CONTRAINDICATIONS AND PRECAUTIONARY CONDITIONS FOR VACCINATION

From selected authoritative sources

Compiled by Epidemiological Unit
Ministry of Health
26th November 2009

Index

Contraindications and precautionary conditions for vaccines

1. Immunization Handbook Sri Lanka - 2002

3. IMMUNIZATION PROCEDURES

3.1. Pre-vaccination questionnaire

Before vaccination, the doctor, the nurse, the public health inspector or the public health midwife should make sure that the individual to be vaccinated does not have a condition (or a history of a previous condition) which could increase the risk of a severe reaction. One way to do this is to routinely inquire about such conditions.

The following information is needed to assess the fitness of a person for vaccination. (Inform the parents, that the conditions listed below do not necessarily mean that their child cannot be vaccinated today. But they should inform the doctor if any of the following conditions are present:]

The person to be vaccinated:

- is unwell today;
- is having treatment which lowers immunity (e.g. steroids such as cortisone and prednisolone, radiotherapy, or chemotherapy);
- has had a severe reaction to any vaccine;
- has any severe allergies to vaccine components (e.g. neomycin);
- has a disease which lowers immunity (e.g. leukaemia, cancer);
- has had a vaccine containing live viruses within the last month (e.g. measles, poliomyelitis, yellow fever or rubella vaccines), or an injection of immunoglobulin or a blood transfusion within the last three months;
- has a disease of the brain or the spinal cord.

3.2. Standard vaccination procedure

Before administering vaccines, the following procedures should be followed:

- Provide details to parents on risks of vaccination and risks of not being vaccinated;
- Check whether preparations have been made to respond immediately to adverse reactions;
- Read the product information;
- Ensure that valid consent is given;
- Provide the parent or guardian with a pre-immunization questionnaire;
- Check whether there are any contra-indications to vaccination from the pre-vaccination assessment;
- Check the identity of the recipient;
- Check the identity of the vaccine to be administered;
- Ensure that vaccines have been stored correctly;
- Check the vaccine to be administered for obvious signs of deterioration (check expiry date and note any particular matter or colour change that may indicate damage to the vaccine);
- Ensure that the correct vaccines are being administered according to the schedule;
- Administer the vaccine, using the correct technique (see details below on needle selection, needle angle, injection location, and position of the subject).

After administering the vaccine, do the following:

- Give instructions, preferably in writing, to the parent or guardian regarding what to do in the event of common reactions or serious adverse reactions;
- Record the vaccination in the child health development record and in the clinical notes.

In situations where large groups of individuals are vaccinated, the detailed arrangements might vary from those recommended above, but the principles of hygiene, valid consent, and thorough pre-immunization assessment must still be adhered to.

3.16. Adverse Events Following Immunization (AEFIs)

Recipients of vaccine should remain under observation until they are seen to be in good health and not be experiencing an immediate adverse reaction. It is not possible to specify an exact length of time for post-vaccination observations but it is recommended that recipients should remain in the clinic/hospital for about 15 minutes. Parents or guardian should be provided with the necessary information before leaving the clinic on how to act if the child develops an adverse event following immunization

Children who have had a serious adverse event following vaccination may be subsequently vaccinated under close medical supervision in a hospital.

3.17. Anaphylaxis

In infants and children, the most important immediate reaction to vaccination is anaphylaxis. The incidence of anaphylaxis reactions varied with the type of vaccine. But the incidence of true anaphylaxis is only 1-3 cases per million vaccinations. Any member of the health staff carrying out vaccination procedures must be able to distinguish between anaphylaxis, convulsions and fainting.

4.2. General contra-indications to vaccination

1. Immunization should be postponed if the subject is suffering from any established acute illness. Minor infections without fever or systemic upset are not contraindications.

2. Live vaccines should not be routinely administered to pregnant women because of possible harm to the foetus; however when there is a significant risk of exposure, for example to poliomyelitis, the need for vaccination of an unvaccinated mother outweighs any risk to the foetus.

3. Live vaccines should not be given to the following:

   a. Patients receiving high-dose corticosteroids(e.g, prednisolone 2 mg/kg/day for more than a week), Immunosuppressive treatment including general irradiation and chemotherapy
   b. Those suffering from malignant conditions such as lymphoma, leukaemia, Hodgkin's disease or other tumours of the reticulo-endothelial system
   c. Patients with impaired immunologica mechanisms for instance, hypogamaglobulinaemia

   Live vaccines should be postponed until at least 3 months after stopping corticosteroids and 6 months after stopping chemotherapy.

   (a) Children on lower daily doses of systemic corticosteroids (less than 2 mg/kg/day) for less than two weeks
   (b) Those on lower doses or alternate day regimes for longer periods, may be given live virus vaccines.

4. Some viral vaccines contain small quantities of antibiotics such as penicillin, neomycin or polymyxin; such vaccines should not be given to persons with documented hypersensitivity to such antibiotics.

5. Live virus vaccines should not be given within 3 months of an injection of immunoglobulin because the immune response may be inhibited.

6. HIV positive individuals and contraindications to the individual vaccines are given in the leaflets supplied with the vaccines; it is necessary to take note of them.

