



# Enfermedades Infecciosas y Microbiología Clínica

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## Consensus statement

### Executive summary of the consensus statement on assistance to women with HIV infection in the health care sector

Panel of experts from the National AIDS Plan (PNS) and AIDS Study Group (GeSIDA)<sup>◇</sup>

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#### ABSTRACT

The aim of this paper was to develop a consensus on clinical recommendations for health care assistance for women with HIV infection. To this end, a panel of experts, appointed by the Secretariat of the National AIDS Plan and GeSIDA was assembled, that included internal medicine physicians with expertise in the field of HIV infection, gynecologists, pediatricians and psychologists, with two members of the panel acting as coordinators. Scientific information was reviewed in publications and conference reports up to October 2012. In keeping with the criteria of the Infectious Disease Society of America, two levels of evidence were applied to support the proposed recommendations: the strength of the recommendation according to expert opinion (A, B, C) and the level of empirical evidence (I, II, III), already used in previous documents from SPNS/GeSIDA. Multiple recommendations are provided for the clinical management of women with HIV infection, considering both the diagnostic and possible therapeutic strategies. This document presents recommendations for the treatment of women with HIV infection. This must be multidisciplinary, taking into account the differences that can be found in the diagnosis, development of disease and treatment between men and women.

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### Resumen del documento de consenso sobre la asistencia en el ámbito sanitario a las mujeres con infección por el VIH

#### RESUMEN

El objetivo de este documento ha sido establecer un consenso sobre recomendaciones clínicas para la asistencia en el ámbito sanitario de las mujeres con infección por el virus de la inmunodeficiencia humana (VIH). Para ello se reunió a un panel de expertos designados por la Secretaría del Plan Nacional sobre el Sida (SPNS) y GeSIDA que incluyó médicos especialistas en medicina interna con experiencia en el ámbito del VIH, ginecólogos/as, pediatras y psicólogas, actuando 2 miembros del panel como coordinadoras. Se revisó información científica hasta octubre de 2012 a partir de publicaciones y comunicaciones a congresos. Como apoyo a las recomendaciones se utilizaron 2 niveles de evidencia: la fuerza de la recomendación según opinión del experto (A, B, C) y el nivel de evidencia empírica (I, II, III), ambos niveles basados en los criterios de la Infectious Disease Society of America, ya utilizada en documentos previos de la SPNS/GeSIDA. Se proporcionan múltiples recomendaciones para el manejo clínico de las mujeres con infección por el VIH, considerando tanto el proceso diagnóstico como posibles estrategias terapéuticas. En este documento se presentan las recomendaciones para el abordaje de las mujeres con infección por el VIH. Este debe ser multidisciplinar, teniendo en cuenta las diferencias que se puedan encontrar en el diagnóstico, en el desarrollo de la enfermedad y en el tratamiento en los hombres y las mujeres.

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#### Introduction

Data from the 2012 UNAIDS report show that women account for 49% of the HIV-infected population worldwide. In 2011, the UN reported 2763 new cases of HIV, of which 17% were women, with heterosexual relations as the primary transmission category. Despite these figures, the representation of women in clinical trials is only between 12% and 23%.

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One of the distinguishing characteristics of the infection in women compared to men is greater vulnerability of women as a result of discrimination, rape, domestic violence, and lack of recognition of fundamental rights, all of which imply a greater need for prevention, care, and support.

This document presents recommendations on the differential approach to women infected by HIV by conducting a review of the available scientific evidence for each of the aspects included in the text.<sup>1</sup>

### Clinical practice from the perspective of gender

The incorporation of the gender perspective in health care requires the different needs of women and men to be addressed in order to avoid gender bias. Consequently, the biopsychosocial model is proposed, as it takes into account biological, psychological, and social qualities and favors a more comprehensive knowledge of the patient. As for health professionals, several factors affect incorporation of the gender perspective in clinical care, as follows:

- Training of health professionals in gender differences in order to achieve real change.
- The relationship between professionals and patients: sex and sexual orientation affect the communication style of health professionals and thereby the relationship with patients.
- Incorporation of the gender perspective in clinical practice guidelines, which should take account of possible biases in the different sections during the preparation phase. Therefore, it is necessary that the people involved in the working group accept the relevance of the gender perspective and improve their training in this area.

