

.....PRIMARY GROUP/TRUST
SOUTHERN DERBYSHIRE

**PATIENT GROUP DIRECTIONS
FOR THE ADMINISTRATION
OF
IMMUNISATIONS IN PRIMARY CARE
FOR PRACTICE STAFF USE ONLY**

24. Inactivated Polio Vaccine
25. Combined Diphtheria/Tetanus/pertussis and IPV (Tetravac)
26. Rabies (Rabipur/ Aventis Pasteur)
27. Rubella
28. Adsorbed Tetanus (Clostet/ Aventis Pasteur)
29. Oral Typhoid – (Vivotif)
30. Typhoid (Typhim Vi/ Typherix)
31. Yellow Fever- (Arilvax)

Purpose of the Patient Group Directions

To enable a nurse who has received specific, appropriate training and has been assessed as competent to administer immunisation in accordance with the following protocol and recommendations issued by the Department of Health 1998, the UKCC Professional Code of Conduct (1992) and the UKCC Standards for the Administration of Medicines (1992)

These PGDs apply to all practice nurses working inpractice in PCG/T, **wherever immunisation is given**. (This may include the patient's home if the patient is unable to attend the surgery, a school or clinic)

Characteristics of Staff

Qualifications Required	Registered nurse with current registration as an appropriate practitioner
Additional Requirements	<p>Access to 'Immunisation against Infectious Disease' (Green Book) and to comply with its recommendations</p> <p>Training and competence in all aspects of immunisation including contraindications and the recognition and treatment of anaphylaxis (see the Green Book. Guidelines for the management of anaphylaxis are being developed and will be sent to accompany this document shortly)</p> <p>Immediate access to adrenaline 1:1000</p>
Continuing Training Requirements	Minimum three yearly update in Immunisation and Vaccination, or sooner If deemed necessary

References:

Department of Health (1996):Immunisation Against Infectious Disease (HMSO)

Department of Health (1998): Review of Prescribing, Supply and Administration of Medicines. A report on the Supply and Administration of Medicines under Patient Group Direction.

UKCC (1992) Standards for the Administration of medicines

UKCC (1992) Professional Code of Conduct

Health Service Circular 2000/26 - Patient Group Directions

**These PGDs have been produced for use in thePrimary Care Trust
by a multi-disciplinary team:**

Dr... General Practitioner -----

..... Pharmacist -----

..... Practice Nurse -----

They have been approved for the PCG/T by:

..... Clinical Governance Lead -----

They have been drawn up with the help of :

Dr Roy Fey Consultant in Communicable Disease at Southern Derbyshire Health
Authority

**These PGDs become valid on 2001, and become due for review before
..... 2003.**

These PGDs expire on2003.

Available resources

1. Immunisation against Infectious Disease, HMSO 1996 edition (Known as the 'green book')
2. Health Information for Overseas Travel, HMSO 1995 edition (Known as the 'yellow book')
3. BNF
4. Drug company Helpline

Aventis Pasteur MSD Vaccine Information Service (VIS): **07000 76673847**

GlaxoSmithKline Enquiries to Customer Response Centre: **0808 100 2228**

Medeva Pharma Ltd (formerly Evans) Medical Information: **01372 364132**

Further Advice

Consultant in Communicable Disease Control at Southern Derbyshire Health –

Dr Roy Fey.

Kirsty MacLean Drug Information and Evaluation Pharmacist

Tel: 01332 626300

Unlicensed vaccines

These are **not** covered by this PGD and are to be given following a written instruction in the patient's notes by a doctor (e.g. Japanese B encephalitis vaccine and Tick borne encephalitis vaccine).

Black triangle vaccines

May be administered under this PGD.

Children with egg allergy or severe reaction to previous vaccination

Children with egg allergy should be referred to Dr Tracy Tinklin Consultant Paediatrician at Derby Children's Hospital 01332 340131 for vaccination under hospital supervision.

Referral is also an option if there has been a severe local or general reaction to previous vaccination (see Green Book page 21). The referral must include a detailed history of the vaccinations already given, the particular adverse reaction that has been documented and a clear indication of what vaccination the child is being referred for.

Note

It is always advisable to use this information in conjunction with other reference sources, particularly

1. **Immunisation against Infectious Disease** HMSO 1996 edition (Known as the 'green book')
2. **The SPC (Summary of Product Characteristics)** for each individual vaccine. These can be found in the ABPI compendium and eMC or are available from the specific drug company upon request.

Immunisation Schedule

Childhood immunisations - Details on the immunisation schedule for childhood immunisation can be found in The Green Book or BNF

Travel Vaccinations - Details on the vaccination requirements for travellers can be found in MIMS and charts provided by GP/Doctor/Pulse. Alternatively specialist travel vaccine advisory services can be contacted e.g. MASTA or the drug company help lines listed on the previous page.

Each PGD lists the indications of use for each vaccine and should be consulted before administration of the vaccine.

Administrative procedures

Complete vaccine administration details as follows

- name of vaccine
- date vaccine given
- primary or booster dose
- vaccine batch number
- expiry date
- site of injection
- the person who administered the vaccine

Ask patient to wait in the surgery 15 minutes following vaccination. N.B There are no UK guidelines on the necessity to wait in the surgery after vaccination, however, most adverse reactions would occur during this stated period.

Whilst there is no legal requirement for a doctor to remain within the premises whilst immunisations are administered, this procedure should only be performed by the nurse involved if she feels competent to undertake the task and there is another responsible adult in the surgery to summon emergency help if necessary.

Consent

All patients for whom vaccination is proposed should give their consent to vaccination.

In adults, consent is implied by request/attendance for vaccination. It does not matter how the patient gives consent it can be written, oral or non-verbal.

In INFANTS and CHILDREN consent of the parent or legal guardian must be obtained.

For courses of vaccination parental consent to the first dose can be accepted as consent to the course.

Patients need sufficient information before they can decide whether to give their consent: for example information about the benefits and risks of the proposed treatment, and alternative treatments .

Further guidance on consent can be found at www.doh.gov.uk/consent and in the Green Book

General Guidance for the Administration of Vaccines

General

1. The identity of the vaccine must be checked to ensure the right product is used in the appropriate way on every occasion
2. The expiry date must be noted. Vaccines must not be used after the expiry date on the label
3. The date of immunisation, title of vaccine and batch number must be recorded on the recipient's record. When two vaccines are given together, the relevant sites should be recorded to allow any reactions to be related to the causative site. It may be considered good practice to record all sites of administration.
4. The recommended storage conditions must have been observed.

Reconstitution of vaccines

1. Freeze dried vaccines must be reconstituted with the diluent supplied and used within the recommended period after reconstitution.
2. The diluent must be added slowly to avoid frothing, a sterile 1ml syringe with a 21G needle should be used for reconstituting the vaccine and a smaller gauge needle for injection, unless only one needle is supplied with a pre-filled syringe.
3. Vaccines must not be mixed before administration. The only exception is Hib and DTP from the same manufacturer.

Cleaning of Skin

If the skin is to be cleaned, alcohol and other disinfecting agents must be allowed to evaporate before injection of vaccine since they can inactivate live vaccine preparations.

Route of Administration

1. By Mouth – Oral polio must never be injected. OPV must not be allowed to remain at room temperature prior to or following administration as this may decrease potency.
2. Subcutaneous and Intramuscular injection – Most vaccines are given by intramuscular or deep subcutaneous injection. In infants, the antero-lateral aspect of the thigh or upper arm are recommended. If the buttock is used, injection into the upper, outer quadrant avoids the risk of sciatic nerve damage. Injection into the fatty tissue of the buttock has been shown to reduce the efficacy of hepatitis B vaccine.

Needle

For deep sc or im immunisation in infants 23 or 25G

For adults a 23G needle

For intradermal immunisations 25G needle

PGD NUMBER 1

Patient Group Direction for the supply/administration of

**ADSORBED DIPHTHERIA,
TETANUS/PERTUSSIS (DTP) AVENTIS
PASTEUR BRAND /WYETH DTP Vaccine
Behring**

to **INFANTS AND CHILDREN UPTO 10 YEARS OF AGE (children over the age of 10, adults and elderly not recommended)**

1. Clinical Condition

Define situation/condition	Given as part of the childhood vaccination programme. Primary Course of immunisation.
Criteria for inclusion	All children under the age of 10
Criteria for exclusion	Current acute illness. Previous severe reaction to vaccination. Children over 10 years of age. Personal history of epilepsy – specialist advice should be sought prior to performing immunisation. Neurological Disease – Immunisation should be deferred until condition is stable.
Action if excluded	Information about when child may have vaccine, if appropriate
Action if patient declines	Advice re immunisation and disease complication.

