HUMAN VACCINES & IMMUNOTHERAPEUTICS
2016, VOL. 12, NO. 11, 2729–2741
http://dx.doi.org/10.1080/21645515.2016.1207013

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REVIEW

Immunization of HIV-infected adult patients — French recommendations

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ABSTRACT

Human immunodeficiency virus (HIV)-infected patients remain at increased risk of infection including vaccine-preventable diseases. Vaccines are therefore critical components in the protection of HIV-infected patients from an increasing number of preventable diseases. However, missed opportunities for vaccination among HIV-infected patients persist and vaccine coverage in this population could be improved. This article presents the French recommendations regarding immunization of HIV-infected adults in the light of the evidence-based literature on the benefits and the potential risks of vaccines among this vulnerable population.

ARTICLE HISTORY
Received 18 February 2016
Revised 25 May 2016
Accepted 24 June 2016

KEYWORDS
HIV infection; immunization; immunocompromised patients; influenza; live vaccines; pneumococcal infections; recommendations; vaccine; vaccine-preventable diseases

In the era of combination antiretroviral treatment (cART), HIV-infected patients remain at risk of vaccine-preventable infectious diseases, including pneumococcal and influenza infections. This population is also at increased risk of exposure to other viruses, such as hepatitis A virus (HAV) and hepatitis B virus (HBV).

Improving the vaccine coverage of people living with HIV to prevent infectious complications is part of the management of these patients in order to sustain good virological response or prevent co-morbidities. Conscious of this, societies of various countries provide vaccination guidelines for HIV-infected patients. In 2012, the French High Council for Public Health published recommendations for the vaccination of immunocompromised and/or asplenic people.[1] These recommendations were updated in 2014.[2]

The aim of this paper is to give insights into these recommendations, which may sometimes differ from the American, British or European ones[3-5] and provide evidence on vaccination in this population in the light of the literature.

General principles

The efficacy of vaccine schedules in HIV-infected patients is based generally on the results of immunogenicity studies rather than on clinical data. In HIV-infected patients, the immunogenicity of vaccines is reduced when HIV replication is not controlled by antiretroviral treatment and/or when the CD4 count is below 500/mm^3, and even more below 200/mm^3. Moreover, the duration of seroprotection is shorter than in non-immunocompromised individuals and may necessitate more frequent boosters. A better immune response to vaccination is achieved when the vaccines are administered early after HIV infection.[6] It is preferable to vaccinate HIV-infected people after the HIV viral load become undetectable and, if possible, when the CD4 count >200/mm.

In HIV infected patients vaccines are generally well tolerated. However, live attenuated vaccines are contraindicated in patients with severe immunodeficiency (CD4 count lower than 200/mm^3).

The vaccines recommended in France for HIV-infected adults are:

- As in the general population:
  - Diphtheria –Tetanus –Poliomyelitis –Pertussis
  - Meningococcal C (for patients < 24 years)
  - Human Papillomavirus (HPV) (in girls aged 11–19 years and men who have sex with men (MSM) under 26 years)
- Specifically recommended:
  - Influenza with trivalent inactivated vaccine (as quadrivalent inactivated are non available until now)
  - Pneumococcal with combination of conjugate vaccine and polysaccharide vaccine
  - Hepatitis B virus (HBV) for non immune patients
  - HPV vaccination in boys aged 11–19 years,
- Other vaccines are recommended only if there is a specific indication and/or if there is evidence of no immunity:
  - Hepatitis A virus (HAV) in MSM, drug addicts, patients with chronic viral HBV or HCV or other liver diseases, travelers in endemic areas
  - Measles–Mumps–Rubella (if not immune and CD4 cell count> 200/mm^3),
  - Varicella (if not immune and CD4 cell count > 200/mm^3)

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- Meningococcal C (previously unvaccinated MSM aged over 24).

BCG is contraindicated regardless of immune status in HIV-infected adults.

Vaccination schedules may be different for the HIV-infected population in comparison to the general population (see Table 1). It is recommended to check immune response by antibodies testing after vaccination against HBV and HAV.

Vaccine coverage

Regarding HBV vaccination, a cross-sectional study performed in HIV-infected patients included in a hospital-based cohort in France in 2011 showed that 61.9% of 2467 patients had received at least one dose of the vaccine.[7] In comparison vaccine coverage in French adolescents in the general populationwas 42.9%.[8] Factors significantly associated with vaccination in HIV infected people were a younger age, male gender, belonging to the group of MSM, and follow-up by an experienced physician. In Brazil, HBV vaccine coverage in HIV infected people was found to be 57.4% in a cross-sectional study published in 2013.[9] In the UK in an observational cohort conducted on 37 000 HIV-infected patients seroprotection rates increased from 42% to 58.2% between 1996 and 2009.[10] A 7-year retrospective analysis of a cohort of HIV-infected adults seen in an urban ambulatory care center in the UK demonstrated that only 49% of patients eligible for HBV vaccination received at least 3 doses of the vaccine and 30% did not receive any dose.[11]

Seasonal flu vaccine coverage was estimated to be 30.9% in a French hospital-based cohort analyzed in 2011,[7] compared to 37.5 to 48.5% in global high risk populations.[12] In the USA, in a prospective observational cohort study of 9131 HIV-infected patients analysed during 8 influenza seasons (1999–2008), the mean percentage of patients annually vaccinated against influenza was only 35%.[13]

In France, pneumococcal vaccine coverage has increased in HIV-infected people since the 2009 A/H1N1 influenza pandemic: it reached nearly 65% in a patient cohort study conducted in 2011, whereas it was only 3.3% in several French studies conducted before the pandemic.[7,14,15] For individuals over 65 years old it ranges from 4.8 to 8.3 % depending on comorbidities.[16]