The most significant barriers to a gender perspective are poor sensitivity and awareness of diversity by the professional, communication problems between patient and professional, and organizational difficulties related to the lack of time or the patient's right to choose the sex of the attending professional.

### Recommendations

1. It is necessary to promote training of health professionals in order to avoid gender bias (**A-III**).
2. The needs of men and women should include differences in morbidity, i.e., differences in disease development, diagnosis, and treatment (**A-II**).
3. We must develop and/or enhance communication and professional skills in order to facilitate identification of psychosocial needs, vulnerability, and social determinants and improve communication between professionals and patients (**B-III**).
4. Clinical trials/studies should include more women to enable conclusions to be drawn and to make an analysis of the different social roles and positions of men and women in order to achieve optimal scientific output from this type of analysis (**B-III**).
5. Gender biases in information, research, and health care should be taken into consideration when developing clinical practice guidelines and recommendations in this area (**B-III**).

### The life cycle of women and HIV

#### Adolescence

One of the most important aspects at this stage is the detection of the disease. It is therefore essential that HIV infection be detected on an individual basis. The detection process should always be

adapted to the psychological, social, and maturational level of the adolescent and involve psychological support whenever possible.

As for initiation of antiretroviral therapy, adolescents infected at this time should start therapy according to established criteria for the adult population. However, in perinatally infected individuals, adolescence is the time for simplification strategies favoring once-daily dosing or coformulations, according to guidelines on antiretroviral drugs. Adult doses are used from Tanner stage V onward. Metabolic toxicity is common, especially that affecting lipid metabolism. Interventions for the control of lipid abnormalities include lifestyle modifications, modification of antiretroviral drugs, and timely use of lipid-lowering agents.

Changes in body fat distribution have negative consequences that can affect psychological well-being and lead to social stigmatization, and adherence problems. Interventions affecting female adolescent nutritional status have the greatest impact on achieving peak bone mass.

The frequency of neurocognitive impairment will depend not only on the course of the disease itself or the treatment received but also on environmental and socioeconomic factors affecting the families of adolescents.

- Sex should be addressed early, by providing appropriate information and involving caregivers. In addition, the infected sexually active teenager should undergo gynecologic evaluations, including human papillomavirus screening and cytology. HIV-infected adolescents should be vaccinated against human papillomavirus.

### Recommendations

1. Adolescents should be informed about the diagnosis of HIV infection on an individual basis, with the participation of a multidisciplinary team. Information should be adapted to their maturational and social characteristics (**C-III**).
2. Therapeutic regimens should be simple, effective, and of low toxicity in order to improve adolescent quality of life (**B-II**).
3. Dietary measures and exercise are advisable in the treatment of abnormal distribution of body fat (**B-II**). Reconstructive surgery should be reserved for adolescents with severe facial lipoatrophy with a marked physical and/or psychological impact and if they have completed growth (**C-III**).
4. DXA to assess bone mineral density should be performed based on age, height and weight, and Tanner stage (**B-II**).
5. HIV-infected adolescents should be vaccinated against human papillomavirus (**A-II**).
6. Barrier methods should be used. Occasionally, combination with oral contraception can prevent unwanted pregnancy (**B-III**). The postcoital contraceptive pill is not contraindicated (**C-III**).
7. We recommend follow-up counseling at multidisciplinary units to ensure that the patient takes her antiretroviral therapy and attends medical check-ups (**C-III**).

#### Reproductive health. Pregnancy and contraception

Before applying measures to prevent vertical transmission, it is essential to know if the mother is infected with HIV; therefore, screening for HIV infection is generally recommended for all pregnant women. This screening should always be offered, unless the woman refuses consent (strategy known as opt-out). Ideally, every woman should know her HIV status before attempting to become pregnant. In addition, all pregnant women whose serostatus is unknown at the time of delivery, in the immediate postpartum, or when admitted during the third trimester of pregnancy should undergo a rapid serological test, which facilitates implementation of specific preventive measures. Moreover,

the Spanish Society of Obstetrics and Gynecology (SEGO) currently recommends repeated universal screening in the third trimester in order to detect seroconversion during pregnancy. In the case of discordant couples planning a pregnancy, specific evaluation by a specialist is recommended in order to provide options: antiretroviral treatment, natural conception, appraisal of fertility, and assisted reproduction techniques.