2. Description of treatment

Name of Medicine	Adsorbed Diphtheria, Tetanus and Pertussis vaccine BP (Available from Farrilon as Aventis Pasteur Brand (DTPw vaccine) or DTP Behring)
POM/P/GSL	POM
Dose/s	0.5 ml
Route Method	Intramuscular or deep subcutaneous injection
Frequency	Primary course consists of 3 doses starting at 2 months of age with an interval of at least 4 weeks between doses. If the course is interrupted it should be resumed allowing appropriate intervals between remaining doses. It is not necessary to continue with the same brand of vaccine for all 3 doses
Total dose number	Primary course – 3 doses
Follow up	None
Advice	Management of local reactions - Pain, tenderness, swelling or redness at injection site. Temperature control. A persistent nodule at the site of vaccination may occur if injection not given deeply enough
Record	Date of administration, vaccine, batch number and site of administration

PGD NUMBER 2

Patient Group Direction for the supply/administration of

ADSORBED DIPHTHERIA, TETANUS/PERTUSSIS (DTP) INFANRIX

to **CHILDREN UNDER 7 YEARS OLD (children over the age of 7, adults and elderly not recommended) N.B. Infanrix is only licensed for use in children up to and including 6 years of age**

1. Clinical Condition

Define situation/condition	Given as part of the childhood vaccination programme. Primary Course of immunisation.
Criteria for inclusion	All children under the age of 7
Criteria for exclusion	Current acute illness. Previous severe reaction to vaccination. Children over 7 years of age. Personal history of epilepsy – specialist advice should be sought prior to performing immunisation. Neurological Disease – Immunisation should be deferred until condition is stable.
Action if excluded	Information about when child may have vaccine, if appropriate
Action if patient declines	Advice re immunisation and disease complication.

2. Description of treatment

Name of Medicine	Adsorbed Diphtheria, Tetanus and Pertussis vaccine BP. Infanrix (DTPa Vaccine)
POM/P/GSL	POM
Dose/s	0.5 ml
Route Method	Intramuscular or deep subcutaneous injection
Frequency	Primary course consists of 3 doses starting at 2 months of age with an interval of at least 4 weeks between doses. If the course is interrupted it should be resumed allowing appropriate intervals between remaining doses. It is not necessary to continue with the same brand of vaccine for all 3 doses
Total dose number	Primary course – 3 doses
Follow up	None
Advice	Management of local reactions - Pain, tenderness, swelling or redness at injection site. Temperature control. A persistent nodule at the site of vaccination may occur if injection not given deeply enough
Record	Date of administration, vaccine, batch number and site of administration

PGD NUMBER 3

Patient Group Direction for the
supply/administration of

ADSORBED DIPHTHERIA AND TETANUS (DT)(Medeva/Aventis Pasteur)

to **INFANTS AND CHILDREN UNDER 10 YEARS (children older than 10, adults and elderly
not recommended)**

1. Clinical Condition

Define situation/condition	Primary Course of immunisation in infants and children under 10, if Pertussis vaccine is contraindicated or not required. Booster immunisation re-enforcement in children under 10 who have had the primary course.
Criteria for inclusion	Infants requiring primary immunisation where Pertussis vaccine is contra-indicated. All children who have received the primary course of immunisation require a booster at least 3 years after completion of primary immunisation.
Criteria for exclusion	Current acute illness. Previous severe reaction to vaccination. Children over 10 years of age, adults and the elderly.
Action if excluded	Advise about when the child can have the vaccines.
Action if patient declines	Advice re immunisation and disease complication.

2. Description of treatment

Name of Medicine	Adsorbed Diphtheria and Tetanus (DT)(Medeva or Aventis Pasteur)
POM/P/GSL	POM
Dose/s	0.5 ml
Route Method	Intramuscular or deep subcutaneous injection.
Frequency	Primary course 3 doses starting at two months of age with an interval of 1 month between doses (2, 3, and 4 months). If course is interrupted, it may be resumed; there is no need to start again whatever the interval. Booster – immunisation re-enforcement – 1 dose at least 3 years after completing the primary course of immunisation
Total dose number	Primary course – 3 doses Booster – immunisation re-enforcement – 1 dose
Follow up	None
Advice	Management of local reactions - Tenderness, swelling and redness at injection site. A persistent nodule at the site of vaccination may occur if injection not given deeply enough.
Record	Date of administration, vaccine, batch number and site of administration

PGD NUMBER 4

Patient Group Direction for the
supply/administration of
to **PERSONS OF TEN YEARS AND OVER**

ADSORBED LOW DOSE DIPHTHERIA VACCINE FOR ADULTS (d)

1. Clinical Condition

Define situation/condition	Primary Immunisation in patients over 10 years
Criteria for inclusion	Primary immunisation of persons over 10 years of age. Reinforcing immunisation. Travellers to epidemic or endemic areas (see 'Health Information for Overseas Travel' for more information). Contacts of diphtheria cases (Note for this indication it can be used in children as there is no other formulation currently available)
Criteria for exclusion	Acute illness (minor infections without fever or systemic upset are not reasons to postpone immunisation). Previous severe reaction to the vaccine. Children under 10 years of age <u>unless</u> the vaccination is being given to contacts of a case of diphtheria – see note above
Action if excluded	Advise about when the person can have the vaccines, if appropriate.
Action if patient declines	Advice re immunisation and disease complication.

2. Description of treatment

Name of Medicine	Adsorbed Diphtheria Vaccine for adults and Adolescents
POM/P/GSL	POM
Dose/s	0.5 ml
Route Method	Intramuscular or deep subcutaneous injection.
Frequency	Primary course consists of three doses with an interval of one month between doses Booster one dose Contacts of a diphtheria case. Unimmunised adults and children should be given the primary immunisation course, immunised adults and children are given the booster dose.
Total dose number	3 or 1 as appropriate
Follow up	None
Advice	Temperature control, Management of local reactions.
Record	Date of administration, vaccine, batch number and site of administration

PGD NUMBER 5

Patient Group Direction for the
supply/administration of
to **PERSONS OF TEN YEARS AND OVER**

**ADSORBED TETANUS AND LOW DOSE
DIPHTHERIA (Td) DIFTAVAX**

1. Clinical Condition

Define situation/condition	Before leaving school (13 to 18 years of age) and unimmunised adults.
Criteria for inclusion	Primary immunisation of persons over 10 years of age. Reinforcing immunisation of pre school leavers. Travellers to epidemic or endemic areas (see 'Health Information for Overseas Travel' for more information).
Criteria for exclusion	Acute illness (minor infections without fever or systemic upset are not reasons to postpone immunisation). Previous severe reaction to the vaccine. Children under 10 years of age. (use DT) Immunisation for tetanus, in some cases (see Green book p71 for detailed advice).
Action if excluded	Advise about when the person can have the vaccines, if appropriate.
Action if patient declines	Advice re immunisation and disease complication.

2. Description of treatment

Name of Medicine	Adsorbed Tetanus and low dose Diphtheria (Td)(DIFTAVAX)
POM/P/GSL	POM
Dose/s	0.5 ml
Route Method	Intramuscular or deep subcutaneous injection.
Frequency	Primary course consists of three doses with an interval of one month between doses or one reinforcing dose before school leaving.
Total dose number	3 or 1 as appropriate
Follow up	None
Advice	Temperature control, Management of local reactions.
Record	Date of administration, vaccine, batch number and site of administration

PGD NUMBER 6

Patient Group Direction for the supply/administration of

ADSORBED DIPHTHERIA, TETANUS, PERTUSSIS AND Hib ACT-HIBDTP dc (Aventis Pasteur) INFANRIX -Hib

to **CHILDREN (Not recommended for children aged 4 years or over, adults and the elderly)**

1. Clinical Condition

Define situation/condition	Given as part of the childhood vaccination programme. Primary Course of immunisation.
Criteria for inclusion	All children.
Criteria for exclusion	Current acute illness. Previous severe reaction to vaccination. Children over 4 years of age. Personal history of epilepsy – specialist advice should be sought prior to performing immunisation. Neurological Disease – Immunisation should be deferred until condition is stable.
Action if excluded	Information about when patient can have vaccine.
Action if patient declines	Information about protective effects of vaccine and dangers of disease.

2. Description of treatment

Name of Medicine	Adsorbed Diphtheria, Tetanus, Pertussis and Hib ACT-HIB DTP/Infanrix HIB
POM/P/GSL	POM
Dose/s	0.5 ml
Route Method	Intramuscular or deep subcutaneous injection
Frequency	Primary course consists of 3 doses starting at 2 months of age with an interval of at least 4 weeks between doses. If the course is interrupted it should be resumed allowing appropriate intervals between remaining doses.
Total dose number	Primary course – 3 doses
Follow up	None
Advice	Management of local reactions - Pain, tenderness, swelling or redness at injection site. Temperature control. A persistent nodule at the site of vaccination may occur if injection not given deeply enough.
Record	Date of administration, vaccine, batch number and site of administration

N.B.WARNING ONLY MIX DTP AND HIB PRODUCTS FROM THE SAME MANUFACTURER

PGD NUMBER 7

Patient Group Direction for the
supply/administration of
to **CHILDREN AND ADULTS**

**HAEMOPHILUS INFLUENZAE TYPE B (Hib)
conjugate vaccine HIBTITER/ACT-HIB**

1. Clinical Condition

Define situation/condition	Given as part of childhood immunisation programme as active immunisation against Haemophilus Influenzae Type B.
Criteria for inclusion	Unimmunised children or children who have not had Hib with primary immunisations. Asplenic patients of any age
Criteria for exclusion	Current acute illness. Previous severe reaction to vaccine. Unstable neurological conditions. Pregnancy.
Action if excluded	Information about when the patient can have vaccine.
Action if patient declines	Information about HIB and disease complications.

