INFORMACIÓN SOBRE LA RECOMENDACIÓN Cód.: 20250804_082_SEMPSPH

1. Recomendación de No Hacer

No recomendar profilaxis posexposición frente al VIH en situaciones en las que el riesgo de transmisión del virus sea insignificante: caso fuente sin VIH, exposición sexual a caso fuente con carga viral indetectable, exposición a fluidos que no suponen un riesgo (lágrimas, saliva, orina, sudor, esputo, heces, vómito o secreciones nasales, sin sangre visible), contacto de fluidos infectantes sobre piel intacta, mordeduras sin solución de continuidad, arañazo superficial con objetos afilados (incluidas las agujas abandonadas en la calle).

2. Objetivo y justificación de la recomendación de abandonar la práctica

La profilaxis posexposición frente al VIH está justificada en aquellos casos en los que existe un riesgo de transmisión del virus. Este riesgo depende de diferentes factores como la probabilidad de presencia de VIH en el caso fuente, la carga viral, el tipo de contacto o el grado de exposición, entre otros.

Los medicamentos empleados en la profilaxis posexposición pueden provocar reacciones adversas y, por tanto, tienen potencial de ocasionar daños. No obstante, el beneficio de su administración supera los riesgos en los casos en los que se siguen los criterios de indicación. Sin embargo, esta relación se invierte cuando el beneficio esperado de la profilaxis posexposición es prácticamente nulo debido a un riesgo de transmisión insignificante. Por ello, es recomendable evitar administrar la profilaxis en dichas situaciones.

Además, existen dudas sobre la posibilidad del desarrollo de resistencias a los antivirales.

Más allá de los propios medicamentos empleados, la profilaxis posexposición consume unos recursos sanitarios (por ejemplo, consultas médicas, consultas de enfermería y pruebas complementarias) y genera unos gastos tangibles e intangibles (por ejemplo, gastos de transporte e incertidumbre y malestar psicológico en las personas supuestamente expuestas) que solo resultan razonables cuando realmente se espera una eficacia de la intervención.

3. Sociedad a la que representa

Sociedad Española de Medicina Preventiva, Salud Pública y Gestión Sanitaria (SEMPSPGS)

4. Especialidades

Especialidad(es) a la(s) que implica esta recomendación (según REAL DECRETO 183/2008, de 8 de febrero):

Medicina del Trabajo

Medicina de Urgencias y Emergencias

Medicina Familiar y Comunitaria

Medicina Interna

Medicina Preventiva y Salud Pública

Microbiología y Parasitología: Biología, Bioquímica, Farmacia, Medicina o Química.

5. Enfermedad (Código CIE-11)

Enfermedad(es) a la(s) que se refiere la recomendación:

Algunas enfermedades infecciosas y parasitarias (1A00-1H0Z)

Factores que influyen en el estado de salud y contacto con los servicios sanitarios (QA00-QF4Z)

6. Experiencia de implementación

7. Indicadores

Profilaxis posexposición frente a VIH iniciada en situación de bajo riesgo de transmisión del virus.

8. Referencias bibliográficas

Se incluirá la bibliografía aportada por el autor(a) así como la aportada por GuíaSalud o panelistas como fuente de alta calidad de evidencia que apoya la recomendación.

Guidelines for HIV post-exposure prophylaxis [Internet]. Geneva: World Health Organization; 2024. PMID: 39259822.
- Exposures that do not require PEP include: • when the exposed individual is already living with HIV; • exposure to bodily fluids that do not pose a significant risk: tears, non-blood-stained saliva, urine, sweat, sputum and diarrhoea/faeces; • when the source is established to be HIV-negative or if the exposure was sexual and the source has an undetectable viral load. Note: Where exposure is suspected, provision of PEP should not be delayed by trying to identify or find out the HIV status or viral load of the source of exposure.
- Before starting PEP, people should be tested for HIV, using the relevant national guidelines. WHO recommends a testing strategy that includes a professional-use rapid test or an HIV self-test. If the HIV test is non-reactive (negative), PEP can be started immediately. If HIV tests are unavailable but the person is suspected to have been exposed to HIV, PEP should be started regardless.
- Do not wait for confirmation of source's HIV status before starting PEP. In some cases it may not be possible to confirm the source's HIV status, but this should not rule out starting PEP for the potentially exposed individual. If the status of the source is confirmed negative, or if the exposure was sexual and the source has an undetectable viral load, discontinue PEP.
- There have been no randomized controlled trials (RCTs) assessing the efficacy HIV PEP. Evidence of PEP efficacy comes from one case-control study (14) and several animal studies and other types of observational studies (15, 16). These studies show that HIV PEP can reduce the risk of infection if taken quickly after exposure and for a long enough period.