For other recommended vaccinations, vaccine coverage remains low. For instance, in an Austrian cohort of HIV-infected patients, seroprotection rates were 84% for diphtheria, 51% for tetanus, and 1% for pertussis; almost half of the patients would require measles-mumps-rubella (MMR) vaccination.[17,18] In a preliminary report, vaccination coverage for MMR was 4.5 % in a French cohort.[19] Similarly, in a French study conducted in 250 patients of sub-Saharan African origin treated with HAART, seroprotection rates were 69.0% for diphtheria, 70.7% for tetanus, and 85.9% for yellow fever. Only 64.4% of patients had protective antibodies against the 3 poliomyelitis strains and 18.6% of patients had no HBV markers.[20]

Inactivated and subunit vaccines

Diphtheria, tetanus, poliomyelitis and pertussis vaccines

HIV-infected adults should receive tetanus, diphtheria, poliomyelitis and pertussis immunizations similar to routine recommendations for adults. These vaccinations are well tolerated among HIV-infected people. Immunogenicity appears lower and shorter-lived than that observed among the general population.[21-23]

Universal administration of tetanus toxoid, inactivated polio vaccine and reduced diphtheria toxoid boosters every 10 years is recommended (see Table 1) because of waning immunity against tetanus and diphtheria over time.[24]

Preparations combining acellular pertussis, low-dose diphtheria, tetanus and inactivated polio (dTaP/IPV) are licensed in France for use in adults as boosters at age 25 (catch up to the age 39)

Recommendations differ between countries for pertussis and poliomyelitis vaccines related to different schedules in the general population (no booster for polio vaccine in adults in the USA and acellular pertussis vaccine for pregnant women) (see Table 1)

Haemophilus influenzae type b (Hib) vaccine

The incidence of *Haemophilus influenza* disease is low among HIV-infected adults. Most reported cases in adults with advanced HIV disease involved non typable strains for which the vaccine is not protective.

Haemophilus influenzae type b (Hib) vaccine is not recommended in HIV-infected adults except in particular situations (asplenia).

Pneumococcal vaccination

Before the ART era, invasive pneumococcal infections (IPD) were extremely frequent, with a 100-times higher risk in HIV-infected adults compared with HIV-uninfected individuals.[25] With the advent of ART, the incidence of these infections dropped by half, but remains much greater than in non-infected people.[26,27] In the developed world, the annual incidence of IPD among HIV-positive adults is estimated to be 245 cases/100 000.[28] Such infections are associated with high mortality.[29] The primary risk factor for pneumococcal infection in HIV-infected patients is immunodeficiency. Other risk factors include smoking, intravenous drug addiction and uncontrolled HIV replication (>500 copies/mL).[27] Given the risk of IPD among HIV-infected persons, guidelines have recommended pneumococcal vaccination since the mid-1990s.

Two kinds of pneumococcal vaccines are currently available: a non-conjugated polysaccharide vaccine containing 23 serotypes, which has been available since 1983; and a 7-valent conjugate vaccine that was marketed in 2000, and has been replaced by the 13-valent vaccine since 2010. The clinical efficacy data for the non-conjugated polysaccharide vaccine in immunocompromised persons are contradictory. In a case-control study conducted in HIV-infected adults, vaccination appeared to be protective against pneumococcal infections, including for the most severely immunocompromised patients.[30] However, in a randomized placebo-controlled study, an increase of all-cause pneumonia was observed in the vaccine group; the mortality rate in both groups remained similar.[31] In 2010, a review of studies on the clinical efficacy of the non-conjugated polysaccharide vaccine in HIV-infected adults did not yield any definitive evidence of a reduction in pneumonia and pneumococcal infection.[32] The loss of the antibodies induced by the non-conjugated polysaccharide vaccine occurs particularly rapidly in the most severely immunocompromised patients or in patients not

Table 1. Comparison of vaccines recommendations for HIV infected people in France, US,UK and Europe (EACS) Differences between other countries guidelines and French ones were underscored.

