

FRENCH EXPERTS GROUP'S  
RECOMMENDATIONS FOR MEDICAL  
MANAGEMENT OF HIV INFECTION

HIGHLIGHTS AND  
RECOMMENDATIONS

2008

**FRENCH GUIDELINES**  
**DIRECTED BY PROFESSOR Patrick YENI, Paris**

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## INTRODUCTION

Today roughly 85,000 people suffering from HIV infections benefit from government sponsored health care services, and this number is increasing every year. In 2006, 6,300 people discovered that they were HIV-infected. The epidemic is thus still active, and the recrudescence of STIs since 2001, especially syphilis, is a sign of slackened HIV sexual transmission measures, in particular in homosexual men. The interest of reinforcing prevention messages, and improving screening techniques, both for the general public and targeted groups, will be completely explained in a chapter of the report dedicated to this subject.

Early screening of infected people is even more necessary, as we see that one third of patients receive health care services only at an advanced stage of Aids. This delay is even more harmful, as today we dispose of spectacular therapeutic progress that has taken place over the past few years with new medicine available, including new therapeutic classes. There are not only many more new treatments, but they have also become easier to take and better tolerated by patients, while being more active on resistant viruses. Today, over 80 % of patients benefiting from government health care receive triple combination therapy, and in at least three fourths of them, the blood viral load is undetectable. New cases of Aids are thus constantly decreasing, and HIV-infected status has gone from the state of being a rapidly fatal disease to being a chronic disease. Unfortunately, progress concerning immune reconstitution has been less striking and often only partial when treatment is started at a late stage. This is a supplementary argument that, associated with arguments of efficacy and better tolerance for new medicine, brings us to recommend that treatment be initiated even at an earlier stage in the disease than the one we recommended in 2006. Carrying out large scale screening on subjects in the early stages of the HIV disease is an essential objective to be able to initiate treatment at an earlier stage, and to allow the treatment to fulfil not only its virological objectives (an undetectable viral load) but also its immunological goal (reconstitution of normal immunity, with a CD4 rate exceeding 500/mm<sup>3</sup>). Using rapid-acting HIV serology tests could facilitate new screening strategies; because their simplicity coupled with almost immediate results would allow high risk populations to be reached more easily.

If the evolution of the HIV infection is better controlled in patients receiving treatment, the need for global care remains important in 2008. Whereas serious infectious and tumorous pathologies that

complicate the infection and define Aids have become less frequent, for most of them, the incidence of other illnesses has remained stable or increased. This is particularly true for cardio-vascular diseases and cancers. The HIV infection is now considered as a factor of cardio-vascular risk in itself, consequence of the infection, of side-effects of treatments, or as risk factors frequently associated with this population. Beside cancers that are a part of the Aids definition, today many other types of cancers can be observed, such as lung cancer, Hodgkin's disease, anal cancer and other types, that are globally two to three times more frequent than in the general population and now constitute the majority of cancers diagnosed. Aging of patients could also contribute to an explication of this evolution.

All in all, if mortality and the number of hospitalisations have decreased, morbidity has diversified. This highlights the necessity of multidisciplinary health care, no longer limited to immuno- virological parameters. In particular eventual co-infections by the hepatitis virus must be taken into account (seen in almost one-third of HIV-infected patients,) as well as cardio-vascular risks factors and side-effects of long-term therapies. This multidisciplinary aspect contributes to the complexity of health care needed for the HIV infection, which associates, an experienced HIV practitioner as well as a general practitioner, a large number of specialists in other fields, health professionals in charge of educational and social, psychological and dietary aspects, as well as activists. This complex organisation needs, in particular, an adaptation of health care at different levels: in the social field, it is important to ensure that eventual difficulties (multiple in the framework of this infection,) do not harm long-term therapeutic success maintenance. In the field of health care organisation, public hospitals find it difficult to cost HIV infections in the framework of a given cost for a given activity, because of its multidisciplinary character and its social constraints. This leads to long term hospitalization in intensive care which shows the absence of fluidity in the downstream health-care system, in spite of its diversity. The Regional Coordination of the fight against HIV infections (COREVIH,) a new organisation with its first year results in this report, will contribute towards better knowledge of regional difficulties in the HIV infection network.

Clinical research is at the origin of continuous therapeutic progress described in this report. It is currently very active, whether its instigators be institutions (and in particular the ANRS, whose key role here must be underlined,) or private (the pharmaceutical industry ;) this leads us to hope the improvement in health care for patients will continue.

As in the past, the many experts who participated in this report stem from different horizons and have spared no efforts to offer recommendations that will become an invaluable guide for all health stakeholders. The implication of the activists must be specially highlighted. May I thank them warmly

here. The fact that so many recommendations in the 2006 report have been followed by the French Ministry of Health is an additional justification of their work.

Patrick Yeni

### STRENGTH OF RECOMMENDATIONS

A	Strong evidence to support the recommendation
B	Moderate evidence to support the recommendation
C	<u>Insufficient evidence to support the recommendation</u>

### QUALITY OF EVIDENCE RATING SCALE

Ia,b*	At least 1 randomized clinical trials; meta analysis of randomized clinical trials
IIa,b	non randomized clinical trials; cohorts or case-control studies; meta-analysis of cohorts or case-control studies
III	Expert opinion

Roman numeral reflects the nature of the evidence supporting the recommendations

\*a= published in the peer-reviewed literature; b= presented in abstract form at peer-reviewed scientific meetings

**HIGHLIGHTS AND RECOMMENDATIONS  
FRENCH EXPERTS GROUP REPORT 2008  
DIRECTED BY PROFESSOR PATRICK YENI**

Epidemiology
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### Highlights

- This chapter demonstrates the importance of descriptive epidemiology, the poor step-sister of epidemiology in France outside the realm of HIV infection. It is important to maintain this research effort by improving on the shortcomings observed (prisons, mental health, etc.).
- The availability of antiretroviral combinations has engendered spectacular progress in terms of controlling viral replication and reducing the morbidity associated with AIDS, as well as mortality from all causes.
- The epidemic is still actively spreading, especially among men who have sex with men
- The population receiving therapy is aging, thanks to progress in treatment and the fact that infections are appearing later in life, and one should emphasise delayed diagnosis in patients over age 50.
- Morbidity is becoming more diverse due to increased risk among HIV-infected people of diseases not constituting AIDS, such as cardiovascular problems, metabolic illnesses, indeterminate cancers and neurological problems.
- The data presented show:
  - therapy starting too late for a significant number of patients;
  - the gain to be had in adopting the treatment objective of a rate of CD4 > 500/mm<sup>3</sup> for all patients. This objective has currently been reached in only 40% of patients treated, whereas the viral load is less than 50 copies/mL in 75% of cases.