4.3 Precautions and contraindications relating to scheduled vaccines

Children with minor illness may be vaccinated safely. But, if they are suffering from a major illness or high fever (102^{o}F) they should not be vaccinated. These children should be vaccinated after they recover

4.4. Precautions and contraindications for immunocompromised children

Live vaccines are usually contraindicated in immune-suppressed individuals, including those with malignant disease or receiving chemotherapy. However, because immune-suppressed individuals are at great risk of certain infections, the question of vaccination needs to be assessed by a specialist.

4.5. False contraindications to vaccination

The following conditions ARE NOT contraindications for vaccination with any of the vaccines in the standard schedule:

- Family history of any adverse reactions following vaccination;
- Family history of convulsions;
- Previous pertussis-like illness, measles, rubella or mumps infection;
- Prematurity (vaccination should not be postponed);
- Stable neurological conditions such as cerebral palsy and Down syndrome;
- Contact with a patient suffering from an infectious disease;
- Child's mother is pregnant;
- History of jaundice after birth;
- Low weight in an otherwise healthy child.

13. Should premature babies have their vaccinations delayed?

Babies born prematurely should receive BCG when they are fit to be discharged from the hospital. They should also receive their 1st dose of DTP and OPV, two months after birth, unless they are seriously ill.

14. Should vaccination be postponed if a child has a cold or a chest infection?

Babies with minor coughs and colds without fever, or those receiving antibiotics in the recovery phase of an acute illness, can be immunized safely and effectively. Vaccination should only be postponed if a child is seriously ill or has high fever. In such cases, vaccination should be arranged for a week or two later.

17. What if a child has a chronic disease?

In general, children with chronic diseases should be immunized as a matter of priority. Care is needed however, in situations where the child's illness, or its treatment, may result in impaired immunity.

18. What if a child has had a fit or has epilepsy?

Stable neurological disease is not a reason to avoid giving pertussis (whooping cough) or DTP vaccination. A child may develop a fever after administration of any vaccine; parents should be warned of this and advised to give the child paracetamol. It should be remembered that the fever following measles vaccine occurs 5-10 days after vaccination. A family history of fits or epilepsy is not a reason to avoid vaccination. You may also consult the family doctor.

19. Should allergic children be immunized?

Asthma, eczema, hay fever and allergies are not contraindications to any vaccine. An important exception is genuine severe egg allergy. A history of an anaphylactic reaction to egg (generalized hives, swelling of the mouth or throat, difficulty in breathing, wheeze, low blood pressure, or shock) is generally a contraindication to influenza and yellow fever vaccines. Measles/MR/MMR can be given to such children under close observation, as anaphylactic reactions to these vaccines are exceedingly rare, even in children with proven severe egg allergy.

BCG vaccine

5.8. Cautions and Contraindications

1. The general contra-indications discussed in 4.2, 4.3 and 4.4 apply

2. The vaccine is contraindicated in those with cell-mediated immune deficiency. Keloid and lupoid reactions may occur at the site of injection and such children should not be revaccinated. HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTED INFANTS: HIV infected, non symptomatic infants should be immunized with BCG vaccine according to the standard schedule. Infants with clinical (symptomatic) AIDS should not receive BCG vaccine (but should receive other EPI vaccine).

3. BCG vaccine may be given concurrently with another live vaccine, but if they are not given at the same time, an interval of at least 3 weeks should be allowed between the administration of BCG vaccine and any other live vaccine, whichever is given first. No further immunization should be given for at least three months in the arm used for BCG vaccination because of the risk of regional lymphadenitis.

TT Vaccine

6.8. Cautions and contraindications

Reinforcing doses of tetanus toxoid at less than 5 year intervals may provoke hypersensitivity reactions and therefore should be avoided. Refer those discussed in section 4.2, 4.3 and 4.4.

Diphtheria Vaccine

7.8. Cautions and Contraindications

7.8.1.

(1) Those discussed in section 4.2, 4.3 and 4.4.

(2) Severe local or general reaction to a preceding dose are explained below;

i. Local reactions: an extensive area of redness and swelling which becomes indurated and involves most of the antero-lateral surface of the thigh or a major part of the circumference of the upper arm; this reaction may increase in severity with each subsequent injection.

ii. General reactions: fever equal to or more than 39.5^{o}C within 48 hours of vaccination, anaphylaxis; bronchospasm, laryngeal oedema, generalized collapse, prolonged unresponsiveness, prolonged inconsolable screaming, convulsions occurring within 72 hours. A personal or family history of allergy is not a contraindication to immunization against whooping cough, nor are stable neurological conditions such as cerebral palsy or spina - bifida.

iii. Progressive neurological disorder (e.g. infantile spasms).

Children with problem histories:

There are certain groups of children in whom the advisability of whooping cough immunization requires special considerations because of their own or their family histories. For them, the risk from vaccine may be higher, but the effects of whooping cough disease could be more severe. The balance of risk and benefit should be assessed in each case. Where there is doubt, appropriate advice should be obtained from a consultant paediatrician before a decision is made to withhold vaccination.

