatal Guidelines Meeting Neonatal Governance Meeting (ratified)	(comments invited by email)
08/07/2014	4	Clinical guidelines coordinator (REM)	Edits
10/11/2016 Jan 2016	5	J Fawke & L Stachow Neonatal guidelines meeting	
June 2017	6	Neonatal Guidelines lead - REM	Text / hyperlinks revised
Sept 2017- Feb 2018	7	LS author / REM	Text / hyperlinks revised appendices added
May 2021	8	L Stachow & J Fawke Neonatal Governance Meeting	Guideline update ratified

<p>May 2023</p>	<p>9</p>	<p>Ruth Radcliffe, J Fawke, L Stachow Neonatal guidelines group March 2023 Neonatal governance group March 2023 Women's quality & safety board April 2023</p>	<p>Added reference to SCID screening in intro and added a new SCID screening section Added related documents Chronic Granulomatous Disease & awaiting SCID screening added to contraindications to BCG vaccination Hepatitis B vaccination information changed from - Higher risk infants receive 200 international units Hepatitis B immunoglobulin IM within 12 hours of birth to - Higher risk infants receive 250 international units Hepatitis B immunoglobulin IM within 24 hours of birth. Updated documentation section to include, reason for any omission and document in the immunisation section on BadgerNet. Digital documentation information updated</p>
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Appendix A: Hepatitis B Form

Please send a copy of this form to:

1. GP name and address:

2. Child Health
 Records Department
 Address

H1
GP copy &
Medical notes

**Child at risk of Hepatitis B infection from birth - first vaccination given.
 Notification to healthcare professional to deliver subsequent vaccine doses.**

Dear Doctor

I would like to inform you of an infant who is at risk of Hepatitis B infection and requires a full course of hepatitis B vaccine. The first dose has been given (see details below). This infant is at risk of Hepatitis B infection for the following reason (*please tick*):

1. Mother has Hepatitis B infection

This infant needs to complete a course of hepatitis B vaccination. It is of vital importance for full protection to be achieved that the second and third doses are given exactly 4 weeks and 8 weeks after the first dose is given. A booster dose at 12 months is also required. Doses at 4 weeks and 12 months should be a monovalent hepatitis B vaccine. Other doses are combined in the routine Infanrix-Hexa vaccination.

2. Father or close household contact has Hepatitis B

Child requires full course of hepatitis B vaccine- it should be ensured that all routine immunisations are given on time – Infanrix-Hexa protects against hepatitis B and no additional monovalent hep b vaccines are required. A blood test at 12 months is not required.

Maternal Details (affix label)

Surname: First name:

DOB: NHS number

Hospital No:

Maternal Hepatitis Status:

	Positive	Negative	Unknown
HBsAntigen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
HBeAntigen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Anti-HBe	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Viral Load:	iu/ml		
Acute Hepatitis In Pregnancy	Yes / No		

Infant Details (affix label)

Surname: First name:

DOB: NHS number

Hospital No:

Hep B Immunoglobulin given: Yes / No

Batch No: Thigh: Left / Right

Date: Time:

Hep B vaccine given: Yes / No

Batch No: Thigh: Left / Right

Date: Time:


Administered by:

Yours sincerely

..... (Signature)(Print name)

Date: Time:

Appendix B: IMM18 Form Notification of an Adverse Reaction to Immunisation

Bridge Park Plaza Bridge Park Road Thurmaston Leicester LE4 8PQ Telephone: 0116 225 2525 Fax: 0116 225 5233	Leicester, Leicestershire and Rutland Specialist Community Child Health Services			
Direct Dial 0116 225 3989		IMM18		
<u>NOTIFICATION OF AN ADVERSE REACTION TO IMMUNISATION</u> (SEE OVERLEAF FOR COMPLETION NOTES)				
<u>CHILD'S DETAILS</u> (PLEASE COMPLETE ALL DETAILS IN BLOCK CAPITALS)				
Surname: _____		Forename: _____		
Date of Birth: _____		Computer Ref No (if known): _____		
Address: _____		_____		
_____		_____		
_____ Postcode: _____		NHS No (if known): _____		
GP: _____		Surgery: _____		
<u>DETAILS OF IMMUNISATION AND REACTION</u>				
Vaccine				
Programme				
Batch No				
Expiry Date				
Manufacturer				
Given by - Name in Full: _____		Designation: _____		
Date Given: _____				
<u>COMMENTS</u>				

Name in Full: _____		Designation: _____		
Signed: _____		Date: _____		
Have you informed the Committee on safety and medicine (completed yellow card) Yes/No _____				

NOTIFICATION OF AN ADVERSE REACTION TO IMMUNISATION

COMPLETION NOTES

The form should be completed with the following details:

1. Child's Details

- a. Surname
- b. Forename
- c. Date of birth
- d. Computer reference number (if known)
- e. Child's NHS number
- f. Child's address and postcode
- g. Name of child's Family Practitioner
- h. Surgery usually attended

2. Details of Immunisation and Reaction

- a. Programme and dose(s) of immunisation given - in plain language, eg 1st Primary Programme Diphtheria, Tetanus, Pertussis and Polio
- b. Date course given
- c. Batch numbers
- d. Expiry date
- e. Manufacturer
- f. Given by
- g. Comments - this should be a brief account of the reaction experienced and any follow up action taken
- h. Signed and dated - the form should be signed and dated by the Doctor in attendance at the session when the vaccination was given (include designation and full name)

Following completion, the form should be forwarded to:

The Immunisation Manager
Child Health Services
Bridge Park Plaza
Bridge Park Road
Thurmaston
LEICESTER
LE4 8PQ

IMMUNISATION SECTION OFFICE USE ONLY

Copy IMM18 placed in office file Date: ___/___/___

Original IMM18 sent to: Prescribing Advisor at appropriate PCT Date: ___/___/___

Outstanding Immunisation Appointment: _____

Outcome: NFA
OTHER: _____ Date: ___/___/___