In total, all these results lead us to believe that it is still possible to improve the treatment of HIV infection in France by earlier detection and treatment of people living with HIV and by adopting treatment strategies that limit the morbidity linked to HIV-infection or to treatments for it given over the long term.

### The Experts Group recommends:

- Doing epidemiological studies in prisons and in the field of mental health;
- Assessing the impact of new recommendations for earlier antiretroviral treatment based on patients' immunological status.
- Not forgetting to report every new diagnosis of HIV infection.



## Detection and New Methods of Prevention

### Highlights

France is estimated to have nearly 36,000 cases of people who are unaware they are infected with HIV or who do not seek out treatment.

The number of new cases in 2006 is estimated to be 6,300.

In France in 2006, despite substantial detection work, there is a time lag in access to hospital care: 33.3% of patients only obtain care at an advanced stage (AIDS or  $CD4 < 200/mm^3$ ).

The appearance on the market of rapid tests will allow us to offer very short turnaround times, provide increased confidentiality under certain circumstances, and integrate screening into locally-based operations directed toward specific populations.

The COREVIHs [regional HIV care management groups] can contribute to the evaluation and promotion, at local levels, of screening strategies.

### The Experts Group recommends:

- That government authorities define new screening strategies targeted based on areas of prevalence and aimed at the most susceptible population groups (men who have sex with men, groups originating from Sub-Saharan Africa, prison populations, etc.).
- The use, in certain situations, of rapid tests, especially in the CDAGs [free and anonymous testing clinics] and CIDDISTs [STD screening info centres].
- That improvements be made to the CDAG/CIDDISTs.
  1. to move toward an organisation consolidated under one roof with a single source of financing and a single focus of action;
  2. to adopt a broad approach to prevention and screening for HIV, hepatitis and STD infections, and of post-exposure treatment as is already the case for STDs;

by organising so-called "non-institutional" serological testing

## Antiretroviral Treatment

### Highlights

- The initiation of antiretroviral therapy must be preceded by a multi-disciplinary approach to maximise adherence to treatment (A III).
- The goal of antiretroviral therapy is to reach and maintain an undetectable viral load ( $< 50$  copies/mL) and a CD4 lymphocyte count  $> 500/mm^3$  (A).
- There is no benefit to stop anti retroviral treatment (A IIa).

- The persistence of viral replication during treatment leads to a risk of accumulating resistant mutations, which reduces the chances of success of subsequent treatments (A IIb) and has a negative effect on CD4 lymphocytes (A IIa).
- Cases of virological failure must be reviewed in multi-disciplinary staff (A III). It is critical that an experienced team be consulted in situations where treatment options seem to be limited. (A III)

### **The Experts Group recommends:**

#### ***In relation to initial antiretroviral treatment***

- Performing a genotypic resistance test when HIV infection is diagnosed and basing the selection of a first-line treatment on this data (A IIIa).
- In symptomatic patients (with an opportunistic infection other than tuberculosis, other Category C illness or marked or recurrent symptoms in Category B, of the CDC 1993 classification, including kidney disease linked to HIV), initiating antiretroviral therapy within two weeks, taking into account treatment of the opportunistic infection and any eventual interactions (A Ia);
- In asymptomatic patients with a CD4 count lower than 200/mm<sup>3</sup>, immediately initiating antiretroviral therapy along with prophylaxis for the opportunistic infections (A Ia).
- In asymptomatic patients with a CD4 count of between 200 and 500/mm<sup>3</sup>:
  - initiating antiretroviral therapy as soon as their CD4 count reaches 350/mm<sup>3</sup> (A IIa) and not varying it unless there are case-specific grounds for doing so (B Ib).
  - considering initiating antiretroviral therapy in patients with a CD4 count > 350/mm<sup>3</sup> if the viral load is > 100,000 copies/mL (A IIa), if the CD4 count is dropping rapidly or is < 15%, in cases of co-infection with HCV or HBV, in cases of kidney disease linked to HIV, in patients over age 50 and/or with cardiovascular risk factors.
- In asymptomatic patients with a CD4 count higher than 500/mm<sup>3</sup>:
  - not using antiretroviral treatment, except in special cases, according to in adequate data (C III).
- opting for one of the following two therapeutic regimens: 2 NRTI + 1 PI/r or 2 NRTI + 1 NNRTI (A Ia).
  - for a PI/r-based regimen: (abacavir or tenofovir) + (emtricitabin or lamivudin) + (atazanavir/r or fosamprenavir/r or lopinavir/r) (A Ia).
  - for an NNRTI-based regimen: (abacavir or didanosin or tenofovir) + (emtricitabin or lamivudin) + efavirenz (A Ia).
- Not prescribing abacavir for patients who are carriers of the HLA-B57\*01 allele (A Ia).

#### ***For management of an effective first-line treatment***

- Considering a change in therapy only if the viral load has been < 50 copies/mL for at least 6 months (A III) and not including in a follow-up therapy any drug known to have side-effects or for which there is evidence of resistance (A Ia).
- If, for tolerance and/or compliance factors, one wishes to change an effective first-line PI/r-based therapy regimen:

- considering a combination of 2 NRTI + 1 NNRTI, effective and likely to improve the lipidic parameters (A Ia).
- not using a combination of 3 NRTIs in patients with a history of failure in treatments containing NRTIs (A Ia). This may only be considered, on a case-by-case basis, for patients who have never had a previous treatment failure if the expected benefits seem greater than the risk of lower antiviral potency (B Ia).
- not using the combination of one NNRTI with one PI/r (A Ia).
- Not resorting to intermittent treatments (A Ia).

