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Recommendations for Post-Exposure Prophylaxis against HIV infection in Health Care Workers in Europe



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Recommendations for Post-Exposure Prophylaxis against HIV infection in Health Care Workers in Europe.

Definition of health care worker (HCW) and occupational exposure

HCW is defined as a person whose activities involve contact with patients or with blood or other body materials from patients in a health-care or laboratory setting.

Occupational exposure is defined as any at risk accidental exposure to at risk body materials during working activity.

Policies

All preventive efforts should be made to reduce the risk of occupational exposures (i.e. development of educational programs, implementation of standard precautions, provision of safety devices and personal protective equipment, implementation of safer procedures, etc)

- **Educational Programs**

All HCWs should be informed and educated about:

- the possible risk of HIV transmission from an occupational exposure
- the importance of seeking urgent advice following any occupational exposure
- the knowledge about efficacy and toxicity of drugs used for PEP
- the benefits from prompt administration of PEP

- **Reporting an occupational exposure**

- Every health authority should identify designated health care providers to whom HCW can be urgently referred to in case of occupational exposure.
- Local health policies should specifically identify who will be responsible for the management of occupational exposures, for the provision of PEP and for clinical and serological post-exposure follow up.
- All HCWs should be made aware of how to report an exposure and to whom it should be reported.

- **Availability of PEP**

- The availability of PEP should be publicly advertised in order that it may be immediately and readily accessible and initiated as soon as possible following an occupational exposure
- In health settings where PEP is not available:
 - start kits should be available, and/or

- a collaborative connection should be established with those centres where PEP may be provided, and information about where and how the drugs may be obtained should be publicly advertised.

PEP When?

The issue of PEP should be evaluated following an occupational exposure with the potential for HIV transmission, based on the type of exposure, the type of body fluid or material involved, and source patient's evaluation.

Type of exposures:

- | | |
|--|-----------------|
| 1. percutaneous injury | PEP recommended |
| 2. exposure of mucous membrane including the eye | PEP considered |
| 3. exposure of non intact skin | PEP considered |
| 4. exposure of intact skin | PEP discouraged |
| 5. bite | PEP considered |

Type of materials:

- | | |
|---|-----------------|
| 1. blood | PEP recommended |
| 2. body materials containing visible blood | PEP recommended |
| 3. cerebrospinal fluid | PEP recommended |
| 4. concentrated virus in a research laboratory or production facility | PEP recommended |
| 5. semen; vaginal secretions; synovial, pleural, peritoneal, pericardial, or amniotic fluid, and tissues. | PEP considered |
| 6. urine, vomit, saliva, faeces, tears, sweat, sputum | PEP discouraged |

Source patient

1. Source patient known to be HIV-infected

PEP recommended

Available clinical information about stage of infection (i.e. primary acute infection, asymptomatic, symptomatic, AIDS diagnosis), CD4+ T-cell count, results of viral load testing, current and previous antiretroviral therapy, and results of any already available genotypic or phenotypic viral resistance testing should be collected for consideration in choosing the most appropriate PEP regimen. If this information is not immediately available, initiation of PEP, if indicated, should not be delayed; changes in the PEP regimen can be made after PEP has been started, as appropriate.

- If genotypic or phenotypic viral resistance tests are not already available, they should not be performed.

2. Source patient serostatus unknown

PEP considered

Inform the source patient and ask for informed consent to HIV testing.

- Efforts should be made to assure “immediate” results in order to prevent unnecessary initiation of PEP.
- Rapid HIV-antibody test could be useful for the diagnosis of HIV infection in the source patient, facilitating the prompt beginning of PEP in the exposed HCW and limiting unnecessary treatment.

3. Source patient who denies his/her consent to HIV test

PEP considered

Consider the likelihood of HIV infection in the source:

- risk behaviors
- results of previous laboratory investigations
- clinical symptoms (e.g. acute syndrome suggestive of primary infection or undiagnosed immunodeficiency disease)

4. Source patient unknown or who cannot be tested

PEP considered

Consider the likelihood of HIV infection in the possible source:

- prevalence of HIV infection on a specific unit

5. Source patient HIV-seronegative

PEP discouraged

In the absence of clinical or epidemiological likelihood of HIV infection in the source patient, p24 HIV antigen testing or biomolecular analyses are not recommended.

Timing of PEP

PEP should be initiated as soon as possible following an occupational exposure.

The time interval from exposure after which PEP should be discouraged is 72 hours.

Duration of PEP

PEP should be administered for 4 weeks.