2. Description of treatment

Name of Medicine	Haemophilus Influenzae Type B vaccine
POM/P/GSL	POM
Dose/s	0.5 ml
Route Method	Intramuscular or deep subcutaneous injection
Frequency and number of doses	Primary course - 3 doses usually starting at 2 months of age with an interval of 1 month between doses. It is not necessary to continue with the same batch of vaccine for all 3 doses. Unimmunised children over 13 months and less than 4 years should be given a single dose of Hib vaccine. Routine vaccination is not normally required for children over 4 years as the risk of infection falls sharply at this age. Asplenic children and adults should receive a single dose; those under 1 year should be given three doses.
Follow up	None
Advice	Local reaction management. Temperature control.
Record	Date of administration, vaccine, batch number and site of administration

PGD NUMBER 8**HEPATITIS A VACCINE AVAXIM / HAVRIX
MONODOSE / VAQTA ADULT**Patient Group Direction for the
supply/administration ofTo **ADULTS OVER 16 YEARS OF AGE****1. Clinical Condition**

Define situation/condition	Adults needing protection for travel, occupation or lifestyle.
Criteria for inclusion	<p>RECOMMENDED FOR:</p> <p>Adults over 16 at risk from Hepatitis A because of travel to countries with medium or high endemicity including military and diplomatic personnel posted to endemic countries.</p> <p>Haemophiliacs treated with factor VIII or factor IX concentrates or who have been infected with hepatitis B or C</p> <p>Homosexuals</p> <p>Patients with chronic liver disease</p> <p>Laboratory workers working with the virus</p> <p>OCCUPATIONAL EXPOSURE</p> <p>Outbreaks of hepatitis A have been associated with residential institutions with severe learning disabilities. Immunisation of staff and residents may be appropriate in the light of local risk assessment.</p> <p>A potential occupational risk exists in those workers who come into direct contact with untreated sewage. Employers are required to undertake their own risk assessment to determine whether immunisation is required.</p>
Criteria for exclusion	<p>Febrile illness.</p> <p>Previous Hepatitis A infection confirmed by blood test.</p> <p>Allergy to any vaccine component.</p> <p>Pregnancy. Breast feeding</p>
Action if excluded	Advice about hygiene (also give this advice if vaccinated)
Action if patient declines	Advice about hygiene(also give this advice if vaccinated)

2. Description of treatment

Name of Medicine	AVAXIM / HAVRIX MONODOSE / VAQTA ADULT
POM/P/GSL	POM
Dose/s	0.5ml pre filled syringe (Avaxim) / 1ml pre filled syringe
Route Method	IM in the deltoid region
Frequency	2 doses, 6-12 months apart. Booster after 10 years. Both vaccines can be used as a booster in subjects previously immunised with any inactivated hepatitis A vaccine
Total dose number	2
Advice	Local reaction, fever, malaise, fatigue, headache, nausea, diarrhoea and loss of appetite.
Record	Date of administration, vaccine, batch number and site of administration on patient records.

PGD NUMBER 9

Patient Group Direction
for the supply/administration of
to **CHILDREN AGED 1 YEAR UP TO 17 YEARS**

HEPATITIS A VACCINE - VAQTA PAEDIATRIC /HAVRIX MONODOSE

1. Clinical Condition

Define situation/condition	Children needing protection from Hepatitis A for travel or exposed to infection.
Criteria for inclusion	Children and adolescents at risk from infection from Hepatitis A due to travel or residence in countries with moderate to high endemicity, or at risk of infection due to contact. During outbreaks of Hepatitis A infection (N.B age of administration Vaqta Paediatric age 2 to 17 Havrix Monodose age 1-15)
Criteria for exclusion	Febrile illness. Previous Hepatitis A infection. Allergy to any component of vaccine. Pregnancy.
Action if excluded	Advice about hygiene (also give this advice if vaccinated)
Action if patient declines	Advice about hygiene (also give this advice if vaccinated)

2. Description of treatment

Name of Medicine	VAQTA PAEDIATRIC /HAVRIX MONODOSE
POM/P/GSL	POM
Dose/s	0.5ml pre-filled syringe
Route Method	IM in the deltoid region
Frequency	Vaqta Paediatric 0.5ml as a single dose a then booster dose 6-18 months after initial dose. Immunity lasts for 10 years Havrix Junior Monodose 0.5ml as a single dose then booster 6-12 months after primary immunisation. Immunity lasts for 10 years Both vaccines can be used as a booster in subjects previously immunised with any inactivated hepatitis A vaccine
Total dose number	2
Advice	Local reaction, fever, malaise, fatigue, headache, nausea, diarrhoea and loss of appetite.
Record	Date of administration, vaccine, batch number and site of administration on patient records.

PGD NUMBER 10

Patient Group Direction for the
supply/administration of

HEPATITIS B VACCINE (HB- VaxII)

to **ADULTS**

1. Clinical Condition

Define situation/condition	Immunisation of adults (16 years of age and older) in high risk groups for contact with Hepatitis B
Criteria for inclusion	<p>Recommended for:</p> <ul style="list-style-type: none"> Parenteral drug abusers Individuals who change sexual partners frequently particularly homosexual or bisexual men Close family contacts of a case or carrier Families adopting children from countries with a high prevalence of hepatitis B Haemophiliacs receiving blood transfusions or blood products and carers responsible for the administration of such products Patients with chronic renal failure including those on haemodialysis During outbreak Inmates of custodial institutions Those travelling to areas of high prevalence who are at increased risk or plan to remain there for lengthy periods NB Short term tourists or business travellers are not generally at increased risk of infection. Health care personnel who have direct contact with blood, blood-stained fluids or patient tissues Trainee healthcare workers Morticians and embalmers Occupational risk groups - Staff and patients of day care residential accommodation for those with severe learning difficulties. Police, ambulance, fire and rescue service personnel. These individuals may be at higher risk than the general population and may require immunisation. Such a recommendation should be decided locally by occupational health services following the necessary risk assessment.
Exclusion criteria	<ul style="list-style-type: none"> Hypersensitivity to a component of the vaccine. Severe febrile infection
Action if excluded	<ul style="list-style-type: none"> Temporary exclusion-Advice as to when the vaccine can be given Permanent exclusion advice about prevention
Action if patient declines	Information about disease transmission and risk

2. Description of treatment

Name of Medicine	H-B-Vax II
POM/P/GSL	POM
Dose/s	1ml
Route Method	IM - deltoid region,. SC may be considered for persons with haemophilia & severe bleeding disorders
Frequency	3 doses of 1ml; the second 1month and third 6 months after the first dose. If more rapid vaccination is required e.g. for travellers, dose at 0,1,2 months and booster at 12 months.
Total dose number	3 (4 if rapid vaccination is used)
Follow up	<p>Antibody titres should be checked in health care workers and babies born to hepatitis B carriers 2-4 months after completion of the course.</p> <p>Post vaccination testing is not recommended for people vaccinated for other reasons.</p> <p>If the antibody level is greater than 100 miu/ml they should only receive one booster after 5 years or after possible exposure to the virus. e.g. needle stick injury</p> <p>If their antibody level is between 10 miu/ml and 100 miu/ml after one complete course they should be offered an immediate booster and retested. If the booster achieves a level of >100 miu/ml follow the above guidance. If they have failed to get to >100miu/ml the situation will need to be assessed by their occupational health service and further tests will need to be done.</p> <p>If the first course produces an antibody level of <10 miu/ml and they do not have markers of previous infection then the full course should be repeated and the person retested. Then follow the guidance above depending on the result.</p> <p>Those over the age of 40 are less likely to respond. Patients who are immunodeficient or on immunosuppressive therapy may respond less well than healthy individuals and may require larger doses of vaccine (HB Vax 11 40)</p> <p>For further advice contact Dr Bullock or Dr Hoque at the DRI or Dr Fey AT SDHA</p>
Advice	Local reactions at the injection site. Rare side effects are fever, rash, malaise, influenza like syndrome, nausea and headache.
Record	Date of administration, vaccine, batch number and site of administration on patient records.