These groups are:

1. Children with a documented history of cerebral damage in the neonatal period.
2. Children with a personal history of convulsions.
3. Children whose parents or siblings have a history of idiopathic epilepsy; in such children there may be a risk of developing a similar condition irrespective of vaccination.

The vaccine should not be given to persons who have shown a severe reaction to previous doses of DTP vaccine.

In those with severe reactions which CONTRAINDICATE further doses of DTP– in such cases DT should be used for subsequent vaccinations i.e.

- Encephalopathy within 7 days, defined as severe acute neurological illness with prolonged seizures and/or unconsciousness and/or focal signs (but not a simple febrile convulsion).
- Immediate severe allergic or anaphylactic reaction to vaccination with DTP.

Pertussis

8.8. Cautions and contraindications

Given under diphtheria, D.T.P. (7.8)

Severe reactions which CONTRAINDICATE further doses of DTP – in such cases DT should be used for further vaccination.

- Encephalopathy within 7 days, defined as severe acute neurological illness with prolonged seizures and/or unconsciousness and/or focal signs (but not a simple febrile convulsion).
- Immediate severe allergic or anaphylactic reaction to vaccination with DTP.

OPV

9.8. Cautions and contraindications

Vaccination is contraindicated in subjects affected by alterations of the immune system (agammaglobulinemia, hypogamaglobulinemia, combined humoral or cell mediated immunodeficiency).

Mild diarrhoea is not a contraindication. These children should be given an additional dose when the chid recover from that diarrhoea episode.

Vaccination should be deferred in the case of acute febrile illness, moderate to severe diarrhoea or treatment with immunosuppressive drugs.

According to the recommendation of the WHO, in subjects affected by symptomatic or asymptomatic HIV, the vaccine can be administered according to the standard schedule.

Measles

10.8. Cautions and contraindications

The general contraindications discussed in section 4.2, 4.3 and 4.4.

Measles virus inhibits the response to tuberculin, so tuberculin-positive individuals may become tuberculin-negative for up to a month after measles infection or immunization. As the measles virus may cause exacerbation of tuberculosis, such patients should be under treatment when immunized.

If the live measles vaccine is produced in chick embryo cell culture and contains neomycin as preservative, the vaccine is contraindicated in individuals with a history of allergy to neomycin and genuine severe egg allergy.

Rubella

11.8. Cautions and contraindications

General contraindications given in 4.2, 4.3 and 4.4.

Do not administer the vaccine during pregnancy; and advise vaccinees not to conceive for two months following vaccination.

Hepatitis B

13.8. Cautions and contraindications

There are very few reasons to withhold or postpone administration of hepatitis B vaccine. Too often immunizations are delayed or denied because of conditions falsely believed by health care workers to be contraindications for administering the vaccine.

Contraindications to hepatitis B vaccine administration include the following:

- **Severe allergic reaction to a previous dose of hepatitis B vaccine**. A child with a history of a severe allergic reaction (e.g. generalized urticaria, difficulty in breathing, swelling of the mouth and throat, hypotension, shock) to a prior dose of hepatitis B vaccine should not receive another dose (from the same manufacturer).

- Severe allergic reaction to baker's yeast (the kind used in making bread). Children with a history of a severe allergic reaction to baker's yeast should not receive formulations of hepatitis B vaccine prepared in yeast cells. These children may receive plasma-derived hepatitis B vaccine.

The following are NOT contraindications for administering hepatitis B vaccine.

- Any minor illness such as respiratory tract infection or diarrhoea with temperature below 38.5^{o}C.
- Allergy or asthma
- Family history of convulsions
- Treatment with antibiotics
- Infection with human immunodeficiency virus (HIV)
- Breastfeeding
- History of seizures (convulsions, fits)
- Chronic illnesses such as chronic diseases of the heart, lung, kidney or liver
- Stable neurological condition such as cerebral palsy and Down's Syndrome.
- Prematurity or low birthweight
- History of jaundice at birth.

Hepatitis B vaccine will only protect against hepatitis B, and will not protect against other types of hepatitis.

More than 95% of children develop protective antibody after three doses of hepatitis B vaccine. However, a small percentage of children will not be protected after vaccination.

2. Live JE vaccine

As per New JE Circular

Contraindications

There are only a few reasons to withhold or to postpone administration of live JE vaccine. General contraindications to vaccination specified in the Immunization Handbook issued by the Epidemiology Unit in 2002 are applicable to the LJEV as well. However, in specific instances given below, it should be avoided.

It should be avoided only for children with;

- Fever more than 38.5 ^{0}C
- Acute infectious diseases including Otitis media, and tympanitis
- Active untreated tuberculosis
- Hepatic, renal or cardiac diseases
- Subjects with an allergy to any component of the LJEV vaccine including Gelatin
- Person with a proven or suspected hypersensitivity to Kanamycin or gentamicin
- Congenital or acquired immunodeficiency states including those who were treated with any immunosuppressive therapy recently
- Pregnancy
- Past history of convulsions

Please note that subjects with a previous history of moderate to severe allergic conditions (urticarea, dyspnoea, peri-oral oedema, and laryngeal oedema) should be vaccinated in the central immunization clinic with an emergency tray and procedures for emergency care being ready.