### Recommendations

1. All pregnant women should undergo HIV testing (**B-III**). In the case of risk practices, testing should be repeated in the third trimester (**C-III**). Universal screening is recommended in the third trimester (**C-III**).
2. In women who go into labor without knowing their HIV status, a rapid test is necessary, as elective cesarean section reduces transmission by 50% (**B-II**).
3. Pregnant women with HIV infection should undergo periodic assessment of immunological and virological status and monitoring in specialized centers with multidisciplinary teams who have experience in this area (**C-III**).
4. Ideally, contraception in women with HIV infection must combine a barrier method with a second method (**B-III**).
5. Prescribing antiretroviral therapy: consider current or planned use of contraceptives. Hormonal contraceptives interact with antiretroviral drugs; therefore, knowledge of interactions is essential. In any case, hormonal contraceptives should be complemented by a barrier method (**B-III**).

### Menopause

In current guidelines for antiretroviral therapy in adults, age is not a differentiating factor for choosing an antiretroviral regimen, although it is recommended to start antiretroviral therapy earlier in patients aged >50 years. Antiretroviral therapy is particularly important for preventing cognitive deterioration associated with HIV infection and other non-AIDS events, which add to those produced by aging in older women.

Some of the most common toxicities of antiretroviral therapy are conditions that are seen most often during menopause: dyslipidemia, insulin resistance, diabetes, and hypertension, which make it more difficult to diagnose and manage these problems. A similar situation can be observed in the loss of bone mineral density associated with menopause (2–6% in the first 2 years) and the initiation of antiretroviral therapy (some regimens are more toxic than others).

Drug interactions and severe toxicity must be taken into account in postmenopausal women.

### Recommendations

1. All women, regardless of age, should receive advice and information on strategies to reduce transmission and ensure access to early diagnosis of HIV infection (**A-III**).
2. The usual recommendations for adult antiretroviral therapy should be followed, with special reference to earlier initiation of antiretroviral treatment in patients aged >50 years in order to avoid immune deterioration and development of non-AIDS events (**B-II**).
3. Given the possible comorbidities and polymedication to which women in menopause and postmenopause are exposed, the symptoms and signs related to adverse reactions and drug interactions should be evaluated and treated at each check-up and in the case of changes in the woman's clinical condition or a change in medication (**A-III**).

4. The age of onset of menopause should be evaluated, as should the symptoms associated with it and other problems such as cardiovascular risk, reduced bone mineral density, emotional problems, and premature aging. The generally accepted recommendations for these conditions should be made, and the antiretroviral regimen should be evaluated if it is not the most appropriate (**A-III**).

### Course of HIV infection in women

Although data are conflicting, studies in seroconverters show that women have higher CD4 counts both at the time of seroconversion and at the time of AIDS diagnosis and death. Regarding HIV viral load in the adult population, several studies have found that women have lower viral loads than men after seroconversion. The clinical impact of these findings does not seem to have any effect on progression to AIDS or mortality.

### Recommendations

1. Well-designed studies are needed to provide information on the differences in clinical, immunological, and virological outcome between men and women and to assess the impact that these differences might have on gender-based antiretroviral therapy recommendations (**C-III**).

### Neoplasia in women with HIV infection

Some neoplasms, by their specific nature, are specific to women. Coexistence with HIV infection requires a different clinical and therapeutic approach.