	French recommendations 2014		US recommendations 2013		UK recommendations 2015[e]		EACS recommendations 2015	
		Comments		Comments		Comments		Comments
Diphtheria, tetanus, poliomyelitis, acellular pertussis	For all patients[a]as in the general population	Boosters every 10 yrs (dTP)	Diphtheria, tetanus, acellular pertussis For all patients as in the general population[a] Poliomyelitis: recommended only for children as in general population[a]	Boosters every 10 yrs (Tetanus toxoid and reduced diphtheria toxoid (Td) Tdap during each pregnancy	Diphtheria, tetanus, poliomyelitis: For all patients as in the general population[a] Acellular pertussis: HIV positive adults meet general indications for pertussis vaccination including HIV positive pregnant women (between week 28 and week 32 of pregnancy)[a]	Boosters every 10 yrs (dTP)	No EACS specific Guidelines, vaccines as recommended in each country	
Pneumococcal disease	For all patients[a]	-In previously unvaccinated adults: 1 dose of the 13-valent conjugate vaccine followed by one dose of the 23-valent polysaccharide vaccine at least 2 months later. -In patients previously vaccinated with the 23-valent polysaccharide vaccine since at least 3 years: 1 dose of the 13-valent conjugate vaccine followed by one dose of the 23-valent polysaccharide vaccine at least 2 months later.	For all patients[a]	In previously unvaccinated adults $\geq$ 19 years-old: 1 dose of the 13-valent conjugate vaccine followed by one dose of the 23-valent polysaccharide vaccine at least 2 months later. In patients previously vaccinated with the 23-valent polysaccharide vaccine since at least 1 year: 1 dose of the 13-valent conjugate vaccine followed by one dose of the 23-valent polysaccharide vaccine at least 2 months later.	For all patients[a]	A single dose of PCV 13 (should be given at least 3 months after any use of PPV-23) For HIV positive adults who meet the indications for PPV-23 vaccination within the national program (aged> 65 years or with co-morbidity other than HIV) follow general guidance and also receive a single dose of PPV-23 (PPV-23 should be given at least 3 months after any PCV-13	For all patients[a]	Prefer 13-Valent Vaccine
Influenza	For all patients[a]	Every year	inactivated influenza vaccine for all patients[a]	Every year	For all patients[a] For close contacts of HIV positive persons	Quadrivalent may be preferred where available	For all patients[a]	Every year
Hepatitis A	At-risk non immune patients[a] (chronic liver disease; HBV or HCV co-infection; MSM; intravenous drug addiction; traveling to endemic countries).	Two injections administered 6 months apart – Depending on antibody titer after the second dose, a third injection should be administered.	At-risk non immune patients[a] (chronic liver disease; HBV or HCV co-infection; MSM; intravenous drug addiction; traveling to endemic countries Hemophiliacs and other individuals who receive clotting factor concentrates).	Two injections administered 6 months apart – Depending on antibody titer after the second dose, a third injection should be administered.	HIV-positive adults at risk of hepatitis A exposure[a] (household and sexual contacts of infected persons, travelers to countries where HAV is common, MSM, injecting and non-injecting drug user individuals at risk of infection during outbreaks, those with occupational exposure to HAV (laboratory workers, sewage workers), persons with hemophilia, persons with special needs living in residential institutions and their carers) Pre-vaccination testing for evidence of HAV immunity cost-effective in some clinical settings : people who were born or lived in extensive periods in geographical areas that have a high to intermediate HAV endemicity, MSM, IDU, those aged > 50 years	Patients with CD4>350 : 2 vaccine doses at 0 and 6 months Patients with CD4 <350 : 3 dosses at 0, 1 and 6 months For patients at continued risk of exposure : a boosting vaccine dose every 10 years	At-risk non immune patients[a] (chronic liver disease; HBV or HCV co-infection; MSM; intravenous drug addiction; traveling to endemic countries).	Two injections administered 6 months apart – Depending on antibody titer after the second dose, a third injection.

(*Continued on next page*)

Table 1. (*Continued*)

	French recommendations 2014		US recommendations 2013		UK recommendations 2015[e]		EACS recommendations 2015	
		Comments		Comments		Comments		Comments
Hepatitis B	For all patients[a] without serological HBV markers	In non vaccinated patients: 4 double-dose injections at M0, M1, M2 and M6 Titrage of anti-HBs antibodies levels after vaccination and once a year; booster injection if anti-HBs < 10 mIU/mL.	For all patients[a] without anti-HBs markers	3 single-dose injections at M0, M1 and M6[b] 3 or (4) double-dose injections at M0, M1, (M2) and M6[c] Titrage of anti-HBs antibodies levels after vaccination and once a year; booster injection if anti-HBs < 10 mIU/mL.	For all patients[a] without serological HBV markers HBsAb levels <10IU/L after primary vaccine course : 3 further vaccine doses at monthly intervals (high dose(40 μg) with Engerix or HBvaxPro and standard dose(20 μg) with Fendrix (preferred in non responders)	Yeast-based vaccines :EngerixB total 40 μg, HBvaxPro 40 μg formulation When using the adjuvanted vaccine Fendrix the standard 20 μg formulation be given An ultra-rapid vaccination course (3 standard-dose administrations given over 3 weeks) can be considered only in selected patients with CD4 > 500/ mm^3	For all patients[a] without serological HBV markers	In non vaccinated patients: 4 double-dose injections at M0, M1, M2 and M6 Titrage of anti-HBs antibodies levels after vaccination and once a year; booster injection if anti-HBs < 10 mIU/mL.
Meningococcal disease And in MSM in several geographical areas (New York city, Los Angeles) Recommended for persons with a risk factor [a] (medical such as aplenic patients, persistent complement component deficiencies)	Meningococcal C: As for the general population up to 24 years. In MSM (> 24 years)[a] Meningococcal B non-recommended specifically in HIV infected patients	Two doses of the conjugate vaccine 6 months apart If traveling to endemic areas, or in cases of anatomical or functional asplenia or complement or properdin deficiencies, quadrivalent conjugated vaccines: 2 doses 6 months apart.	Meningococcal conjugate quadrivalent: As for the general population[a]: Recommended for persons with a risk factor (medical, occupational, lifestyle, or other indication)					
	Two doses of the conjugate vaccine 8 weeks between doses. Two doses	HIV positive adults follow the general indications for meningococcal vaccination[a] :<25 years of age who have not been previously vaccinated or received the last MenC vaccine below the age of 10 years : MenC and MenACWY and possibly MenB according to national guidance functional or anatomical asplenia or persistent complement deficiency : MenC, MenB and/or MenACWY, according to vaccination history at risk of exposure through travel : MenACWY at risk of exposure through an outbreack : MenC, MenB or MenACWY	Two vaccine doses at the interval of 2 months(in order to increase immunogenicity)	As recommended in general population[a]				