The following are NOT contraindications**:**

- Minor illnesses such as respiratory tract infection or diarrhea with temperature below 38.5^{0}C (101^0 C)
- Family history of convulsions
- Treatment with topical corticosteroids or systemic use of corticosteroids at low dosages (less than 0.5mg/kg of prednisolone or equivalent) in case of skin diseases like dermatitis, eczema or other localized skin disorders
- Stable neurological conditions e.g. cerebral palsy, down syndrome.

Precautions:

Precautions should be taken to avoid undesirable reactions before administering the vaccine. These precautions include review of the child's medical history, particularly regarding hypersensitivity reactions to previous administration of any type of vaccine, past history of convulsions and the child's history of recent health problems.

There should be a gap of at least four weeks between the live JE vaccine and another live vaccine administered before or after the live JE vaccine.

3. Pentavalent Vaccine

As per new and reintroduction circulars

The committee further noted that in a majority of the reported deaths were following the administration of **first dose of pentavalent vaccine at two months** with the pre-existence of certain risk conditions during the neonatal period.

Hence, the committee recommended that in the future when immunizing children with the following risk conditions, adequate precautions be taken and as an interim measure where possible such children may be admitted to a suitable in-ward facility for immunization and kept under observation for 24 hours following immunization. Such conditions are;

a) Prematurety less than 36 week of gestation and required to spend over one week in PBU

b) Recent history of significant illness requiring over one week hospitalization e.g. neonatal sepsis, pneumonia etc

c) Severe congenital anomalies which required prolong hospitalization during neonatal period

d) History of HHE to previous doses of pentavalent or any other pertussis containing vaccine

In addition please note to adhere to the following directions on reintroduction:

1. In addition to the precautionary conditions mentioned in my letter No. EPI/81/VII/2007 dated 15/10/2007, the above conditions also should be considered as where precautionary measures should be taken.

2. All children should be screened for the presence of such conditions prior to immunization. Children receiving the **first dose of pentavalent vaccine** on completion of two months with such risk conditions may be admitted to a suitable in-ward facility for immunization and kept under observation for 24 hours following immunization.

3. Hypotonic hyporesponsive episodes (HHE) following pentavalent or any other vaccine is not a contraindication for further immunization with the incriminated vaccine or any other vaccine used in the national immunization programme.

4. WHO generic guidelines on contraindications

Module 3: Immunization safety

(Training for mid-level managers (MLM) - WHO/IVB/08.03)

1.5 Reasons for delaying or withholding vaccines (Contraindications)

Health workers should use every opportunity to immunize eligible infants and adults, unless the infant or adult has a health condition that does not permit vaccination. Sometimes there are reasons why a specific vaccine should NEVER be administered (also called an absolute contraindication) and sometimes the health worker should delay giving the vaccine for a short time (also called a temporary contraindication). These different types of reasons for delaying or withholding a vaccine are listed in Table 3.5. Health workers must know about the correct reasons for withholding immunization. The incorrect reasons for withholding a vaccine are called « false contraindications » and these are listed in Table 3.6.

Key point : Delaying immunization because of false reasons (false contraindications) results in a missed opportunity to fully immunize an infant or adult.

Table 3.5 : Reasons why specific vaccines should NEVER be administered and reasons why vaccines may be DELAYED for a short time

Reasons for NEVER administering a specific vaccine (also called absolute contraindications). If the infant or person has :

• symptomatic (showing symptoms) or **documented** human immunodeficiency virus (HIV) infection — do NOT immunize with BCG ;

• symptomatic (showing symptoms) HIV infection — do NOT immunize with yellow fever vaccines;

• a history of a severe adverse event following a dose of a specific vaccine (anaphylactic reaction or severe shock) — do NOT give follow-up doses of that particular vaccine, but provide the infant or adult with other vaccines.

Reasons for delaying administering a specific vaccine (also called temporary contraindications). The following vaccines should not be administered until the specific condition is no longer present.

- On theoretical grounds, measles and yellow fever vaccines are not recommended during pregnancy.
- Do not give measles vaccine to persons with a history of an anaphylactic reaction to neomycin, gelatin or other components.
- Yellow fever vaccine is contraindicated for persons with severe allergy to egg.
- Measles and yellow fever vaccines are contraindicated in persons who are severely immunocompromised as a result of congenital disease, HIV infection, advanced leukaemia or lymphoma, serious malignant disease, or treatment with high-dose steroids, alkylating agents or antimetabolites, or in persons who are receiving immunosuppressive therapeutic radiation.

Table 3.6 : Conditions which ARE NOT contraindications to immunization

The incorrect reasons for withholding a vaccine are called « false contraindications ». The list below of conditions comprises some examples of « false contraindications ». If an infant or adult presents with any of these, they should be vaccinated.

• Minor illnesses such as upper respiratory infections, or diarrhoea with fever < 38.5°C.
• Allergy, asthma, or other atopic manifestations such as hay fever or ‘snuffles’.
• Prematurity ; low-birth-weight infant.
• Malnutrition.
• Infant being breastfed.
• Family history of convulsions.
• Treatment with antibiotics, low-dose corticosteroids or locally acting (e.g. topical or inhaled) steroids.
• Dermatoses, eczema or localized skin infection.
• Chronic diseases of the heart, lung, kidney and liver.
• Stable neurological conditions, such as cerebral palsy and Down syndrome.
• History of jaundice after birth.