Cervical carcinoma is the most common tumor in women. The main etiological factor is human papillomavirus. All women should undergo cytology and even colposcopy with biopsy if cytology reveals dysplasia or if there are suspicious lesions on physical examination. A Pap smear must be performed every 6 months after diagnosis of HIV and annually once 2 negative results are detected. Human papillomavirus carriers should undergo a check-up every 6 months. A similar approach is adopted for the early diagnosis of anal carcinoma, which is also related to human papillomavirus. Besides specific therapy for neoplasm, antiretroviral therapy must be administered early to improve immune status and clearance of human papillomavirus and (occasionally) to facilitate the regression of cervical intraepithelial neoplasia.

### Recommendations

1. In the first year after diagnosis of HIV infection, 2 cervical smears should be performed (1 every 6 months); if both are normal, cytology should be repeated annually, including inspection of the anus, vulva, and vagina (**C-II**). If polymerase chain reaction is used to confirm the diagnosis of human papillomavirus infection, detection of a subtype with a high oncogenic risk requires smear testing and determination of human papillomavirus every 6 months (**C-II**).
2. Invasive cancer treatment follows the same pattern as that of women not infected with HIV (**C-II**). Antiretroviral therapy must be started early (**A-II**).
3. Women with HIV infection should receive the human papillomavirus vaccine—both the tetravalent vaccine (serotypes 6, 11, 16, and 18) and the bivalent vaccine (serotypes 16 and 18)—to prevent the development of carcinoma of the cervix, anus, vulva, and vagina. The tetravalent vaccine also provides protection against anogenital warts (**B-II**).

## Antiretroviral treatment in women

### Pharmacokinetic data

There are still many unknowns surrounding the effect of gender on the pharmacokinetics of antiretroviral drugs. However, the limited information available suggests that the levels of many of the most commonly used drugs are higher in women than in men and that clearance is slower in women. These findings have occasionally been associated with an increased incidence of adverse effects and in some cases have been associated with more rapid virologic suppression.

### Recommendations

1. Studies should be designed to specifically investigate the use of combinations of antiretroviral drugs in nonpregnant women (**B-II**).
2. We suggest monitoring drug levels and considering dosage adjustment in patients with toxicity (**A-III**).

### Efficacy of antiretroviral drugs

Studies have revealed no differences in the efficacy and safety of antiretroviral drugs between naïve and pretreated patients. A higher rate of treatment suspension was observed in women, the most frequent reasons being loss to follow-up and adverse effects.

### Recommendations

1. The initiation and objectives of antiretroviral therapy are the same in women and men (**A-I**).
2. Currently available data indicate that the efficacy of treatment is the same for men and women; therefore, there are no limitations on the choice of drug to be prescribed (**A-I**).
3. Women stop treatment for reasons other than virologic failure more than men; therefore, they should be monitored more closely (**A-I**).

### Toxicity of antiretroviral therapy

Female sex has been reported to be a risk factor for hyperlactatemia, anemia, neuropathy, and pancreatitis.

Nevirapine should not be used in naïve women with CD4 > 250 cells/mm<sup>3</sup>; however, when given as a result of switching antiretroviral therapy because of toxicity or simplification in patients with an undetectable viral load, CD4 counts did not correlate with increased toxicity. With regard to the side effects of efavirenz, a recent study shows that women are at greater risk of stopping treatment than men, the root cause being central nervous system side effects.

Protease inhibitors generally result in a higher incidence of gastrointestinal side effects such as nausea and vomiting in women. The aspects that determine the need for dose adjustment in women and that can increase toxicity include differences in weight and body mass index, changing hormonal profile, lower hemoglobin averages than men, and differences in plasma cytokine levels.

Data have also been published on prevalence of metabolic syndrome and bone metabolism disorders (osteopenia and osteoporosis) in women.

### Recommendations

1. Further studies are necessary to assess the toxicity and long-term adverse effects of antiretroviral therapy in women (**A-II**).

2. Given the differences in metabolic profile and redistribution of body fat between men and women, these areas must be appropriately evaluated so that preventive and therapeutic measures may be taken (**A-II**).
3. Correct analysis of early toxicity of antiretroviral therapy, especially in women, is essential for maintaining effectiveness (**A-I**).

### Adherence

Although there are no comparative studies, data show poor adherence in women.

No studies have measured adherence specifically in women. Strategies should be initiated at the first visit and maintained over time. Assessment should be multidisciplinary, taking into consideration from the outset all those factors that can affect adherence.

