

Preventing Vaccine-Preventable Diseases in HIV-Infected Children and Adults

1. Objective

The objectives of this chapter are to underline the role of vaccination in reducing morbidity and mortality in HIV infected individuals and to provide a list of recommended vaccines. These recommendations, although based on evidence coming mostly from high income countries (HICs), are tailored to low and middle income countries (LMIC), the settings where MSF mainly intervenes¹.

Rationale

Immunization is one of the most successful and cost-effective public health interventions preventing 2 to 3 million deaths annually (1).

The Expanded Programme of Immunization (EPI) was launched in 1974 to decrease morbidity and mortality of vaccine-preventable diseases (VPDs) worldwide. As part of the program, each country has developed a national EPI calendar that includes the list of vaccines provided and the specific age and interval at which each antigen should be received.

HIV- infected individuals are at increased risk of acquiring and dying of VPDs; this risk is particularly high in settings where vaccination coverage is low² (usually the countries where MSF intervenes) and the risk of VPDs is increased because of poor living conditions and hygiene.

Although survival of HIV infected individuals has increased in the last decades, thanks to the availability of new diagnostic tools and HAART, adults, adolescents and children with HIV still remain susceptible to dying from diseases that could be easily prevented (3,4).

There is evidence that caregivers of HIV positive children have reduced access to vaccination services (1) and leave their children under-vaccinated compared to HIV negative children of the same age. Furthermore, in countries heavily affected by the HIV epidemic, individuals receiving HAART who remain susceptible to VPDs could become sufficiently numerous to sustain transmission and jeopardize control efforts (2)

A proactive approach for vaccinating HIV positive patients also serves an important public health purpose, by reducing the pool of susceptible individuals and contributing to the control of prevalent and re-emerging infections.

¹ Vaccines against Influenza and Varicella for which specific recommendations are available for HIV positive individuals have not been taken into account as they are not systematically part of national immunization schedule in low and middle income countries (LMIC)

² Estimates of national immunization coverage per antigen and country can be found: [http://apps.who.int/immunization_monitoring/globalsummary/countries?countrycriteria\[country\]\[\]=PHL](http://apps.who.int/immunization_monitoring/globalsummary/countries?countrycriteria[country][]=PHL)

To offer free-of-charge vaccination to HIV positive individuals must be considered a priority in all settings where MSF intervenes and must be included in the package of care offered to HIV positive patients.

2. Summary of recommendations

- Although vaccine efficacy is usually compromised in advanced HIV disease, adequate responses can still be achieved when vaccines are administered early after HIV infection.
- All inactivated vaccines (anti- pneumococcus vaccines, tetanus containing vaccines, inactivated polio vaccine, ³) can be administered safely to individuals with altered immune competence. In addition, because of the risks of increased vaccine-preventable disease, severity-specific recommendations have been developed for vaccination in HIV-infected individuals beyond the routinely recommended ages for healthy individuals.
- Patients with severe cell-mediated immune deficiency should not receive live-attenuated vaccines. However, HIV-infected individuals are at higher risk than those who are immunocompetent for complications of varicella, herpes zoster, yellow fever and measles, diseases for which only live vaccines are available. The benefit of vaccination in these cases appears to outweigh the risks and HIV status should not be considered an absolute contraindication to vaccination with live vaccines.
- For specific vaccines (Hepatitis B vaccine, measles containing vaccines), due to their reduced immunogenicity in HIV-infected individuals, adapted vaccination strategies are recommended.
- For certain vaccines there may be variation in immunogenicity on the basis of viral load (improved immune response with lower HIV viral load), such as with yellow fever vaccine. For other vaccines (e.g., Hepatitis A and B, influenza, MMR, yellow fever) the immune response is better when the CD4 is higher, implying that the response is likely to be better after being on ART for a while.
- As for HIV-negative individuals or for HIV-infected who have interrupted their ART, vaccination can be resumed without repeating previous doses.
- It is crucial to ensure that HIV-infected individuals are isolated from measles cases in any Hospital or primary care setting.
- All clinicians should ensure that the vaccination status of each HIV infected individual is up to date and that information about received or delayed vaccination is included in the clinical file.
- The national Expanded Programme on Immunization (EPI) schedules of each country and the possibility for MSF to offer vaccination to specific groups not in the EPI target (by

³ For children below 6 years of age combined vaccine against diphtheria, tetanus, pertussis, hepatitis B and Haemophilus influenza type b is used for routine vaccination.

using MSF's supply chains) should be taken into account when implementing these recommendations in the field.