Human Papilloma Virus	In girls and boys[a] (11–19 years).	In young girls: 3 doses depending on the marketing authorization of the vaccine. In boys: 3 doses of quadrivalent vaccine (M0, M2, M6).	Male and female ≥ 26 years-old not vaccinated in childhood[a]	For female: 9-, quadri-, or bi-valent vaccine: 3 doses at 0, 1–2, 6 months For male: quadri- or 9-valent vaccine ACIP recommendations	Previously unvaccinated HIV-positive men and women aged up to 26 years[a] Previously unvaccinated HIV-positive MSM aged up to 40 years[a] Previously unvaccinated HIV-positive women aged up to 40 years[a] Considered for HIV positive patients who develop high grade HPV disease (with the aim of potentially reducing the risk of recurrences)[a]	Three doses of the quadrivalent 4vHPV at 0,1–2, and 6 months Use 9vHPV once it becomes available in place of 4vHPV	For all patients[a]	
BCG	Contraindicated		Contraindicated		Absolutely contraindicated		Contraindicated	
Measles, mumps, rubella	Only for patients with CD4 cell count > 200//mm^3 non immune patients (routine serological testing for measles and routine serological testing for rubella in women), non pregnant women of childbearing age	In adults: 2 doses of measles, mumps, rubella vaccine at least 1 month apart.	Only for patients with CD4 cell count > 200//mm^3 non immune patients	In adults born after 1957: 2 doses of measles, mumps, rubella vaccine at least 1 month apart for secondary school students in postsecondary educational institutions; Work in a healthcare facility; Plan to travel internationally One dose for other patients	Only for patients with CD4 cell count > 200/mm^3 non immune patients (routine serological testing for measles and routine serological testing for rubella in women), non pregnant women of childbearing age After exposure to measles : MMR vaccine within 3 days of contact if CD4> 200/mm^3 and stable viral load suppression on ART		No EACS specific guidelines	
Varicella	Non immune adolescents and adults, non pregnant women of childbearing age Only for patients with CD4 cell count > 200/mm^3	Two doses 4–8 weeks apart.	Non immune adolescents and adults born after 1979 non pregnant women of childbearing age Only for patients with CD4 cell count > 200/mm^3	Two doses 3 months apart	Non immune adolescents and adults, non pregnant women of childbearing age Only for patients with CD4 cell count > 200/mm^3	Two doses 3 months apart	Recommended for all HIV positive VZV seronegative patients with CD4 cell count > 200/mm^3	Two doses 4–8 weeks apart.
Zoster	Not recommended		Contraindicated[b] ACIP has not made recommendation Recommended for patients ≥ 60 years old and with CD4 cell count > 200/mm^3 [d]		We recommend VZV IgGseropositive patients who have CD4>200 and preferably are established on ART be offered one dose of the shingles vaccine (in line with national age related indications From the age of 60 years		no specific recommendations	
Yellow fever	Mandatory in French Guiana and for travels incountries where yellow fever is endemic Only for patients with CD4 cell count > 200/mm^3	One injection	Mandatory for travels in countries where yellow fever is endemic Only for patients with CD4 cell count > 200/mm^3	One injection	Persons aged < 60 years and CD4> 200 for travels in countries where yellow fever is endemic		Only for patients with CD4 cell count > 200/mm^3	One injection
Haemophilusinfluenzae serotype b	For all children as in the general population		For all children as in the general population		Not recommended routinely in hiv-positive adults	Hiv positive adults with aspenia, splenic dysfunction or complement deficiency should receive one parenteral dose of a Hib containing vaccine (Hib/Men C in UK)	No specific recommendations	

[a]whatever CD4 cells count
[b]Recommended by Panel on Opportunistic Infections in HIV-Infected Adults and Adolescents. Guidelines for the prevention and treatment of opportunistic infections in HIV-infected adults and adolescents: Recommendations from the Centers for Disease Control and Prevention, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. http://aidsinfo.nih.gov/contentfiles/lvguidelines/adult_oi.pdf
[c]2013 IDSA Clinical Practice Guideline for Vaccination of the Immunocompromised Host
[d]Aberg JA, Gallant JE, Ghanem KG, et al. Primary care guidelines for the management of persons infected with HIV: 2013 update by the HIV medicine association of the Infectious Diseases Society of America. Clin Infect Dis 2014; 58:e1.
[e]accessible at http://www.bhiva.org/documents/Guidelines/Vaccination/2015-Vaccination-Guidelines.pdf.

virologically controlled by cART.[33] Conjugated vaccines induce higher immunogenicity and have been tested in HIV-infected patients. A randomized double-blind placebo-controlled clinical trial in HIV-infected adults conducted in Malawi demonstrated the efficacy of 2 doses of the 7-valent conjugate vaccine, which reduced invasive pneumococcal infections by 74% in secondary prophylaxis.[34] A review of immunogenicity studies conducted in HIV-infected adults showed that response to conjugated vaccines was improved when vaccination was carried out in patients treated with antiretroviralsindependently of baseline CD4+ cell count.[35] Regarding the 13-valent conjugate vaccine, clinical data are lacking. However satisfactory immunogenicity and safety data, including in patients previously vaccinated with the polysaccharide vaccine have been reported.[36-38] There are no head to head trials comparing non conjugated polysaccharide vaccines and conjugate vaccines in HIV-infected patients. The prime-boost vaccination strategy was assessed in HIV-infected adults. The immunogenicity of the 23-valent polysaccharide vaccine may be increased by administering a dose of 7-valent conjugate vaccine 1 month earlier.[39] The strategy allows the number of serotypes covered by pneumococcal vaccination to be widened.

None of the studies conducted with the different pneumococcal vaccines revealed any safety problems or unfavourable impact on the course of the HIV disease in this population.

Given the demonstration of better immunogenicity with the conjugated vaccine and the theoretical risk of hypo responsiveness induced by the non-conjugated vaccine, we suggest using a strategy that combines the conjugated vaccine followed by the non-conjugated vaccine with an interval of at least 2 months between the two.

