

**In forthcoming issues:**

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## **HIV Post Exposure Prophylaxis Following Sexual Exposure**

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In April 2004 the British Association for Sexual Health and HIV (BASHH) produced guidelines for clinicians to assist them in prescribing HIV Post Exposure Prophylaxis following Sexual Exposure (PEPSE). In July 2004 the Terence Higgins Trust (THT) launched a national awareness raising campaign aimed at gay men as part of the Department of Health's Community HIV/AIDS Preventions Strategy (CHAPS) to inform them about the availability and effectiveness of PEPSE, referred to from now on as PEP. In response to increased requests for information about PEP, this briefing is designed to equip you to answer enquiries from the public. The information in this briefing is taken from the BASHH guidelines and the THT campaign.

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### **What is Post Exposure Prophylaxis?**

Post Exposure Prophylaxis (PEP) is the name given to a course of anti-retroviral drugs prescribed to someone who has been exposed to HIV. Previously, it was only available to healthcare workers after occupational exposure such as a needle stick injury, but it has now become available to people following sexual exposure. It is recommended that PEP be administered inside of 72 hours after exposure for it to be effective in preventing HIV transmission. After 72 hours the chances of PEP being effective are vastly reduced.

The course of drugs usually lasts 28 days and is obtainable through the GUM/HIV departments of major London hospitals, or through their Accident and Emergency Departments outside normal clinic hours. People may therefore self-refer for PEP, but they must also meet clearly defined prescribing criteria which assess the likelihood that they have come into contact with HIV. Individuals are assessed on a case-by-case basis and there is no guarantee that PEP will be prescribed merely because it has been requested.

PEP is not a 'morning after pill', and is certainly not a cure for HIV. It is not guaranteed to prevent HIV from taking hold once the virus has entered the body. Also., the drugs can cause severe side effects such as diarrhoea, nausea and prolonged headaches.

**It should be emphasised that following safer sex practices sex remains the most efficient way of staying safe from HIV.**

## What are the prescribing criteria for PEP?

The guidelines require an assessment of the risk of HIV transmission to be made using the following formula:

*risk of HIV transmission = risk that source is HIV positive x risk of exposure*

Where the HIV status of the source contact is not known for definite to be positive, membership of a high prevalence group or coming from a high prevalence area is used to judge the likelihood of exposure having occurred.

Tables are provided in the BASHH guidelines to enable this calculation; this is a broad summary:

<i>HIV status of partner</i> <i>Sexual activity of patient</i>	Partner with known HIV positive status	Partner with unknown HIV status but from high prevalence area/group
<i>Receptive anal sex</i>	<b>PEP 'recommended'</b>	<b>PEP 'recommended'</b>
<i>Insertive anal sex</i>	<b>PEP 'recommended'</b>	<b>PEP 'considered'</b>
<i>Oral sex with ejaculation</i>	<b>PEP 'considered'</b>	<b>PEP 'considered'</b>
<i>Oral sex no ejaculation</i>	<b>PEP 'not recommended'</b>	<b>PEP 'not recommended'</b>
<i>Mucous membrane exposure (e.g. semen in eye)</i>	<b>PEP 'considered'</b>	<b>not stated</b>

If the source contact is neither known to be HIV positive nor from a high prevalence area or group, PEP is 'not recommended' for any sexual acts, except receptive anal intercourse when it would be 'considered'.

There are other factors which may influence the likelihood of HIV transmission where exposure has occurred and these will also be taken into consideration.

For example, in a known HIV positive source an undetectable viral load will significantly reduce the likelihood of transmission. However, it should be noted that an undetectable viral load in plasma (blood) does not always correlate with an undetectable viral load in semen.

Equally, the presence of another sexually transmitted infection in either partner will increase the risk of HIV transmission from a known HIV positive source.

Trauma to mucous membranes (bleeding) during sex is not uncommon and this can increase the likelihood of transmission from a known HIV positive source. This is of particular importance in cases of sexual assault.

It must be emphasised once more that these guidelines are just that—they are recommendations to clinics and are not enforceable. There are no guarantees that PEP will be prescribed. It remains at the discretion of the individual clinician to take account of patients' wishes and other circumstances.

