**BCG**

**BCG vaccine (WHO position paper)**

Infants and children with symptomatic human immunodeficiency virus (HIV) or those known to have other immunodeficiency states should not be BCG-vaccinated.

**BCG vaccine (WHO position paper)**

HIV-positive infants may receive BCG vaccine only when asymptomatic and living in areas where TB is highly endemic. Long-term follow-up of such children following vaccination is desirable. HIV-positive, asymptomatic infants in low-burden areas should not be BCG-vaccinated. Indications for vaccination of groups likely to contract HIV should always be considered carefully. The efficacy of BCG vaccination in HIV-infected infants is not known.

**BCG vaccine (WHO position paper)**

Given the high risk of acquiring TB and the low risk of serious adverse events following BCG vaccination of HIV-exposed neonates, WHO maintains that, in HIV-infected areas, all neonates be given BCG. Older infants or children suspected of being HIV-infected should not be vaccinated if they have symptomatic disease or other evidence of immunosuppression.

**Global Advisory Committee on Vaccine Safety, 34 December 2003**

There are few population-based data on the effectiveness, or otherwise, of BCG vaccine in preventing severe tuberculosis in HIV-positive infants. Given the high prevalence of HIV and tuberculosis in certain countries and of the current development of new tuberculosis vaccines, some of which are based on BCG, GACVS advises no change in the current recommendations for BCG immunization of infants in countries with a high prevalence of tuberculosis and that population-based studies should be undertaken to determine the efficacy and safety of BCG and related vaccines in HIV-negative and HIV-positive children in countries with a high endemic rate of tuberculosis.
BCG vaccine (WHO position paper)

BCG vaccination is indicated

- for all infants living in areas where TB is highly endemic (concerning HIV, see below);
- for infants and children at particular risk of TB exposure in otherwise low-endemic areas;
- for persons exposed to multidrug-resistant Mtb (impact not established.)

BCG vaccination is contraindicated

- for persons with impaired immunity symptomatic HIV infection, known or suspected congenital immunodeficiency, leukaemia, lymphoma or generalized malignant disease);
- for patients under immunosuppressive treatment (corticosteroids, alkylating agents, antimetabolites, radiation);
- in pregnancy.

GACVS

Global Advisory Committee on Vaccine Safety, 23 December 2004

GACVS reiterates that particular care should be taken that the (17D yellow fever) vaccine is received only by those travellers who are truly at risk of exposure to yellow fever. In addition, vaccine providers should give careful consideration to the risks and benefits for elderly travellers and should routinely enquire about a history of thymus disorder, irrespective of the age of the subject. Where a history of thymus disorder is reported, alternative prevention measures should be considered.

Global Advisory Committee on Vaccine Safety, 34 December 2003

(GACVS stated that) particular care should be taken that the (yellow fever) vaccine is received only by those travellers truly at risk for yellow fever exposure. Furthermore, care should be taken that routine yellow fever vaccination programmes are not jeopardized by riskbenefit ratios that may be inapplicable to the target populations in endemic countries.

Global Advisory Committee on Vaccine Safety, 34 December 2003

There are few population-based data on the effectiveness, or otherwise, of BCG vaccine in preventing severe tuberculosis in HIV-positive infants. Given the high prevalence of HIV and tuberculosis in certain countries and of the current development of new tuberculosis vaccines, some of which are based on BCG, GACVS advises no change in the current recommendations for BCG immunization of infants in countries with a high prevalence of tuberculosis and that population-based studies should be undertaken to determine the efficacy and safety of BCG and related vaccines in HIV-negative and HIV-positive children in countries with a high endemic rate of tuberculosis.
Global Advisory Committee on Vaccine Safety, 34 December 2003

A critical and unresolved issue is the safety and efficacy of yellow fever vaccine in human subjects infected with immunodeficiency virus (HIV). It remains to be determined whether HIV-positive status materially affects seroconversion, the risk of invasion of the nervous system and of encephalopathy, the stage of HIV disease at which yellow fever vaccination should be contraindicated, and whether there are differences in the incidence of minor and major adverse effects in HIV-positive subjects.

Contraindications

General

Introduction of Haemophilus influenzae type b vaccine into immunization programmes

There are no contra-indications to Hib immunization, except a history of hypersensitivity to any of the components in the vaccine (for example, tetanus or diphtheria toxoids).

Measles vaccines (WHO position paper)

Mild, concurrent infections are not considered a contraindication, and there is no evidence that measles vaccination exacerbates tuberculosis. However, vaccination should be avoided if there is high fever or other signs of serious disease. On theoretical grounds, measles vaccine should also be avoided in pregnancy.

Measles vaccines (WHO position paper)

Persons with a history of an anaphylactic reaction to neomycin, gelatin or other components the vaccine should not be vaccinated (with measles vaccine.) Furthermore, measles vaccine is 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.

BCG vaccine (WHO position paper)

Infants and children with symptomatic human immunodeficiency virus (HIV) or those known to have other immunodeficiency states should not be BCG vaccinated.

BCG vaccine (WHO position paper)

HIV-positive infants may receive BCG vaccine only when asymptomatic and living in areas where TB is highly endemic. Long-term follow-up of such children following vaccination is desirable. HIV-positive, asymptomatic infants in low-burden areas should not be BCG-vaccinated. Indications for vaccination of groups likely to contract HIV should always be considered carefully. The efficacy of BCG vaccination in HIV-infected infants is not known.
BCG vaccine (WHO position paper)

Given the high risk of acquiring TB and the low risk of serious adverse events following BCG vaccination of HIV-exposed neonates, WHO maintains that, in HIV-infected areas, all neonates be given BCG. Older infants or children suspected of being HIV-infected should not be vaccinated if they have symptomatic disease or other evidence of immunosuppression.

Hepatitis B vaccines (WHO position paper)

Hepatitis B vaccine is contraindicated for individuals with a history of allergic reactions to any of the vaccines components.

Neither pregnancy nor lactation is a contraindication for use of this vaccine.

Influenza vaccines (WHO position paper)

Except for anaphylactic allergic reactions to egg or other components of the (trivalent, inactivated influenza) vaccines, there are no contraindications to the use of these vaccines in age groups >6 months.

