

Immunisation of patients in Paediatrics and Neonates

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Policy Executive Owner:	Clinical Director, Children's Services ICSU
Designation of Author:	Dr W Leith, Consultant
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Version Control Sheet

Version	Date	Author	Status	Comment
One	July 2003	D W Leith	NEW	New guideline
Two	July 2011	W Leith, V Merrick, R Blumberg		Review
Three	Dec 2013	J de Sa, W Leith,		Schedule updated, Rotavirus, Influenza
4	Oct 2014	Dr W Leith		Insert of second paragraph, page 6
5	Sept 2015	Dr W Leith, Dr Raoul Blumberg		Revised Palivizumab guidance
6	March 2016	Dr W Leith, Dr K Stone		Schedule Updated, Meningitis B

➤ **Criteria for use**

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Section 2: Selected children who may need:

- BCG.....pg 6
- Hepatitis B vaccine (see separate guideline).....pg 6
- Influenza vaccination.....pg 6
- Palivizumab (RSV monoclonal antibody).....pg 7

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➤ **Section 1: All Children**

The national immunisation schedule (updated Summer 2015) is detailed below:

AGE	Immunisation (Vaccine Given)
2 months	<ul style="list-style-type: none"> • DTaP/IPV(polio)/Hib (diphtheria, tetanus, pertussis (whooping cough), polio, and <i>Haemophilus influenzae</i> type b) - all-in-one injection: Pediacel®; plus: • PCV (pneumococcal conjugate vaccine) - in a separate injection: Prevenar 13®. • Rotarix® (rotavirus gastroenteritis) - oral route. • MenB Bexsero®
3 months	<ul style="list-style-type: none"> • DTaP/IPV(polio)/Hib (2nd dose: Pediacel®); plus: • MenC (meningitis C) - in a separate injection: NeisVac-C® or Meningigate®. • Rotarix® (rotavirus gastroenteritis) - oral route.
4 months	<ul style="list-style-type: none"> • DTaP/IPV(polio)/Hib (3rd dose: Pediacel®); plus: • PCV (2nd dose: Prevenar 13®) - in a separate injection. • MenB Bexsero®
Between 12 and 13 months	<ul style="list-style-type: none"> • Hib/MenC (combined as one injection) - 4th dose of Hib and 2nd dose of MenC: Menitorix®; plus: • MMR (measles, mumps and rubella) - combined as one injection: Priorix® or MMR II®; plus: • PCV (3rd dose: Prevenar 13®) - in a separate injection. • MenB booster Bexsero®
2 to 6 years	<ul style="list-style-type: none"> • Influenza (Each year from September) Fluenz Tetra® (Administered nasally)
3 years and four months to 5 years	<ul style="list-style-type: none"> • Pre-school booster of DTaP/IPV(polio): Repevax® or Infanrix-IPV®; plus: • MMR (second dose: Priorix® or MMR II®) - in a separate injection.
Around 12-13 years (girls)	<ul style="list-style-type: none"> • HPV (human papillomavirus types 16 and 18 and genital warts caused by types 6 and 11) – Two doses 6-12 months apart. Gardasil®
Around 13-18 years	<ul style="list-style-type: none"> • Td/IPV(polio) booster: Revaxis®. • MenACWY Nimenrix® or Menveo®- in a separate injection.

If the primary course is interrupted, it should be resumed – allow an interval of one month between doses.

All children receiving immunisations in hospital should have

- i) written parental consent documented in notes (see appendix 1 for consent form).
- ii) prescription of the immunisation on the drug chart
- iii) Documentation of the vaccine given (Including batch number and expiry date) on
 - Drug chart
 - Red book
 - Clinical notes
 - More information for parents can be found on NHS choices (<http://www.nhs.uk/conditions/vaccinations/pages/vaccination-schedule-age-checklist.aspx>) or patient.co.uk (<http://www.patient.co.uk/health/immunisation-usual-uk-schedule>)

Prematurity

Premature infants should be immunised according to chronological age.

Infants born <28 weeks gestation should have respiratory monitoring for 28-72 hours when given their first immunisation. If there are any concerns during this period (apnoea, bradycardia, desaturations) then the second immunisation should also be given in hospital with a period of monitoring.