***For cases of virological failure:***

- Regardless of the conditions of the failure (first line, subsequent lines, including following multiple failures), focussing on the goal in question and maintaining a plasma viral load < 50 copies/mL (A III);
- analysing the failure, examining the clinical situation, the CD4 level and viral load, compliance, tolerance and potential drug interactions (A III).
- taking into account treatment history in order to optimise the choice of the new antiretroviral treatment, and doing a genotypic test during treatment (A IIIa). Any available results of previous testing (A III) and, when available, therapeutic drug monitoring (TDM) should also be taken into account (B III).
- Combining at least two new active drugs, one of which should ideally belong to a treatment class not yet used (A IIa).
- If at most one drug remains active and the CD4 count is < 200/mm<sup>3</sup>, attempting to maximise the treatment using the current drugs or ones already used, potentially increasing the doses of PI and drawing on TDMs (A III).
- Not interrupting therapy for any period of time whatsoever (A Ia).

<b>Management of patients living with HIV infection</b>
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**Highlights**

- Care provided for seropositive person must be global, integrating therapeutic, psychological, preventive and social factors.
- Health care for a patient undergoing antiretroviral therapy is a complex process and requires the involvement of an experienced specialised hospital team and close coordination with the attending physician.
- At the time of first-line antiretroviral therapy, the frequency and potential seriousness of side effects justify informing the patient of the treatment goals. Educational support is essential in caring for patients infected with HIV.
- Compliance is one of the key elements of successful therapy. Declared side effects depression are some of the major factors that negatively affect compliance. Structured approaches designed to improve compliance have been found to be effective.
- Recent epidemiological and behavioural data indicate a need consider the quality of the patient's affective and sexual life.

- Even though effective antiretroviral therapy greatly reduces the risk of transmission, the systematic use of condoms during any sexual contact remains the preventive norm.

### **The Experts Group recommends (A):**

- Performing a hospital-based work-up at least annually, updating information on HIV infection, its treatment, its side effects and co-morbidities.
- Organising sessions specifically devoted to therapy education within healthcare institutions and networks.
- Performing annual screening for syphilis and HCV and HBV infection in the absence of vaccination in men having sex with men not systematically using condoms.
- Offer annual gynaecological examinations for women and proctologic exams for men.
- Considering offering special, individual support sessions for:
  - patients who have just learned of their condition, especially in the acute HIV infection stage.
  - patients who have not yet received antiretroviral treatment or whose therapy has been interrupted.
  - patients with detectable plasma viral load.
- Ensuring that patients receive information about treatment following exposure to a viral risk of transmission.
- Systematically offering screening to the sexual partners of people living with HIV.
- Adopting an attentive and non-judgemental approach that allows patients to express their views on the quality of their sexual life, their problems with using condoms and their circumstances.
- Providing, on an individual basis, to patients not using condoms systematically, prevention messages focussing on the importance of having an undetectable blood viral load
- In patients with a CD4 count  $> 200/\text{mm}^3$ , in addition booster vaccinations, more specific vaccinations (pneumococcal, influenza, Hepatitis B) and vaccinations for travellers should be included.

<h2>Complications of HIV and Antiretroviral Therapy</h2>
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### **Highlights**

- Long-term complications found over the course of HIV infection - lipodystrophy, lipidic or glucidic metabolic problems, cardiovascular morbidities, changes in bone structure - are multi-faceted, linked to the antiretroviral treatments as well as to the HIV infection.
- HIV infection is now considered to be a cardiovascular risk factor in and of itself.
- HIV infection may accelerate certain aging processes.

- Patients with chronic hepatitis C and/or B show a higher risk of drug hepatotoxicity, which is even greater if cirrhosis is present.
- Improvements in care given to HIV-infected patients and experience acquired in transplants and with hepatitis allow us to consider liver transplants for patients on dialysis or at the cirrhosis stage.

**The Experts Group recommends:**

- As part of treatment for metabolic complications:
  - observance of hygieno-dietetic rules and stopping smoking,
  - modifying the antiretroviral therapy by using the least toxic compounds,
  - before considering, if necessary, specific treatment for these metabolic anomalies:
- Including in the annual work-up an assessment of the various metabolic risks;
- Assessing, in the short and mid term, the effect of new compounds on the complications and co-morbidities associated with antiretroviral therapies in the context of therapeutic trials;
- Screening for early kidney damage linked to HIV and/or antiretroviral treatments;
- Seeking to diagnose cognitive impairment in patients over age 50 and/or co-infected with HCV in the event of complaints of amnesia or problems with organising one's daily life. It is important to insist on examinations and treatments for cognitive impairments.

HIV Infection and Procreation
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## **SCREENING**

### **Highlights**

- French health policy mandates that all pregnant women be systematically offered screening for HIV, contingent on their being informing and consenting.
- Screening of fathers-to-be is all too rarely done, and should be promoted more.

**The Experts Group recommends (A IIa):**

1. Offering serological testing at the 6<sup>th</sup> month consultation for pregnant women who are seronegative but exposed to a viral risk, especially if their partner is seropositive for HIV or his HIV status is unknown.
2. Offering a rapid test to any pregnant woman whose HIV status is unknown upon arrival in the labour room [when she is admitted to the hospital while going into labour];
3. Offering HIV screening to all fathers-to-be.

## **WANTING TO HAVE CHILDREN**

### **Highlights:**

- People infected with HIV should be able to express a legitimate desire to have children and receive information and support in making decisions.

- Providing complete information to both partners is critical.
- Women's fertility decreases with age, especially in the event of HIV infection, which is good reason not to put off screening and treatment for women after age 35.
- If the man is HIV-infected, MAP [medically assisted procreation] helps ensure maximum prevention of transmission of the risk.
- There is no situation in which, given current knowledge, one can state that the risk of sexual transmission of HIV is negligible. Some doctors recommend natural procreation in cases where the plasma viral load is undetectable over the long term in the infected man, where the prognosis of fertility is favourable, and in the absence of a related STD in both partners, but this approach has not been evaluated;

**The Experts Group recommends:**

1. Referring people wishing to have children to a specialised pre-conception consultation (B III);
2. Recommending and explaining artificial insemination for women infected with HIV to prevent infecting the seronegative partner (B III);
3. Selecting antiretrovirals that are compatible with pregnancy when an infected woman plans to have a child (B IIa);
4. Recommending MAP for couples where the man is infected and who want to have a child (A IIa);
5. If a duly informed couple does not wish to use MAP, medical care involving a precise assessment of the couple's case may result in a way to help reduce risks on a case-by-case basis, but this does not constitute a valid alternative to MAP for preventing the risks of sexual transmission.