None of the above list is a true reason for withholding vaccination. If an infant or adult has any of these health issues they should be vaccinated.

5. Contraindications and special considerations according to The Green Book of UK

Almost all individuals can be safely vaccinated with all vaccines. In very few individuals, vaccination is contraindicated or should be deferred. Where there is doubt, rather than withholding vaccine, advice should be sought from an appropriate consultant pediatrician or physician, the immunization coordinator or consultant in health protection.

All vaccines are contraindicated in those who have had:

1) a confirmed anaphylactic reaction to a previous dose of a vaccine containing the same antigens, or
2) a confirmed anaphylactic reaction to another component contained in the relevant vaccine, e.g. neomycin, streptomycin or polymyxin B (which may be present in trace amounts in some vaccines).

Live vaccines may be temporarily contraindicated in individuals who are:

1) immunosuppressed (see below)
2) pregnant.

Some vaccines are contraindicated in specific groups. These are outlined in the relevant chapters.

Egg allergy

Individuals with a confirmed anaphylactic reaction to egg should not receive influenza or yellow fever vaccines. MMR vaccine can be safely given to most children with a previous history of allergy after ingestion of egg or egg containing food, and vaccination with MMR can be performed under normal circumstances. For the small number of individuals who have a history of confirmed anaphylactic reaction after any egg-containing food, specialist advice should be sought with a view to immunization under controlled conditions.

Severe latex allergy

Some pre-filled syringes may contain latex proteins in the tip cap and/or rubber plunger of the syringe. Similarly, the stoppers of some vaccines supplied in vials may contain latex proteins.
It is theoretically possible that latex protein from these tip caps, plungers or vial stoppers may cause allergic reactions when the vaccines are administered to latex-sensitive individuals. There is little evidence that such a risk exists and any such risk would be extremely small (Russell *at al*., 2004). Millions of doses of vaccines in pre-filled syringes are administered every year and the risk of anaphylaxis due to any allergen following immunization is about one per million vaccine doses (see Chapter 8)

As a precaution, if an individual has a history of severe (i.e. anaphylactic) allergy to latex, vaccines supplied in vials or syringes that contain latex should not be administered, unless the benefit of vaccination outweighs the risk of an allergic reaction to the vaccine. If possible, an alternative latex-free vaccine should be administered.
For latex allergies other than anaphylactic allergies (e.g. a history of contact allergy to latex gloves), vaccines supplied in vials or syringes that contain latex can be administered (ACIP, 2006).

Pregnancy

There is a theoretical concern that vaccinating pregnant women with live vaccines may infect the fetus. There is no evidence that any live vaccine (including rubella and MMR) causes birth defects. However, since the theoretical possibility of fetal infection exists, live vaccines should generally be delayed until after delivery. Termination of pregnancy following inadvertent immunization is not

recommended. Since inactivated vaccines cannot replicate they cannot cause infection in either the mother or the fetus. However, inactivated vaccines should be administered to pregnant women only if protection is required without delay.

Immunosuppression

Live vaccines can, in some situations, cause severe or fatal infections in immunosuppressed individuals due to extensive replication of the vaccine strain. For this reason, severely immunosuppressed individuals (see bullet list below) should not be given live vaccines, and vaccination in immunosuppressed individuals should only be conducted in consultation with an appropriate specialist.

Inactivated vaccines cannot replicate and so may be administered to immunosuppressed individuals, although they may elicit a lower response than in immunocompetent individuals.

The following individuals should not receive live vaccines:

- patients with evidence of severe primary immunodeficiency, for example, severe combined immunodeficiency, Wiskott-Aldrich syndrome and other combined immunodeficiency syndromes
- patients currently being treated for malignant disease with immunosuppressive chemotherapy or radiotherapy, or who have terminated such treatment within at least the last six months
- patients who have received a solid organ transplant and are currently on immunosuppressive treatment
- patients who have received a bone marrow transplant, until at least12 months after finishing all immunosuppressive treatment, or longer where the patient has developed graft-versus-host disease. The decision to vaccinate should depend upon the type of transplant and the immune status of the patient. Further advice can be found in current guidance produced by the European Group for Blood and Marrow Transplantation (www.ebmt.org) and the Royal College of Pediatrics and Child Health (RCPCH) (www.rcpch.ac.uk)
- patients receiving systemic high-dose steroids, until at least three months after treatment has stopped. This would include children who receive prednisolone, orally or rectally, at a daily dose (or its equivalent) of 2mg/ kg/day for at least one week, or 1mg/kg/day for one month. For adults, an equivalent dose is harder to define but immunosuppression should be considered in those who receive at least 40mg of prednisolone per day for more than one week. Occasionally, individuals on lower doses of steroids may be immunosuppressed and at increased risk from infections. In those cases, live vaccines should be considered with caution, in discussion with a relevant specialist physician
- patients receiving other types of immunosuppressive drugs (e.g. azathioprine, cyclosporin, methotrexate, cyclophosphamide, leflunomide and the newer cytokine inhibitors) alone or in combination with lower doses of steroids, until at least six months after terminating such treatment. The advice of the physician in charge or immunologist should be sought
- patients with immunosuppression due to human immunodeficiency virus (HIV) infection (see section below).