Cowan E, Kerr CA, Fernandez A, Robinson LG, Fayorsey R, Vail RM, Shah SS, Fine SM, McGowan JP, Merrick ST, Radix AE, Monroe AK, Rodrigues J, Hoffmann CJ, Norton BL, Gonzalez CJ. PEP to Prevent HIV Infection [Internet]. Baltimore (MD): Johns Hopkins University; 2024 Oct. PMID: 33026756.
- In the context of sexual exposure, there is a robust body of evidence that individuals do not sexually transmit HIV if they are taking antiretroviral therapy and have an undetectable viral load (HIV RNA <200 copies/mL).
- No data are currently available regarding HIV transmission via needle sharing when the source has an undetectable viral load.
- If the source is known to have HIV and an undetectable viral load (HIV RNA <200 copies/mL) at the time of the exposure and is taking ART, the clinician should explain that an individual with an undetectable viral load will not transmit HIV through sex. In the case of a sexual exposure to a source with HIV, the exposed individual may discontinue PEP if the source is taking ART and has an undetectable viral load at the time of exposure; providing information about U=U (undetectable = untransmittable) to the exposed individual may be reassuring. However, if an exposed individual requests PEP, it should not be denied.
- Research has established that a source with HIV who is taking ART and has an undetectable viral load (HIV RNA <200 copies/mL) at the time of a consensual sexual exposure will not transmit the virus through sex [Rodger, et al. 2019; Cohen, et al. 2016; Rodger, et al. 2016]. U=U does not apply to exposure through

needle sharing, breast/chestfeeding, or needlestick injury.
- Exposures that DO NOT warrant PEP: Kissing, spitting, oral-to-oral contact in the absence of mucosal damage (e.g., mouth-to-mouth resuscitation); human bites not involving blood; exposure to needles or sharps that have not been in contact with an individual with or at risk of HIV
- Exposures for which PEP should be promptly considered: Condomless vaginal or anal intercourse during sexual abuse; oral sex with ejaculation or blood exposure during sexual abuse; injuries with exposure to blood from a source known to have HIV; injuries with exposure to blood from a source of unknown HIV status (including needlesticks and human bites). See Box 1: Risk per 10,000 Exposures of Acquiring HIV From an Infected Source and Factors That Increase Risk, above, for risk calculations for specific exposures.

Broyles LN, Luo R, Boeras D, Vojnov L. The risk of sexual transmission of HIV in individuals with low-level HIV viraemia: a systematic review. Lancet. 2023 Aug 5;402(10400):464-471. doi: 10.1016/S0140-6736(23)00877-2. Epub 2023 Jul 22. PMID: 37490935; PMCID: PMC10415671.
- There is almost zero risk of sexual transmission of HIV with viral loads of less than 1000 copies per mL.
- There are no data on risk of transmission through sharing of injection drug use equipment at varying levels of viraemia.