**PREGNANCY**

**Highlights:**

- In a woman infected with HIV, the pregnancy is at risk and requires treatment and multi-disciplinary care.
- Preventive treatment of mother-child transmission (MCT) has two objectives: obtaining viral load suppression in the mother in the 3rd trimester and limiting drug-related side effect in the mother and child, while preserving the mother's future therapeutic options.
- The risk of mother-child transmission (MCT) of HIV-1 is 0.3% if the mother's viral load at the time of delivery is < 50 copies/mL.
- In women treated during pregnancy, the main causes of failure of prevention are: a high viral load in the mother in the last trimester and at delivery, and a short period of treatment.
- Compliance is generally good in pregnant women, but problems with follow-up and compliance are the biggest cause of prevention failure today.
- The toxicity of the antiretrovirals taken during pregnancy remains a major concern, and vigilance is recommended for the newest drugs.

**The Experts Group recommends:**

1. Informing the woman and, as much as possible, the father of the child, of the risk/benefit ratio of preventive treatment for MCT (A III).
2. Continuing, in a woman treated before her pregnancy, with an effective and well-tolerated antiretroviral treatment unless it comprises a drug that is counter-indicated or not recommended (A III). In so far as possible (resistance, tolerance, related pathologies), the antiretrovirals should be selected from among those recommended for first-line use with pregnant women.
3. Beginning MCT prevention therapy at the end of the 2<sup>nd</sup> trimester (around 26 weeks after amenorrhea), and earlier in the event of a high viral load or the presence of an increased risk of premature delivery (B IIa).
4. Using, except in special cases, of a PI/r-based regimen including two NRTIs (A IIa), giving preference to zidovudin and lamivudin (A IIa) and, among the PI/r's, to those with the longest history of trials.
5. Counter-indicating: a) efavirenz (risk of foetal deformation); b) starting nevirapin on a long-term basis (risks of immuno-allergies); c) combining stavudin and didanosin (risk of lactic acidosis in the mother) (A IIa).
6. Promoting compliance by means of close monitoring and, if needed for women who have difficulty, seeking psychosocial assistance, the intervention of midwives or even traditional hospitalisation or at-home midwife care ((A III).
7. Reporting to health authorities all cases of perinatal exposure to the newest antiretrovirals (A III).
8. Not performing caesarean sections systematically on women receiving HAART therapy that has resulted in an undetectable viral load at the end of the 8th month (B IIa); a planned caesarean remains recommended in the case of obstetrical reasons or of a viral load > 400 copies/mL.
9. Including a hepatologist in treatment for co-infections with HCV or HBV (A III).
10. Ensuring continued treatment of the HIV infection and gynaecological follow-up for women following delivery and in the long term (A III).

## **CHILDREN BORN OF HIV-INFECTED MOTHERS**

### **Highlights**

- Early diagnosis is done using HIV-1 DNA PCR or HIV-1 RNA PCR. Absence of mother-child transmission may be confirmed following two negative PCR samples with one sample taken at least 1 month following termination of prophylactic treatment in the child, regardless of the actual period of treatment.

### **The Experts Group recommends:**

1. A prophylactic post-natal treatment using zidovudin for 4 to 6 weeks.
  2. Intensified post-natal treatment starting at birth, in the following cases:
    - If the mother was not treated during pregnancy (A Ia).
    - If the therapy or initiation of treatment for the mother is late (B IIa).
    - If the mother's plasma viral load remains high (> 1,000 copies/mL) at delivery despite receiving treatment (B IIa).
- In all cases, or in the event of doubt concerning an indication, we recommend that you seek the opinion of a specialised centre.

3. In the event of intensified prophylactic treatment for the newborn over time, a combination of zidovudin, lamivudin and lopinavir/r for 4 - 6 weeks, or zidovudin, lamivudin and monodose nevirapine for premature babies (B III).
4. Prospective assessment at the national level of cases of intensified post-natal treatment.
5. Extended hospitalisation of the newborn in the event of a HAART therapy (A III).
6. Taking into account potential maternal virus resistance mutations (B IIb), especially if viral replication in the mother has not been controlled.
7. Strict counter-indication of breast feeding (A I).
8. Adherence to the normal vaccination schedule, except for BCG, which should be postponed until a diagnosis of non infection in the child is confirmed.
9. Avoidance of systematic prevention using TMP-SMZ while awaiting said diagnosis (B III).

## **MEDICALLY ASSISTED PROCREATION (MAP)**

### **Highlights**

- If the man or woman, or both, are infected with HIV, MAP meets two objectives:
  - o allowing the couple to have children without foregoing means of protection against HIV transmission;
  - o providing the couple with treatment for infertility.
- No contamination has been found to date in the woman or their children using MAP for an HIV-infected partner.
- Recourse to MAP in the context of HIV infection requires the same lead times, rules and constraints as for an infertile couple.
- When MAP is possible, around one couple in two can hope to have children.
- Women's fertility decreases rapidly after age 35.
- Preliminary antiretroviral treatment for the man or woman is not systematically required for MAP.
- The Biodmedicine Agency recently updated the rules of good practice for MAP in the viral context.

### **The Experts Group recommends:**

1. MAP centres receiving HIV-infected couples offer them every available method of MAP (whether the man, woman or both are infected) indiscriminately, just as in the case of infertile couples (A III).
2. That cases of couples who do not have state medical coverage or documents certifying their legal residence on French territory be considered on a case-by-case basis without their administrative status constituting an automatic obstacle, bearing in mind our primary objective of reducing the risk of transmitting the HIV infection in sexual partner and from mother to child.
3. That evaluation of this activity be pursued, with clinical research needing further development especially in order to improve the effectiveness of medical care.



## Highlights

- In 2008, the number of children living with HIV in France continues to be estimated at around 1,500. Many adolescents today reach adulthood under clinical and psychological conditions that are often positive.
- Every year in France, 10 - 20 newborns are diagnosed with HIV infection. Most new cases diagnosed, however, were born abroad in a country with a high endemic rate.
- Around a hundred adolescents are infected every year by sexual transmission.
- Most of our knowledge of how to treat children is extrapolated from our experience in treating adults.
- In a child, HIV infection continues to constitute a psychological handicap given the substantial social stigmatisation. Individual psychotherapy, support groups and group play activities for seropositive children help alleviate their psychological suffering and that of their family.
- Announcement of the diagnosis is based on a principle of gradual information depending on the age and individual circumstances of each child.