Table 1 summarizes recommendations for vaccines in HIV positive individuals.

Recommended in all age groups without safety concern
 Recommended only if not severely immunocompromised
 Lack of consensus

Table 1

Vaccine	Age							Re-vaccination after ART initiation
	Birth	0-11 months	12-23 months	24-59 months	6-9 years	9-26 years	>26 years	
BCG*								NO
HepB monodose*								YES
DTP-HepB-Hib								NA
Hib monovalent [¶]								NA
Tdap/dT						1 dose dTaP + 1 booster dose of dT every 10 years		NA
MCV0†		6-9 months						NO
MCV†		>9 months. 2 doses at minimum interval of 4 weeks						YES
PCV		3 doses at minimum interval of 4 weeks	2 doses at minimum interval of 8 weeks			1 dose		YES
PPSV23					1 dose at minimum interval of 8 weeks from last PCV dose + booster dose every 5 years			NA
MenACWY.‡		2 doses at 2-3 months interval		2 doses at minimum interval of 2 months				NA
HPV						3 doses 0-1-6 months		NA
Yellow Fever†		1 dose						YES
Polio vaccination	*	4 doses at minum interval of 4 weeks (IPV dose to be given with bOPV dose from 14 weeks of age)	If no proof of vaccination: a series of 4 doses of bOPV at minimum interval of 4 weeks (IPV dose to be given with 1st dose of bOPV) series completed, administer 1 dose of IPV					NA
Rotavirus [∞]		2 or 3 doses starting from 6 weeks of age and at minimum interval of 4 weeks						NA

* one dose as soon as possible after birth

‡ Like healthy children, HIV-infected children should routinely receive meningococcal conjugate vaccine at age 11 to 12 years and again at age 16. In addition HIV-infected individuals who have evidence of splenic dysfunction or complement deficiency should receive a 2-dose primary series of MenACWY administered 2 months apart followed by booster doses every 5 years

¶ There is not consensus about the need of Hib vaccination in HIV infected individuals above 5 years of age. Nevertheless Hib vaccination is recommended if there is evidence of splenic dysfunction

∞ The number of doses will depend on the vaccine available in the national EPI schedule

◊ HIV-positive infants and pre-term neonates who have received their 3 primary vaccine doses before reaching 12 months of age may benefit from a booster dose in the second year of life

† All HIV infected individuals regardless the immunological status should be vaccinated against measles and yellow fever in case of an outbreak

3.1 HIV-Exposed (but Uninfected) Children

In studies in LMIC, HIV-exposed but uninfected (HEU) infants have higher early mortality (primarily because of bacterial pneumonia and sepsis) than those born to uninfected mothers.

There is increasing evidence for insufficient maternally derived antibody levels in HEU infants that put those infants at increased risk of pneumococcal and other vaccine-preventable infections (5). Ensuring that these HIV-exposed children receive timely vaccinations should be seen as a priority in all HIV projects.

BCG vaccination:

Children who are HIV infected when vaccinated with BCG at birth are at increased risk of developing disseminated BCG disease. However, if HIV infected individuals, including children, are receiving ART, are clinically well and immunologically stable (CD4 >25% for children aged <5 years or CD4 count ≥ 200 if >5 years) they should be vaccinated with BCG.