Pneumococcal vaccination is recommended for HIV-infected patients according to the following vaccination schedules: for previously unvaccinated adults, a dose of 13-valent conjugate vaccine followed by a dose of 23-valent polysaccharide vaccine at least 2 months after the 13-valent conjugate vaccine; for adults previously vaccinated with the 23-valent polysaccharide vaccine, an interval of at least 3 years is recommended before revaccinating with a dose of 13-valent conjugate vaccine followed 2 months later by a dose of 23-valent polysaccharide vaccine. At present, data are lacking for recommendations to be made for vaccine boosters against pneumococcal infections.

Influenza vaccine

HIV-infected patients are at high risk of influenza-related complications and death.[40,41] Data from the pre-cARTera indicated elevated hospitalization rates and substantial excess mortality due to pneumonia or influenza during influenza seasons.[42,43] Dramatic declines in hospitalization and mortality rates were observed with the introduction of cART with hospitalization rates comparable to rates in other high-risk groups but mortality rates that remain greater than in the general population.[43,44] Two types of influenza vaccines are available in France; the trivalent inactivated vaccine which contains 2 Influenza A strains and one Influenza B strain for parenteral administration and the trivalent live attenuated vaccines for administration by nasal spray approved for use in France in healthy children.[2] The quadrivalent inactivated vaccine is not currently available in France.

Inactivated influenza vaccines are less immunogenic in HIV-infected patients than in HIV-uninfected individuals. Immune response to influenza vaccines has been positively correlated with increasing CD4 cell counts, particularly for CD4 cell count $> 200/mm^3$, and have been inversely correlated with HIV viral load.[45] Studies conducted during the 2009 A/H1N1 influenza pandemic showed the superiority of adjuvanted vaccines both for inducing and maintaining immune response against influenza.[46,47] Few studies have investigated the clinical efficacy of the influenza vaccine in this population but they agree that the vaccine is clinically effective, with a relative risk reduction of 66 % for the development of symptomatic disease in HIV-infected individuals.[48,49] A randomized trial conducted in Africa in 2008 showed a 75.5% reduction in risk in a population of HIV-infected adults who had a CD4 count $>100/mm^3$ and no associated co morbidities.[50] A recent systematic review indicates that influenza vaccination is effective in preventing laboratory confirmed influenza infection in HIV-infected adults with a pooled efficacy of 85%.[51] Influenza infection, as well as influenza vaccination, may sometimes cause a temporary, moderate increase in HIV viral load without significant alteration of the CD4 lymphocyte count.[52]

Annual administration of the seasonal influenza vaccine is recommended for all HIV-infected patients. It is the trivalent inactivated vaccine that is used in this population. The live attenuated vaccine via the intranasal route is contraindicated in HIV-infected people with CD4 lymphocyte count lower than $200/mm^3$. The vaccination schedule is the same as that for the general population.

Hepatitis A vaccine

Many HIV-infected patients are at risk of being infected by HAV, especially MSM, drug addicts and travelers in endemic areas. In HIV-infected patients, HAV is more severe and is accompanied by higher and longer viremia and fecal excretion of the virus. Patients with chronic viral HBV or HCV, or liver disease of another origin, are at risk of severe HAV-related complications.

There are no data on the clinical efficacy of HAV vaccine in HIV-infected patients. Its safety profile is excellent. The immunogenicity of the inactivated vaccine, which is more than 90% in the general population, is lower in HIV-infected patients, particularly in patients with a CD4 count lower than $500/mm^3$. In a study conducted in France in HIV-infected adults, seroconversion was achieved in only 39% of patients after a vaccine dose.[53] Seroconversion rates after 2 doses were between 48.5% and 93.9%.[54] Factors associated with poorer response include a low CD4 count, uncontrolled HIV viral load and coinfection by HCV. Studies that have compared vaccination response on the basis of the number of doses received (2 versus 3) showed that the proportion of responders and titer of antibodies were higher after the third dose.[53,55] The duration of protection is shorter than in HIV-uninfected subjects. After 4 years of follow-up, 85% of vaccinated patients who were responders have maintained a level of protective antibodies.[56] The duration of protection is linked to the control of HIV virus replication at the time of vaccination.[57]

As in the general population, vaccination against HAV is recommended in non immune (negative for anti-HAV IgG)

HIV-infected patients in certain situations, including HCV and/or HBV co infection, chronic liver disease, and patients at risk of exposure (MSM, intravenous drug addicts, travelers in endemic areas). The administration schedule comprises at least 2 vaccine doses. The first 2 doses are at 6 to 12 months intervals. A third dose is administered if seroconversion assessment after the second injection reveals an antibody titer that is lower than the protection threshold (< 20 UI/ml).

Hepatitis B vaccine

Due to shared modes of transmission of HIV and HBV, the prevalence of HIV–HBV co infection is high, particularly in low income countries. In France, in 2004, 37.6 % of HIV-infected people were anti-HBc positive and 7% presented a chronic HBV infection (HBsAg+ or HBV DNA+).[58] Progression from chronic HBV to advanced liver disease and hepatocellular carcinoma is shown to be more rapid in HIV-infected patients than in HBV mono infected patients. Screening for HBV markers and vaccination of non immune patients are highly recommended in HIV-infected patients, even if the response to vaccination is lower than in the general population.