Influenza vaccines (WHO position paper)

Following nasal administration, (t)ranmission of the (influenza) vaccine virus to exposed non-immune people appears to be very rare. However, as a precaution the vaccine should not be given to highly immunosuppressed individuals or their close contacts.

Contraindications for use (of CAIV-T influenza vaccine) include anaphylactic reactions to eggs, a history of Guillain-Barr syndrome, patients aged <18 years on long-term aspirin therapy, pregnancy during the first trimester, and various states of immunosuppression.

Influenza vaccines (WHO position paper)

(Inactivated) influenza vaccination in pregnancy is considered safe and is recommended for all pregnant women during the influenza season. This recommendation is motivated not only by the potential severe course of influenza during pregnancy, but also in order to protect infants against influenza during their vulnerable first months of life.

Pneumococcal vaccines (WHO position paper)

There are no absolute contraindications to vaccination with pneumococcal polysaccharide vaccine except for an anaphylactic reaction to the previous dose.
### Rubella vaccines (WHO position paper)

Rubella vaccination should be avoided in pregnancy because of the theoretical, but never demonstrated, teratogenic risk. No cases of CRS have been reported in more than 1 000 susceptible pregnant women who inadvertently received a rubella vaccine in early pregnancy. Consequently, there is no need to screen women for pregnancy before rubella vaccination. If pregnancy is being planned, then an interval of 1 month should be observed after rubella immunization. Rubella vaccination during pregnancy is not an indication for abortion.

**Contraindications**

- Rubella vaccination should be avoided in pregnancy because of the theoretical, but never demonstrated, teratogenic risk.
- No cases of CRS have been reported in more than 1 000 susceptible pregnant women who inadvertently received a rubella vaccine in early pregnancy.
- Consequently, there is no need to screen women for pregnancy before rubella vaccination.
- If pregnancy is being planned, then an interval of 1 month should be observed after rubella immunization. Rubella vaccination during pregnancy is not an indication for abortion.

### Yellow fever vaccine (WHO position paper)

The (yellow fever) vaccine is contraindicated in children aged under 6 months and is not recommended for those aged 6-8 months, except during epidemics when the risk of YF virus transmission may be very high. It is also contraindicated for persons with severe allergy to egg and for severely immunocompromised persons. On theoretical grounds, the 17D vaccine is not recommended during pregnancy. However, pregnant women may be vaccinated during epidemics when the risk of YFV transmission may be very high.

**Contraindications**

- The (yellow fever) vaccine is contraindicated in children aged under 6 months and is not recommended for those aged 6-8 months, except during epidemics when the risk of YF virus transmission may be very high.
- It is also contraindicated for persons with severe allergy to egg and for severely immunocompromised persons.
- On theoretical grounds, the 17D vaccine is not recommended during pregnancy. However, pregnant women may be vaccinated during epidemics when the risk of YFV transmission may be very high.

### Yellow fever vaccine (WHO position paper)

Contraindications against YF vaccination include age less than 6 months, severe hypersensitivity to egg antigens and severe immunodeficiency. Whereas it is relatively easy to avoid immunization of the first two categories, the principal contraindications against immunization during pregnancy and in severe immunodeficiency cause significant practical problems. Fortunately, the few published cases of congenital infection caused by 17D have not been associated with fetal abnormalities. Similarly, no adverse events occurred in a small study of HIV-infected children with low CD4+ counts who received the vaccine. These observations are important considering the likelihood that many pregnant women and HIV-positive individuals, including children, will be immunized inadvertently during large-scale immunization activities in at-risk countries.

For international travellers, where laboratory and other resources are available, YF (yellow fever) vaccination may be offered to asymptomatic HIV-infected persons with CD4+ counts above 200 cells/mm3 who require vaccination for unavoidable travel. Individual expert assessments are required before YF vaccination may be offered to persons taking high-dose corticosteroids or antineoplastic drugs. If possible, tests should be performed to ensure that protective levels of neutralizing antibodies have been achieved, as primary vaccination failure is common in immunodeficient individuals.

### Yellow fever vaccine (WHO position paper)

Given the very rare, but potentially severe, adverse effects, YF (yellow fever) vaccine for travellers should be administered on strict indications only, particularly in the elderly. Restriction of YF vaccination to authorized centres is likely to promote the appropriate use of YF vaccine.
Contraindications

**Typhoid vaccines (WHO position paper)**

It is not known whether this live attenuated vaccine (Ty21a typhoid vaccine) can cause fetal harm when administered to pregnant women. Ty21a can be administered to HIV-positive, asymptomatic individuals without risk as long as the T-cell count (CD4) is above 200/mm³.

**Global Advisory Committee on Vaccine Safety, 23 December 2004**

GACVS reiterates that particular care should be taken that the (17D yellow fever) vaccine is received only by those travellers who are truly at risk of exposure to yellow fever. In addition, vaccine providers should give careful consideration to the risks and benefits for elderly travellers and should routinely enquire about a history of thymus disorder, irrespective of the age of the subject. Where a history of thymus disorder is reported, alternative prevention measures should be considered.

**Global Advisory Committee on Vaccine Safety, 34 December 2003**

(GACVS stated that) particular care should be taken that the (yellow fever) vaccine is received only by those travellers truly at risk for yellow fever exposure. Furthermore, care should be taken that routine yellow fever vaccination programmes are not jeopardized by riskbenefit ratios that may be inapplicable to the target populations in endemic countries.

**Global Advisory Committee on Vaccine Safety, 34 December 2003**

There are few population-based data on the effectiveness, or otherwise, of BCG vaccine in preventing severe tuberculosis in HIV-positive infants. Given the high prevalence of HIV and tuberculosis in certain countries and of the current development of new tuberculosis vaccines, some of which are based on BCG, GACVS advises no change in the current recommendations for BCG immunization of infants in countries with a high prevalence of tuberculosis and that population-based studies should be undertaken to determine the efficacy and safety of BCG and related vaccines in HIV-negative and HIV-positive children in countries with a high endemic rate of tuberculosis.