## The Experts Group recommends:

- Offering antiretroviral therapy to all children under 12 months of age in order to avoid the development of an early and acute progressive form with encephalopathy (A I). Therapeutic abstention in this age range is possible under strict conditions:
- of initiating treatment for older children at a CD4 threshold of 25% (ages 1-3) or 20% (beyond age 3) (A IIa), on condition that they show few or no symptoms.
- of initially giving preference to a 3-drug regimen combining two NRTIs (abacavir+lamivudin or zidovudin+abacavir or zidovudin+lamivudin) and one PI/r (A IIa).
- Performing TDM for certain antiretrovirals, especially for compounds not approved by the French Drug Agency (B IIa) and in patients presenting virus resistance mutations to PIs (A IIa).
- Not interrupting therapy except in the case of intolerance, obvious non-compliance, the wishes of the patient, or of a specific research protocol (B IIa).
- Referring infected children to a specialised centre (A III).
- Encouraging the pharmaceutical industry to pursue research on galenic formulas adapted to the needs of children (A III).
- Early sexual education for infected adolescents (A III).
- Reinforced HIV/AIDS programs for young people, especially in schools and promoting awareness of the availability of a system for anonymous and free screening (A III).

Acute HIV Infection
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## Highlights

- In France in 2006-2007, the number of people diagnosed with acute HIV infection was low relative to the predicted number of new cases. A concerted effort must be made in terms of training and information in order to improve recognition of the symptoms associated with an acute retroviral syndrome.

- Without therapy, the risk of a rapid decrease in CD4 lymphocytes is substantial if, at the time of the acute infection, the CD4 count is less than  $500/\text{mm}^3$ , or if the HIV RNA and/or HIV DNA counts are high. In these patients, this situation requires close monitoring in the first months.
- In recent observational trials, a transitory antiretroviral treatment has not shown persistent benefit for CD4 and HIV RNA counts following halting of treatment. Results from the random SPARTAC trial are still forthcoming.

**The Experts Group recommends:**

- Offering screening for HIV and for STD's, including HBV in the presence of symptoms of acute infection compatible with an acute HIV infection, or of sexually transmitted infection or any high-risk behaviour;
- Making a special effort to offer screening for the partners involved (B IIa);
- Informing the patient of the very high risk of HIV transmission during the period of acute HIV infection and of the means of preventing this risk (A IIa);
- Performing a genotypic resistance test as soon as the diagnosis is made (A IIa);
- Rapidly prescribing a PI/r-based regimen comprised of two NRTIs for patients with severe and/or on-going symptoms in the event of immuno-deficiency with CD4 counts  $< 350/\text{mm}^3$ , and discussing the possibility with patients showing a CD4 count  $> 350/\text{mm}^3$  and with an HIV RNA count  $> 1000,000$  copies/mL. We recommend continuing treatment without interruption once the acute infection is past, just as for a chronic infection (B IIa);
- Continuing to include patients in trials and cohorts in order to improve therapeutic and epidemiological knowledge concerning acute HIV infection (A III).

Antiretroviral Pharmacology
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**Highlights:** (Evidence Level I)

- Protease inhibitors are boosted with low-dose ritonavir (PI/r), which serves to improve their pharmacokinetic properties and to obtain residual concentrations much higher than the  $\text{IC}_{90}$  of susceptible viruses.
- The combination of PIs with CYP3A-metabolised drugs with a narrow treatment margin should be avoided.
- Only certain statins can be combined with PIs; simvastatin and atorvastatin are counter-indicated.
- The induction effect of PI/r's decreases methadone concentrations.
- The absence of any major interaction of raltegravir with the other antiretrovirals is noteworthy.

**The Experts Group recommends:**

- Doing an HLA B5701 genotyping before prescribing abacavir (A I).
- Measuring the residual plasma concentrations of the PIs and/or NNRTIs in the following situations: failure (A I), drug interactions (A II), liver failure or co-infection with HCV or HBV (A II), children (A II) and pregnant women in certain situations (B III). Interpretation of

plasma levels should be done in the context of a multi-disciplinary staff involving at least a physician, a virologist and a pharmacologist.

- Controlling the effect of the adjusted doses on the antiretrovirals' plasma concentrations and on the viral load (A).
- For new antiretroviral regimens, enhancing assessment of the pharmacological parameters (especially in the viral sanctuary) and of their effectiveness and tolerance in clinical trials.
- Using tenofovir with caution in case of kidney failure, especially if it is combined with PI/r (A I).
- Caution in using maraviroc in combination with enzyme inducers or inhibitors (A I).

## HIV-1 Resistance to Antiretrovirals

### Highlights

- 1- In France, we are seeing a general increase in the prevalence of resistant viruses in patients who are infected and untreated, a decrease in this prevalence in patients currently in treatment and stability during the acute infection period.
- 2- Preventing the selection of resistant mutations requires maintaining a viral load during treatment that is below the detection threshold of 50 copies/mL.
- 3- Genotypic resistance tests are of substantial assistance in deciding on a choice of follow-up treatment. This choice may require the input of a multi-disciplinary group including physicians, virologists and pharmacologists.
- 4- The algorithm for interpreting genotypic resistance tests is changing constantly. You should check the site: <http://www.hivfrenchresistance.org> for the latest updates.
- 5- The genetic barrier of anti-integrases is weak, with crossed resistances between the two drugs in this class.
- 6- A virologist is better prepared to interpret the resistance algorithms, especially in the case of "potential" resistances, of multiple failures or if the data are preliminary.

### The Experts Group recommends:

1. Performing a genotypic resistance test at the time of the diagnosis of HIV infection (A IIa) or on the latest sample available, before beginning treatment (A IIa).
2. Repeating this test before starting treatment if there is a risk of superinfection (B III).
3. Performing resistance tests in the case of virological failure while the patient is under antiretroviral treatment (A Ia).
4. Submitting the first genotypic resistance result, along with identification of the HIV-1 sub-type (A IIa).

5. Re-interpreting previous results of genotypic tests using the latest algorithm (B III).
6. Performing a tropism test before prescribing a CCR-5 co-receptor antagonist (A Ia).
7. Conducting clinical research studies on the prevalence and effects of less common variants.