PGD NUMBER 11

Patient Group Direction for the
supply/administration of
to **NEONATES AND CHILDREN**

HEPATITIS B VACCINE (HB VAX II Paediatric)

1. Clinical Condition

Define situation/condition	Immunisation of neonates and children up to and including 15 years of age, considered at risk of exposure to hepatitis B
Criteria for inclusion	<p>Children frequently receiving blood products; children in haemodialysis and oncology units, children suffering from thalassaemia, sickle cell anaemia, haemophilia, and children receiving frequent blood transfusions or clotting factor concentrates, organ transplants</p> <p>Infants born to mothers who are carriers</p> <p>Children residents of institutions for severe learning disabilities</p> <p>Those travelling to areas of high prevalence who are at increased risk or plan to remain there for lengthy periods NB Short term tourists not generally at increased risk of infection.</p> <p>Household contacts of anyone at increased risk of HBV infection and contacts with acute or chronic HBV infection</p>
Criteria for exclusion	Hypersensitivity to a component of the vaccine. Severe febrile infection.
Action if excluded	Advice as to when the vaccine can be given
Action if patient declines	Information about disease transmission and risk

2. Description of treatment

Name of Medicine	H-B-Vax II Paediatric
POM/P/GSL	POM
Dose/s	0.5ml pre filled syringe
Route Method	Intramuscular injection in the deltoid region. The anterolateral thigh is the preferred site for injection in neonates, infants and young children
Frequency	<p>3 doses of 1ml; the second 1 month and third 6 months after the first dose. If more rapid vaccination is required e.g. for travellers, dose at 0,1,2 months and booster at 12 months.</p> <p>Infants born to HbeAg mothers, 4 doses of 0.5ml first dose at birth (0,1,2,12) Hepatitis B immunoglobulin may also be required under certain circumstances. Consultant microbiologist will advise and obtain HBIG</p>
Total dose number	3 (4 if rapid vaccination is used)

Follow up	<p>Antibody titres should be checked in babies born to hepatitis B carriers 2-4 months after completion of the course.</p> <p>There is no consensus on the need for booster doses. On present evidence it is felt that a single booster dose five years after completion of the primary course is sufficient to retain immunity in those who continue to be at risk of infection.</p>
Advice	<p>Local reactions at the injection site. Rarely can cause fever, rash, malaise, influenza like syndrome, nausea and headache.</p>
Record	<p>Date of administration, vaccine, batch number and site of administration on patient records.</p>

PGD NUMBER 12

Patient Group Direction for the
supply/administration of
to **ADULTS**

HEPATITIS B VACCINE (ENGERIX B)

1. Clinical Condition

Define situation/condition	Immunisation of adults and children in high risk groups for contact with Hepatitis B
Criteria for inclusion	<p>Recommended for :</p> <ul style="list-style-type: none"> Parenteral drug abusers Individuals who change sexual partners frequently particularly homosexual or bisexual men Close family contacts of a case or carrier Families adopting children from countries with a high prevalence of hepatitis B Haemophiliacs receiving blood transfusions or blood products and carers responsible for the administration of such products Patients with chronic renal failure including those on haemodialysis During outbreak Inmates of custodial institutions Those travelling to areas of high prevalence who are at increased risk or plan to remain there for lengthy periods NB Short term tourists or business travellers are not generally at increased risk of infection. Health care personnel who have direct contact with blood, blood-stained fluids or patient tissues Trainee healthcare workers Morticians and embalmers Occupational risk groups - Staff and patients of day care residential accommodation for those with severe learning difficulties. Police, ambulance, fire and rescue service personnel. These individuals may be at higher risk than the general population and may require immunisation. Such a recommendation should be decided locally by occupational health services following the necessary risk assessment.
Criteria for exclusion	Hypersensitivity to a component of the vaccine. Severe febrile infection
Action if excluded	<p>Temporary exclusion-Advice as to when the vaccine can be given</p> <p>Permanent exclusion advice about prevention</p>
Action if patient declines	Information about disease transmission and risk

2. Description of Treatment

Name of Medicine	Energix B
POM/P/GSL	POM
Dose/s	Adults and children over 12 years 20mcg (1ml) Neonates and children 12 years and under 10mcg (0.5ml)
Route Method	Intramuscular injection in the deltoid region. In infants the antero-lateral thigh is the preferred site
Frequency	3 doses of 1ml; the second 1 month and third 6 months after the first dose. If more rapid vaccination is required e.g. for travellers, dose at 0,1,2 months and booster at 12 months. In exceptional circumstances in adults aged over 18 years, where a more rapid induction of protection is required. e.g. persons travelling to areas of high endemicity and who commence a course of vaccination within one month of departure a schedule of three injections given at 0,7 and 21 days may be used. A booster is recommended 12 months after first dose.
Total dose number	3 (4 if rapid vaccination is used)
Follow up	Antibody titres should be checked in health care workers and babies born to hepatitis B carriers 2-4 months after completion of the course. Post vaccination testing is not recommended for people vaccinated for other reasons. If the antibody level is greater than 100 miu/ml they should only receive one booster after 5 years or after possible exposure to the virus. e.g. needle stick injury If their antibody level is between 10 miu/ml and 100 miu/ml after one complete course they should be offered an immediate booster and retested. If the booster achieves a level of >100 miu/ml follow the above guidance. If they have failed to get to >100miu/ml the situation will need to be assessed by their occupational health service and further tests will need to be done. If the first course produces an antibody level of <10 miu/ml and they do not have markers of previous infection then the full course should be repeated and the person retested. Then follow the guidance above depending on the result. Those over the age of 40 are less likely to respond. Patients who are immunodeficient or on immunosuppressive therapy may respond less well than healthy individuals and may require larger doses of vaccine (HB Vax 11 40) For further advice contact Dr Bullock or Dr Hoque at the DRI or Dr Fey at SDHA
Advice	Local reactions at the injection site. Very rare are fever, rash, malaise, influenza like syndrome, nausea and headache.
Record	Date of administration, vaccine, batch number and site of administration on patient records.

PGD NUMBER 13

Patient Group Direction for the supply/administration of
to **Adults**

COMBINED INACTIVATED HEPATITIS A AND HEPATITIS B VACCINE (TWINRIX)

1. Clinical Condition

Define situation/condition	Immunisation of non-immune adults and adolescents aged 16 years and over who are at risk of both Hepatitis A and Hepatitis B
Criteria for inclusion	<p>Travellers to high risk areas (Indian subcontinent, Far East, some areas of Eastern Europe), individuals at risk because of their sexual behaviour or who change sexual partners frequently, haemophiliacs treated with Factor VIII or Factor IX concentrates or who have liver disease or who have been infected with hepatitis B or hepatitis C, laboratory staff who work directly with the virus,</p> <p>Consider use in:</p> <p>Staff and residents of institutions for the mentally handicapped following local assessment, those with chronic liver disease including parental drug abusers, workers at risk of exposure to untreated sewage</p> <p>Consult PGDs for individual vaccines for further information</p>
Criteria for exclusion	<p>Patients with known sensitivity to any component of the vaccine or previous sensitivity to Hepatitis A or Hepatitis B vaccine.</p> <p>Acute febrile illness.</p> <p>Pregnancy except where high risk of infection</p> <p>Not recommended for post-exposure prophylaxis following percutaneous (needle-stick), ocular or mucous membrane exposure to hepatitis B virus. The vaccine will not prevent infection caused by hepatitis C and E and other pathogens known to infect the liver. Combined vaccine has not been tested in patients with impaired immunity.</p>
Action if excluded	Advice as to when vaccine may be given or risks of infection. Hygiene advice if travelling, reschedule if excluded due to intercurrent illness.
Action if patient declines	Advice as to risks of infection and hygiene advice if travelling

2. Description of treatment

Name of Medicine	Inactivated Hepatitis A and rDNA Hepatitis B vaccine – Twinrix adult
POM/P/GSL	POM
Dose/s	1ml
Route Method	Intramuscular injection into deltoid region. Not to be injected into the buttock. Subcutaneous route preferred for haemophiliacs or those with thrombocytopenia, bleeding disorders (but immune response may be reduced).
Frequency	Three doses, the second 1-month after the first and third 6 months after the first. Once initiated the primary course of vaccination should be completed with the same vaccine. If monovalent vaccines are used as boosters they can be administered five years after initiation of the primary course for hepatitis B and 10 years after the initiation of hepatitis A Consult PGD for individual vaccines for further information
Total dose number	3
Follow up	See Frequency for boosters
Advice	Tenderness, redness at site of injection, occasional ‘flu like symptoms, temperature control if pyrexia. Information about signs and symptoms of disease, advise continued vigilance
Record	Date of administration, vaccine, batch number and site of administration.