Other considerations

Many patients with relatively minor immunodeficiencies can, and indeed should, receive all recommended vaccinations, including live vaccines. Where there is doubt or a relatively severe immunodeficiency is present, it is important to obtain individual specialist advice.

Some patients with 22q11 deletion syndromes, including partial DiGeorge syndrome, may be able to receive live vaccines safely provided that they have no evidence of severe immunocompromise (Perez *et al.*, 2003). Specialist advice should be sought.

Non-systemic corticosteroids, such as aerosols or topical or intra-articular preparations, do not cause systemic immunosuppression. Therefore, administration of live vaccines is not contraindicated. Live vaccines are likely to be safe in those receiving other immunomodulating drugs, for example interferon. However, advice should be sought from the specialist in charge of the therapy to ensure that the patient has not been immunosuppressed by the treatment. Deferral of immunization may be suggested to avoid side effects of the drugs being confused with reactions to vaccination.

Replacement schedules of corticosteroids for people with adrenal insufficiency do not cause immunosuppression and are not, therefore, contraindications for administration of live vaccines. For further information, please refer to the RCPCH Best Practice Statement (www.rcpch.ac.uk).

HIV infection

HIV-positive individuals should be given MMR vaccine according to national recommendations unless they have evidence of severe immunosuppression (Table 6.1). For children under 12 months of age, CD4 counts may not be an accurate representation of levels of immunosuppression and immune status should be assessed by an expert using a combination of laboratory and clinical criteria.

Varicella vaccine is contraindicated for HIV-infected individuals with severe immunosuppression (Table 6.1). This guidance may be relaxed in the near future, as evidence is emerging that patients with moderate immunosuppression can be safely vaccinated and will make an adequate response (M Levine, pers. comm., 2005). For HIV-infected individuals with no immunosuppression who are susceptible to varicella, vaccine is indicated to reduce the risk of serious chickenpox or zoster should their condition deteriorate.

Table 6.1 Measure of immunosuppression by CD4 count

CD4 count/µl (% of total lymphocytes)			
Age	1–5 years	6–12 years	>12 years
No suppression	ε1000 (15–24%)	ε500 (ε25%)	ε500 (ε25%)
Moderate suppression	500–999 (15–24%)	200–499 (15–24%)	200–499 (15–24%)
Severe suppression	<500 (<15%)	<200 (<15%)	<200 (<15%)

Because there have been reports of dissemination of Bacillus Calmette-Guérin (BCG) in HIV-positive individuals, such individuals should **not** receive BCG vaccine in the UK (Talbot *et al.*, 1997; Fallo *et al.*, 2005; Langley *et al.*,2004).

Infants born to HIV-positive mothers where the infant has an indeterminate HIV status may have an increased risk of contracting tuberculosis. Where indicated, BCG vaccine can be given after two appropriately timed negative postnatal PCR blood tests for HIV infection. Unless a mother is known to be at risk of HIV, it is not necessary to test her before giving BCG vaccine to her infant.

Yellow fever vaccine should not be given to HIV-positive individuals. If such individuals intend to visit countries where a yellow fever certificate is required for entry but where there is no risk of

exposure, then they should obtain a letter of exemption from a medical practitioner. Fatal myeloencephalitis following yellow fever vaccination has been reported in an individual with severe HIVinduced immunosuppression (Kengsakul *et al*., 2002). There are limited data, however, suggesting that yellow fever vaccine may be given safely to HIVinfected persons with a CD4 count that is greater than 200 and a suppressed HIV viral load (Receveur *et al*., 2000; Tattevin *et al*., 2004). Therefore, if the yellow fever risk is unavoidable, specialist advice should be sought with a view to the vaccination of asymptomatic HIV-infected individuals.

Further guidance is provided by the Royal College of Paediatrics and Child Health (www.rcpch.ac.uk), the British HIV Association (BHIVA) *Immunization guidelines for HIV-infected adults* (BHIVA, 2006) and the Children's HIV Association of UK and Ireland (CHIVA) immunization guidelines (www.bhiva.org/chiva).

Deferral of immunization

There will be very few occasions when deferral of immunization is required. Minor illnesses without fever or systemic upset are not valid reasons to postpone immunization. If an individual is acutely unwell, immunization may be postponed until they have fully recovered. This is to avoid wrongly attributing any new symptom or the progression of symptoms to the vaccine.

In individuals with an evolving neurological condition, immunization should be deferred until the neurological condition has resolved or stabilized.

Immunoglobulin may interfere with the immune response to live vaccine viruses because it may contain antibodies to measles, varicella and other viruses. Live virus vaccines should therefore be given at least three weeks before or three months after an injection of immunoglobulin. This does not apply to yellow fever vaccine, because immunoglobulin used in the UK is unlikely to contain high levels of antibody to this virus.