The response to the standard vaccine schedule – 3 intramuscular (IM) doses at 0, 1 and 6 months – is lower than that of immunocompetent individuals. In a recent systematic review, response rates varied from 34 to 88.6% depending on the study, whereas they are >90% in the general population.[54] HBV vaccine immunogenicity is strongly linked to the patient immunovirological status, better response being reported in patients with undetectable HIV viral load and good immune reconstitution on treatment (CD4 cell count > 350–500/mm^3).[54,59–62] Induced anti-HBs antibodies titeris generally lower in HIV-infected people and declines more rapidly over time.[24] HCV co infection is associated with lower vaccine response.[63]

Among the strategies to improve the immunogenicity of HBV vaccination in HIV-infected patients, intensifying the vaccination schedule is associated with better response. In a controlled trial, 210 patients were randomized to receive either the standard vaccination schedule or a double dose at 0, 1 and 6 months. The seroconversion rate was significantly higher in the second arm only in the subgroup of patients with more than 350 CD4/mm^3.[64] In a large French multicenter trial, 437 patients with CD4 cell count > 200/mm^3 were randomized into 3 arms: the standard schedule of 3 IM injections (weeks 0, 4, 24); 4 IM double-dose injections on weeks 0, 4, 8 and 24; or four intradermal (ID) injections with a low vaccine dose (4 μg) on weeks 0, 4, 8 and 24. The percentage of responders to vaccination was significantly higher in the 4 IM double-dose (82%) and the 4 low-dose ID (77%) arms compared with the standard schedule (65%). At week 24, the geometric mean antibody titer was significantly higher in the IM double-dose (795 mIU/mL) and ID low-dose (104 mIU/mL) arms compared with the standard schedule (55 mIU/mL). An anti-HBs titer>100 mIU/mL (high responders) was obtained in 74% of patients who received 4 IM double doses compared with 53% in the ID arm and 40% in the standard arm.[65] The duration of response was longer in the 4 IM double-dose arm than in the standard schedule (P = 0.003) but did not differ between the 4 low-dose ID arm and the standard schedule group (P = 0.39).[64] A randomized study in Thailand in patients with a CD4 count >200/mm^3 and undetectable viral load on ART confirmed a higher antibody titer with an intensified vaccination schedule (4 IM double-dose), even if the response rate did not seem to be different from the standard vaccination schedule.[66]

In HBV vaccine non-responders, it appears to be preferable to wait for the CD4 count to rise above 350/mm^3 before considering revaccination, if the initial HBV vaccination was performed while the CD4 lymphocyte count was <200/mm^3.[62] Restarting vaccination using an intensified schedule of 4 double-dose does not improve the response rate compared with the standard schedule; however, the double-dose regimen resulted in a more robust and durable immunological response, with a safety profile similar to that of the standard-dose regimen.[67]

For patients who do not respond to vaccination, an annual screening for HBV markers (HBsAg, anti-HBs and anti-HBc antibodies) must be performed. The use of at least one active medication against HBV in the antiretroviral treatment of these patients is also recommended.[68]

In people who display isolated anti-HBc, a dose of vaccine may be suggested to test for an anamnestic response (measurement of anti-HBs). If there is no response and no detectable HBV DNA, vaccination against HBV with a reinforced triple double-dose scheme should be offered to these patients.[69,70]

Vaccination against HBV is recommended in all HIV infected adults without HBV serological markers (negative HBsAg, and anti-HBs and anti-HBc antibodies). An intensified vaccination schedule of 4 IM double-dose (40 μg) on M0, M1, M2 and M6 must be proposed in particular to patients with poor response factors (male gender, age > 40 years, smoker, detectable HIV viral load, and HCV co infection).[62] It is recommended that the anti-HBs antibodies titer obtained be checked between 1 and 2 months after the last vaccine injection. In patients who respond to vaccination, an annual serological check-up is recommended in order to propose a booster dose if the anti-HBs titer falls below the protective titer of 10 mIU/mL.

If there is no response to vaccination (anti-HBs < 10 mIU/mL), additional double-dose injections (40 μg in adults) should be administered while allowing 1 to 2 months between each injection and measuring anti-HBs 4 to 8 weeks after each injection. This must be continued until a protective titer is achieved, but without exceeding 2 additional injections in adults, or 6 injections in total.

Meningococcal vaccine

Invasive meningococcal infections have been reported in HIV-infected patients but it is not certain whether HIV infection is an independent risk factor. A single retrospective study suggests a higher risk in HIV-infected patients living in New York City, with a 10-fold increased risk (95% CI, 7.2 to 14.1); particularly in patients with less than 200 CD4/mm^3; data on smoking status and co-morbidities are missing.[71] Outbreaks of invasive meningococcal C infections among MSM, with or without HIV infection, described in the US and Europe, have prompted vaccination campaigns targeting MSM.[72,73] A case–control study, conducted in the context of a prolonged outbreak of serogroup C meningococcal disease among MSM in New York City, identified 2 key risk factors: having a sexually

transmitted disease during the year before diagnosis and having used methamphetamine or cocaine during the month before illness onset.[74]

Immunogenicity data of meningococcal C conjugate vaccine HIV-infected patients are limited. The only comparative study to date, conducted in Brazil in HIV-infected children, adolescents and young adults, showed a lower immunogenicity compared to seronegative controls (72.1% of the HIV-infected patients were responders to a single dose of meningococcal C conjugate vaccine - this rate increased to 81.4% when those receiving a second dose were included, while 100% of the non-HIV-infected persons achieved protective levels after receiving the first dose).[75] Factors associated with seroconversion were: never had AIDS clinical event, undetectable HIV viral load at immunization and higher CD4 nadir.[76]

In a phase I/II trial evaluating the safety and immunogenicity of a quadrivalent A,C,W135,Y conjugate vaccine (MCV4) in HIV-infected children and young adults (11–24 years old), the responder rates to serogroups A, C, W-135, and Y were 68%, 52%, 73%, and 63%, respectively. Lower CD4%, higher HIV viral load, and CDC Class B/C diagnosis were associated with lower response to serogroup C.[77] The administration of a second dose of MCV4 6 months after the initial dose improves response rates.[78]

Policies for meningococcal vaccines vary between countries considerably (see Table 1), based upon local attack rates of illness.