N.B If a combined vaccine is used then it only attracts one item of service fee

PGD NUMBER 14

Patient Group Direction for the supply/administration of

COMBINED INACTIVATED HEPATITIS A AND HEPATITIS B VACCINE (TWINRIX)

to Children from age 1 year to 15 years

1. Clinical Condition

Define situation/condition	Immunisation of non-immune children of 1 year of age up to including 15 years of age who are at risk of both hepatitis A and Hepatitis B
Criteria for inclusion	Travellers to high risk areas (Indian subcontinent, Far East, some areas of Eastern Europe), haemophiliacs treated with Factor VIII or Factor IX concentrates or who have liver disease or who have been infected with hepatitis B or hepatitis C
Criteria for exclusion	<p>Patients with known sensitivity to any component of the vaccine or previous sensitivity to Hepatitis A or Hepatitis B vaccine. Acute febrile illness.</p> <p>Not recommended for post-exposure prophylaxis following percutaneous (needle-stick), ocular or mucous membrane exposure to hepatitis B virus. The vaccine will not prevent infection caused by hepatitis C and E and other pathogens known to infect the liver. Combined vaccine has not been tested in patients with impaired immunity.</p> <p>Consult PGDs for individual vaccines for further information</p>
Action if excluded	Advice as to when vaccine may be given or risks of infection. Hygiene advice if travelling, reschedule if excluded due to intercurrent illness.
Action if patient declines	Advice as to risks of infection and hygiene advice if travelling

2. Description of treatment

Name of Medicine	Combined inactivated Hepatitis A and rDNA Hepatitis B vaccine Twinrix Paediatric
POM/P/GSL	POM
Dose/s	0.5ml
Frequency	<p>Three doses, the second 1-month after the first and third 6 months after the first. Once initiated the primary course of vaccination should be completed with the same vaccine. If monovalent vaccines are used as boosters they can be administered five years after initiation of the primary course for hepatitis B and 10 years after the initiation of hepatitis A</p> <p>Consult PGDs for individual vaccines for further information</p>

Total dose number	3
Follow up	See Frequency for boosters
Advice	Tenderness, redness at site of injection, occasional 'flu like symptoms, temperature control if pyrexia. Information about signs and symptoms of disease, advise continued vigilance
Record	Date of administration, vaccine, batch number and site of administration.

N.B If a combined vaccine is used then it only attracts one item of service fee

PGD NUMBER 15

Patient Group Direction for the
supply/administration of
to **Adults and children of 15 years and over**

TYPHOID AND HEPATITIS A VACCINE (HEPATYRIX)

1. Clinical Condition

Define situation/condition	For immunisation against Typhoid and Hepatitis A
Criteria for inclusion	Adults and adolescents travelling to areas of high prevalence of both diseases including Asia, some areas of Eastern Europe and where sanitation may be poor (see also PGD for Hepatitis A and Typhoid Laboratory workers handling specimens, which may contain hepatitis A or typhoid organisms.
Criteria for exclusion	Patients with known sensitivity to any of the components. Acute febrile illness. Outbreaks of typhoid fever in the UK (no immediate protection and may temporarily increase susceptibility to infection). Pregnancy except where high risk of infection The vaccine will not prevent infection caused by hepatitis B, C and E and other pathogens known to infect the liver. Protection is not conferred against paratyphoid fever or illness caused by non-invasive Salmonellae.
Action if excluded	Advice as to when vaccine may be given or risks of infection. Hygiene advice if travelling, reschedule if excluded due to intercurrent illness.
Action if patient declines	Advice as to risks of infection or hygiene advice if travelling or offer of single vaccine to cover either disease

2. Description of treatment

Name of Medicine	Combined Hepatitis A and typhoid vaccine (Hepatyrix)
POM/P/GSL	POM
Dose/s	1ml
Route Method	Intramuscular injection into deltoid region. Not to be injected into the buttock. Subcutaneous route preferred for haemophiliacs or those with thrombocytopenia, bleeding disorders (but immune response may be reduced).
Frequency	1ml single dose.
Total dose number	Single dose

Follow up	<p>Single dose provides immunity for up to three years for typhoid</p> <p>Hepatyrix may also be given as a single dose for booster vaccination between 6 and 12 months following primary immunisation with hepatitis A vaccine to give long-term protection, against hepatitis A and up to 3 years protection against typhoid fever.</p> <p>A booster of hepatitis A vaccine is recommended at any time between 6-12 months after a single dose of Hepatyrix to ensure long-term protection against hepatitis A. Those who remain at risk of typhoid fever should be revaccinated using a single dose of typhoid Vi polysaccharide vaccine every 3 years</p>
Advice	<p>Tenderness, redness at site of injection, occasional 'flu like symptoms, temperature control if pyrexia.</p> <p>Information about signs and symptoms of disease, advise continued vigilance</p> <p>Contains traces of neomycin, use with caution in patients with known hypersensitivity</p>
Record	Date administered, batch number and site of administration.

N.B If a combined vaccine is used then it only attracts one item of service fee

PGD NUMBER 16
INFLUENZA VACCINE (ALL BRANDS)

Patient Group Direction for the supply/administration of

to **ADULTS and CHILDREN (over 6 months).**

1. Clinical Condition

Define situation/condition	Prophylaxis of influenza.
Criteria for inclusion	All patients aged 65 years and over People of all ages in the following risk groups: Chronic respiratory disease, including asthma Chronic heart disease Chronic renal disease Diabetes Immunosuppressed patients. Residents of nursing homes or residential homes or other long stay facilities.
Criteria for exclusion	Patients with current acute infection or febrile illness. Patients with hypersensitivity to eggs or gentamicin Patients who are pregnant Patients who had a previous severe reaction to flu vaccination.
Action if excluded	Advise with regard to flu symptom management.
Action if patient declines	If declines no further action.

2. Description of treatment

Name of Medicine	Inactivated Influenza Vaccine (Suspension for injection) Inactivated Influenza BP Available from Aventis Pasteur, Begrivac (Wyeth) Fluarix (GSK) Fluvirin (Evans) Influvac (Solvay)
POM/P/GSL	POM
Dose/s	Adults and children over 36 months- 0.5 mls Children aged 6 months – 35months - clinical data limited. Doses of 0.25mls or 0.5mls have been used
Route Method	Intramuscular or Deep Subcutaneous injection
Frequency	Adults annual single dose. Children aged 6 months to 12 years repeat dose after 4-6 weeks if receiving influenza vaccine for the first time
Total dose number	Annual single dose
Follow up	None required
Advice	Advice about side effects e.g. fever, malaise and local reactions
Record	Date of administration, vaccine, batch number and site of administration

PGD NUMBER 17

MEASLES, MUMPS AND RUBELLA VACCINE (MMR II/PRIORIX)

Patient Group Direction for the
supply/administration of

To **CHILDREN and ADULTS**

1. Clinical Condition

Define situation/condition	Part of childhood immunisation programme. During a measles outbreak within 3 days of exposure to infection School leaving or entry into further education not previously vaccinated
Criteria for inclusion	Children over the age of 12 months and adults
Criteria for exclusion	Current acute illness especially if febrile or active or suspected infection. Previous severe reaction to immunisation. History of hypersensitivity to eggs, chicken or chicken feathers Pregnancy. Allergy to neomycin, kanamycin or other vaccine component Other live vaccine within 3 weeks. Immunoglobulin within 3/12. Untreated malignant disease or altered immunity Current treatment for malignant disease or within 6 months of receiving immunosuppressive or x-ray therapy or 3 months of high dose steroids. (See Green Book section 7)
Action if excluded	Refer to GP /Paediatrician for advice.
Action if patient declines	Information on disease complications.

2. Description of treatment

Name of Medicine	Measles, Mumps and Rubella Vaccine live attenuated (MMR II/PRIORIX)
POM/P/GSL	POM
Dose/s	0.5 ml
Route Method	IM or SC injection preferably in the outer aspect of the arm
Frequency	Course consists of 2 doses, first dose given shortly after first birthday and second dose prior to school entry. Unimmunised children presenting for pre-school booster should be given 1 st dose of MMR followed by 2 nd dose 3 months later. Protection for susceptible contacts during a measles outbreak a single dose within 3 days of contact. At school leaving age or entry into further education individuals not previously immunised should be offered immunisation
Follow up	None
Advice	Temperature control. Management of local reactions including rash Give patient information leaflet if available.
Record	Date of administration, vaccine, batch number and site of administration

PGD NUMBER 18

MENINGOCOCCAL POLYSACCHARIDE VACCINE (AC VAX SmithKline Beecham)

Patient Group Direction for the supply/administration of

to **ADULTS AND CHILDREN over 2 months (Does not provide reliable long-lived protection for children under 2 years)**

1. Clinical Condition

Define situation/condition	Active immunisation against types A and C meningitis For subjects at risk i.e. <ul style="list-style-type: none"> - travellers to areas where there is increased risk of the disease, - epidemic situations of group A. For group C use Meningococcal GroupC conjugate.
Criteria for inclusion	Immediate family or close contacts of cases of group A disease. During outbreaks in closed communities immunisation may be given to control the epidemic. In outbreaks of Group C disease, Meningococcal Group C Conjugate vaccine is preferred. This polysaccharide vaccine should only be used for Group C outbreaks if MCC is not available. Before travelling to areas with increased risk of type A infection, especially long stay travellers and backpackers. (For Hajj use ACW_{135Y}) Individuals travelling abroad should be immunised with A and C vaccine even if they have received the MenC conjugate vaccine before.
Criteria for exclusion	Children under 2 years for immunization against infections due to Neisseria meningitidis group C disease. Current febrile or infectious illness Pregnancy and lactation consult GP. Do not give if previous severe reaction to meningococcal vaccine.
Action if excluded	Give vaccine at earliest opportunity if postponed for intercurrent illness. Advise with regard to risk
Action if patient declines	If appropriate discuss with Consultant in Communicable Disease. Advise with regard to risk.