The following conditions are NOT contraindications to routine immunization (in some of these situations, additional precautions may be required – refer to the relevant chapter for further information):

- family history of any adverse reactions following immunization
- previous history of the disease (with the exception of BCG for people who have evidence of past exposure to tuberculosis)
- contact with an infectious disease
- premature birth
- stable neurological conditions such as cerebral palsy and Down's syndrome
- asthma, eczema or hay fever
- mild self-limiting illness without fever, e.g. runny nose
- treatment with antibiotics or locally acting (e.g. topical or inhaled) steroids
- child's mother or someone in the household being pregnant
- currently breast-feeding or being breast-fed
- history of jaundice after birth
- under a certain weight

- being over the age recommended in the routine childhood immunization schedule
- personal history of febrile convulsions or epilepsy
- close family history (parent or sibling) of febrile convulsions or epilepsy
- being a sibling or close contact of an immunosuppressed individual
- •recent or imminent elective surgery
- imminent general anaesthesia
- unknown or inadequately documented immunization history.

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6. Contraindications to vaccination according to the Australian Hand Book of immunization

There are only 2 absolute contraindications applicable to *all* vaccines:

1) anaphylaxis following a previous dose of the relevant vaccine, and
2) anaphylaxis following any component of the relevant vaccine.

There are 2 further contraindications applicable to live (both parenteral and oral) vaccines:

3) Live vaccines should not be administered to individuals with impaired immunity, regardless of whether the impairment is caused by disease or treatment. The exception is that, with specialist advice, MMR can be administered to HIV-infected individuals in whom impaired immunity is mild. (See Section 2.3.3, *Vaccination of individuals with impaired immunity due to disease or treatment*, and individual vaccine chapters.)
4) In general, live vaccines should not be administered during pregnancy, and women should be advised not to become pregnant within 4 weeks of receiving a live vaccine (see Table 2.3.1 *Vaccinations in pregnancy* **false contraindications to vaccination)**

Conditions listed in Table 1.3.4 below are not contraindications to vaccination. People with these conditions should be vaccinated with all recommended vaccines.

Table 1.3.4: False contraindications to vaccination.

The following conditions are not contraindications to any of the vaccines in the National Immunization Program schedule:

• mild illness without fever (T <38.5°C),
• family history of any adverse events following immunization,
• past history of convulsions,
• treatment with antibiotics,
• treatment with locally acting (inhaled or low-dose topical) steroids,
• replacement corticosteroids,
• asthma, eczema, atopy, hay fever or 'snuffles',
• previous pertussis-like illness, measles, rubella, mumps or meningococcal disease,
• prematurity (vaccination should not be postponed),
• history of neonatal jaundice,
• low weight in an otherwise healthy child,
• any neurological conditions including cerebral palsy and Down syndrome,
• contact with an infectious disease,
• child's mother is pregnant,
• child to be vaccinated is being breastfed,
• woman to be vaccinated is breastfeeding,
• recent or imminent surgery,
• poorly documented vaccination history.

7. Contraindications and Precautions to Routine Childhood & Adolescent Vaccinations BY VACCINE (CDC, Atlanta, USA)

For more complete and detailed information, see pages 2 through 6, or read the ACIP's recommendations for the indivdual vaccines (www.cdc.gov/vaccines/pubs/acip-list.htm).

General for all vaccines,

Including diphtheria and tetanus toxoids & acellular pertussis vaccine (DTaP); pediatric diphtheria-tetanus toxoid (DT); adult tetanus-diphtheria toxoid (Td); inactivated poliovirus vaccine (IPV); measles-mumps-rubella vaccine (MMR); Haemophilus influenzae type b vaccine (Hib); hepatitis A vaccine, hepatitis B vaccine; varicella vaccine; pneumococcal conjugate vaccine (PCV); influenza vaccine; and pneumococcal polysaccharide vaccine (PPV)

Contraindications

- Serious allergic reaction (e.g., anaphylaxis) after a previous vaccine dose
- Serious allergic reaction (e.g., anaphylaxis) to a vaccine component

Precautions

- Moderate or severe acute illness with or without fever

DTaP

Contraindications

- Severe allergic reaction after a previous dose or to a vaccine component
- Encephalopathy (e.g., coma, decreased level of consciousness; prolonged seizures) within 7 days of administration of previous dose of DTP or DTaP
- Progressive neurologic disorder, including infantile spasms, uncontrolled epilepsy, progressive encephalopathy; defer DTaP until neurologic status clarified and stabilized.

Precautions

- Fever of >40.5° C <48 hours after vaccination with a previous dose of DTP or DTaP
- Collapse or shock-like state (i.e., hypotonic hyporesponsive episode) <48 hours after receiving a previous dose of DTP or DTaP
- Seizure <3 days of receiving a previous dose of DTP/DTaP^

- Persistent, inconsolable crying lasting >3 hours <48 hours after receiving a previous dose of DTP or DTaP
- Moderate or severe acute illness with or without fever

DT, Td

Contraindications

- Severe allergic reaction after a previous dose or to a vaccine component

Precautions

- Guillain-Barré syndrome <6 weeks after previous dose of tetanus toxoid-containing vaccine
- Moderate or severe acute illness with or without fever