In general, populations with high prevalence of HIV infection also have the greatest burden of TB; in such populations the benefits of potentially preventing severe TB through vaccination at birth are outweighed by the risks associated with the use of BCG vaccine. Therefore, it is recommended that in such populations:

- Neonates born to women of unknown HIV status should be vaccinated as the benefits of BCG vaccination outweigh the risks.
- Neonates of unknown HIV status born to HIV infected women should be vaccinated if they have no clinical evidence suggestive of HIV infection, regardless of whether the mother is receiving ART or not.
- Although evidence is limited, for neonates with HIV infection, confirmed by early virological testing, BCG vaccination should be delayed until ART has been started and the infant is confirmed to be clinically and immunologically stable (CD4 >25%).

In conclusion BCG ⁴ vaccination should be provided to HEU infants as soon as possible after birth except:

- if the mother has pulmonary TB. In this case, BCG vaccination should be delayed until 2 weeks after the end of IPT (provided active TB is excluded).
- If the child is known to be HIV-infected.

3.2 Recommended vaccines for HIV-positive children up to 5 years of age

In addition to ART, one of the most important interventions to prevent viral and bacterial infections in HIV-infected children is to ensure that they are timeously vaccinated according to the country EPI schedule.

As it is reported from several authors that HIV-infected children are at increased risk of under-vaccination (1), vaccination status for all recommended vaccines should be reviewed at every clinical visit and vaccination performed if necessary.

Although there is concern about the magnitude, quality or duration of immunologic response from pre-cART vaccines, there is not consensus about the need for routine re-vaccination once on effective cART (with the exception of measles and Hepatitis B vaccination (see below)

Polio vaccination (6):

Two vaccines are available against polio: Oral Polio Vaccine (OPV-a live vaccine) and injectable vaccine (Inactivated polio vaccine -IPV).

All available evidence indicates that OPV is safe to administer to HIV-infected persons. The immune response to OPV in HIV-infected and non-infected infants at standard routine immunization age does not appear to differ.

In a small proportion of individuals with a primary immunodeficiency disease, OPV immunization can lead to persistent immunodeficiency-associated vaccine-derived polio viruses (iVDPV) infections, with chronic shedding. Data suggest that acquired (secondary) immunodeficiency syndromes, such as those caused by HIV infection, do not lead to prolonged poliovirus excretion after OPV vaccination.

HIV infection does not appear to be a risk factor for vaccine-associated paralytic poliomyelitis (VAPP) or paralytic poliomyelitis caused by wild poliovirus (WPV) ⁵ (6).

⁴ The WHO Strategic Advisory Group of Experts (SAGE) revised BCG recommendations in HIV exposed and infected individuals in October 2017 and these are included in the BCG vaccine position paper (6)

In some countries that routinely use OPV, IPV is given instead of OPV to special risk groups, including HIV- infected infants (6).

The zero dose (OPV0) of bivalent oral polio vaccine (bOPV) should be administered at birth, or as soon as possible after birth, to maximize seroconversion rates following subsequent doses and to induce mucosal protection.

The primary series consisting of 3 bOPV doses plus 1 IPV dose can be initiated from the age of 6 weeks with a minimum interval of 4 weeks between the bOPV doses. If 1 dose of IPV is used, it should be given at 14 weeks of age or later (when maternal antibodies have diminished and immunogenicity is significantly higher) and can be co-administered with a bOPV dose.

HIV infected children should be vaccinated against polio according to the national EPI schedule.

Hepatitis B vaccination:

HBV transmission from mother to child in the early perinatal period remains a significant contributor to the burden of HBV-related disease in many LMIC. One dose of HepB monovalent vaccine provided as soon as possible after birth (Hepatitis Birth dose-HePB-BD) is >90 % effective in preventing HBV perinatal transmission and thus should be provided to all babies born to HIV infected mothers regardless of they are on cART or not.

The HepB series should be completed with either monovalent HepB or a combination vaccine containing HepB³. Infants who did not receive a birth dose should receive 3 doses of a HepB-containing vaccine on an age-appropriate schedule.