2. Description of treatment

Name of Medicine	AC Vax (Meningococcal polysaccharide vaccine)
POM/P/GSL	POM
Dose/s	0.5ml single dose
Route Method	Deep SC or IM
Frequency	Single dose
Total dose number	1

Follow up	None. In adults and children over the age of 5 one dose provides immunity for up to 5 years. Children under the age of 5 when first vaccinated should be considered for revaccination after 2-3 years if they remain at high risk
Advice	Tenderness, redness at site of injection. Temperature control if pyrexia Information about signs and symptoms of disease, advise continued vigilance Give patient leaflet if available
Record	Date of administration, vaccine, batch number and site of administration

PGD NUMBER 19

Patient Group Direction for the supply/administration of

MENINGOCOCCAL POLYSACCHARIDE VACCINE (Mengivac A + C Aventis)

to **ADULTS AND CHILDREN over 18 months (Does not provide reliable long-lived protection for children under eighteen months)**

1. Clinical Condition

Define situation/condition	Active immunisation against types A and C meningitis For subjects at risk i.e. <ul style="list-style-type: none"> - travellers to areas where there is increased risk of the disease, - epidemic situations of group A. For group C use Meningococcal GroupC conjugate.
Criteria for inclusion	Immediate family or close contacts of cases of group A disease. During outbreaks in closed communities immunisation may be given to control the epidemic. In outbreaks of Group C disease, Meningococcal Group C Conjugate vaccine is preferred. This polysaccharide vaccine should only be used for Group C outbreaks if MCC is not available. Before travelling to areas with increased risk of type A infection, especially long stay travellers and backpackers. (For Hajj use ACW₁₃₅Y) Individuals travelling abroad should be immunised with A and C vaccine even if they have received the MenC conjugate vaccine before.
Criteria for exclusion	Children under 18 months Current febrile or infectious illness Pregnancy and lactation consult GP. Do not give if there has been previous severe reaction to meningococcal vaccine or hypersensitivity. The vaccine should not be given within 2 weeks of Meningitis C vaccine unless needed as a requirement for entry into a country.
Action if excluded	Give vaccine at earliest opportunity if postponed for intercurrent illness. Children under 18 months refer to GP/Paediatrician Advise with regard to risk
Action if patient declines	If appropriate discuss with Consultant in Communicable Disease. Advise with regard to risk.

2. Description of treatment

Name of Medicine	Mengivac A + C (Meningococcal polysaccharide vaccine)
POM/P/GSL	POM
Dose/s	0.5ml single dose
Route Method	Deep SC or IM
Frequency	Single dose

Total dose number	1
Follow up Advice	None Tenderness, redness at site of injection. Temperature control if pyrexia. Information about signs and symptoms of disease, advise continued vigilance
Record	Date of administration, vaccine, batch number and site of administration

PGD NUMBER 20

Patient Group Direction for the supply/administration of

MENINGOCOCCAL POLYSACCHARIDE VACCINE (Groups A, C, W135 and Y) (ACWY Vax)

to **ADULTS AND CHILDREN over 2 years (does not provide protection against C in children less than two years and although immune responses may be achieved to serogroup A, W135 AND Y antigens the degree of protection may be unreliable and short lived)**

1. Clinical Condition

Define situation/condition	For subjects at risk of A, Y or W 135-disease .(For protection against C use MenC Conjugate vaccine.) Living or travelling where the disease is endemic or epidemic for close contacts of cases with the disease epidemic situations
Criteria for inclusion	Immediate family or close contacts of cases of group W or Y meningococcal disease(meningitis or septcaemia). During outbreaks in closed communities immunisation may be given to control the epidemic. Mandatory for pilgrims travelling to the Hajj (for 2002 and beyond) Before travelling to areas with increased risk of type W or Y infection, especially long stay travellers and backpackers, and pilgrims travelling to the Hajj. If a patient has had A and C before it is recommended they still receive ACW ₁₃₅ Y.
Criteria for exclusion	Current febrile or infectious illness Pregnancy and lactation consult GP. Do not give if there has been previous severe reaction to meningococcal vaccine or hypersensitivity to vaccine components The vaccine should be given at least 2 weeks after Meningitis C vaccine
Action if excluded	Give vaccine at earliest opportunity if postponed for intercurrent illness. Children under two years refer to GP/Paediatrician as immunity unreliable and short-lived Advise with regard to risk
Action if patient declines	If appropriate discuss with Consultant in Communicable Disease. Advise with regard to risk.

2. Description of treatment

Name of Medicine	ACW ₁₃₅ Y Vax
POM/P/GSL	POM
Dose/s	0.5ml single dose
Route Method	Deep SC

Frequency	Single dose
Total dose number	1
Follow up	None
Advice	Tenderness, redness at site of injection. Temperature control if pyrexia. Information about signs and symptoms of disease, advise continued vigilance Immunity lasts up to 5 years in adults and children over 5 (2-3years under 5s) Give patient leaflet if available
	Date of administration, vaccine, batch number and site of administration

PGD NUMBER 21

Patient Group Direction for the
supply/administration of
to **Children from 2 months and adolescents and adults**

MENIGOCOCCAL GROUP C CONJUGATE VACCINE (Meningitec /Menjugate/ Neis Vac C

1. Clinical Condition

Define situation/condition	Given as part of the childhood vaccination programme or to older children and adults not previously vaccinated Patients with an absent or dysfunctional spleen
Criteria for inclusion	All children as part of childhood vaccination programme Other programmes as indicated by the Department of Health
Criteria for exclusion	Current acute febrile illness. Thrombocytopenia or other coagulation disorder Previous severe reaction to vaccination and hypersensitivity including diphtheria toxoid The vaccine should not normally be administered to individuals who have received Meningitis A and C vaccine for travel purposes within the previous 6 months. (Consult GP) Pregnancy and lactation consult GP
Action if excluded	Arrange alternative date for vaccination Advise on disease risk if contraindicated Or Consult GP
Action if patient declines	Information about incidence of meningitis in children/young adults and dangers of disease

2. Description of treatment

Name of Medicine	Meningococcal group C conjugate vaccine (Meningitec)Menjugate/NeisVac-C
POM/P/GSL	POM
Dose/s	0.5ml
Route Method	Intramuscular injection - not mixed with any other vaccine – anterolateral thigh in infants and deltoid region in older children, adolescents and adults.
Frequency and number of doses	Primary course consists of 3 doses starting at 2 months of age at intervals of 1 month between doses. Children over 12 months adolescents and adults one dose
Total dose number	See above depends on age
Follow up	
Advice	Temperature control, management of local reactions
Record	Date of administration, vaccine, batch number and site of administration

PGD NUMBER 22

Patient Group Direction for the supply/administration of

PNEUMOCOCCAL VACCINE (PNEUMOVAX II/PNU-IMMUNE)

to **ADULTS AND CHILDREN OVER 2**

1. Clinical Condition

Define situation/condition	Immunisation against pneumococcal disease
Criteria for inclusion	All patients aged two years or over in whom pneumococcal infection is likely to be more common or dangerous, i.e. those with <ul style="list-style-type: none"> i) asplenia or sever dysfunction of the spleen, including homozygous sickle cell disease and coeliac syndrome ii) chronic renal disease or nephrotic syndrome iii) immunodeficiency or immunosuppression due to disease or treatment, including HIV infection at all stages iv) chronic heart disease/lung disease v) chronic liver disease including cirrhosis vi) diabetes mellitus
Criteria for exclusion	Hypersensitivity to any component of the vaccine. It should not be given during acute febrile illness, pregnancy or when breast feeding. Children under 2 should not be immunised. Persons who have received any pneumococcal immunisation in the last three years. Patients who are receiving immunosuppressive therapy or have done so in the last 10 days. Patients with Hodgkin's disease who have received extensive chemotherapy or nodal irradiation.
Action if excluded	
Action if patient declines	Advice about symptom recognition and when to seek medical aid.