Methods for improving adherence should be tailored to the patient.

### Recommendations

1. Adherence is the main determinant of immunological and virological control in patients with HIV infection (**A-I**).
2. Adherence in women may be poorer owing to lower tolerance of treatment, anxiety and depression, worse psychosocial support, and the role of caregiver characteristic of women (**A-II**).
3. We should design strategies for control, support, and treatment that cover the specific needs of women (**A-III**).

### Specific interactions with hormonal contraception

Hormonal and intrauterine contraceptives have generally proven safe in women with HIV infection. Hormonal contraception does not appear to interfere with the progression of disease or the efficacy of antiretroviral therapy, but interactions between hormonal contraceptives and antiretroviral drugs can lead to undesirable side effects.

The decrease in plasma levels of hormones, in turn, can result in decreased contraceptive efficacy, risk of pregnancy, and menorrhagia.

The clinical impact of these interactions results from the narrow therapeutic range of estrogens/progestins. Their basic mechanisms are not fully elucidated but undoubtedly include induction/inhibition of glucuronidation and CYP1A2 and CYP3A4.

### Recommendations

1. When prescribing antiretroviral therapy, consider current or planned use of contraceptives (**A-III**).
2. Replace and/or supplement different contraceptive methods to avoid unwanted effects due to interactions with the antiretroviral drug (**A-III**).

### Antiretroviral therapy during pregnancy

The main objective is the prevention of mother to child transmission; therefore, it is essential that HIV-infected pregnant women receive antiretroviral therapy regardless of their CD4 count. In treatment-naïve women, antiretroviral therapy should be started at the 14th week of pregnancy. Fig. 3 shows an algorithm for women wishing to become pregnant. Switches in therapy during pregnancy will depend on the occurrence of adverse effects or lack of efficacy. However, if a woman who was receiving therapy becomes pregnant, the first step is to replace potentially teratogenic drugs and nonrecommended drugs.

After this initial assessment, we can face 2 possible situations: presence or absence of viral replication. If the mother is receiving antiretroviral therapy and viral replication is not detected, then the treatment she had been receiving should be continued. If possible, potentially teratogenic drugs should be replaced. If the regimen does not contain ZDV, then this drug should be included, as long as no resistance or severe intolerance is detected. If the mother is receiving antiretroviral therapy and viral replication is observed, we must assess whether the lack of efficacy is due to poor adherence or resistance to antiretroviral drugs. The regimen is adjusted by applying the same criteria as in the previous case.

Antiretroviral therapy can be suspended depending on the adverse effects for the newborn and the mother. The suspension remains in force until the causes have been resolved. Other regimens must be assessed cautiously during the last weeks of pregnancy.

There is no specific recommendation for withdrawal of antiretroviral therapy when it was started to prevent vertical transmission. While there are currently no universally accepted recommendations in this regard, and with changes in the criteria for initiating antiretroviral therapy, many authors recommend that treatment be maintained.

### Recommendations

1. The goal of antiretroviral therapy is to achieve an undetectable viral load (**A-I**). If there is no resistance or prior documented severe toxicity or adherence problems or doubts about whether to switch to a drug with an easier dosing schedule, then ZDV should be the drug administered during pregnancy, at delivery (intravenous), and to the newborn (**A-I**).
2. Resistance testing must be performed in all HIV-infected pregnant women not receiving antiretroviral therapy or in whom the viral load is detectable (**A-I**).
3. Control of viral load must be planned before delivery, by week 32–36 to decide whether to perform elective cesarean or not (**B-III**).
4. Drugs with a teratogenic risk should not be used. Drugs whose risk is not well known should be avoided when possible (**C-III**).
5. d4T + ddI is not recommended because of the risk of lactic acidosis (**B-II**).
6. If an undetectable viral load is not reached, cesarean section should be planned for week 37–38 (**A-II**).