## Non-B Sub-type HIV-1, O Group HIV-1 and HIV-2 Infections

### Highlights

#### ***Non-B M Group HIV-1 infections***

- Are increasing and accounted for 41.8% of new cases of HIV infection diagnosed in 2006, around half of which are variants related to the CRF02\_AG form (prevalent in West Africa).
- Are sensitive *in vitro* to all antiretrovirals currently in use, including fusion inhibitors.
- Seem to respond to treatment like B sub-type infections but the results of comparative analysis between each of the non-B sub-types and B sub-types have yet to be documented. Tipranavir seems to be less effective against the K sub-type of HIV-1.
- D sub-type HIV infections progress more rapidly to death in the absence of antiretroviral treatment.

#### ***O Group HIV-1 infections***

- Are rare (0.1% of new seropositive cases reported from 2003 to 2006), and are found basically in patients - or their partners - who come from Cameroon.
- Cannot be monitored by most commercially-available HIV-1 viral load tests and specially-adapted tests must be used. The O group should be considered if there is immuno-virological discordance with low or undetectable viral load and low CD4 counts in naive patients.
- Cannot be treated with NNRTIs due to a natural resistance.
- Fall under the same therapeutic indications as B sub-type HIV-1 infections.

#### ***HIV-2 infections***

- Accounted for 1.8% of new seropositive cases reported from 2003 to 2006, most of which are connected with West Africa.
- Have a slower natural progression than that of HIV-1 infections. Sexual and mother-foetus transmission is lower but justifies using the same prevention strategies as those for HIV-1.
- Should be monitored using the special HIV-2 viral load methods available in a few specialised virology laboratories, especially in the context of an ANRS C05 HIV-2 study. Less than 50% of patients have a detectable viral load (> 100 copies/mL), for which the median value is on the order of 1,000 copies/mL.
- Cannot be treated with NNRTIs due to a natural resistance. Their sensitivity to amprenavir, tipranavir and atazanavir also seems lower.
- Have a progression of CD4 counts under effective treatment that is lower than that of HIV-1 infections, prompting initiation of treatment at a higher CD4 count than for HIV-1 infection.

- Must be handled, in the event of treatment failure, using the same approaches as those recommended for HIV-1: verification of compliance, TDM, and prescription of genotypic resistance tests for the choice of follow-up treatment.
- Are sensitive to anti-integrases.

**The Experts Group recommends:**

***For Non-B M Group sub-type HIV-1 infections***

- Identifying the M group virus sub-types when an HIV infection is diagnosed (A III).
- Using with patients infected with a non-B sub-type of HIV-1 the same treatment procedures, indications and treatment choices recommended for the B sub-type (A I).
- Evaluating the treatment response in patients infected with non-B sub-types in the context of clinical trials (B III).
- Closely monitoring patients infected with the D sub-type, given the rapid progression of the infection (A III).

***For O Group HIV-1 infections***

- Using serotyping to search for an O group HIV-1 virus if there is immunovirological discordance (low CD4 count and low or undetectable viral load in the absence of treatment), especially if the patient or their partner is from Cameroon (A IIa).
- Not prescribing NNRTIs or enfuvirtide (A Ia). Currently available data on anti CCR-5 and integrase inhibitors do not allow us to assume they are effective.

***For HIV-2 infections***

- Checking the plasma viral load every 6 months if it is undetectable and every four months if detectable in asymptomatic untreated patients (A III).
- Starting antiretroviral treatment in symptomatic patients.
- Considering antiretroviral treatment earlier in asymptomatic patients than for HIV-1 infection, as soon as the CD4 lymphocyte count falls below 500/mm<sup>3</sup> (B III) and starting it systematically if it is below 350/mm<sup>3</sup> (A III), or if the plasma viral load is detectable (B IIa).
- Not prescribing either NNRTIs or enfuvirtide (A Ia) and cautious use of fosamprenavir/r, atazanavir/r and tipranavir/r (possible reduced sensitivity) (B IIIb).
- Systematically prescribing preventive treatment for mother-child transmission (A).
- Continuing to include these patients in the national cohort in order to enhance the knowledge base, especially concerning treatments (A III).

Infections in HIV -Infected patients
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**Highlights**

- An opportunistic infection may reveal the presence of an HIV infection, especially in subjects from endemic countries or with behaviour at high risk for HIV contamination (A III).
- One should suspect an immunitary reconstitutive inflammatory syndrome (IRIS) in the presence of atypical clinical manifestations occurring in the weeks following the start of an antiretroviral therapy in highly immuno-deficient patients.
- The initiation of an anti-tuberculosis or anti-fungal treatment requires taking into account drug interactions with the antiretrovirals (A II).
- The recent increase in STDs implies a need to reinforce prevention messages with patients and to regularly check screening for STDs and viral hepatitis strains A, B and C (A III).

#### **The Experts Group recommends:**

- In the context of a recent OI (excluding tuberculosis), starting an antiretroviral treatment within two weeks of initiating treatment of the infection (A I).
- In highly immuno-deficient patients ( $CD4 < 100/mm^3$ ), seeking out and treating a latent or pauci-symptomatic OI (mycobacteriosis, cryptococcus, CMV) before starting ARVs in order to prevent IRIS (A III).
- Prescribing prophylaxis for pneumocystosis (or toxoplasmosis) in patients with a  $CD4$  count of less than  $200/mm^3$  (or  $< 15\%$ ) (A I).
- Doing an eye ground [fundus oculi] and a CMV PCR every 2 - 3 months in highly immuno-deficient patients ( $CD4 < 100/mm^3$ ) (A II). A pre-emptive treatment with valganciclovir is justified in the event of clear and confirmed positive results of the CMV PCR (B III).
- In a patient presenting a Multi focal progressive encephalopathy, early initiation or maximum use of an antiretroviral therapy giving preference to the use of compounds with the best penetration into the central nervous system (B II).
- Screening for syphilis following any sexual risk exposure or at least annually for subjects with multiple partners (A III).

### **Hepatitis Virus Co-infections**

#### **Highlights**

##### *HCV*

- Infection with HCV affects more than a quarter of HIV-infected people and the HIV infection negatively influences the prognosis of hepatitis C, which progresses more rapidly toward cirrhosis.
- In 2006, 78% of HIV-HCV co-infected patients were screened for evaluation of liver activity and fibrosis, but only about half of these patients received any treatment.
- Evaluation of an liver damage using non-invasive diagnostic methods for fibrosis should improve therapy for patients while reducing the number of liver biopsy
- Educating the patient and his family, evaluation of his socio-professional and family contexts, and prevention and treatment for side-effects provide increased adherence to treatment.

