

HIV Preexposure Prophylaxis (PrEP) - Recommendation on practical handling 2017

The reference group for antiviral therapy (RAV) has, under the leadership of Dr Bo Hejdeman, Venhålsan, Södersjukhuset, Stockholm, produced recommendations on practical management of pre-exposure prophylaxis. A remaining problem (August 2017) that in practice affects the prescribing of PrEP is the financing issue, which is highlighted in the document.

Recommendation

Pre-exposure prophylaxis (PrEP) is primarily recommended for men who have sex but men (MSM) who in an overall assessment have a sexual behavior that constitutes a significant risk of being infected with HIV and where other infection prevention measures are deemed insufficient (recommendation level A). PrEP can also be considered for other people where the risk of infection is judged to be significant (recommendation grade C).

Insertion and follow-up of PrEP should always take place in parallel with other infection prevention measures such as information on how various sexually transmitted infections (STIs) are transmitted, condom use, advice regarding risk reduction, support and help for drug withdrawal and possibly also counselor contact. In the overall assessment, the conditions for compliance must also be taken into account. Prescribing should only be done by or in close collaboration with doctors and clinics with experience of HIV treatment.

Background

PrEP in the form of medicines containing tenofovir / emtricitabine (Truvada®) is given for preventive purposes together with other infection prevention measures to people who are judged to be at high risk of becoming infected with HIV. PrEP has a very good effect provided that the drug is actually taken, which has been shown in two European studies among MSM and transgender people. In an English study (PROUD) 1 tablet of Truvada® was given daily and in a French study (IPERGAY) treatment was given instead "as needed", ie 2 tablets 2–24 hours before intercourse and then one tablet daily for two days after the last sexual contact. In both studies, a 86% reduction in HIV transmission was seen [1-2]. The protective effect in women has varied in different studies. One reason may be that the pharmacokinetics of tenofovir are different in cervical and rectal tissue [3], another is possible interaction with the microflora in the vagina [4], but it is uncertain what significance this has because there are also studies that have shown that the protective effect is equally good in both men and women if there is high adherence to medication [5-6]. There are no published studies with PrEP "when needed" during heterosexual intercourse or during transmission in connection with intravenous drug use.

The use of PrEP in particularly at-risk individuals, such as MSM and transgender people, is recommended by the European AIDS Clinical Society (EACS), the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO) [7]. The WHO advocates PrEP, in combination with other infection prevention measures, in populations where the HIV incidence is 3 per 100 person-years or higher. The corresponding HIV incidence in Sweden is only seen in certain subgroups of MSM with a high incidence of other STIs. In Sweden, Pharmaceutical Benefits

The Board (TLV) in a decision from October 2016 determined that Truvada®, prescribed for adults for continuous use as PrEP, is included in the so-called high-cost protection.

Prescribing of Truvada® as PrEP, or where applicable the corresponding generics, has not yet started in Sweden. This is mainly due to the fact that the issue of financial reimbursement to clinics that will be responsible for prescribing medicines and follow-up of patients has not been resolved and as national guidelines for follow-up have so far been lacking.

Factors that may indicate that a person is at high risk of becoming infected with HIV

MSM with two or more episodes of recurrent gonorrhea and / or chlamydia anal and / or infection with lymphogranuloma venereum regardless of local (oral, urethral and / or anal) during the last 2-year period and / or syphilis during the last 5-year period.

Other anamnestic data that may indicate an increased risk of HIV infection among MSM are;

- Drug use in connection with sex
- Information on sales of sexual services
- Travel to countries where the incidence of HIV is high and unprotected sexual contact is expected to take place

HIV-negative sexual partners of people living with HIV are rarely relevant for PrEP as almost everyone with known HIV in Sweden is on well-functioning antiretroviral treatment, which means that the risk of infection can thus be considered negligible.

In a general calculation based solely on the occurrence of recurrent rectal STIs and / or syphilis within the last 2 year period, approximately 500 MSM per year should be relevant for PrEP in Sweden. The calculation is made on the basis of the public health authority's national statistics and based on the presence of STI among MSM who visit the Venhälsan clinic at Södersjukhuset in Stockholm.

Fact box 1: Processing at PrEP**Before starting treatment**

Information about

- that PrEP does not constitute 100% protection against HIV
- that PrEP does not protect against other STIs which condoms do
- potential side effects (kidney function and bone mineralization)

Sampling

- HIV serology (4th generation)
- Hepatitis B serology (exclusion of chronic carriers)
- B-creatinine / GFR
- U-protein HC / creatinine [8]
- Chlamydia and gonorrhea from all premises, syphilis serology

Vaccination

- Offer hepatitis B vaccination to anyone who lacks protection

Prescription of drugs

- Truvada® (or, as the case may be, the corresponding generic product) is initially prescribed for 1 month (one withdrawal).
- Indication "PrEP" is stated on prescription and dosage 1 tablet once daily
- Benefit type; "With benefit"

Follow-up

After 1 month

- Conversations about compliance and any side effects
- HIV serology (4th generation)
- P-creatinine
- U-protein HC / creatinine
- Prescription renewal for another 2 months.

Thereafter every 3 months

- Conversations about compliance, safe sex, risk reduction.
- HIV serology (alternative HIV rapid black test; Alere Determine™ HIV 1/2 Ag / Ab Combo)
- Sampling for chlamydia, gonorrhea, syphilis
- Prescription renewal for 3 months (one withdrawal)

Sample supplement every 6 months

- P-creatinine
- U-protein HC / creatinine

Additional measures that can be considered

- Hepatitis A serology before starting treatment and offering vaccination to those who do not have protection
- Hepatitis C serology once / year and addition of ALT at each blood sample for early detection of hepatitis C
- 6 ml of EDTA blood that is saved in connection with each blood sample in order to be able to subsequently analyze HIV RNA in the event of HIV infection

References

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