

Summary of BASHH guidelines for use of PEP following sexual exposure

What follows is a summary of the final draft of guidelines drawn up by the British Association for Sexual Health (BASHH), due for publication June 2005. This summary highlights parts of the guidelines of most relevance to health promoters and focuses on sex between men. The guidelines also deal with sex between men and women which is not covered here - see the BASHH guidelines for details of HIV transmission risks of heterosexual sex and recommendation for PEP prescription. Areas of the guidelines intended for clinicians (such as drug prescribing and clinic protocols) are not covered in this summary.

The BASHH guidelines are recommendations to clinic and hospital staff and are neither enforceable nor do they represent what 'must' happen. Ultimately PEP prescription remains at the discretion of individual clinicians and should take into account the patient's circumstances and wishes.

Risk of HIV transmission

Use of PEP depends on the likelihood that the 'source' individual had HIV. When this is unknown HIV prevalence for different risk groups and geographical areas is used to judge the likelihood of exposure to HIV.

The BASHH guidelines estimate of risk of HIV transmission per exposure from a known HIV positive individual.

Receptive anal sex	0.1 - 3%
Insertive anal sex	0.06%
Fellatio	0 - 0.04%
Mucous membrane exposure	0.09%

BASHH recommendations for prescribing PEP

	Source is known to have HIV	HIV status of source is unknown but from group or area with HIV prevalence (greater than 10%)
Receptive anal sex	PEP 'recommended'	PEP 'recommended'
Insertive anal sex	PEP 'recommended'	PEP 'considered'
Fellatio with ejaculation	PEP 'considered'	PEP 'considered'
Fellatio without ejaculation	PEP not 'recommended'	PEP not 'recommended'
Semen in eye (an example of mucous membrane exposure)	PEP 'considered'	not stated

If the source is not from a group or area of high HIV prevalence PEP is not 'recommended' for any sexual act and is only 'considered' for receptive anal sex.

However, other factors that can influence the risk of HIV transmission and therefore whether PEP is prescribed include:

- Viral load in the 'source' individual (however, low or 'undetectable' viral load in blood does not rule out the possibility of HIV transmission or of a higher viral load in semen)
- Presence of other sexually transmitted infections
- Bleeding during sex or sexual assault

Does PEP work?

In the absence of studies showing how effective PEP is with humans, the following research is cited by BASHH to support PEP use:

- Studies with apes: two studies with the drug tenofovir showed 100% protection against SIV (the ape equivalent of HIV) or HIV-2 if given within 24-36 hours and for 28 days. One study cited using zidovudine, lamuvudine and indinavir showed no protection against infection
- Studies of health care staff: a study of health care workers receiving just one drug (zidovudine aka AZT) which proved protective against infection is cited, although reference is made to over 20 cases of PEP failing following exposure in health care settings. No human evidence exists supporting extra benefit of using additional antiretroviral drugs but the guidelines repeat the argument that triple drug PEP therapy should be given in view of its greater effectiveness at low-ering viral load
- Studies of infants born to HIV-infected women: several studies are referred to suggesting PEP's protective effect if given to the child after delivery
- Studies of those receiving PEP following sexual exposure: two Brazilian studies are cited showing no or much reduced sero-conversions in those taking PEP compared to those who did not

Factors influencing the effectiveness of PEP as identified in the BASHH guidelines are:

- Delay in starting treatment, with PEP seen as possibly less effective or ineffective after 72 hours but possibly still considered if exposure is 'high risk'
- Drug-resistant strains of HIV may reduce PEP's effectiveness with resistance testing of the 'source' of infection considered and/or factoring in resistance when prescribing PEP drug combinations
- HIV remaining in parts of the body where antiretroviral drugs' ability to penetrate is variable
- Poor adherence to the PEP drug regime

Risks of PEP

Side effects

The guidelines document frequent side effects such as diarrhoea and nausea, which can be alleviated with medication. More serious side effects such as lipid abnormalities, liver problems, diabetes and insulin resistance are associated with particular antiretroviral drugs and these are detailed in the guidelines.

BASHH note that HIV negative people taking PEP appear to experience side effects more than HIV positive people taking antiretrovirals.

Drug-resistance

One risk of PEP is that of a permanent infection with drug-resistant HIV. This could occur after someone fails to adhere to the PEP drug regime and in so doing the virus becomes resistant to those drugs used in the PEP combination. Or the virus was already resistant to one or more of the drugs prescribed for PEP before entering the body, leading to a permanent infection with a drug-resistant strain of HIV.

Increases in risk-taking

Regarding concerns that PEP increases risk behaviour the guidelines cite studies suggesting PEP availability or use may increase or decrease willingness to engage in sexual risk-taking, with a greater number of studies suggesting PEP use leads to less risk behaviour. The guidelines recommend that community based organisations should proactively provide information about PEP alongside other HIV prevention strategies.

Prescribing recommendations

BASHH stress PEP should be seen as the last resort when conventional HIV prevention methods have failed. Decisions about PEP prescribing should be taken on a case by case basis using a risk versus benefit analysis. Rapid HIV antibody testing should be used to determine pre-existing HIV infection in the person presenting for PEP (to avoid an established HIV infection being treated inadequately with a short four week course of PEP). Ability to adhere to PEP and the individual's wishes should also be considered.

Drugs used for PEP are chosen from those used against established infection, including:

- Nucleoside reverse transcriptase inhibitors (NRTIs)
- Non-nucleoside reverse transcriptase inhibitors (NNRTIs)
- Protease inhibitors (PIs)

The NRTI zidovudine (AZT) is the only drug for which there is evidence of reduction of HIV risk in humans and is considered by many for inclusion in a PEP regime (unless there is evidence of resistance to this drug in the source individual). As with established infection a three drug combination is recommended for PEP. Details of drugs recommended and not recommended for PEP can be found in the guidelines.

Individuals repeatedly asking for PEP or with ongoing risk behaviour

No data exists suggesting significant numbers of people use PEP repeatedly. Individuals are considered for repeat courses of PEP according to the risk of HIV at the time of presentation, particularly if that person is a sex worker, in a sero-discordant relationship or unable to get their partner to follow safer sex behaviour. The guidelines recommend that those repeatedly asking for PEP are strongly encouraged to see a Health Advisor and/or psychologist.

Those presenting more than once a year, unless in the categories above, should be referred for discussion of safer sex strategies but also considered for PEP (conditional on discussing their safer sex behaviour).

The finalised BASHH guidelines on PEP following sexual exposure are due for release in June 2005. They will be available to download from www.bashh.org