2. Description of treatment

Name of Medicine	Pneumococcal Vaccine (PNEUMOVAX II/PNU-IMMUNE)
POM/P/GSL	POM
Dose/s	0.5 ml
Route Method	Intramuscular or Deep Subcutaneous injection
Frequency	Single dose. Revaccination is not recommended except, after 5 – 10 years, in individuals in whom antibody concentration is likely to decline more rapidly (e.g. asplenia, splenic dysfunction and nephrotic syndrome) <u>SEEK MEDICAL ADVICE BEFORE REVACCINATION</u>
Advice	Temperature control. Local reaction. 2weeks to elapse before chemotherapy or immunosuppressant therapy.
Record	Date of administration, vaccine, batch number and site of administration

PGD NUMBER 23

Patient Group Direction for the supply/administration of

POLIOMYELITIS VACCINE Live (ORAL)

to **CHILDREN AND ADULTS**

1. Clinical Condition

Define situation/condition	Children and adults requiring Poliomyelitis immunisation.
Criteria for inclusion	Babies from 2 months. Pre-school children. Adults.
Criteria for exclusion	Current acute febrile illness, diarrhoea or vomiting. Previous severe reaction to immunisation. Pregnancy. Untreated malignant disease or impaired immune response. Other live vaccine within 3 weeks. Immunoglobulin within 3/12. Those receiving immunosuppressive or x-ray therapy or high dose steroids; those with immunosuppressed household members. The vaccine should not be given within 3 months of high dose steroids or within 6 months of immunosuppressants. Severe history of anaphylaxis to penicillin, streptomycin or neomycin.
Action if excluded	Advice when they can have the vaccine. Inactivated polio vaccine is available if live vaccine is contraindicated N.B Tetravac (PGD 25) is available for use for primary vaccination when OPV is contraindicated. Use of Tetravac will decrease the number of injections required
Action if patient declines	Information about disease complications.

2. Description of treatment

Name of Medicine	Poliomyelitis, live (oral) vaccine
POM/P/GSL	POM
Pharmaceutical form	Oral drops, solution
Dose/s	3 drops
Route Method	Oral-do not administer on foods which contain preservatives
Frequency	Children 5 doses as follows -Primary Course: 3 doses usually starting at 2 months of age with intervals of 1 month between doses, given at the same time as diphtheria/tetanus/pertussis and HIB vaccine. Pre-school booster: single doses, preferably at least 3 years after primary course. Single dose prior to leaving school in year 10. Unimmunised adults 3 doses as follows – 3 doses of OPV at intervals of 4 weeks
Follow up	Repeat if dose is regurgitated
Total dose number	
Advice	Careful hygiene with toileting and nappy changes
Record	Date of administration, vaccine, batch number and site of administration.

PGD NUMBER 24

Patient Group Direction for the
supply/administration of

INACTIVATED POLIOMYELITIS VACCINE

to **CHILDREN AND ADULTS**

1. Clinical Condition

Define situation/condition	Children and adults requiring Poliomyelitis immunisation in whom poliomyelitis vaccine (oral) is contraindicated because of immunosuppressive disorders It should also be used for siblings and other household contacts of immunosuppressed individuals N.B Ordered on a named patient basis and only when required for use
Criteria for inclusion	Babies from 2 months. Pre-school children. Adults.
Criteria for exclusion	Current acute febrile illness Allergy to streptomycin
Action if excluded	Advice when they can have the vaccine.
Action if patient declines	Information about disease complications.

2. Description of treatment

Name of Medicine	Inactivated Poliomyelitis
POM/P/GSL	POM
Pharmaceutical form	0.5ml injection
Dose/s	0.5ml
Route Method	S/c or im
Frequency	Primary immunisation 3 injections of 0.5ml, minimum of one month apart A course started with OPV Can be completed with IPV and vice versa Reinforcing doses should be given as OPV
Follow up	None required
Total dose number	3
Advice	Advise about the possible side effects of local reactions and fever after immunisation
Record	Date of administration, vaccine, batch number and site of administration

PGD NUMBER 25

Patient Group Direction for the
supply/administration of

COMBINED DIPHTHERIA, TETANUS/PERTUSSIS AND IPV (TETRAVAC)

To **CHILDREN**

1. Clinical Condition

Define situation/condition	Active immunisation against diphtheria, tetanus, pertussis and poliomyelitis
Criteria for inclusion	For primary vaccination in infants This vaccine would be best used in a specialist unit such as Special Care Baby Units or in other circumstances where babies require IPV for primary immunisation instead of OPV and avoids the need for a separate injection of IPV For booster in children who have previously received a primary vaccination with a diphtheria-tetanus whole cell or acellular pertussis-poliomyelitis vaccine
Criteria for exclusion	Current acute illness. Known hypersensitivity to any component of the vaccine or to pertussis vaccines Evolving encephalopathy.
Action if excluded	Information about when child may have vaccine.
Action if patient declines	Information about protective effects of vaccine and dangers of Diphtheria, Tetanus and Pertussis AND Polio

2. Description of treatment

Name of Medicine	Combined diphtheria, tetanus/pertussis and ipv (TETRAVAC)
POM/P/GSL	POM
Dose/s	0.5 ml
Route Method	Intramuscular The recommended injection sites are the anterolateral aspect of the upper thigh in infants and the deltoid muscle in older children
Frequency	Primary course immunisation can be given as 3 doses at an interval of 1-2 months starting at the age of 2 or 3 months or as 2 doses at an interval of 2 months starting at the age of 3 months and a third dose at the age of 12 months A fourth dose should be administered within the second year of life to children who received TETRAVAC (or a diphtheria-tetanus whole cell or acellular pertussis-poliomyelitis vaccine whether mixed or not with Hib) as a three dose primary series between the ages of 2-6 months
Total dose number	Primary course – 3 doses
Follow up	Booster if required
Record	Date of administration, vaccine, batch number and site of administration

PGD NUMBER 26

Patient Group Direction for the
supply/administration of
to **ADULTS AND CHILDREN**

RABIES VACCINE (AVENTIS PASTEUR/RABIPUR)

1. Clinical Condition

Define situation/condition	Prophylaxis of rabies
Criteria for inclusion	<p>Pre exposure immunisation should be offered to</p> <p>Laboratory workers handling the virus</p> <p>Those who in their course of work regularly handle imported animals (see Green Book for further details)</p> <p>Licensed bat handlers</p> <p>Workers in enzootic areas abroad who by the nature of their work are at special risk of contact with rabid animals e.g. veterinary staff and zoologists</p> <p>Health workers who are likely to come into close contact with a patient with rabies</p> <p>Pre exposure immunisation is also recommended for those living in or travelling to enzootic areas who may be exposed to unusual risk of being infected or are undertaking especially long journeys in remote parts where medical treatment may not be immediately available.</p> <p>For these individuals the vaccine is not supplied free from the NHS</p>
Criteria for exclusion	Pre exposure vaccine should only be given to pregnant women if the risk of exposure to rabies is high
Action if excluded	There are no absolute contraindications to the vaccine
Action if patient declines	Information about the disease and risk

2. Description of treatment

Name of Medicine	Rabies Vaccine Aventis Pasteur/Rabipur
POM/P/GSL	POM
Dose/s	1ml vial
Route Method	Deep s.c or i.m Avoid gluteal region use deltoid region
Frequency	<p>For primary pre exposure protection</p> <p>Aventis Pasteur Prophylaxis 3 doses of 1ml on days 0,7 and 28 Reinforcing dose of 1ml every 2-3 years</p> <p>Rabipur Prophylaxis 3 doses of 1ml on days 0,7 and 21 or 28 Reinforcing dose of 1ml every 2-5 years</p> <p>Where post exposure treatment is readily available as in the UK reinforcing doses are not normally required for individuals who have received three doses of vaccine unless exposure is regular and continuous e.g. laboratory workers handling the virus/licensed bat handlers</p>

Total dose number	3 + reinforcing dose if required
Advice	<p>Advise about the possible side effects of local reactions, fever, malaise, headache and vomiting after immunisation</p> <p>Serological testing is advised for those who work with the live virus They should have their antibodies tested every 6 months and be given reinforcing doses of vaccine as necessary to maintain protective levels Serological testing is otherwise only advised for those who have had a severe reaction to a previous dose of vaccine to confirm the need for a reinforcing dose</p> <p>All travellers to enzootic areas should also be informed by their medical advisers of practical steps to be taken if an animal bite is sustained</p> <p>If exposure to a potentially rabid animal occurs (bite or lick on broken skin , from an animal in rabies endemic areas), post exposure treatment is required even if the person has had pre exposure prophylaxis (see Green Book p 186)</p>
Record	Date of administration, vaccine, batch number and site of administration Issue certificate of vaccination

PGD NUMBER 27

Patient Group Direction for the
supply/administration of
to **UNIMMUNISED ADULTS**

**RUBELLA VACCINE (ERVEVAX SmithKline
Beecham)**

1. Clinical Condition

Define situation/condition	Unimmunised adults
Criteria for inclusion	Susceptible women of child bearing age who have not previously been immunised or who have tested sero-negative to rubella. Health care workers who might put pregnant women at risk of infection (See Green Book section 28)
Criteria for exclusion	Pregnancy or inability to avoid pregnancy within the following month. Current febrile illness Within three weeks of another live vaccine Within three months of injection of immunoglobulin or blood or plasma transfusion. Hypersensitivity to neomycin or other vaccine components Where the normal immunological mechanism is impaired Patients receiving high dose corticosteroids within the last three months or within six months of immunosuppressing treatment including chemotherapy and radiotherapy. .
Action if excluded	Advise about disease complications and risk to unborn foetus
Action if patient declines	Advise about disease complications and risk to unborn foetus