**Vaccine introduction guidelines. Adding a vaccine to a national immunization programme: decision and implementation**

Yellow fever vaccine is contraindicated for infants less than 6 months of age, immune-deficient persons and persons with egg allergy. The risk of disease should be weighed against the risk of vaccination in pregnant women and in persons with symptomatic HIV infection. These are important factors to consider before planning a mass preventive vaccination campaign.
Contraindications

**Introduction of hepatitis B vaccine into childhood immunization services. Management guidelines, including information for health workers and parents**

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

The following are NOT contraindications:

- minor illness, such as respiratory tract infection or diarrhoea with temperature below 38.5°C;
- allergy or asthma;
- family history of convulsions;
- treatment with antibiotics;
- infection with HIV;
- breastfeeding;
- history of seizures (convulsions, fits);
- chronic illnesses such as chronic diseases of the heart, lung, kidney or liver;
- stable neurological conditions such as cerebral palsy and Down syndrome;
- prematurity or low birth weight;
- history of jaundice at birth.

**Typhoid vaccines (WHO position paper)**

There are no contraindications (to the Vi polysaccharide typhoid vaccine) other than prior severe reaction to vaccine components. Although the vaccine is safe for HIV-infected persons, the induction of protective antibodies is directly correlated to the levels of CD4 positive T-cells.

**Global Advisory Committee on Vaccine Safety, 34 December 2003**

A critical and unresolved issue is the safety and efficacy of yellow fever vaccine in human subjects infected with immunodeficiency virus (HIV). It remains to be determined whether HIV-positive status materially affects seroconversion, the risk of invasion of the nervous system and of encephalopathy, the stage of HIV disease at which yellow fever vaccination should be contraindicated, and whether there are differences in the incidence of minor and major adverse effects in HIV-positive subjects.

**Hepatitis A vaccines (WHO position paper)**

Contraindications to hepatitis A vaccination include a known allergy to any of the vaccine components.

**Mumps virus vaccines (WHO position paper)**

There are few contraindications to mumps vaccination. As with all live attenuated vaccines, mumps vaccine should not be administered to individuals with advanced immune deficiency or immunosuppression. Fetal damage has not been documented when mumps vaccines have been given to pregnant women. Allergy to vaccine components such as neomycin and gelatin is a contraindication to administration of the vaccine.
**Tetanus vaccine** (WHO position paper)

(Im)munodeficiency including HIV infection is not a contraindication to (the use of TT or dT.)

*WER 2006, vol. 81, 20, pp 198-208 page 204*

**Pneumococcal conjugate vaccine for childhood immunization** (WHO position paper)

The only contraindication to PCV-7 immunization is a severe hypersensitivity reaction to a previous dose of the vaccine.

*WER 2006, vol. 82, 10, pp 93-104 page 102*

**Rabies vaccines** (WHO position paper)

Because rabies is a lethal disease, no contraindications to post-exposure prophylaxis following high-risk exposure exist. This also pertains to post-exposure rabies prophylaxis in infancy and pregnancy.

*WER 2007, vol. 82, 49/50, pp 425-436 page 431*

**Rabies vaccines** (WHO position paper)

For pre-exposure immunization, previous severe reaction to any of the vaccine components is a contraindication to further use of the same vaccine.

*WER 2007, vol. 82, 49/50, pp 425-436 page 431*

**Rabies vaccines** (WHO position paper)

In immunocompromised individuals, including patients with HIV/AIDS, comprehensive wound management and local infiltration with RIG, in combination with a complete intramuscular CCV series, are of utmost importance for the successful prevention of rabies. In these situations, the VNA response should be determined 24 weeks following vaccination to assess the possible need for an additional dose of the vaccine.

*WER 2007, vol. 82, 49/50, pp 425-436 page 431*

**Rabies vaccines** (WHO position paper)

People taking chloroquine for treatment or malaria prophylaxis can have a reduced response to ID rabies vaccination. These patients should receive the vaccine by the IM route.

*WER 2007, vol. 82, 49/50, pp 425-436 page 432*

**Typhoid vaccines:** WHO position paper

There are no contraindications to the use of this vaccine other than previous severe hypersensitivity reaction to vaccine components. Although the Vi polysaccharide vaccine is safe for HIV-infected individuals, the induction of protective antibodies is directly correlated to the levels of CD4 positive T-cells.

*WER 2008, vol. 83, 6, pp 49-60 page 54*
BCG vaccine (WHO position paper)

BCG vaccination is indicated

- for all infants living in areas where TB is highly endemic (concerning HIV, see below);
- for infants and children at particular risk of TB exposure in otherwise low-endemic areas;
- for persons exposed to multidrug-resistant Mtb (impact not established.)

BCG vaccination is contraindicated

- for persons with impaired immunity symptomatic HIV infection, known or suspected congenital immunodeficiency, leukaemia, lymphoma or generalized malignant disease);
- for patients under immunosuppressive treatment (corticosteroids, alkylating agents, antimetabolites, radiation);
- in pregnancy.

HIV/AIDS and immunosuppression

Measles vaccines (WHO position paper)

Persons with a history of an anaphylactic reaction to neomycin, gelatin or other components the vaccine should not be vaccinated (with measles vaccine.) Furthermore, measles vaccine is 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.

BCG vaccine (WHO position paper)

Infants and children with symptomatic human immunodeficiency virus (HIV) or those known to have other immunodeficiency states should not be BCG vaccinated.

BCG vaccine (WHO position paper)

Given the high risk of acquiring TB and the low risk of serious adverse events following BCG vaccination of HIV-exposed neonates, WHO maintains that, in HIV-infected areas, all neonates be given BCG. Older infants or children suspected of being HIV-infected should not be vaccinated if they have symptomatic disease or other evidence of immunosuppression.
Contraindications

**Influenza vaccines (WHO position paper)**

Following nasal administration, (t)ransmission of the (influenza) vaccine virus to exposed non-immune people appears to be very rare. However, as a precaution the vaccine should not be given to highly immunosuppressed individuals or their close contacts.

Contraindications for use (of CAIV-T influenza vaccine) include anaphylactic reactions to eggs, a history of Guillain-Barré syndrome, patients aged <18 years on long-term aspirin therapy, pregnancy during the first trimester, and various states of immunosuppression.