Measles containing vaccines:

Early measles vaccination (from 6 months of age) should be administered to all HIV infected or exposed infants due to their higher vulnerability to measles and lack of maternal antibodies.

Two doses of measles containing vaccine (MCV) are recommended for all HIV-infected individuals aged ≥ 9 months that do not have evidence of current severe immunosuppression (or if their clinical appearance suggests it) ⁶

On the basis of the safety and high rates of measles sero-protection associated with MCV re-vaccination once children are receiving cART, current recommendations are for routine MCV re-vaccination after cART (2).

⁵ The only serious adverse events associated with OPV are rare cases of vaccine-associated paralytic poliomyelitis (VAPP), which can occur in vaccinated individuals or their contacts, and the emergence of vaccine-derived polio viruses (VDPV)

⁶ Defined as individuals aged ≤ 5 years must have CD4 percentages $\geq 15\%$ for ≥ 6 months and those aged > 5 years must have CD4 percentages $\geq 15\%$ and CD4 cell counts ≥ 200 lymphocytes/mm³ for ≥ 6 months).

It is crucial to ensure that HIV infected individuals are isolated from measles cases in any hospital or primary care setting.

All HIV infected individuals, regardless of their immunological status, should be vaccinated against measles in case of an outbreak.

Anti-pneumococcus pneumoniae vaccines:

HIV-infected children have a markedly higher risk of pneumococcal infection than HIV-uninfected children (4). HIV infection is an indication to receive anti-pneumococcus pneumoniae vaccines.

Acute pneumonia, often presumptively diagnosed in children, is associated with increased risk of long-term mortality in HIV-infected children. HIV-infected children not receiving cART who present with pneumonia are more likely to be bacteraemic and die than HIV-uninfected children with pneumonia (4).

Pneumococcus conjugate vaccine (PCV10 or PCV13 depending on the one available in the national EPI schedule) is recommended in HIV infected children. The number of doses and the intervals will vary according the age of the child. For:

- Children < 12 months: 3 doses of PCV vaccine at minimum interval of 4 weeks
- Children 12-59 months: 2 doses at a minimum interval of 8 weeks

In children aged ≥ 2 years the administration of 23-valent pneumococcal polysaccharide vaccine (PPSV23) is recommended at least 8 weeks after the last dose of PCV13. A single revaccination dose should be administered 5 years thereafter⁷.

Haemophilus influenzae type b (Hib)-containing vaccines

HIV-infected children are at increased risk of Haemophilus influenza type b (Hib) infection. In a study in South African, the estimated relative annual rate of overall invasive Hib disease in children aged <1 year who had not received Hib conjugate vaccine was 5.9 times greater in those who were HIV-infected than in those who were uninfected (4).

Three doses of Hib-containing vaccine should be administered at a minimum interval of 4 weeks to all children below one year of age regardless of their HIV status. For children up to 5 years of

⁷ <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5911a1.htm#Tab1>

age, a combination vaccine against diphtheria, tetanus, pertussis, hepatitis B and Haemophilus influenza type b (DTP/HepB/Hib⁸) is used for routine vaccination.

Rotavirus vaccine:

The limited data available do not indicate that rotavirus vaccines have a substantially different safety profile in HIV-infected infants who are clinically asymptomatic or mildly symptomatic than in infants who are HIV-uninfected. Two other considerations support rotavirus vaccination of HIV-exposed or HIV-infected infants: first, the HIV diagnosis may not be established in infants born to HIV-infected mothers before the age of the first rotavirus vaccine dose (6 weeks); and second, vaccine strains of rotavirus are considerably attenuated. HIV-exposed or -infected infants should receive rotavirus vaccine according to the national EPI schedule for uninfected infants.

Meningococcal vaccine (MenACWY9):

HIV infection is associated with an increased risk of meningococcal disease.

In many LMIC MenACWY is not part of the national EPI schedule although the vaccine is available in the MSF catalogue and is used for staff vaccination and as part of outbreaks response. In contrast to healthy children, the primary series of MenACWY for all HIV-infected children aged ≥ 9 months is 2 MenACWY doses 2 to 3 months apart for children aged 9 to 23 months and at least 2 months apart for children aged 2 to 10 years.