3. Description of treatment

Name of Medicine	Rubella Vaccine, Live (ERVEVAX)
POM/P/GSL	POM
Dose/s	0.5 ml
Route Method	Deep subcutaneous or intramuscular injection
Frequency	Single dose
Follow up	Can be repeated if patient found subsequently to be seronegative
Advice	Temperature control and advice on adverse reactions. Give patient leaflet if available. Avoid pregnancy for 1 month
Record	Date of administration, vaccine, batch number and site of administration record of serological testing

PGD NUMBER 28

Patient Group Direction for the supply/administration of

ADSORBED TETANUS VACCINE (T) (CLOSTET/AVENTIS PASTEUR)

To **ADULTS and children over 10 years**

1. Clinical Condition

Define situation/condition	Primary immunisation of unimmunised adults & children over 10 years or after a tetanus prone wound.
Criteria for inclusion	Unimmunised adults. Patients with tetanus prone wounds (with >10 years since last reinforcing dose). These are: a) any wound or burn sustained more than 6 hours before surgical treatment of the wound or burn b) Any wound or burn at any interval after injury that shows one or more of the following characteristics: <ul style="list-style-type: none"> ▪ a significant degree of devitalised tissue ▪ puncture type wound ▪ contact with soil or manure likely to harbour tetanus organisms ▪ clinical evidence of sepsis
Criteria for exclusion	Documented evidence of 5 doses of tetanus vaccine in the absence of a tetanus prone wound. Patients suffering acute febrile illness (except in the presence of a tetanus prone wound). Minor infections without fever and systemic upset are not reasons to postpone immunisation.
Action if excluded	None
Action if patient declines	Specific advice with regard to tetanus risk.

2. Description of treatment

Name of Medicine	Adsorbed Tetanus Vaccine Clostet/Aventis Pasteur
POM/P/GSL	POM
Dose/s	0.5 mls
Route Method	Intramuscular or Deep Subcutaneous injection
Frequency	Primary immunisation: 3 doses at 4 weekly intervals. Reinforcing dose for adults is one dose 10 years after primary course with a further dose 10 years later DO NOT CONTINUE TO GIVE BOOSTERS ROUTINELY EXCEPT FOR TETANUS PRONE WOUNDS

	<p>Any adult who has received 5 doses is likely to have life long immunity.</p> <p>Clean wounds - If not immunised or immunisation status unknown, give primary immunisation course. If last of 3 dose course or reinforcing dose more than 10 years previously give reinforcing dose. If last of 3 dose course or reinforcing dose within last 10 years no vaccine necessary.</p> <p>Tetanus prone wound –As for clean wounds plus a tetanus immunoglobulin at a separate site. If an immunised individual has received a dose of tetanus vaccine within the previous 10 years the immunoglobulin may only be required if the risk of infection is considered to be high. Normally these wounds would require secondary care treatment.</p>
Total dose number	5 except in case of tetanus prone wound
Advice	Temperature control, local reaction management
Record	Date of administration, vaccine, batch number and site of administration

PGD NUMBER 29

Patient Group Direction for the
supply/administration of
to

ORAL TYPHOID (Ty21a) VACCINE

CHILDREN over 6 YEARS AND ADULTS

1. Clinical Condition

Define situation/condition	Immunisation against Typhoid Fever for adults and children over 6 years of age.
Criteria for inclusion	Adults and children over 6 years travelling to areas of high prevalence including Africa, Asia, Central and South America, Caribbean, some areas of Eastern Europe and where sanitation may be poor Laboratory workers handling specimens, which may contain typhoid organisms.
Criteria for exclusion	Patients with known sensitivity to any of the components. Acute febrile illness. Gastrointestinal illness. Current use of antibiotics. If persistent diarrhoea and/or vomiting. Outbreaks of typhoid fever in the UK (no immediate protection and may temporarily increase susceptibility to infection). Impaired immunity Pregnancy except if high risk of infection Contraindicated in HIV positive individuals
Action if excluded	Advice as to when vaccine may be given or risks of infection. Hygiene advice if travelling, reschedule if excluded due to intercurrent illness.
Action if patient declines	Advice as to risks of infection and hygiene advice if travelling

2. Description of treatment

Name of Medicine	Live attenuated oral typhoid (Ty 21a) vaccine - Vivotif
POM/P/GSL	POM
Dose/s	3 capsules containing not less than 2×10^9 salmonella typhi organisms per dose
Route Method	oral
Frequency	One capsule swallowed whole 1 hour before meals with a cold drink on days 1, 3 and 5
Total dose number	3
Follow up	Annual booster (3 caps) if remaining at risk of infection
Advice	Mild GI upset (nausea, vomiting, abdominal cramps, diarrhoea), urticarial rash, occasional 'flu like symptoms, temperature control if pyrexia. Capsules should be stored in a refrigerator between doses. Keep dry and out of light

	<p>If mefloquine is being taken for malaria prophylaxis the vaccine should be taken at least 12 hours before or after the mefloquine</p> <p>Oral typhoid and oral polio vaccines should be given at least three weeks apart</p> <p>Information about signs and symptoms of disease, advise continued vigilance</p>
Record	Date of administration vaccine, batch number and site of administration

PGD NUMBER 30

Patient Group Direction for the **TYPHOID VACCINE (TYPHERIX/TYPHIM Vi)**
 supply/administration of _____
 to **CHILDREN 18 MONTHS AND ADULTS**

1. Clinical Condition

Define situation/condition	Immunisation against Typhoid Fever for adults and children Typhim children under 2 years may show suboptimal response Typherix children under 18 months may show suboptimal response
Criteria for inclusion	Adults and children over 18 months travelling to areas of high prevalence including Africa, Asia, Central and South America, Caribbean, some areas of Eastern Europe and where sanitation may be poor Laboratory workers handling specimens with may contain typhoid organisms.
Criteria for exclusion	Patients with known sensitivity to any of the components. Acute febrile illness. Impaired immunity Pregnancy except if high risk of infection Typhoid immunisation is not recommended for contacts of a known typhoid carrier or for controlling common source outbreaks
Action if excluded	Advice as to when vaccine may be given or risks of infection. Hygiene advice if travelling, reschedule if excluded due to intercurrent illness.
Action if patient declines	Advice as to risks of infection and hygiene advice if travelling

2. Description of treatment

Name of Medicine	Polysaccharide Typhoid Vaccine TYPHIM VI/TYPHERIX
POM/P/GSL	POM
Dose/s	0.5 ml
Route Method	IM or deep SC
Frequency	Single dose booster every three years if continued exposure
Total dose number	1
Follow up	Every 3 years if remaining at risk of infection
Advice	Tenderness, redness at site of injection, occasional 'flu like symptoms, temperature control if pyrexia. Information about signs and symptoms of disease, advise continued vigilance
Record	Date of administration, vaccine, batch number and site of administration

PGD NUMBER 31

YELLOW FEVER VACCINE (ARILVAX)

Patient Group Direction for the
supply/administration of
to Adults and Children **ONLY FROM YELLOW FEVER DESIGNATED CENTRES**

1. Clinical Condition

Define situation/condition	Persons aged nine months and over travelling through or living in endemic areas Laboratory workers handling infected material or handle the virus
Criteria for inclusion	Children 9 months and over, adults and elderly at risk of infection by travel to countries with moderate to high endemicity. Also where countries require International Certificate of Vaccination as proof of vaccination.
Criteria for exclusion	Febrile illness. Impaired immune system due to radiotherapy, cytotoxic drugs and high dose steroids. Patients suffering from malignant conditions such as leukaemia, Hodgkin's disease or other tumours of the reticulo-endothelial system Hypersensitivity to any component of vaccine e.g. egg allergy. HIV positive. Patients who have received another live vaccine within the previous three weeks e.g. poliomyelitis Pregnancy (if there is a significant risk of exposure the need for immunisation outweighs any risk to the fetus)
Action if excluded	If travellers in whom the vaccine is contraindicated still intend to visit countries where a yellow fever certificate is required for entry, then they should obtain a letter of exemption from a medical practitioner
Action if patient declines	Explain risks of disease, reschedule if contraindicated because of intercurrent illness.

2. Description of treatment

Name of Medicine	Yellow Fever Vaccine, live (ARILVAX)
POM/P/GSL	POM
Dose/s	0.5 ml
Route Method	SC
Frequency	1 dose 10 yearly
Total dose number	1
Advice	Advise about the possible side effects of mild headache, myalgia, fever soreness at injection site 5-10 days after immunisation
Record	Date of administration, vaccine, batch number and site of administration Issue certificate of vaccination

NB – ONLY AVAILABLE AT YELLOW FEVER DESIGNATED CENTRES

Patient Group Direction Agreement

The following PGDs are agreed for use in

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Agreed by the following practice nurses working for this practice

Name..... Signature.....

Name..... Signature.....

Name..... Signature.....

Name..... Signature.....

Name..... Signature.....

Name..... Signature.....

Name..... Signature.....

Agreed by General Practitioner on behalf of the practice.

Signature..... Date.....

Please note. These PGDs expire on2003 and may be amended prior to that date.