Notes on Updated Schedule 2015

Meningitis B

- New vaccine to be given at 2 months and 4 months of age with a booster at 12 months.
- In term infants, it is recommended that Men B vaccination should be administered in the left thigh, ideally on its own, with other immunisations being administered into the remaining three limbs.
- In ex preterm infants, only Men B should be administered in the left thigh, with the other immunizations administered into the right thigh. If 2 vaccines need to be administered into the right thigh, they must be given at least 2.5cm apart. The sites at which each vaccine was given should be noted in the individual's health records.
- The Joint Committee on Vaccination and Immunisation have recommended that paracetamol should be given prophylactically when MenB is given with the routine vaccines in infants under one year of age.

Dosage and timings of infant paracetamol suspension (120mg/5ml) following Men B vaccination for the routine immunisation programme at 2 and 4 months:

Age of Baby	First Dose	Second Dose	Third Dose
Ex-preterm baby	20mg/kg as soon as possible after vaccination	10-15mg/kg 6 hours after 1 st dose	10-15mg/kg 6 hours after 2 nd dose
Term baby at 2 and 4 Months	One 2.5ml dose as soon as possible after vaccination	One 2.5ml dose 6 hours after 1 st dose	One 2.5ml dose 6 hours after 2 nd dose

provided that the child appears otherwise well, additional doses of paracetamol may be administered at intervals of four to six hours for up to 48 hours. Parents should be advised to seek medical advice if their child is noticeably unwell with a fever present, or if the fever occurs at other times.

Meningitis ACWY

Replaces the MenC vaccination previously given at 13-18 years.

Influenza

As part of the phased introduction of influenza vaccination for all children aged between two and seventeen, which began in 2013/14, all children aged two to six years are eligible for annual influenza vaccination from September 2015. See annual flu letter for future updates. For precautions and contraindications to the intranasal live attenuated vaccine (Fluenz Tetra®) see The Green Book.

Notes on updated schedule 2013

Rotavirus

This aims to provide 2 doses of rotarix vaccine to infants from 6 weeks to 24 weeks of age to prevent severe gastroenteritis due to rotavirus. This should begin by 15 weeks of age.

The minimum interval between doses is 4 weeks.

- *Infants 15 weeks or older should not be commenced on Rotarix due to an increased risk of intussusception.*
- *Rotarix must not be administered to any infants over 24 weeks of age*

This is a live attenuated vaccine. Contra-indications include severe combined immunodeficiency (SCID), however it can be given in most other forms of immunosuppression as benefits exceed risk. Other contraindications are:

- confirmed anaphylaxis to previous rotavirus vaccination
- confirmed anaphylaxis to component of rotavirus vaccination
- previous history of intussusception or with a GI malformation predisposing them to intussusception
- hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency

Dosage is 1.5ml of rotarix vaccine orally. Standard infection control precautions should be maintained for those patients receiving the vaccine in hospital.

Note this is being routinely given on the neonatal unit unless infants have any contra-indications as above

Vaccination should be postponed for an acute febrile illness or acute diarrhoea and vomiting.

Contra-indications to national schedule vaccinations

All vaccines are contraindicated in those who have had:

- A confirmed anaphylactic reaction to a previous dose of a vaccine containing the same antigen
- A confirmed anaphylactic reaction to another component contained in a relevant vaccine e.g. neomycin and polymyxin B

Live vaccines may be temporarily contraindicated in individuals who are immunosuppressed or pregnant.

For specific advice regarding individuals with egg allergy, latex allergy, pregnancy and immunosuppression, please refer to the Green Book (1).

Deferral of immunisations

Minor illnesses without fever or systemic upset should not necessitate deferral of immunisation.

However if an individual is acutely unwell, it may be sensible to postpone immunisation until they are fully recovered to avoid wrongly attributing symptoms to the vaccine.

Adverse reactions

Advice on the management of fever must be given before immunisation. Pain, redness and swelling at the injection site are common and occur more commonly following second or third doses of vaccines. **All suspected adverse reaction to vaccines must be reported to the Committee On Safety Of Medicines using the yellow card scheme.**

➤ Section 2: Children requiring specific vaccines

BCG

This is a live attenuated vaccine. The aim is to immunise those at increased risk of exposure to tuberculosis or at risk of developing severe disease.

BCG immunisation should therefore be offered to:

- all infants (aged 0 to 12 months) living in areas of the UK where the annual incidence of TB \geq 40/100,000.
 - *Note in 2014 this included the boroughs of Haringey, Islington and Barnet.*
- all infants and children with a parent or grandparent who was born in a country where the annual incidence of TB \geq 40/100,000
- contacts of cases of respiratory tuberculosis (after negative tuberculin testing)
- those coming from or visiting countries with high incidence of TB as above for more than 3 months

Hepatitis B

Please see separate guideline.