### ***HBV***

- The prevalence of chronic HBV infection is estimated to be around 7% in HIV-infected patients.
- The HIV infection negatively influences the course and prognosis of chronic hepatitis B
- In contrast to HCV, eradication of HBV is rarely obtained using current treatments and the duration of anti-HBV treatments is long, with the risk of selecting resistant strains.
- The choice of anti-HBV treatment in patients co-infected with HIV-HBV is contingent on the antiretroviral treatment indicated.

### **The Experts Group recommends:**

#### ***For all patients***

- Reinforcing prevention messages in order to prevent HCV contamination, especially in drug users and homo- or bi-sexuals (A IIa).
- Systematically looking for HCV and HBV infections when HIV infection is found, and maintaining a regular course of serology, at least annually, for seronegative subjects with continuing exposure to risk (A IIa).
- Vaccinating non-immunised patients against hepatitis B, including re-vaccinating people who do not respond to a first vaccination protocol (A IIa) and giving hepatitis A vaccinations to patients co-infected with HCV or HBV (A IIa).
- Assessing the degree of liver damage and fibrosis by doing one or more biochemical tests and, if possible, an elastometry. If there is concordance, a liver biopsy is pointless; in the event of discordance between the tests or with the elastometry, or in the case of related co-morbidities, a liver biopsy should be included (B IIa).
- Not delaying the initiation of an antiretroviral treatment that should maintain the same virological objectives and should take into account the particular aspects of an eventual treatment for the hepatitis.
- Deciding on hepatitis treatment in the context of a multi-disciplinary consultation (A III).
- Referring to an hepatologist cirrhotic patients for treatment of complications (A III) and to a liver transplant centre before the first decompensation (A IIb).

#### ***For HVC co-infected patients***

- Considering an anti-HCV indication for HIV-infected patients (A III).
- Treating a case of acute hepatitis C with a combination of pegylated interferon and ribavirin over 24 or 48 weeks if the RNA of the HCV is not spontaneously eliminated in the three months following onset of the infection (A IIa).
- Treating a chronic case of hepatitis C with a combination of pegylated interferon and ribavirin over 48 weeks if the therapeutic indication is adopted (A Ia).
- Counter-indicating didanosin, advising against the use of zidovudin and stavudin, and being cautious with abacavir in the event of concomitant antiretroviral and anti-HCV treatments (A Ia).

- Doing everything possible to maintain the treatment with pegylated interferon and ribavirin (dose and duration); in particular, counting on the serial doses of ribavirin and resorting to a treatment by growth factors in case of neutropenia ( $< 600/\text{mm}^3$ ) (A III), and/or acute anaemia ( $< 10\text{g/dl}$ ) (A Ia).
- Evaluating the early HCV viral load at 4 and 12 weeks of treatment and interrupting treatment in the absence of a substantial decrease ( $> 2 \log$ ) in the viremia at 12 weeks in patients with a minimal or moderate fibrosis (A IIa).
- Re-examining the possibilities of repeat treatment with pegylated interferon +/- ribavirin in patients having failed with a first anti-HCV treatment (B III).

#### ***For HBV co-infected patients***

- Testing for anti-delta antibodies in any carrier of Ag HBs (A III). Repeating this test in the event of a known risk factor.
- Considering starting an HIV treatment with mixed effectiveness (HIV-HBV) earlier in patients with chronic hepatitis B.
- Using drugs that present a double HIV/HBV action if the indication is to initiate HBV and HIV treatments (A III). Using lamivudin and emtricitabin or entecavir in a single-drug HBV regimen is not recommended (A IIa).
- Never interrupting without follow-up an antiretroviral treatment effective against HBV (A IIa).
- Monitoring, in the course of an HBV treatment, the HBV viral load at least every 3 months (A IIa). Any increase in the viral load of more than one log copies/mL should result in testing for a resistance mutation, and in adapting the treatment for HBV (A IIa).

#### ***For inmates***

- Systematically offering HIV/HBV/HCV screening on incarceration and again offering this screening during the detention period in the event of risk-related behaviour.
- Facilitating access to prevention advice and to hepatitis B vaccination.
- Facilitating the performance of a biological workup at the medical centre in the prison .
- Facilitating access to non-invasive assessment methods for liver fibrosis (biological or other).
- Encouraging specialised examinations (hepatological and/or infectiological).
- Facilitating access to treatment, regardless of the predicted length of the sentence.

<h3>Tumours during HIV infection</h3>
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#### **Highlights**

- There are strong epidemiological evidence for blaming an immuno-suppressive effect for the risk of tumours occurring in HIV-infected persons.



- Despite the benefits of antiretrovirals, the incidence of tumours caused by AIDS remains much higher in HIV-infected patients than in the general population.
- To a lesser extent, the rate of non-AIDS related cancers is likewise higher in HIV-infected patients.
- The survival rates 2 years after a cancer diagnosis are substantially lower in HIV-infected patients than in those not infected.
- Control of HIV viral replication using antiretrovirals is associated with a significant improvement in the survival of patients treated for lymphoma.

### **The Experts Group recommends:**

- Doing a yearly cervical smear on women to screen for dysplasias (A II). A colposcopy should be done in the presence of any cytological anomaly (A II).
- Performing a yearly proctologic exam (digital rectal exam, anoscopy) on men who have anal sexual relations, on any patient with a history of ano-genital condylomas, and on women with dysplasia or cancer of the cervix (B III).
- In HIV- infected patients suffering from a neoplasia, starting an effective antiretroviral treatment if they are antiretroviral naive, regardless of the CD4 lymphocyte cell count (B III).
- In patients without a major immuno-deficiency, providing treatment for the neoplasias comparable to that for subjects not infected with HIV (B III). This nevertheless requires taking into account drug interactions with the antiretrovirals and the combined toxicity of the various drugs. Lastly, prophylaxis for pneumocystosis, toxoplasmosis and any eventual CMV-based infection must be instituted (B II).
- Strongly discouraging smoking due to the high incidence of lung or laryngeal neoplasias in seropositive subjects and offering patients who smoke a treatment to stop smoking, if possible at a centre for quitting smoking (B III).
- Systematically screening for hepatitis B and C co-infections (A II), and treatment of them to limit the incidence of cirrhosis and hepatocarcinomas. It is also important to insist on the value of stopping drinking and of treating resistance to insulin (B II). A multi-year screening for hepatocarcinoma is justified in cirrhotic patients (A II).