In France, HIV adults follow the general indications for meningococcal vaccination: meningococcal C conjugated vaccination (MenC vaccine) is part of the general population schedule and is also specifically recommended for MSM aged over 24 who frequent gay bars, cafes, clubs and other meeting places using a single-dose schedule. In contrast to the UK, there are no current French guidelines for meningococcal B vaccination (MenB vaccine) in the general population as well as in HIV infected patients. In the UK, recommendations for HIV infected people follow general population policy using quadrivalent A,C,W,Y conjugate vaccines (MCV4) as well as in the US where specific recommendations exist driven by local outbreaks (see Table 1).

Specific indications for meningococcal vaccination in HIV-infected individuals in France are the same as those for the uninfected patients and include:

- Age between 11 and 18 years and catch-up vaccination to the age of 24 years (MenC vaccine)
- Asplenia (MCV4+ MenB),
- Complement component or properdin deficiency (MCV4 + MenB),
- Travel exposure (MCV4)
- Exposure during an outbreak
- MSM aged over 24 (Men C with a single-dose schedule)

Human papillomavirus (HPV) vaccine

High-risk HPV types are detected in almost all cervical cancers (approximately 70% of cervical cancers are due to types 16 and 18); high-risk HPV infection is also associated with cancer of the vulva, vagina, penis and anus and play a role in the development of some oropharyngeal cancers. Several studies have highlighted the high frequency of HPV infection in the HIV-infected population, in both men and women. A prospective South African study in heterosexual couples followed for 24 months has shown increased incidence rates of HPV infections in HIV-infected women (57 vs. 27 new infections/1000 person-months) and in HIV-infected men (80 versus 52 cases/1000 person-months) compared with HIV-negative people. In a recent meta-analysis, the prevalence of oncogenic HPV anal infections was considerably higher in HIV-infected MSM (74%) than in non-HIV-infected MSM (37%).[79] HPV infection in HIV-infected patients tends to persist and progress more frequently to intraepithelial mucosal lesions and cancerous lesions. The incidence of cervical cancer is high in HIV-infected women with 21.5 per 100 000 woman-years in France (CI95%: 6.6–36.5) in 2011. In the US, the standardized incidence rate of cervical cancer in HIV-infected women is 2.9 (CI95%: 1.9–4.2), which is significantly higher than in non-HIV-infected women. French data from the FHDH cohort have shown an association between a low CD4 cell count and the risk of cervical cancer.[80] However, the effect of cART on the incidence of this cancer continues to be debated.[81] All HIV-infected patients, including women, have a risk of squamous-cell anal cancer that is judged to be 29 times greater than that of the general population.[82] HIV-infected HSM are almost 60-times more likely to develop anal cancer than the average HIV-negative individual.[83]

Two sub-unit vaccines are currently in use for the prevention of HPV disease in France; the bivalent vaccine (Cervarix®, GlaxoSmithKline HPV 16 and 18) and the quadrivalent vaccine (Gardasil®, Merk, HPV type 6,11, 16, 18). The nonavalent vaccine is not yet available in France. Schedules for other countries are listed in Table 1.

To date, there are no data on the clinical efficacy of HPV vaccines in the HIV-infected population. Available results come from immunogenicity and safety trials. The quadrivalent-vaccine has been studied in HIV-infected children and adults. In cART treated patients who have more than 350 CD4/mm^3, the seroconversion rates are high and comparable with those of the noninfected population, but with lower antibody titers. The clinical safety profile is good and there is no impact on HIV viral load or CD4 lymphocytes count. HIV-infected adolescents and young adults of both sexes aged 13 to 27 years whose disease was controlled with treatment and who had a CD4 count $>$ 350 received 3 doses of the quadrivalent vaccine (M0, M2, M6). Their antibody response 1 month after each injection, and then at M12 and M18, was compared with that obtained in age- and sex-matched seronegative adolescents. Seroconversion rates were similar (85% vs. 91%), and the antibody titer obtained 1 month after the third injection was lower than in seronegative controls.[84] A study carried out on the quadrivalent vaccine in HIV-infected men (median age of 44 years) has shown good vaccine immunogenicity without any impact on CD4 count or viral load.[85] The ACTG A5240 study was carried out on women aged 13 to 45 years who were stratified according to CD4 count and showed that the quadrivalent vaccine was well tolerated and resulted in high seroconversion rates; immunogenicity was lower in women with CD4 lymphocyte counts $<$200/mm^3 or a HIV viral load $>$ 10 000 copies/mL.[86]

In the HPV-020 study carried out in South Africa, 22 non-HIV-infected women and 42 HIV-infected women (WHO clinical stage 1) received the bivalent vaccine. All female subjects

were seropositive for HPV 16 and 18 a month after the third dose (M7) on the ELISA test. Their seropositivity for HPV 16 and 18 persisted until M12. Geometric mean titers of antibodies were lower among HIV-infected women. The clinical relevance of this observation is unknown. No information exists regarding protection against persistent infection or precancerous lesions in HIV-infected women.[87]

The high HPV infection rate and associated mucosal lesions are good reasons to recommend HPV vaccination in HIV-infected patients.

While awaiting clinical efficacy data in HIV-infected patients, HPV vaccination is recommended in young girls and in boys infected with HIV at the age of 11 years and as catch-up vaccination up to the age of 19 years. In young girls infected with HIV, a 3-dose schedule is used depending on the vaccines' marketing authorization. Vaccination must be accompanied by continued cervical smear screening in accordance with the recommendations. In HIV-infected boys, the quadrivalent vaccine using a 3-dose schedule according to the marketing authorization (M0, M2, M6) is recommended. HPV vaccination is also recommended in previously unvaccinated HIV positive MSM aged up to 26 years with 3 doses of the quadrivalent vaccine (M0, M2, M6). In both populations, vaccination must be accompanied by continued screening for anal and genital lesions.