**Yellow fever vaccine (WHO position paper)**

The (yellow fever) vaccine is contraindicated in children aged under 6 months and is not recommended for those aged 6-8 months, except during epidemics when the risk of YF virus transmission may be very high. It is also contraindicated for persons with severe allergy to egg and for severely immunocompromised persons. On theoretical grounds, the 17D vaccine is not recommended during pregnancy. However, pregnant women may be vaccinated during epidemics when the risk of YFV transmission may be very high.

**Yellow fever vaccine (WHO position paper)**

Contraindications against YF vaccination include age less than 6 months, severe hypersensitivity to egg antigens and severe immunodeficiency. Whereas it is relatively easy to avoid immunization of the first two categories, the principal contraindications against immunization during pregnancy and in severe immunodeficiency cause significant practical problems. Fortunately, the few published cases of congenital infection caused by 17D have not been associated with fetal abnormalities. Similarly, no adverse events occurred in a small study of HIV-infected children with low CD4+ counts who received the vaccine. These observations are important considering the likelihood that many pregnant women and HIV-positive individuals, including children, will be immunized inadvertently during large-scale immunization activities in at-risk countries.

For international travellers, where laboratory and other resources are available, YF (yellow fever) vaccination may be offered to asymptomatic HIV-infected persons with CD4+ counts above 200 cells/mm3 who require vaccination for unavoidable travel. Individual expert assessments are required before YF vaccination may be offered to persons taking high-dose corticosteroids or antineoplastic drugs. If possible, tests should be performed to ensure that protective levels of neutralizing antibodies have been achieved, as primary vaccination failure is common in immunodeficient individuals.

**Typhoid vaccines (WHO position paper)**

It is not known whether this live attenuated vaccine (Ty21a typhoid vaccine) can cause fetal harm when administered to pregnant women. Ty21a can be administered to HIV-positive, asymptomatic individuals without risk as long as the T-cell count (CD4) is above 200/mm3.
Global Advisory Committee on Vaccine Safety, 34 December 2003

There are few population-based data on the effectiveness, or otherwise, of BCG vaccine in preventing severe tuberculosis in HIV-positive infants. Given the high prevalence of HIV and tuberculosis in certain countries and of the current development of new tuberculosis vaccines, some of which are based on BCG, GACVS advises no change in the current recommendations for BCG immunization of infants in countries with a high prevalence of tuberculosis and that population-based studies should be undertaken to determine the efficacy and safety of BCG and related vaccines in HIV-negative and HIV-positive children in countries with a high endemic rate of tuberculosis.

Vaccine introduction guidelines. Adding a vaccine to a national immunization programme: decision and implementation

Yellow fever vaccine is contraindicated for infants less than 6 months of age, immune-deficient persons and persons with egg allergy. The risk of disease should be weighed against the risk of vaccination in pregnant women and in persons with symptomatic HIV infection. These are important factors to consider before planning a mass preventive vaccination campaign.

Introduction of hepatitis B vaccine into childhood immunization services. Management guidelines, including information for health workers and parents

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

The following are NOT contraindications:
  minor illness, such as respiratory tract infection or diarrhoea with temperature below 38.5°C;
  allergy or asthma;
  family history of convulsions;
  treatment with antibiotics;
  infection with HIV;
  breastfeeding;
  history of seizures (convulsions, fits);
  chronic illnesses such as chronic diseases of the heart, lung, kidney or liver;
  stable neurological conditions such as cerebral palsy and Down syndrome;
  prematurity or low birth weight;
  history of jaundice at birth.

Typhoid vaccines (WHO position paper)

There are no contraindications (to the Vi polysaccharide typhoid vaccine) other than prior severe reaction to vaccine components. Although the vaccine is safe for HIV-infected persons, the induction of protective antibodies is directly correlated to the levels of CD4 positive T-cells.
Global Advisory Committee on Vaccine Safety, 34 December 2003

A critical and unresolved issue is the safety and efficacy of yellow fever vaccine in human subjects infected with immunodeficiency virus (HIV). It remains to be determined whether HIV-positive status materially affects seroconversion, the risk of invasion of the nervous system and of encephalopathy, the stage of HIV disease at which yellow fever vaccination should be contraindicated, and whether there are differences in the incidence of minor and major adverse effects in HIV-positive subjects.

Mumps virus vaccines (WHO position paper)

There are few contraindications to mumps vaccination. As with all live attenuated vaccines, mumps vaccine should not be administered to individuals with advanced immune deficiency or immunosuppression. Fetal damage has not been documented when mumps vaccines have been given to pregnant women. Allergy to vaccine components such as neomycin and gelatin is a contraindication to administration of the vaccine.

Tetanus vaccine (WHO position paper)

(Im)munodeficiency including HIV infection is not a contraindication to (the use of TT or dT.)

BCG vaccine (WHO position paper)

BCG vaccination is indicated

- for all infants living in areas where TB is highly endemic (concerning HIV, see below);
- for infants and children at particular risk of TB exposure in otherwise low-endemic areas;
- for persons exposed to multidrug-resistant Mtb (impact not established.)

BCG vaccination is contraindicated

- for persons with impaired immunity symptomatic HIV infection, known or suspected congenital immunodeficiency, leukaemia, lymphoma or generalized malignant disease);
- for patients under immunosuppressive treatment (corticosteroids, alkylating agents, antimetabolites, radiation);
- in pregnancy.

Hepatitis A

Hepatitis A vaccines (WHO position paper)

Contraindications to hepatitis A vaccination include a known allergy to any of the vaccine components.
**Hepatitis B**

**Hepatitis B vaccines (WHO position paper)**

Hepatitis B vaccine is contraindicated for individuals with a history of allergic reactions to any of the vaccines components.

Neither pregnancy nor lactation is a contraindication for use of this vaccine.

**Introduction of hepatitis B vaccine into childhood immunization services. Management guidelines, including information for health workers and parents**

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

The following are NOT contraindications:
- minor illness, such as respiratory tract infection or diarrhoea with temperature below 38.5°C;
- allergy or asthma;
- family history of convulsions;
- treatment with antibiotics;
- infection with HIV;
- breastfeeding;
- history of seizures (convulsions, fits);
- chronic illnesses such as chronic diseases of the heart, lung, kidney or liver;
- stable neurological conditions such as cerebral palsy and Down syndrome;
- prematurity or low birth weight;
- history of jaundice at birth.