<h3><b>Post-Exposure Prophylaxis</b></h3>
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### **Highlights**

- Care for post-exposure cases has been updated by law on 13 May 2008.
- The regional coordination against HIV (COREVIH) have a role to play in organising the system.

- The monitoring period for accidental HIV exposure has been reduced for healthcare professionals to 3 months without treatment and to 4 months in the event of prophylactic treatment.
- An exposed child will receive the special care stipulated in the extended guideline book.

**The Experts Group recommends:**

- 24/24h access to a healthcare system for viral risk exposures, including in prisons,
- Increased availability of information on HIV transmission and hepatitis strains, on the prophylaxis treatment following exposition to viral risk system and on the need for confidentiality
  - by healthcare professionals,
  - by personnel of prisons
- a simple standardised assessment of the system.

## HIV Immunotherapy

**Highlights:**

The prescription of IL-2 in the context of a case to case decision remains an option for patients having started IL-2 before 2006 in accordance with the following indication: plasma HIV-RNA count < copies/mL with CD4 lymphocyte T-cell count < 200/mm<sup>3</sup> despite effective antiviral therapy for at least 6 months.

Mid and long-term monitoring of IL-2 tolerance is recommended, especially in the context of the prospective CO14 cohort of the French research agency (ANRS).

## Lifestyles conducive to successful therapy

**Highlights**

- HIV infection may lead to deterioration of people's lifestyles.
  - Successful therapy depends on a person's lifestyle and social conditions.
- Anticipating problems can help reduce the risk of isolation from health care.

*Access to rights and to care*

- The French healthcare system currently guarantees the right to quality healthcare in the vast majority of cases.
- accommodating the rights of populations without healthcare coverage remains a complex issue;
- the high level of "co-payments" represents a heavy financial burden for some patients;
- a legal framework guarantees the right to residence of foreigners for medical reasons;
- the living conditions of foreigners in precarious legal status negatively affects the success of therapy and the effectiveness of the healthcare system.

*Lodging, accommodations*

- Many shelter systems make accommodation for people's social and health conditions, but they appear to be inadequately coordinated;
- the responses to certain social conditions are inadequate, especially for women left alone with children, inmates released from prison and transsexual persons.

*Employment, resources, social services*

- One quarter of the HIV-infected population lives in poor financial conditions;
- maintaining one's employment may run up against very strong resistance in the workplace.
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*Aging*

- From a societal point of view, accommodation within an appropriate structure of the seropositive population after age 60, who are growing older, should be planned for and accompanied by involving geriatric healthcare professionals.

*Assistance, support and quality of life*

- There are many institutions and associations that contribute to assisting people living with HIV. They play an essential role in providing psychosocial support for people and in contributing to the success of therapy.

*Discrimination*

- The types of discrimination people living with HIV are subjected to remain common and affect their social, professional and private lives.

*Incarceration*

- Existing rules for releasing from detention people whose state of health is clearly incompatible with prison life are not used to best effect;
- The change of status from detention to freedom and the lack of coordination between the penal and medical realms result in discontinuities in people's medical care.

*Recommendations***The Experts Group recommends:***Access to rights and to care*

- In order to ensure effective care over time, that doctors be concerned with the social welfare of their patients right from the first consultation;
- That social welfare services examine the "co-payments" patients have to assume.

*Foreign patients*

- That legal and regulatory provisions concerning foreign patients be obeyed.

*Lodging and accommodations*

- That initiatives be developed to facilitate access to public housing for patients who qualify;
- Ensuring that the governmental organisation system lodging for vulnerable patients leaving with HIV meet the needs of populations inadequately cared for (single mothers, prison releases, transsexual people, etc.).

*Employment, resources, social services*

- Making partial leave for medical reasons more flexible so that it can be granted for longer periods of time to better accommodate the needs of people living with HIV;

- That the personnel at the disabled administrative centre be trained in the specifics of HIV illness and the needs of patients.

#### *Aging*

- That members of the geriatrics field be trained to handle people with HIV.

#### *Assistance, support and quality of life*

- That patients be able to more broadly benefit from educational support and assistance programs.

#### *Discrimination*

- That combating discrimination continue to be a priority;
- That information on patients' rights and legal recourse be widely distributed.

#### *Incarceration*

- That medical findings be given consideration in the context of reducing and suspending sentences;

That organisation be provided for continuing healthcare and promoting human rights from the beginning of incarceration through post-release care.

HIV Healthcare Management
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### **The Experts Group recommends:**

#### **REGIONAL HIV COORDINATION GROUP (COREVIH)**

- That attention be given to broad distribution of activity reports to all members of the Corevih.
- That the annual report of the national Corevih steering committee be made public.
- That the computer-based collection of epidemiological and clinical data be extended to all hospital organisations connected to the Corevih.
- That new technicians be trained for clinical studies.

#### *Hospital activities*

- That a range of specific studies be carried out:
  - o a study of hospital costs for HIV-infected patients so as to ensure the relevancy of the calculations underlying the national cost analysis;
  - o a study on the incidence and causes of extended stays greater than one month so as to better understand the contributing factors;
  - o a national transversal survey to better determine the match-up of supply and demand in SSRs [Post-Op and Rehab Units];
- That a schedule of charges be established for complex or multi-disciplinary consultations that do not fall under the HDJ;
- Promoting recognition of the special technical and financial aspects of HIV SSRs in organising the financing support for ARVs and other costly medications;
- Including the needs for HIV SSRs in upcoming regional healthcare management schemes (SROS);
- Creating a series of HIV-oriented healthcare offerings with the USLD and in the public healthcare system, and including the specific aspects of HIV/AIDS in the next PRIAC, at least for priority regions;

- Performing a national survey of operating conditions at the ACTs [governmental organisation system lodging for vulnerable patients] (updating of objectives, financing, training, etc.) in order to upgrade the system to meet current needs.

*Local healthcare*

- Promote giving consideration to how to involve general practitioners in providing therapy for HIV-infected patients.