Yellow Fever vaccination:

In endemic countries one dose of Yellow Fever Vaccine is recommended for all HIV-infected individuals aged ≥ 9 months who do not have evidence of current severe immunosuppression (or their clinical appearance suggests it)⁶. Booster dose is not required as lifelong protection is conferred by one dose.

All HIV infected individuals regardless of the immunological status should be vaccinated against yellow fever in case of an outbreak

⁸ This vaccine is often called Pentavalent as five antigens are included in the formulation

⁹ Quadrivalent-conjugate vaccines

3.2 Recommended vaccines for HIV-positive children aged > than 5 years, adolescents and adults

Although VPDs represent a high burden in HIV-infected individuals they don't have access to free-of-charge vaccination as they are not part of EPI target.

Polio Vaccination (6):

If there is no proof of vaccination, a series of 4 doses bOPV at a minimum interval of 4 weeks should be provided (IPV to be given with 1st dose of bOPV). If a primary series of bOPV has been completed, one dose of IPV should be provided.

Tetanus, diphtheria, and pertussis vaccination

Apart from the primary vaccine series, a single dose of a vaccine containing tetanus toxoid, reduced diphtheria toxoid, and reduced acellular pertussis (Tdap) should be administered to all individuals aged 6 years and older who have not received Tdap previously. This strategy is used to address waning immunity against pertussis. Universal administration of tetanus toxoid and reduced diphtheria toxoid (Td) boosters every 10 years is also recommended because of waning immunity against tetanus and diphtheria over time¹⁰.

One dose of tetanus-containing vaccine should be administered to adults and adolescents who were not previously vaccinated or for which vaccination status is uncertain.

One dose of Tdap should be administered to women during each pregnancy, preferably in the early part of gestational weeks 27–36.

In addition to the routine booster doses needed to confer long lasting immunity against tetanus, increased risk of tetanus has been reported after surgical circumcision with the collar compression device method (PrePex). Because of this, vaccination status against tetanus must be assessed in all HIV pos individual undergoing surgical circumcision. The administration of two doses of tetanus containing vaccine at 6 and 2 weeks respectively prior to the surgery is recommended.

¹⁰ Tetanus containing vaccine recommended in children from the age of 6 and adults is Tdap (tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccine)

Measles-containing vaccines:

Two doses of MCV vaccine are recommended for all HIV-infected individuals who do not have evidence of measles immunity (or have experienced measles in the past) and/or have evidence of current severe immunosuppression (they have a CD4 \geq 15% (if <5 years old) or a CD4 cell count \geq 200 (if \geq 5 years old).

It is crucial to ensure that HIV-infected individuals are isolated from measles cases in any hospital or primary care setting.

All HIV infected individuals regardless of the immunological status should be vaccinated against measles in case of an outbreak.

Anti-meningococcus vaccine (MenACWY⁶):

Accumulating evidence indicates that HIV infection increases the risk of meningococcal disease and HIV infection is an indication for routine MenACWY vaccination.

Like healthy adolescents, those HIV-infected should routinely receive meningococcal conjugate vaccine at age 11 to 12 years and again at age 16.

In addition HIV-infected individuals who have evidence of splenic dysfunction or complement deficiency should receive a 2-dose primary series of MenACWY vaccine administered 2 months apart followed by booster doses every 5 years.

Human Papillomavirus Vaccine (HPV):

Research has firmly established that HPV infection and HPV-associated disease prevalence are higher in HIV-positive populations (8). Linkage studies between HIV/AIDS and cancer registries have shown a 2- to 22-fold increase in cervical cancer among HIV-positive women. Furthermore, higher numbers of multiple HPV infections have been observed more frequently in HIV-positive women when compared with HIV-negative women (9).