Live attenuated vaccines

Tuberculosis vaccination

BCG is contraindicated in HIV-infected adults because of the risk of local/regional or disseminated BCG disease.[88] The contraindication to BCG can be certified, for instance for healthcare professionals.

If exposed to tuberculosis, HIV-infected patients should be closely monitored, and in some cases need to undergo tuberculosis chemoprophylaxis. The risk of professional exposure to tuberculosis must be avoided for HIV-infected care staff, at least by means of standard and airborne hygiene precautions.

Measles, mumps, rubella (MMR) vaccine

Re-emergence of measles occurred recently in developed countries due to inadequate vaccine coverage.[89-91] In developing countries the mortality rate associated with measles remains high, and increased in HIV-infected patients; access to vaccination is a priority.

In HIV-infected adults, the immunogenicity of measles vaccine is reduced.[92]

HIV-infected patients in developed countries should be vaccinated according to the provided recommendations for the general population if CD4 count $>200/mm^3$, with 2 doses of the trivalent MMR vaccine. In women of childbearing age, it must be ensured that they are not in the early stages of pregnancy and that pregnancy is avoided in the 2 months following vaccination, because of a theoretical risk of teratogenesis.

In the event of exposure to measles, vaccination can be performed in the 3 days following exposure in those who have no history of measles and who have not received 2 doses of the measles vaccine, if CD4 count $>200/mm^3$. If vaccination is contraindicated (immunodeficiency or pregnancy), intravenous immunoglobulins should be offered.

Varicella vaccination and zoster vaccination

The varicella vaccine was evaluated in HIV-infected adults with CD4 count $>400/mm^3$ in the prevention of shingles. Safety was good but immunogenicity was low.[93] Two cases of vaccine-associated varicella with visceral involvement were reported in one HIV-infected child and one adult with undiagnosed HIV infection at the time of vaccination.[94] The potential seriousness of varicella in HIV-infected adults highlighted in a case reporting a fulminant evolution underline the usefulness of the varicella vaccine.[95]

Vaccination against varicella is recommended in HIV-infected adolescents and adults who have no history of varicella and who are none immune. This vaccination is contraindicated in cases of advanced immunodeficiency (CD4 $<200/mm^3$) and in pregnant women. Two injections of varicella vaccine are recommended, allowing 4 to 8 weeks between the 2 doses. Acyclovir can be used in the event of post-vaccination varicella. In the event of exposure to varicella, vaccination may be performed in the 3 days (and up to 5 days) after exposure in those who have no history of varicella or whose vaccination history is uncertain provided that their CD4 count $>200/mm^3$ and that they are not pregnant. If vaccination cannot be performed specific immunoglobulins should be offered. Women of childbearing age must avoid becoming pregnant during the month following vaccination.

In the cARTera, the incidence of shingles in HIV-infected people has significantly decreased, but it remains higher than that in the general population.[96] Recent data from a French cohort show that the risk of shingles is 3 times greater than in the general population.[97] The zoster vaccine that is currently available (Zostavax®) is a live attenuated vaccine that is contraindicated in immunocompromised subjects. This vaccine was evaluated in a randomized placebo-controlled phase II trial (ACTG 5247) in 295 HIV-infected subjects with CD4 count $>$ $200/mm^3$ and virologic suppression on cART. The safety data were reassuring despite an increased rate of reactions at the injection site in the vaccine group; immunogenicity was higher in subjects with CD4 $>$ $350/mm^3$.[98]

On the basis of current knowledge, zoster vaccination cannot be recommended in HIV-infected people.

Seasonal influenza vaccination with live attenuated vaccine

The live attenuated influenza vaccine is well tolerated and immunogenic in immunocompetent children and adolescents.[99] It may be used according to its marketing authorization in HIV-infected children aged 24 months to 17 years for whom annual influenza vaccination is recommended.

This live intranasal vaccine is contraindicated in the immunocompromised. In such cases the inactivated influenza vaccineis recommended.

Yellow fever vaccination

This vaccination is mandatory for French Guiana residents and for those traveling to countries where yellow fever is endemic.

The risk of post-vaccination disease, though low, represents a contraindication for patients with CD4 count <200/mm^3.[100] In case of contraindication in previously vaccinated people quantitative measurementof yellow fever antibodies can be performed.

The vaccine immunogenicity is reduced in HIV-infected patients; therefore performing a post-vaccination serological check-up may be warranted.[101] A recent Cochrane review underlines the importance of viral replication control and immune reconstitution for improving the efficacy and safety of the vaccine in this population.[102]

In conclusion, vaccination coverage in HIV-infected patients is still inadequate, despite vaccination being an essential element of disease management in preventing infections preventable by immunization. A systematic verification of the immunization status of HIV-infected patients should be carried out by the physician in charge. Training and awareness regarding vaccination recommendations must be reinforced among doctors who take care of HIV-infected patients. At the diagnosis of HIV infection, the patient's vaccinations must be reviewed and boosters scheduled on the basis of immunovirological data. The most severely immunocompromised patients (CD4 < 200/mm^3) have a greater risk of infections however since they present lower response to vaccines, it is recommended to wait for immune reconstitution and viral replication control after cART introduction.

Disclosure of potential conflicts of interest

No potential conflicts of interest were disclosed.

Acknowledgment

We thank Ms GlynThoiron for the English editing of the manuscript.

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