IPV

Contraindications

- Severe allergic reaction to previous dose or vaccine component

Precautions

- Pregnancy
- Moderate or severe acute illness with or without fever

MMR

Contraindications

- Severe allergic reaction to previous dose or vaccine component
- Pregnancy
- Known severe immunodeficiency (e.g., hematologic and solid tumors; congenital immunodeficiency; long-term immunosuppressive therapy## or severely symptomatic human immunodeficiency virus [HIV] infection)

Precautions

- Recent (<11 months) receipt of antibody-containing blood product (specific interval depends on product) $$
- History of thrombocytopenia or thrombocytopenic purpura
- Moderate or severe acute illness with or without fever

Hib

Contraindications

- Severe allergic reaction to previous dose or vaccine component
- Age <6 weeks

Precautions

- Moderate or severe acute illness with or without fever

- **Hepatitis B**

Contraindications

- Severe allergic reaction to previous dose or vaccine component

Precautions

- Infant weighing < 2,000 grams
- Moderate or severe acute illness with or without fever

Hepatitis A

Contraindications

- Severe allergic reaction to previous dose or vaccine component

Precautions

- Pregnancy
- Moderate or severe acute illness with or without fever

Varicella

Contraindications

- Severe allergic reaction to previous dose or vaccine component
- Substantial suppression of cellular immunity
- Pregnancy

Precautions

- Recent (<11 months) receipt of antibody-containing blood product (specific interval depends on product) $$
- Moderate or severe acute illness with or without fever

PPV

Contraindications

- Severe allergic reaction to previous dose or vaccine component

Precautions

- Moderate or severe acute illness with or without fever

PCV

Contraindications

- Severe allergic reaction to previous dose or vaccine component

Precautions

- Moderate or severe acute illness with or without fever

Influenza

Contraindications

- Severe allergic reaction to previous dose or vaccine component, including egg protein

Precautions

- Moderate or severe acute illness with or without fever

8. Contraindications and cautions according to the manufacturers

BCG (Serum institute of India)

- Hypogamma-globulinemia
- Congenital immunodeficiency
- Sarcoidosis
- Leukaemia
- Generalised malignancy
- On immunosuppresive therapy, corticosteroids, radiotherapy.
- Chronic eczema, other dermatological diseases- can be given in a healthy area
- Should not be revaccinated-if has keloid and lupoid reactions at the site of injection
- HIV infections
- Disorder which alters natural immune response

Diphtheria, pertussis and tetanus (Serum institute of India)

- Personal or family history in parents or siblings of idiopathic epilepsy
- Hereditary or familial diseases of the central nervous system
- History of seizures, convulsions, cerebral irritation in the neonatal period
- Developmental neurological defect
- Disorders of the central nervous system
- Should be postponed- if has acute disease
- Persisting screaming, shock, convulsions or encephalopathy to the previous dose

OPV (GlaxoSmithKline Biologicals s.a.)

- Systemic hypersensitivity to neomycin, polymyxin or to any other component of the vaccine
- Primary immune deficiency diseases
- Suppressed immune response from medication
- Leukaemia, lymphoma or generalised malignancy
- Should be postponed- suffering from acute severe febrile illness or persistent diarrhoea or vomiting

Hepatitis B (Berna)

- Hypersensitivity to any component of the vaccine
- Severe reaction to a previous dose

Diphtheria and tetanus (Paediatric) (Serum institute of India)

- Severe reaction to a previous dose of diphtheria tetanus toxoid vaccine
- History of systemic allergic or neurological reactions following a previous dose of DT
- Should be deferred- any severe febrile illness

Diphtheria and tetanus (adults and adolescents) (Serum institute of India)

- Severe reaction to a previous dose of DT vaccine
- History of systemic allergic or neurological reactions following a previous dose of Td
- Should be deferred- any severe febrile illness

Tetanus Toxoid (Serum institute of India)

- Severe reactions to a previous dose of tetanus toxoid immunization
- Should be deferred- any severe febrile illness or acute infection

Measles (Serum institute of India)

- On corticosteroids, other immunosuppressive drugs or undergoing radiotherapy
- Acute infectious diseases
- Leukaemia, severe anaemia, severe disease of the blood system, severe impairment of the renal function, decompensated heart disease
- Following administration of gamma-globulin or blood transfusions
- Pregnancy

Measles and Rubella (Serum institute of India)

- On corticosteroids, other immunosuppressive drugs or undergoing radiotherapy
- Acute infectious diseases
- Leukaemia, severe anaemia, severe disease of the blood system, severe impairment of the renal function, decompensated heart disease
- Following administration of gammaglobulin or blood transfusions
- Potential allergies to vaccine components
- Anaphylactic or anaphylactoid reactions to neomycin
- History of anaphylactic or anaphylactoid reactions
- Pregnancy

Rubella (Serum institute of India)

- On corticosteroids, other immunosuppressive drugs or undergoing radiotherapy
- Acute infectious diseases
- Leukaemia, severe anaemia, severe disease of the blood system, severe impairment of the renal function, decompensated heart disease
- Following administration of gammaglobulin or blood transfusions
- Anaphylactic or anaphylactoid reactions to neomycin
- History of anaphylactic or anaphylactoid reactions
- Pregnancy