Cresswell F, Asanati K, Bhagani S, Boffito M, Delpech V, Ellis J, Fox J, Furness L, Kingston M, Mansouri M, Samarawickrama A, Smithson K, Sparrowhawk A, Rafferty P, Roper T, Waters L, Rodger A, Gupta N. UK guideline for the use of HIV post-exposure prophylaxis 2021. HIV Med. 2022 May;23(5):494-545. doi: 10.1111/hiv.13208. Epub 2022 Feb 14. Erratum in: HIV Med. 2022 Jul;23(6):701. doi: 10.1111/hiv.13327. PMID: 35166004.
- PEP is not recommended if the index partner has been on ART for at least 6 months with an undetectable plasma HIV viral load (at the time of last measurement and within the last 6 months) and with good reported adherence.
- PEP is generally not indicated following a sharps injury if the index case has been on ART for at least 6 months with an undetectable plasma HIV viral load (at the time of last measurement and within the last 6 months) and with good reported adherence; however, because of lack of direct evidence, a case-by-case decision can be made depending on the nature of the injury.
- PEP is not recommended following a splash injury if the index case is known to have a sustained undetectable viral load.
- PEP is not recommended where there is no or negligible risk of HIV transmission, e.g. through intact skin that comes into contact with HIV-infected blood or other bodily fluids.
- The extensive data informing elimination of transmission risk with suppressive ART only applies to sexual exposures. In the context of sharps and mucocutaneous splash injuries, the transmission risk when the index is on suppressive ART is likely to be negligible. PEP is not recommended following any splash injury where the index case has been on ART for at least 6 months with an undetectable plasma HIV viral load (at the time of last measurement and within the last 6 months) with good reported adherence, but can be considered if there is a blood splash to a mucosal surface and the index case is not known to have an undetectable viral load. Although it is highly likely that viral suppression eliminates the risk of HIV transmission through sharps injuries, the lack of evidence to support this should be discussed, and a case-by-case decision can be made in the context of high-risk sharps injuries. Where there are concerns about the viral load of the index case being detectable, or concerns around ART adherence or if the injury is particularly high risk (e.g. deep wound with hollow bore needle), then PEP could be considered.

Bamford A, Tudor-Williams G, Foster C. Post-exposure prophylaxis guidelines for children and adolescents potentially exposed to HIV. Arch Dis Child. 2017 Jan;102(1):78-83. doi: 10.1136/archdischild-2015-309297. Epub 2016 Jun 28. PMID: 27974330.
- As in the UK adult PEPSE guideline, PEP is not usually recommended unless the estimated risk of transmission is greater than 1:1000. This is considered to be a high enough risk to outweigh the known risks of severe toxicity that can occur with antiretroviral agents used for PEP such as raltegravir (hypersensitivity reactions, myopathy, rhabdomyolysis, suicidal ideation and pancreatitis) and

tenofovir/emtricitabine (associated with renal dysfunction and pancreatitis).

Libois A, Florence E, Derdelinckx I, Yombi JC, Henrard S, Uurlings F, Vandecasteele S, Allard SD, Demeester R, Van Wanzeele F, Ausselet N, De Wit S. Belgian guidelines for non-occupational HIV post-exposure prophylaxis 2017. Acta Clin Belg. 2018 Aug;73(4):275-280. doi: 10.1080/17843286.2018.1428506. Epub 2018 Feb 12. PMID: 29429390.
- NONOPEP [profilaxis posexposición no ocupacional] is not recommended if the source is on cART [combination antiretroviral drugs] with a confirmed and sustained (>6 months) pVL [carga viral plasmática] <200 copies/ml.