Two HPV vaccines are available in LMIC: a quadrivalent vaccine (HPV4) and a bivalent vaccine (HPV2). An HPV nonavalent vaccine is licensed and used only in HICs (HPV9). These vaccines differ in the virus serotypes against which they confer protection. Both HPV vaccines available for LMIC prevent over 95% of HPV infections caused by HPV types 16 and 18, and have some cross-protection against other less common HPV serotypes which cause cervical cancer. The

advantage of Quadrivalent vaccine is that this also protects against HPV types 6 and 11 which cause ano-genital warts.

The immunogenicity and efficacy of HPV vaccines in HIV infected individuals appear to be preserved and the potential benefit of vaccination in this group is particularly great owing to their increased risk of HPV-related disease, including cervical cancer. HIV testing should not be a prerequisite before routine HPV immunization.

According to recent WHO recommendations, countries should explore opportunities for integration of HPV vaccine into HIV programs.

HPV vaccination is recommended in all HIV-positive patients from age 9 years through age 26 years (3). The vaccine should be administered according to a 3-dose schedule (0.5 mL at 0, 2, 6 months). No data are available at the moment on use of the 2-dose schedule for bivalent and quadrivalent vaccines in persons infected with HIV.

Anti-pneumococcus vaccination:

Streptococcus pneumoniae is the leading bacterial opportunistic infection in HIV-infected individuals. Anti-retroviral treatment (ART) in HIV-infected children reduces their risk of invasive pneumococcal disease (IPD) but the risk remains 20- to 40-fold greater compared with age-matched general population. HIV positive adults have 10–300 times greater susceptibility to IPD compared with HIV uninfected individuals, and are at increased risk of recurrent IPD (10). Several studies have demonstrated that PCV are safe in the HIV-infected persons and, in high income countries PCV is actually among the recommended vaccines in HIV-positive adults. Additionally, in settings with high TB prevalence, knowing that the presentation of both pneumococcal and TB disease may be rather non-specific in HIV-positive patients, vaccinating HIV-positive people against pneumococcus could reduce the misdiagnosis and unnecessary treatment of TB.

A single dose pneumococcal conjugate vaccine (PCV13 or PCV 10 according to the country schedule) should be routinely administered to HIV-infected individuals who did not previously receive a dose of PCV13.

In addition to PCV the administration of 23-valent pneumococcal polysaccharide vaccine (PPSV23) is also recommended at least 8 weeks after the last dose of PCV13. A single revaccination dose should be administered 5 years thereafter.

Yellow Fever vaccination:

In endemic countries one dose of Yellow Fever Vaccine is recommended for all HIV-infected individuals aged ≥ 9 months who do not have evidence of current severe immunosuppression (or their clinical appearance suggests it)⁶. A booster dose is not required as lifelong protection is conferred by one dose.

All HIV infected individuals regardless of the immunological status should be vaccinated against yellow fever in case of an outbreak.

Hepatitis B vaccination

All HIV-infected patients are at increased risk of hepatitis B virus (HBV) infection due to shared modes of transmission (3). Hepatitis B virus (HBV) co-infection is responsible for high morbidity and mortality among people infected with Human Immunodeficiency Virus (HIV). The advent of combined antiretroviral therapy (cART) has led to an increase in survival among HIV-infected patients. Complications of viral hepatitis have ranked as one of the leading causes of death in this population in recent years. Vaccination is the most effective way to prevent HBV infection and its consequences.

All HIV-infected patients susceptible to HBV should receive hepatitis B vaccination. The magnitude and duration of immunogenicity to hepatitis B vaccination in HIV-infected adults is significantly lower than in HIV-seronegative healthy adults. Several studies have been conducted to identify the best regimen in HIV positive individuals (4 double-dose, 4 single-dose or 3 double-dose) but there is not yet consensus about the optimal vaccination strategy.

While additional studies are needed to determine the most effective schedule, the default international recommendation remains the administration of 3 doses at 0, 1 and 6 months and the vaccination series for HBV should be initiated at the first visit regardless of CD4 cell count (11).

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