## **How effective is PEP?**

There is no definitive study in humans on the clinical effectiveness of PEP following sexual exposure, so most information is taken from cohort studies of healthcare workers who received PEP following occupational exposure. In these, it has been established that taking one drug only, most commonly AZT, can be effective in preventing transmission, but the PEP guidelines recommend using triple drug therapy because of its proven effectiveness in lowering viral load quickly in HIV infected people.

However, studies from Brazil of gay men who actually received PEP showed no or much lower numbers of men contracting HIV compared to those who did not receive any treatment.

In apes, two studies using one drug, tenofovir, showed 100% protection against SIV (Simian Immunodeficiency Virus, 'ape HIV') if given within 36 hours, but a further study using the drugs AZT, 3TC and indinavir showed no protection against infection.

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## **So which drugs will they use?**

The starter pack of 3 to 5 days medication which would be given through an A&E department usually consists of AZT, 3TC (in one pill called Combivir) and nelfinavir. This regimen can be continued or modified within 5 days at the follow-up appointment with an HIV clinician. However, the drugs used in any PEP regimen may vary if there is additional information about an HIV positive source contact's viral load, treatment regimen and resistance profile.

It remains to be determined what the optimum duration of PEP should be. The animal studies and the experience with healthcare workers suggest that four weeks of treatment is required to minimise the potential for HIV transmission.

There are well known side effects to the drugs when they are used to treat HIV infected individuals, and these appear to be exacerbated in HIV negative individuals. The side effects include nausea and vomiting, diarrhoea and body rashes, and have been known to last for more than a week.

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## **Confidentiality issues**

When people are treated through the HIV clinic of a hospital, their notes fall under the provisions of the NHS Venereal Diseases Regulations 1974. This means that the hospital is required by law to keep all information relating to HIV testing, PEP and other STIs confidential. Case notes from GUM clinics are kept separately from other hospital records and GPs are not routinely informed of the patient's attendance at such clinics, although the patient may request that the GP is informed. Moreover it does not allow a GUM clinic to inform an insurance company of a patient's history of sexually transmitted disease – even with the patient's consent.

However, concerns have been raised that these protections would not be in force if PEP is initiated through an A&E department. In consultation with one

of the major London hospitals which offers PEP, the position of medical records following a request for PEP and any subsequent treatment through the A&E department has been clarified.

The initial consultation through A&E would be recorded in the hospital medical records. Any initial treatment would also therefore be recorded - and because part of the protocol for being given PEP is to have an initial HIV test, that would also be recorded. It needs to be noted that these records are confidential, although not as rigorously confidential as GUM records. Any person seen through A&E would be referred for further treatment through the HIV clinic, which is part of the GUM directorate, and so any further records would be treated as any through a GUM clinic.

A&E records would not be passed to a GP unless care was transferred there.

As part of the discussion it was felt it would be wise to advise men attending A&E for PEP not to pass on any details of their GP to the hospital. That way the notes could not be passed on.

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### **Will PEP undermine other safer sex strategies?**

Concerns have been expressed that the availability of PEP will undermine commitment to consistent condom use and may be seen by some as a simple 'morning after' pill. There is research from the USA which appears to show that some groups of younger gay men are reporting greater levels of *intention* to use PEP, but these observations seem to be confined to men with a history of high risk sexual behaviour and intravenous drug use.

Other studies, in particular the Brazilian study mentioned previously, show a significant *decrease* in high risk sexual behaviour following a course of PEP. Some authors have argued that PEP may well capitalise on the psychological effect of 'near misses' to motivate and sustain risk reduction strategies in people who have previously engaged in high risk behaviour. This may well be due to the unpleasant side effects of the treatment.

In other words, there is no definitive answer to this question and further research remains to be done.

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### **Local availability of PEP**

PEP is available at Ealing Hospital, West Middlesex University Hospital and Charing Cross Hospital. It is also available through the Chelsea and Westminster Hospital. In order that each case gets optimal advice the Chelsea and Westminster HIV/GUM Directorate has an on-call consultant rota for PEP advice which runs out of office hours, including the weekend, so the SHO and Specialist Registrar have round the clock access to consultant advice.

**PLEASE PHOTOCOPY AND PASS ON AS NECESSARY**