**Hib**

**Introduction of Haemophilus influenzae type b vaccine into immunization programmes**

There are no contra-indications to Hib immunization, except a history of hypersensitivity to any of the components in the vaccine (for example, tetanus or diphtheria toxoids).

**Influenza**

**Influenza vaccines (WHO position paper)**

Except for anaphylactic allergic reactions to egg or other components of the (trivalent, inactivated influenza) vaccines, there are no contraindications to the use of these vaccines in age groups >6 months.
### Influenza vaccines (WHO position paper)

Following nasal administration, transmission of the influenza vaccine virus to exposed non-immune people appears to be very rare. However, as a precaution the vaccine should not be given to highly immunosuppressed individuals or their close contacts.

Contraindications for use (of CAIV-T influenza vaccine) include anaphylactic reactions to eggs, a history of Guillain-Barré syndrome, patients aged <18 years on long-term aspirin therapy, pregnancy during the first trimester, and various states of immunosuppression.

### Influenza vaccines (WHO position paper)

(Inactivated) influenza vaccination in pregnancy is considered safe and is recommended for all pregnant women during the influenza season. This recommendation is motivated not only by the potential severe course of influenza during pregnancy, but also in order to protect infants against influenza during their vulnerable first months of life.

### Measles

### Measles vaccines (WHO position paper)

Mild, concurrent infections are not considered a contraindication, and there is no evidence that measles vaccination exacerbates tuberculosis. However, vaccination should be avoided if there is high fever or other signs of serious disease. On theoretical grounds, measles vaccine should also be avoided in pregnancy.

### Measles vaccines (WHO position paper)

Persons with a history of an anaphylactic reaction to neomycin, gelatin or other components the vaccine should not be vaccinated (with measles vaccine.) Furthermore, measles vaccine is 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.

### Mumps

### Mumps virus vaccines (WHO position paper)

There are few contraindications to mumps vaccination. As with all live attenuated vaccines, mumps vaccine should not be administered to individuals with advanced immune deficiency or immunosuppression. Fetal damage has not been documented when mumps vaccines have been given to pregnant women. Allergy to vaccine components such as neomycin and gelatin is a contraindication to administration of the vaccine.
Outbreak Control

Yellow fever vaccine (WHO position paper)

The (yellow fever) vaccine is contraindicated in children aged under 6 months and is not recommended for those aged 6-8 months, except during epidemics when the risk of YF virus transmission may be very high. It is also contraindicated for persons with severe allergy to egg and for severely immunocompromised persons. On theoretical grounds, the 17D vaccine is not recommended during pregnancy. However, pregnant women may be vaccinated during epidemics when the risk of YFV transmission may be very high.

Pneumococcal

Pneumococcal vaccines (WHO position paper)

There are no absolute contraindications to vaccination with pneumococcal polysaccharide vaccine except for an anaphylactic reaction to the previous dose.

Pneumococcal conjugate vaccine for childhood immunization (WHO position paper)

The only contraindication to PCV-7 immunization is a severe hypersensitivity reaction to a previous dose of the vaccine.

Policy

Introduction of Haemophilus influenzae type b vaccine into immunization programmes

There are no contra-indications to Hib immunization, except a history of hypersensitivity to any of the components in the vaccine (for example, tetanus or diphtheria toxoids).

Measles vaccines (WHO position paper)

Mild, concurrent infections are not considered a contraindication, and there is no evidence that measles vaccination exacerbates tuberculosis. However, vaccination should be avoided if there is high fever or other signs of serious disease. On theoretical grounds, measles vaccine should also be avoided in pregnancy.
Contraindications

Measles vaccines (WHO position paper)

Persons with a history of an anaphylactic reaction to neomycin, gelatin or other components the vaccine should not be vaccinated (with measles vaccine.) Furthermore, measles vaccine is 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.

BCG vaccine (WHO position paper)

Infants and children with symptomatic human immunodeficiency virus (HIV) or those known to have other immunodeficiency states should not be BCG-vaccinated.

BCG vaccine (WHO position paper)

HIV-positive infants may receive BCG vaccine only when asymptomatic and living in areas where TB is highly endemic. Long-term follow-up of such children following vaccination is desirable. HIV-positive, asymptomatic infants in low-burden areas should not be BCG-vaccinated. Indications for vaccination of groups likely to contract HIV should always be considered carefully. The efficacy of BCG vaccination in HIV-infected infants is not known.

BCG vaccine (WHO position paper)

Given the high risk of acquiring TB and the low risk of serious adverse events following BCG vaccination of HIV-exposed neonates, WHO maintains that, in HIV-infected areas, all neonates be given BCG. Older infants or children suspected of being HIV-infected should not be vaccinated if they have symptomatic disease or other evidence of immunosuppression.

Hepatitis B vaccines (WHO position paper)

Hepatitis B vaccine is contraindicated for individuals with a history of allergic reactions to any of the vaccines components.

Neither pregnancy nor lactation is a contraindication for use of this vaccine.

Influenza vaccines (WHO position paper)

Following nasal administration, transmission of the (influenza) vaccine virus to exposed non-immune people appears to be very rare. However, as a precaution the vaccine should not be given to highly immunosuppressed individuals or their close contacts.

Contraindications for use (of CAIV-T influenza vaccine) include anaphylactic reactions to eggs, a history of Guillain-Barr syndrome, patients aged <18 years on long-term aspirin therapy, pregnancy during the first trimester, and various states of immunosuppression.
Influenza vaccines (WHO position paper)

(Inactivated) influenza vaccination in pregnancy is considered safe and is recommended for all pregnant women during the influenza season. This recommendation is motivated not only by the potential severe course of influenza during pregnancy, but also in order to protect infants against influenza during their vulnerable first months of life.

Pneumococcal vaccines (WHO position paper)

There are no absolute contraindications to vaccination with pneumococcal polysaccharide vaccine except for an anaphylactic reaction to the previous dose.