Influenza

This is aimed at those who would be at risk of serious illness or death if they contracted influenza.

The influenza vaccine should be offered to those with:

- Chronic respiratory disease
- Congenital heart disease
- Chronic kidney or liver disease
- Type 1 or 2 diabetes
- Immunosuppression due to disease or treatment
- Asplenia or splenic dysfunction (ie sickle cell disease)
- Pregnancy

With regards to babies on and graduates from NICU the following recommendations apply;

- **The flu vaccine can only be given to babies 6 months or older.**
- **The flu vaccine is recommended for any baby who has had significant respiratory disease and or we ask the GP to give once they reach 6 months.**
- **The flu vaccine is also recommended for the parents of such babies, particularly if they are still on oxygen**

There are currently 2 different preparations for children:

- 1) Live attenuated intranasal vaccination (for precautions and contraindications see Green Book)
- 2) Inactivated intramuscular vaccination

Those in clinical risk groups above who have not previously been offered influenza vaccine should have a second dose 4 weeks after the first.

Palivizumab for Respiratory Syncytial Virus

This is a humanised monoclonal antibody that can be given to high-risk infants. This works as passive immunisation against respiratory syncytial virus which is associated with severe morbidity and mortality in the winter season.

Palivizumab is recommended for:

High Risk - Bronchopulmonary dysplasia (BPD) – (also known as chronic lung disease)

Moderate or severe BPD in preterm infants, defined as “preterm infants with compatible x-ray changes who continue to receive supplemental oxygen or respiratory support at 36 weeks post-menstrual age”. Children who fall into the light and dark shaded area of Table 1 should be offered prophylaxis.

Infants with respiratory diseases who are not necessarily pre-term but who remain on oxygen at the start of the season are considered to be at higher risk.

These infants may include those with conditions including:

- a) pulmonary hypoplasia due to congenital diaphragmatic hernia
- b) other congenital lung abnormalities (sometimes also involving heart disease or lung malformation)
- c) interstitial lung disease

and including those receiving long term ventilation at the onset of the season.

Table 1 – Cost effective use of Palivizumab (shaded area) for pre-term infants with Moderate or severe BPD by chronological age (months) at the start of the RSV season (usually 1st October) and gestational age at birth (weeks) Gestational age at birth (weeks+days)

Chronological age (months)	Gestational age at birth (weeks + days)						
	≤24+0	24+1 to 26+0	26+1 to 28+0	28+1 to 30+0	30+1 to 32+0	32+1 to 34+0	≥34+1
<1.5							
1.5 to <3							
3 to <6							
6 to <9							
≥9							

High Risk - Congenital Heart Disease (CHD) defined as

Preterm Infants with haemodynamically significant, acyanotic CHD at the chronological ages at the start of the RSV season and gestational ages covered within the dark shaded area in Table 1.

Cyanotic or acyanotic CHD plus significant co-morbidities particularly if multiple organ systems are involved.

Children under the age of 24 months who have severe combined immunodeficiency syndrome (SCID), until immune reconstituted

SCID is the most severe form of inherited deficiency of immunity. Affected infants are unable to mount either T-cell responses or produce antibody against infectious agents.

Dosage and schedule:

Recommended dose is 15mg/kg by intramuscular injection in the antero-lateral thigh area. This should be administered in a separate site to other routine immunisations (if being given at the same time), preferably in a different limb or at least 2.5 cm apart.

The patient should receive 5 doses, one month apart, beginning in October.

If the course begins later in the season, doses do not need to be given after February.

Infants in neonatal units should only be immunised 24 – 48 hours before discharge.

All palivizumab prescriptions need to be prescribed by Consultants only and in liaison with Lead Clinician and Lead Pharmacist for Palivizumab (Dr R Blumberg and Maxine Phelops/Nisha Nakrani).

Only patients meeting the guidance outlined above will be eligible to receive Palivizumab funded by the CCG. All other patients are funded by the local NHS Trust