PEP What?

Any combination of antiretrovirals approved for the treatment of HIV-infected patients can be used in PEP regimens.

- **Triple combination therapy is recommended as first line PEP regimen.**

Suggested first-choice treatment (i.e. start kits) in case of exposure to a source patient with unknown HIV serostatus, or HIV-positive but never treated

2 NRTI + 1 PI or 1 NNRTI

i.e. ZDV/3TC (Combivir) + NFV or EFV

- Dual NRTI combination therapy could be considered an option on a case-by-case evaluation (i.e. pregnancy).
- Nevirapine is not indicated for a full course of PEP because of the reported severe hepatotoxicity, and could be considered only if no other choice exists.
An initial single dose of Nevirapine could be considered, on a case-by-case evaluation.
- Zidovudine (ZDV) is the only drug to date for which there is evidence of a reduction of risk of HIV transmission following occupational exposure. It is reasonable that ZDV is included in all first line PEP treatments, if not otherwise contraindicated (i.e. resistance in the source patient).
- A simplified regimen should be used whenever possible, in order to increase adherence.
- If constitutional adverse reactions are reported which could be controlled through the administration of symptomatic drugs, this could enhance adherence to the prescribed regimen, with the ultimate goal of achieving treatment completion in the exposed HCW.
- Any information available in the source patient's medical record and history taking about previous and current antiretroviral treatment may be important in the choice of PEP regimen.
Consider the possibility that the virus may be antiretroviral resistant:
 - prolonged treatment with any antiretroviral
 - clinical progression of disease
 - persistently increasing viral load and/or a decline in CD4 T-cell
 - lack of virological response to a change in therapy
 - antiretroviral drug profiling (i.e., genotypic or phenotypic viral resistance tests), if available
- Ad hoc genotypic and/or phenotypic resistance tests are not recommended.
- When prescribing PEP, check for:
 - any existing medical conditions and any medications (auto-medication, drugs) an exposed HCW may be taking, in order to prevent toxicity and drug interactions.

PEP in pregnancy

- Women should be asked about the possibility of pregnancy
- If pregnancy cannot be excluded, a pregnancy tests should be performed
- Pregnancy *per se* should not preclude the use of HIV PEP
- The decision to use PEP during pregnancy should involve discussion with the exposed HCW regarding the risk of HIV infection, the risk of transmission to her baby, and the potential benefits and potential risks for her and her baby, in order to help her reach an informed personal decision about the use of PEP.
- Because teratogenic effects were observed in primates after drug exposures similar to those representing human therapeutic exposure, the use of efavirenz should be avoided in pregnant women.
- Recent reports of fatal and nonfatal lactic acidosis in pregnant women treated throughout gestation with a combination of d4T and ddI have prompted warnings about the use of these drugs during pregnancy.
- Indinavir is associated with hyperbilirubinemia and it should not be administered shortly before delivery.

Follow-up

All HCWs occupationally exposed to HIV should receive follow-up counseling, post-exposure testing and medical evaluation regardless of whether they have received PEP or not.

Toxicity monitoring:

Regular medical follow-up during PEP treatment is necessary to monitor acceptability and possible toxicity of drugs, according to toxic profiles of the drugs included in the PEP regimen.

Routine laboratory tests could be performed on a case-by-case basis.

Complete blood cell count, ALT, AST, creatinine, glucose, amylase blood levels and urine test could be performed at baseline and thereafter at 15 days, and, only if altered, at 30 days.

HIV serological follow-up:

HIV testing should be performed shortly after exposure and thereafter at 6 weeks, 3 and 6 months.

The routine use of direct virus assay (HIV p 24 antigen or tests for HIV-RNA) to detect infection in exposed HCW is not recommended.

Visits and clinical evaluation are recommended at 6 weeks, 3 and 6 months, and in the case of development of signs/symptoms.

Patients should be strongly encouraged to promptly report signs/symptoms, and should be counseled in order to prevent secondary transmission during the follow-up period.

Management of occupational HIV infection and of PEP failure

Therapy for primary HIV infection is based on theoretical considerations, and the potential benefits should be weighed against the potential risks. Therefore, in case of seroconversion, the infected HCW should be immediately referred to a specialist in the management of HIV infection.

Any case of PEP failure should be thoroughly investigated, in order to avoid misclassification and to gather important information that could be beneficial to others. Standardized mechanisms for the prompt reporting of cases of HIV infection despite PEP should be implemented to support the epidemiological as well as clinical management of cases.