Rubella vaccines (WHO position paper)

Rubella vaccination should be avoided in pregnancy because of the theoretical, but never demonstrated, teratogenic risk. No cases of CRS have been reported in more than 1 000 susceptible pregnant women who inadvertently received a rubella vaccine in early pregnancy. Consequently, there is no need to screen women for pregnancy before rubella vaccination. If pregnancy is being planned, then an interval of 1 month should be observed after rubella immunization. Rubella vaccination during pregnancy is not an indication for abortion.

Yellow fever vaccine (WHO position paper)

The (yellow fever) vaccine is contraindicated in children aged under 6 months and is not recommended for those aged 6-8 months, except during epidemics when the risk of YF virus transmission may be very high. It is also contraindicated for persons with severe allergy to egg and for severely immunocompromised persons. On theoretical grounds, the 17D vaccine is not recommended during pregnancy. However, pregnant women may be vaccinated during epidemics when the risk of YFV transmission may be very high.
Contraindications

**Yellow fever vaccine (WHO position paper)**

Contraindications against YF vaccination include age less than 6 months, severe hypersensitivity to egg antigens and severe immunodeficiency. Whereas it is relatively easy to avoid immunization of the first two categories, the principal contraindications against immunization during pregnancy and in severe immunodeficiency cause significant practical problems. Fortunately, the few published cases of congenital infection caused by 17D have not been associated with fetal abnormalities. Similarly, no adverse events occurred in a small study of HIV-infected children with low CD4+ counts who received the vaccine. These observations are important considering the likelihood that many pregnant women and HIV-positive individuals, including children, will be immunized inadvertently during large-scale immunization activities in at-risk countries.

For international travellers, where laboratory and other resources are available, YF (yellow fever) vaccination may be offered to asymptomatic HIV-infected persons with CD4+ counts above 200 cells/mm3 who require vaccination for unavoidable travel. Individual expert assessments are required before YF vaccination may be offered to persons taking high-dose corticosteroids or antineoplastic drugs. If possible, tests should be performed to ensure that protective levels of neutralizing antibodies have been achieved, as primary vaccination failure is common in immunodeficient individuals.

**Yellow fever vaccine (WHO position paper)**

Given the very rare, but potentially severe, adverse effects, YF (yellow fever) vaccine for travellers should be administered on strict indications only, particularly in the elderly. Restriction of YF vaccination to authorized centres is likely to promote the appropriate use of YF vaccine.

**Typhoid vaccines (WHO position paper)**

It is not known whether this live attenuated vaccine (Ty21a typhoid vaccine) can cause fetal harm when administered to pregnant women. Ty21a can be administered to HIV-positive, asymptomatic individuals without risk as long as the T-cell count (CD4) is above 200/mm3.

**Vaccine introduction guidelines. Adding a vaccine to a national immunization programme: decision and implementation**

Yellow fever vaccine is contraindicated for infants less than 6 months of age, immune-deficient persons and persons with egg allergy. The risk of disease should be weighed against the risk of vaccination in pregnant women and in persons with symptomatic HIV infection. These are important factors to consider before planning a mass preventive vaccination campaign.
Introduction of hepatitis B vaccine into childhood immunization services. Management guidelines, including information for health workers and parents

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

The following are NOT contraindications:
- minor illness, such as respiratory tract infection or diarrhoea with temperature below 38.5°C;
- allergy or asthma;
- family history of convulsions;
- treatment with antibiotics;
- infection with HIV;
- breastfeeding;
- history of seizures (convulsions, fits);
- chronic illnesses such as chronic diseases of the heart, lung, kidney or liver;
- stable neurological conditions such as cerebral palsy and Down syndrome;
- prematurity or low birth weight;
- history of jaundice at birth.

Typhoid vaccines (WHO position paper)

There are no contraindications (to the Vi polysaccharide typhoid vaccine) other than prior severe reaction to vaccine components. Although the vaccine is safe for HIV-infected persons, the induction of protective antibodies is directly correlated to the levels of CD4 positive T-cells.

Hepatitis A vaccines (WHO position paper)

Contraindications to hepatitis A vaccination include a known allergy to any of the vaccine components.

Mumps virus vaccines (WHO position paper)

There are few contraindications to mumps vaccination. As with all live attenuated vaccines, mumps vaccine should not be administered to individuals with advanced immune deficiency or immunosuppression. Fetal damage has not been documented when mumps vaccines have been given to pregnant women. Allergy to vaccine components such as neomycin and gelatin is a contraindication to administration of the vaccine.

Tetanus vaccine (WHO position paper)

(Immunodeficiency including HIV infection is not a contraindication to (the use of TT or dT.)
Contraindications

**Pneumococcal conjugate vaccine for childhood immunization (WHO position paper)**

The only contraindication to PCV-7 immunization is a severe hypersensitivity reaction to a previous dose of the vaccine.

**Rabies vaccines (WHO position paper)**

Because rabies is a lethal disease, no contraindications to post-exposure prophylaxis following high-risk exposure exist. This also pertains to post-exposure rabies prophylaxis in infancy and pregnancy.

**Rabies vaccines (WHO position paper)**

For pre-exposure immunization, previous severe reaction to any of the vaccine components is a contraindication to further use of the same vaccine.

**Rabies vaccines (WHO position paper)**

In immunocompromised individuals, including patients with HIV/AIDS, comprehensive wound management and local infiltration with RIG, in combination with a complete intramuscular CCV series, are of utmost importance for the successful prevention of rabies. In these situations, the VNA response should be determined 24 weeks following vaccination to assess the possible need for an additional dose of the vaccine.

**Rabies vaccines (WHO position paper)**

People taking chloroquine for treatment or malaria prophylaxis can have a reduced response to ID rabies vaccination. These patients should receive the vaccine by the IM route.
**Contraindications**

**BCG vaccine (WHO position paper)**

BCG vaccination is indicated
- for all infants living in areas where TB is highly endemic (concerning HIV, see below);
- for infants and children at particular risk of TB exposure in otherwise low-endemic areas;
- for persons exposed to multidrug-resistant Mtb (impact not established.)

BCG vaccination is contraindicated
- for persons with impaired immunity symptomatic HIV infection, known or suspected congenital immunodeficiency, leukaemia, lymphoma or generalized malignant disease);
- for patients under immunosuppressive treatment (corticosteroids, alkylating agents, antimetabolites, radiation);
- in pregnancy.