Nwaiwu CA, Egro FM, Smith S, Harper JD, Spiess AM. Seroconversion rate among health care workers exposed to HIV-contaminated body fluids: The University of Pittsburgh 13-year experience. Am J Infect Control. 2017 Aug 1;45(8):896-900. doi: 10.1016/j.ajic.2017.03.012. Epub 2017 Apr 24. PMID: 28449921.
- We recommend that PEP be offered even in exposures involving a source patient with very low or undetectable viral loads because the risk of transmission still exists.
Grupo de expertos de Secretaría del Plan Nacional sobre el Sida (SPNS); Grupo de Estudio de Sida (GeSIDA); Sociedad Española de Medicina y Seguridad del Trabajo (SEMST); Sociedad Española de Medicina Preventiva, Salud Pública e Higiene (SEMPSPH); Asociación Española de Especialistas en Medicina del Trabajo (AEEMT); Sociedad Española de Salud Laboral en Administración Pública (SESLAP); Asociación Nacional de Médicos del Trabajo en el Ámbito Sanitario (ANMTAS); Sociedad Española de Infectología Pediátrica (SEIP); Sociedad Española de Medicina de Urgencias y Emergencias (SEMES); Grupo de Estudio de Hepatitis Víricas-SEIMC (GEHEP); Federación Española de Enfermería del Trabajo (FEDEET). Documento de Consenso sobre profilaxis postexposición ocupacional y no ocupacional en relación con el VIH, VHB y VHC en adultos y niños [Consensus Document on post-exposure prophylaxis against HIV, HBV and HCV in adults and children]. Enferm Infecc Microbiol Clin. 2016 Feb;34(2):121.e1-15. Spanish. doi: 10.1016/j.eimc.2015.08.005. Epub 2015 Sep 26. PMID: 26409726.
- Recomendaciones generales de PPEO (ocupacional): “En general se recomienda realizar PPE cuando el riesgo de transmisión es alto, cuando el riesgo no es alto se debe valorar individualmente cada caso y cuando el riesgo es despreciable o nulo no se recomienda”.
- En PPEO por exposición percutánea a sangre u otros líquidos potencialmente infectantes, cuando la carga viral es indetectable se puede considerar no realizar PPE porque el riesgo de transmisión es muy bajo.
- Recomendaciones de PPENO (no ocupacional): “En general se recomienda realizar PPE cuando el riesgo de transmisión es apreciable, cuando el riesgo es bajo o mínimo se debe valorar individualmente cada caso y cuando el riesgo es despreciable o nulo no se recomienda”.
- La toxicidad del TAR es un problema de gran relevancia que condiciona la adherencia al mismo. A esto hay que añadir la existencia de posibles interacciones farmacológicas derivadas de la administración previa o concomitante de otros fármacos, que pueden reducir el beneficio de la PPE o aumentar la posibilidad de efectos adversos. Existen comunicaciones que ponen de relieve que los FARV son peor tolerados entre los sujetos que reciben PPE que entre los pacientes infectados por el VIH. Por este motivo, se hace precisa una adecuada planificación de la pauta de la PPE, y una estrecha monitorización de los pacientes y de sus efectos adversos.

Webster DP. Is HIV post-exposure prophylaxis required following occupational exposure to a source patient who is virologically suppressed on antiretroviral therapy? HIV Med. 2015 Feb;16(2):73-5. doi: 10.1111/hiv.12187. PMID: 25597403.
- In summary, the data suggest that the risk of HIV transmission from virologically suppressed individuals on cART is extremely low (even assuming a significant injury) and this is likely to be outweighed by the potential risks associated with PEP. HIV cell-associated DNA might be a source of virus transmission in these individuals, but compelling data are lacking and require extrapolation from very different transmission scenarios. A panel of experts felt that a thorough review of the literature reveals no new data at this time to warrant a change in the UK guidance to bring it in line with that of the USA.

Young TN, Arens FJ, Kennedy GE, Laurie JW, Rutherford Gw. Antiretroviral post-exposure prophylaxis (PEP) for occupational HIV exposure. Cochrane Database Syst Rev. 2007 Jan 24;2007(1):CD002835. doi: 10.1002/14651858.CD002835.pub3. PMID: 17253483; PMCID: PMC8989146.

- The use of occupational PEP is based on limited direct evidence of effect. However, it is highly unlikely that a definitive placebo-controlled trial will ever be conducted, and, therefore, on the basis of results from a single case-control study, a four-week regimen of PEP should be initiated as soon as possible after exposure, depending on the risk of seroconversion.
- Healthcare workers should be counseled about expected adverse events and the strategies for managing these. They should also be advised that PEP is not 100% effective in preventing HIV seroconversion. A randomized controlled clinical trial is neither ethical nor practical. Due to the low risk of HIV seroconversion, a very large sample size would be required to have enough power to show an effect. More rigorous evaluation of adverse events, especially in the developing world, are required. Seeing that current practice is partly based on results from individual primary animal studies, we recommend a formal systematic review of all relevant animal studies.