### Sexual and emotional health in HIV-infected women

#### *Sexual dysfunction*

Female sexual dysfunction can be categorized into 2 main groups: arousal disorders (hypoactive sexual desire, sexual aversion, female sexual dysfunction, anorgasmia) and pain syndromes (dyspareunia and vaginismus). Sexual dysfunction in HIV-infected patients may have specific medical causes, although common causes are also observed in the general population, for example, the simple estrogen depletion that accompanies menopause. Although few studies have been performed, it is necessary to assess sexual satisfaction in patients with HIV infection, taking into account the chronicity of infection, the duration of treatment, and the longer survival observed today. Treatment will vary according to the causes that lead to dysfunction; however, the best approach is a multidisciplinary combination of clinical, psychological, and relational aspects. In addition, inclusion of the woman's partner will certainly be a more effective approach.

#### *Emotional health of HIV-infected women*

Depressive symptoms are more common in women than in the general population. This observation is also reflected in HIV-infected women. Stigma and guilt come into play when deciding whether to share the diagnosis with relatives and with other health professionals, such as gynecologists.

### Recommendations

1. The subject of sexual health should be addressed, focusing not only on the prevention of risks associated with sexual behavior, but also on promoting the concept of comprehensive and holistic sexuality, namely, one that is healthy, pleasurable, and egalitarian (**B-III**).
2. The incidence of depression is high in HIV-infected women and higher than that of HIV-negative women. These symptoms should always be evaluated at routine clinical visits (**A-II**).
3. In women with alterations such as sexual dysfunction, repeated intolerance to drugs, or somatization, emotional status should always be assessed, as it is associated with alterations of this type (**A-II**).
4. Given the negative impact that inadequate emotional status can have on the health of women and their care, it is critical to refer to mental health professionals in the event of detection of a psychological disorder (**A-III**).

### Violence against women in the context of HIV infection

Women experiencing gender-based violence have difficulty exercising their rights as individuals and making autonomous decisions about their bodies and their sexual and reproductive health; therefore, they are more vulnerable to unwanted pregnancy, as well as HIV and other sexually transmitted infections. Gender violence is often associated exclusively with physical violence; however, in most cases, it is associated with psychological violence and sexual violence, and it is in relation to the latter that an increased risk of HIV infection can be identified. From a clinical and legal perspective, initiating postexposure antiretroviral therapy should be considered, and diagnosis and prophylaxis and/or treatment of other sexually transmitted infections should be evaluated. Prevention of pregnancy in women of childbearing age should be addressed with emergency contraception. When sexual violence is recurrent, postexposure prophylaxis is not advisable, and the woman must be informed about personalized ways of reducing as much as possible the risk of HIV transmission, if protection is not available. These include maintaining good lubrication to reduce the risk of lesions and erosions of the genital mucosa and preventing ejaculation during anal and vaginal intercourse.

In HIV-infected women, gender violence is not usually detected during the first few visits. Health professionals should foster a relationship of trust in which women can express their suffering and express a need for help.

Gender violence requires the active involvement of all health care staff, who should be aware that detection is the first step toward management.

### Recommendations

1. Assessment of risk of HIV transmission and administration of prophylactic antiretroviral treatment should be considered both a clinical and a legal requirement in women who are victims of sexual assault (**B-III**).
2. Postexposure prophylaxis is recommended in cases of sexual violence when the attacker is HIV-infected and the sexual practices involve risk (**B-III**).

3. If the risk of transmission is low and the serological status of the attacker is unknown or cannot be determined, antiretroviral prophylaxis should be agreed upon by the woman who has suffered the assault and her physician after assessing risks and benefits (**C-III**).
4. If postexposure prophylaxis is recommended, it should be initiated preferably within 6–72 h after the assault (**B-III**).

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### Conflict of interest

In order to avoid and/or minimize any conflicts of interests, the members of the Expert Panel have made a formal declaration of interests. In this statement, some of the authors have received funding to take part in conferences and to conduct research, as well as having received payments as speakers for public institutions and pharmaceutical companies. These activities do not affect the clarity of the present document on not entering into a conflict of interests as recommended with the fees and/or help received. It should be pointed out that as regards the drugs in the document, only the active ingredients are mentioned and not any commercial brand.

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### Appendix 1.

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