**Pregnant Women**

**Measles vaccines (WHO position paper)**

Mild, concurrent infections are not considered a contraindication, and there is no evidence that measles vaccination exacerbates tuberculosis. However, vaccination should be avoided if there is high fever or other signs of serious disease. On theoretical grounds, measles vaccine should also be avoided in pregnancy.

**Hepatitis B vaccines (WHO position paper)**

Hepatitis B vaccine is contraindicated for individuals with a history of allergic reactions to any of the vaccines components.

Neither pregnancy nor lactation is a contraindication for use of this vaccine.

**Influenza vaccines (WHO position paper)**

Following nasal administration, (t)ransmission of the (influenza) vaccine virus to exposed non-immune people appears to be very rare. However, as a precaution the vaccine should not be given to highly immunosuppressed individuals or their close contacts.

Contraindications for use (of CAIV-T influenza vaccine) include anaphylactic reactions to eggs, a history of Guillain-Barré syndrome, patients aged <18 years on long-term aspirin therapy, pregnancy during the first trimester, and various states of immunosuppression.
Contraindications

Influenza vaccines (WHO position paper)

(Inactivated) influenza vaccination in pregnancy is considered safe and is recommended for all pregnant women during the influenza season. This recommendation is motivated not only by the potential severe course of influenza during pregnancy, but also in order to protect infants against influenza during their vulnerable first months of life.

Rubella vaccines (WHO position paper)

Rubella vaccination should be avoided in pregnancy because of the theoretical, but never demonstrated, teratogenic risk. No cases of CRS have been reported in more than 1000 susceptible pregnant women who inadvertently received a rubella vaccine in early pregnancy. Consequently, there is no need to screen women for pregnancy before rubella vaccination. If pregnancy is being planned, then an interval of 1 month should be observed after rubella immunization. Rubella vaccination during pregnancy is not an indication for abortion.

Yellow fever vaccine (WHO position paper)

The (yellow fever) vaccine is contraindicated in children aged under 6 months and is not recommended for those aged 6-8 months, except during epidemics when the risk of YF virus transmission may be very high. It is also contraindicated for persons with severe allergy to egg and for severely immunocompromised persons. On theoretical grounds, the 17D vaccine is not recommended during pregnancy. However, pregnant women may be vaccinated during epidemics when the risk of YFV transmission may be very high.

Yellow fever vaccine (WHO position paper)

Contraindications against YF vaccination include age less than 6 months, severe hypersensitivity to egg antigens and severe immunodeficiency. Whereas it is relatively easy to avoid immunization of the first two categories, the principal contraindications against immunization during pregnancy and in severe immunodeficiency cause significant practical problems. Fortunately, the few published cases of congenital infection caused by 17D have not been associated with fetal abnormalities. Similarly, no adverse events occurred in a small study of HIV-infected children with low CD4+ counts who received the vaccine. These observations are important considering the likelihood that many pregnant women and HIV-positive individuals, including children, will be immunized inadvertently during large-scale immunization activities in at-risk countries.

For international travellers, where laboratory and other resources are available, YF (yellow fever) vaccination may be offered to asymptomatic HIV-infected persons with CD4+ counts above 200 cells/mm3 who require vaccination for unavoidable travel. Individual expert assessments are required before YF vaccination may be offered to persons taking high-dose corticosteroids or antineoplastic drugs. If possible, tests should be performed to ensure that protective levels of neutralizing antibodies have been achieved, as primary vaccination failure is common in immunodeficient individuals.
Contraindications

Typhoid vaccines (WHO position paper)

It is not known whether this live attenuated vaccine (Ty21a typhoid vaccine) can cause fetal harm when administered to pregnant women. Ty21a can be administered to HIV-positive, asymptomatic individuals without risk as long as the T-cell count (CD4) is above 200/mm3.

Vaccine introduction guidelines. Adding a vaccine to a national immunization programme: decision and implementation

Yellow fever vaccine is contraindicated for infants less than 6 months of age, immune-deficient persons and persons with egg allergy. The risk of disease should be weighed against the risk of vaccination in pregnant women and in persons with symptomatic HIV infection. These are important factors to consider before planning a mass preventive vaccination campaign.

Mumps virus vaccines (WHO position paper)

There are few contraindications to mumps vaccination. As with all live attenuated vaccines, mumps vaccine should not be administered to individuals with advanced immune deficiency or immunosuppression. Fetal damage has not been documented when mumps vaccines have been given to pregnant women. Allergy to vaccine components such as neomycin and gelatin is a contraindication to administration of the vaccine.

BCG vaccine (WHO position paper)

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- for persons exposed to multidrug-resistant Mtb (impact not established.)

BCG vaccination is contraindicated

- for persons with impaired immunity symptomatic HIV infection, known or suspected congenital immunodeficiency, leukaemia, lymphoma or generalized malignant disease);
- for patients under immunosuppressive treatment (corticosteroids, alkylating agents, antimetabolites, radiation);
- in pregnancy.

Program Management

Yellow fever vaccine (WHO position paper)

Given the very rare, but potentially severe, adverse effects, YF (yellow fever) vaccine for travellers should be administered on strict indications only, particularly in the elderly. Restriction of YF vaccination to authorized centres is likely to promote the appropriate use of YF vaccine.
**Rabies**

**Rabies vaccines (WHO position paper)**

Because rabies is a lethal disease, no contraindications to post-exposure prophylaxis following high-risk exposure exist. This also pertains to post-exposure rabies prophylaxis in infancy and pregnancy.

**Rabies vaccines (WHO position paper)**

For pre-exposure immunization, previous severe reaction to any of the vaccine components is a contraindication to further use of the same vaccine.

**Rabies vaccines (WHO position paper)**

In immunocompromised individuals, including patients with HIV/AIDS, comprehensive wound management and local infiltration with RIG, in combination with a complete intramuscular CCV series, are of utmost importance for the successful prevention of rabies. In these situations, the VNA response should be determined 24 weeks following vaccination to assess the possible need for an additional dose of the vaccine.

