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Consensus statement

Executive summary: Pre-exposure prophylaxis for prevention of HIV infection in adults in Spain: July 2016

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A B S T R A C T

Administration of antiretroviral drugs to individuals exposed to, but not infected by, HIV has been shown to reduce the risk of transmission. The efficacy of pre-exposure prophylaxis (PrEP) makes it obligatory to include it in an integral program of prevention of HIV transmission, together with other measures, such as use of the condom, training, counseling, and appropriate treatment of infected individuals. In this document, the AIDS Study Group (GeSIDA) of the Spanish Society of Infectious Diseases and Clinical Microbiology (*Sociedad Española de Enfermedades Infecciosas y Microbiología Clínica* [SEIMC]) provides its views on this important subject. The available evidence on the usefulness of PrEP in the prevention of

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transmission of HIV is presented, and the components that should make up a PrEP program and whose development and implementation are feasible in Spain are set out.
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Resumen ejecutivo: profilaxis pre-exposición en adultos para la prevención de la infección por VIH en España: Julio 2016

R E S U M E N

Se ha demostrado que la administración de fármacos antirretrovirales a personas expuestas y no infectadas por el VIH puede reducir el riesgo de transmisión. La eficacia de la profilaxis pre-exposición obliga a considerar su inclusión en un programa integral de prevención de la transmisión del VIH, junto con otras medidas como el uso del preservativo, la formación y el consejo asistido y el tratamiento adecuado de las personas infectadas. En este documento, el Grupo de Estudio de SIDA (GeSIDA) de la SEIMC aporta su visión sobre este importante tema. Se presenta la evidencia disponible acerca de la utilidad de la PrEP en la prevención de la transmisión del VIH y se enumeran los elementos que deberían integrar un programa de PrEP, cuyo desarrollo y puesta en marcha sea factible y viable en nuestro medio.
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Despite the considerable advances in control of HIV infection, the number of newly infected persons continues to grow. The male condom and other barrier methods, while clearly efficacious, have not had the desired effect for control of the epidemic; therefore, alternative approaches to preventing transmission of HIV infection are necessary.

In this context, pre-exposure prophylaxis (PrEP) has been investigated as an additional prevention strategy. Administration of antiretroviral drugs to individuals exposed to but not infected by HIV has been shown to reduce the risk of transmission. Consequently, these individuals should be included in programs for the prevention of transmission of HIV. Supporters of PrEP do not consider it the only, or even the best, preventive measure, but as a tool that should be used in conjunction with current measures. The cornerstone of the struggle against HIV infection continues to be based on use of the condom, training, counseling, and appropriate treatment of infected individuals.

The AIDS Study Group (GeSIDA) of the Spanish Society of Infectious Diseases and Clinical Microbiology (Sociedad Española de Enfermedades Infecciosas y Microbiología Clínica [SEIMC]) is committed to addressing this important subject and providing its views on it. In this document, we aim to present available evidence on the usefulness of PrEP in the prevention of transmission of HIV. Based on the data supporting this strategy, we set out the components that should make up a PrEP program and whose development and implementation are feasible in Spain. The recommendations are graded based on scientific evidence and expert opinion by a letter indicating the strength of the recommendation (A, recommended, should be followed; B, consider, applicable in most situations; C, optional) and a number indicating the source of the recommendation (I, results of randomized clinical trials, meta-analyses; II, results of nonrandomized clinical trials or cohort studies; III, expert opinion).

The HIV epidemic in Spain: state of the art

New diagnoses (incidence) of HIV infection (2009–2014)

In 2014, the Spanish System for Information on New Diagnoses of HIV Infection (Sistema de Información sobre Nuevos Diagnósticos de VIH [SINIVIH]) was notified of 3366 new cases of HIV infection in Spain; of these 85% were men, and the mean age was 35 years. Men who have sex with men (MSM) accounted for 54% of all new diagnoses, heterosexual men and women for 26%, and injection drug users (IDU) for 3.4%.[1] The EPIVIH study provides the soundest national estimations of incidence, which stands at 1 case per 100 person-years (95%CI, 0.9–1.1) among the 30 679 first-time testers with at least one follow-up test between 2000 and 2009.[2] The highest risk of infection was recorded among male commercial sex workers (3.0 per 100 person-years; 95%CI, 2.2–4.1), MSM (2.5 per 100 person-years; 95%CI, 2.3–2.7), and IDU (1.6 per 100 person-years; 95%CI, 1.1–2.2). The incidence was 0.1 cases per 100 person-years in heterosexual men and women and female commercial sex workers.

Prevalence of HIV infection

In 2014, it was estimated that approximately 150 000 people were infected with HIV, that is, a prevalence in the general population of 0.4% (95%CI, 0.4%–0.5%). Furthermore, the prevalence of occult HIV infection was estimated to be 0.1%.[1] The prevalence of infection varies considerably between the different collectives who engage in risk practices. The EPIVIH study revealed a prevalence of HIV infection of 2.5% (95%CI, 2.4%–2.6%) in 145 337 first-time testers during the period 2000–2009.[2] By category of transmission and risk situations, the highest prevalence was recorded in transgender women (24.5%; 95%CI, 20.4%–29.0%), male sex workers (19%; 95%CI, 10.5%–24.5%), and IDU (17%; 95%CI, 13.3%–21.2%). Prevalence was 7.6% (95%CI, 7.2%–7.9%) in MSM, 0.9% in heterosexual men and women, and 0.8% (95%CI, 0.5%–1.2%) in female commercial sex workers.[2]

Risks and benefits of PrEP

Tables 1 and 2 present the results of clinical trials performed to evaluate the efficacy of PrEP. The trials were performed in different groups, including MSM (iPrEx [Iniciativa Profilaxis Pre-exposición],[3–8] PROUD,[9] and IPERGAY[10]), heterosexual men and women (Partners-PrEP,[11] TDF2,[12] FEM-PrEP,[13,14] and VOICE [Vaginal and Oral Interventions to Control the Epidemic][15]), and IDU (Bangkok Tenofovir Study).[16] As can be seen in the tables, efficacy was 44%–86%, except in 2 studies on women (FEM-PrEP[13,14]

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