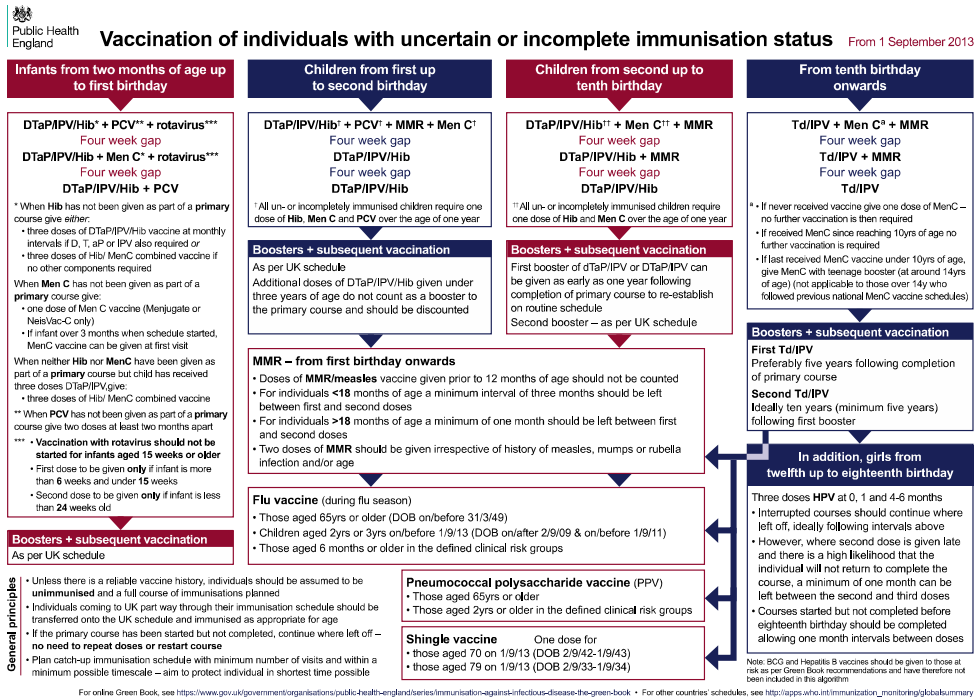
To arrange a course of palivizumab:

- Prescribe all doses required by weight (using estimates from growth chart for subsequent months) on an outpatient form.
- Liaise with Consultant and Pharmacist above
- Liaise with Clinic 4D to book appropriate appointments and give parents letter in appendix 2
- Complete the current list on I:/Paediatrics/Clinical Information/Palivizumab

➤ Section 3: Patients with incomplete or uncertain immunisation status

Please see below or visit weblink

http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1194947406156



➤ References (evidence upon which the guideline is based)

- 1) The Green Book – immunisation against infectious disease. Updated 2013. Available at: <https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>
- 2) NHS Choices <http://www.nhs.uk/conditions/vaccinations/pages/vaccination-schedule-age-checklist.aspx>
- 3) Patient.co.uk <http://www.patient.co.uk/health/immunisation-usual-uk-schedule>

Immunisation consent form



This form is for parents/guardians to give permission for their child to be vaccinated.

Name of parent/guardian:

Child's name and NHS number (if known):

Address of parent/guardian:

Postcode:

Phone number of parent/guardian:

Date of birth of child:

Date of vaccination:

Please inform the person giving the vaccination, if your child:

has had a severe reaction to any medicines, including vaccines,

is allergic to anything, or

has a condition for which he or she has, or is, receiving medical treatment.

Vaccines may contain minute traces of animal products and other components. If you have concerns about any of the contents in the vaccine you can check at:

(Doctor/nurse to insert link to the appropriate vaccine at: <http://www.medicines.org.uk/emc/>)

If you are signing this at home and/or are unable to speak to the person giving the vaccination, this web link gives full details about what the vaccine is for and how it will be given. It also describes any expected side effects that may occur afterwards.

By signing this form you will be giving consent for your child to have the vaccination described.

Having read the above information and/or listened to the doctor/nurse, I agree to my child being vaccinated with:

(Doctor/nurse to enter brand name of vaccine)

Signed:

Name:

Date:

Office use only

Vaccine given

Vaccination site

Batch number

Expiry date

Name and address of administrator

Postcode

Signed

Date

September 2013

Parent of:

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Whittington Hospital NHS Trust
Highgate Hill
London N19 5NF

Tel: 0207 272 3070
Tel: 0207 288 5635/5616 (Direct Line)
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Outpatient Fax: 0207288 5629
Outpatient Tel: 0207288 5359/5321
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Prevention of Respiratory Syncytial Virus for this winter 2013/2014

The RSV virus is an infection of the respiratory system affecting almost all children by the age of 2 years. It is usually a mild disease for healthy infants but your child's particular medical condition makes him particularly vulnerable to this infection of the lungs which may result in serious breathing difficulties.

There is a recommended vaccination available for infants at high risk. The vaccination is a course of 5 single injections, once a month from October to February . It has now been in use for over 8 years and has a good safety record.