**Rabies vaccines (WHO position paper)**

People taking chloroquine for treatment or malaria prophylaxis can have a reduced response to ID rabies vaccination. These patients should receive the vaccine by the IM route.

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**Research**

**Global Advisory Committee on Vaccine Safety, 34 December 2003**

There are few population-based data on the effectiveness, or otherwise, of BCG vaccine in preventing severe tuberculosis in HIV-positive infants. Given the high prevalence of HIV and tuberculosis in certain countries and of the current development of new tuberculosis vaccines, some of which are based on BCG, GACVS advises no change in the current recommendations for BCG immunization of infants in countries with a high prevalence of tuberculosis and that population-based studies should be undertaken to determine the efficacy and safety of BCG and related vaccines in HIV-negative and HIV-positive children in countries with a high endemic rate of tuberculosis.
## Rubella

**Rubella vaccines (WHO position paper)**

Rubella vaccination should be avoided in pregnancy because of the theoretical, but never demonstrated, teratogenic risk. No cases of CRS have been reported in more than 1,000 susceptible pregnant women who inadvertently received a rubella vaccine in early pregnancy. Consequently, there is no need to screen women for pregnancy before rubella vaccination. If pregnancy is being planned, then an interval of 1 month should be observed after rubella immunization. Rubella vaccination during pregnancy is not an indication for abortion.

**Schedule**

**BCG vaccine (WHO position paper)**

Given the high risk of acquiring TB and the low risk of serious adverse events following BCG vaccination of HIV-exposed neonates, WHO maintains that, in HIV-infected areas, all neonates be given BCG. Older infants or children suspected of being HIV-infected should not be vaccinated if they have symptomatic disease or other evidence of immunosuppression.

**Yellow fever vaccine (WHO position paper)**

Given the very rare, but potentially severe, adverse effects, YF (yellow fever) vaccine for travellers should be administered on strict indications only, particularly in the elderly. Restriction of YF vaccination to authorized centres is likely to promote the appropriate use of YF vaccine.

**Global Advisory Committee on Vaccine Safety, 23 December 2004**

GACVS reiterates that particular care should be taken that the (17D yellow fever) vaccine is received only by those travellers who are truly at risk of exposure to yellow fever. In addition, vaccine providers should give careful consideration to the risks and benefits for elderly travellers and should routinely enquire about a history of thymus disorder, irrespective of the age of the subject. Where a history of thymus disorder is reported, alternative prevention measures should be considered.

**Global Advisory Committee on Vaccine Safety, 34 December 2003**

(GACVS stated that) particular care should be taken that the (yellow fever) vaccine is received only by those travellers truly at risk for yellow fever exposure. Furthermore, care should be taken that routine yellow fever vaccination programmes are not jeopardized by risk/benefit ratios that may be inapplicable to the target populations in endemic countries.
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There are few population-based data on the effectiveness, or otherwise, of BCG vaccine in preventing severe tuberculosis in HIV-positive infants. Given the high prevalence of HIV and tuberculosis in certain countries and of the current development of new tuberculosis vaccines, some of which are based on BCG, GACVS advises no change in the current recommendations for BCG immunization of infants in countries with a high prevalence of tuberculosis and that population-based studies should be undertaken to determine the efficacy and safety of BCG and related vaccines in HIV-negative and HIV-positive children in countries with a high endemic rate of tuberculosis.

BCG vaccine (WHO position paper)

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BCG vaccination is contraindicated

- for persons with impaired immunity symptomatic HIV infection, known or suspected congenital immunodeficiency, leukaemia, lymphoma or generalized malignant disease);
- for patients under immunosuppressive treatment (corticosteroids, alkylating agents, antimetabolites, radiation);
- in pregnancy.

Tetanus

Tetanus vaccine  (WHO position paper)

(Immunodeficiency including HIV infection is not a contraindication to (the use of TT or dT.)
Travellers

Yellow fever vaccine (WHO position paper)

Contraindications against YF vaccination include age less than 6 months, severe hypersensitivity to egg antigens and severe immunodeficiency. Whereas it is relatively easy to avoid immunization of the first two categories, the principal contraindications against immunization during pregnancy and in severe immunodeficiency cause significant practical problems. Fortunately, the few published cases of congenital infection caused by 17D have not been associated with fetal abnormalities. Similarly, no adverse events occurred in a small study of HIV-infected children with low CD4+ counts who received the vaccine. These observations are important considering the likelihood that many pregnant women and HIV-positive individuals, including children, will be immunized inadvertently during large-scale immunization activities in at-risk countries.

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Typhoid

Typhoid vaccines (WHO position paper)

It is not known whether this live attenuated vaccine (Ty21a typhoid vaccine) can cause fetal harm when administered to pregnant women. Ty21a can be administered to HIV-positive, asymptomatic individuals without risk as long as the T-cell count (CD4) is above 200/mm3.
**Typhoid vaccines (WHO position paper)**

There are no contraindications (to the Vi polysaccharide typhoid vaccine) other than prior severe reaction to vaccine components. Although the vaccine is safe for HIV-infected persons, the induction of protective antibodies is directly correlated to the levels of CD4 positive T-cells.

**Typhoid vaccines: WHO position paper**

There are no contraindications to the use of this vaccine other than previous severe hypersensitivity reaction to vaccine components. Although the Vi polysaccharide vaccine is safe for HIV-infected individuals, the induction of protective antibodies is directly correlated to the levels of CD4 positive T-cells.

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**Contraindications**

**Yellow Fever**

**Yellow fever vaccine (WHO position paper)**

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**Yellow fever vaccine (WHO position paper)**

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Global Advisory Committee on Vaccine Safety, 34 December 2003

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Vaccine introduction guidelines. Adding a vaccine to a national immunization programme: decision and implementation

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Global Advisory Committee on Vaccine Safety, 34 December 2003

A critical and unresolved issue is the safety and efficacy of yellow fever vaccine in human subjects infected with immunodeficiency virus (HIV). It remains to be determined whether HIV-positive status materially affects seroconversion, the risk of invasion of the nervous system and of encephalopathy, the stage of HIV disease at which yellow fever vaccination should be contraindicated, and whether there are differences in the incidence of minor and major adverse effects in HIV-positive subjects.