The vaccination will be administered for all the children at the same time and will take place in the

Paediatric outpatient clinic 4D, led by Paediatric Nurses Ms G. Williams, and assisted by Ms S Gentles – contact details – Tel: 7288 5359 and 7288 5882/3.

Please expect an appointment reminder. Contact me or your own hospital consultant if you would like to discuss this further

Yours sincerely

Dr Raoul Blumberg
Consultant Paediatrician



➤ **Contacts (inside and outside the Trust including out-of-hours contacts)**

Paediatric Registrar or Consultant on duty (via switch)

Paediatric Pharmacist (via switch)

To be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval

		Yes/No	Comments
1.	Does the procedural document affect one group less or more favourably than another on the basis of:		
	• Race	No	
	• Ethnic origins (including gypsies and travellers)	No	
	• Nationality	No	
	• Gender	No	
	• Culture	No	
	• Religion or belief	No	
	• Sexual orientation including lesbian, gay and bisexual people	No	
	• Age	No	
	• Disability - learning disabilities, physical disability, sensory impairment and mental health problems	No	
2.	Is there any evidence that some groups are affected differently?	No	
3.	If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?	No	
4.	Is the impact of the procedural document likely to be negative?	No	
5.	If so can the impact be avoided?	N/A	
6.	What alternatives are there to achieving the procedural document without the impact?	N/A	
7.	Can we reduce the impact by taking different action?	N/A	

If you have identified a potential discriminatory impact of this procedural document, please refer it to the Director of Human Resources, together with any suggestions as to the action required to avoid/reduce this impact.

For advice in respect of answering the above questions, please contact the Director of Human Resources.

Checklist for the Review and Approval of Procedural Document

To be completed and attached to any procedural document when submitted to the relevant committee for consideration and approval.

	Title of document being reviewed:	Yes/No	Comments
1.	Title		
	Is the title clear and unambiguous?	Yes	
	Is it clear whether the document is a guideline, policy, protocol or standard?	Yes	
2.	Rationale		
	Are reasons for development of the document stated?	Yes	
3.	Development Process		
	Is it clear that the relevant people/groups have been involved in the development of the document?	Yes	
	Are people involved in the development?	Yes	
	Is there evidence of consultation with stakeholders and users?	Yes	
4.	Content		
	Is the objective of the document clear?	Yes	
	Is the target population clear and unambiguous?	Yes	
	Are the intended outcomes described?	Yes	
5.	Evidence Base		
	Are key references cited in full?	N/A	
	Are supporting documents referenced?	N/A	
6.	Approval		
	Does the document identify which committee/group will approve it?	Yes	
7.	Dissemination and Implementation		
	Is there an outline/plan to identify how this will be done?	Yes	
8.	Document Control		
	Does the document identify where it will be held?	Yes	
9.	Process to Monitor Compliance and Effectiveness		

	Title of document being reviewed:	Yes/No	Comments
	Are there measurable standards or KPIs to support the monitoring of compliance with and effectiveness of the document?	Yes	
	Is there a plan to review or audit compliance with the document?	Yes	
10.	Review Date		
	Is the review date identified?	Yes	
	Is the frequency of review identified? If so is it acceptable?	Yes	
11.	Overall Responsibility for the Document		
	Is it clear who will be responsible for co-ordinating the dissemination, implementation and review of the document?	Yes	

Executive Sponsor Approval			
If you approve the document, please sign and date it and forward to the author. Procedural documents will not be forwarded for ratification without Executive Sponsor Approval			
Name		Date	
Signature			
Relevant Committee Approval			
The Director of Nursing and Patient Experience's signature below confirms that this procedural document was ratified by the appropriate Governance Committee.			
Name		Date	
Signature			
Responsible Committee Approval – only applies to reviewed procedural documents with minor changes			
The Committee Chair's signature below confirms that this procedural document was ratified by the responsible Committee			
Name		Date	
Name of Committee		Name & role of Committee Chair	
Signature			

Tool to Develop Monitoring Arrangements for Policies and guidelines

What key element(s) need(s) monitoring as per local approved policy or guidance?	Who will lead on this aspect of monitoring? Name the lead and what is the role of the multidisciplinary team or others if any.	What tool will be used to monitor/check/observe/Assess/inspect/ authenticate that everything is working according to this key element from the approved policy?	How often is the need to monitor each element? How often is the need complete a report ? How often is the need to share the report?	What committee will the completed report go to?
Element to be monitored	Lead	Tool	Frequency	Reporting arrangements
Rotavirus administration timing	W Leith	Audit		
Palivizumab administration	R Blumberg	Audit		