

Sector Summary Report:

PEP: Post Exposure Prophylaxis following sexual exposure to HIV

Post Exposure Prophylaxis (PEP) has been available to health workers exposed to HIV for many years and has been increasingly available to people exposed to HIV sexually. This briefing paper, primarily for sexual health promotion workers is an expanded and updated version of a briefing that was developed in June 2005. Since the last briefing, a number of things have changed, new research findings have been released and as awareness of, and demand for PEP increases, it is important that up to date information is available to people working in the HIV and sexual health sector.

This briefing focuses on PEP following potential sexual exposure to HIV. It does not address PEP for health workers following occupational exposure such as needlestick injury or contact with blood. For information on occupational exposure see guidelines produced by the Department of Health⁽¹⁾.

The first UK guidelines for PEP following sexual exposure were published by the British Association for Sexual Health & HIV (BASHH) in February 2006⁽²⁾. This briefing provides a summary of the guidelines as well as information on recent research findings and an outline of activities that have been developed to support the implementation of PEP. The BASHH guidelines are available on the association's website www.bashh.org

What is PEP?

PEP involves taking anti-retroviral drugs for four weeks soon after exposure to HIV in an attempt to prevent HIV infection. The hope is that the drugs inhibit HIV

from reproducing before it can enter cells and establish infection in the body. The earliest form of PEP was a month long course of AZT (zidovudine) offered to health care workers exposed to HIV at work through a needle stick injury or blood spill. Now it usually consists of two or three anti-retroviral drugs and is also given to prevent infection following sexual exposure.

How might it work?

It is believed that after entering the body it may take between 48 and 72 hours before HIV can be detected within lymph nodes and up to five days before detection in the blood. For PEP to prevent infection it would need to be taken during this 'window of opportunity'. Animal studies suggest the greater the delay in giving PEP the less likely it is to be effective. Health care workers given PEP often begin treatment one or two hours after exposure. Animal research is cited by some to suggest PEP may be ineffective if administered later than 24 to 36

hours; others believe PEP becomes less effective or entirely ineffective if it is initiated more than 72 hours after exposure. Some hospitals will not offer PEP later than 24 to 48 hours. The Department of Health's Expert Advisory Group on AIDS (EAGA) guidelines on PEP in occupational settings from 2004⁽¹⁾ state that starting PEP may be justified as late as two weeks after exposure. Studies on primates suggest that the later PEP is taken, the greater its effectiveness; 28 days is recommended.

What PEP involves

It is believed that monotherapy (one anti-HIV drug) is the least effective, frequently duotherapy (two drugs) is prescribed and many consider a three drug combination best which is recommended in the BASHH and UK occupational exposure guidelines. Drug combinations inadequate to treat established HIV infection may be adequate to prevent infection. AZT with 3TC is not sufficient to treat established HIV infection

but is given as PEP. This mirrors other infections such as tuberculosis and malaria where drug regimes that prevent infection are insufficient to treat established infection. It is recommended that HIV testing is carried out before the first PEP dose to check that the person is not already infected. This prevents waste and ensures an already infected person is not given medication (e.g. PEP consisting of AZT and 3TC duotherapy) inadequate to treat established HIV infection. Follow-up HIV tests should also be carried out at one, three and six months following the start of PEP treatment.

Does PEP work?

The belief that PEP stops infection is based on 'biological plausibility' - i.e. it is reasonable to assume PEP could work based on what the drugs achieve when used by people with HIV. This is supported by some, but not all, studies of primates infected with a simian retrovirus (SIV) similar to HIV and given PEP. Questions remain whether conclusions drawn from PEP's effect on SIV and primates can be transferred to HIV and humans. There is some but less than conclusive evidence showing PEP works in adult humans or, if it does, to what extent. There are documented cases of PEP failing to prevent infection in health care workers after occupational exposure despite being taken within and for the required time period. Failures have also been seen in those taking PEP after sexual exposure⁽³⁾ and with few studies of PEP for sexual exposure, its effectiveness remains unproven. Prospective randomised control trials to determine the efficacy of PEP in humans are problematic due to the ethical issue of withholding a potentially efficacious treatment and the difficulty in recruiting the high numbers of people necessary to prove the effectiveness of PEP.

The research

The first study suggesting PEP prevents HIV infection came when month-long AZT monotherapy was shown to reduce infection rates by 80% among health care staff⁽⁴⁾. This encouraged PEP use in medical settings and helped establish its use for babies born to HIV positive women. Evidence also shows that anti-HIV drugs have a preventative effect when given to babies breastfed by infected mothers.

As mentioned above, there are no human randomised control trials to determine the efficacy of PEP but there are data available from research where PEP has been evaluated with comparisons made between people who did not receive PEP. In a study of Brazilian MSM⁽³⁾, individuals were given PEP to commence immediately after sexual exposure. Seroconversion occurred in significantly fewer of those who utilised PEP than those who did not.

In a second Brazilian study⁽⁵⁾, individuals who presented within 72 hours for PEP following sexual assault were offered PEP. HIV seroconversion did not occur in any of the individuals who took PEP but did occur in 2.7% of individuals who did not receive PEP as they presented after the recommended 72 hours.

In a recent UK study⁽⁶⁾ of 333 people who had taken PEP, no sero conversions were detected. Two people in the study did report a HIV positive status during follow up but reported a subsequent risk event after taking PEP.

Side effects of PEP

Side effects are generally the same as those experienced by people taking antiretroviral drugs for established HIV infection. Longer term side effects are rarely seen among PEP users. The 28 day regime is usually an insufficient time to produce effects such as heart disease, diabetes, liver problems or lipodystrophy (changes in body shape due to abnormal fat deposits around the body). However, rare cases exist of serious side effects occurring within days or a couple of weeks of starting some PEP drug combinations, including lipodystrophy and serious liver damage. Metabolic abnormalities (such as increased levels of fats in the blood) have also been seen while taking PEP.

Far more common are side effects typical of starting anti-HIV medications such as diarrhoea, nausea, headaches and vomiting, serious enough to prevent some from completing PEP. Some drugs seem better tolerated than others. PEP users who receive effective support and assistance in managing side effects with medication or other means such as modifying the treatment regime are more likely to complete the treatment. In a recent qualitative study of gay and bisexual men who had tried to access PEP, most participants were warned of the possible side effects but less than half said they had been given advice on how to manage them during the initial consultation.⁽⁷⁾

"Side effects are generally the same as those experienced by people taking antiretroviral drugs for established HIV infection."

The risk of HIV being passed on

When considering PEP it is necessary to consider the estimated risk of infection from various types of contact with an HIV positive individual. Epidemiological studies vary considerably in these estimates. The most frequently cited studies place the odds of infection after unprotected receptive anal sex with an infected partner at between 1 in 125 to 1 in 31 episodes of such sex.^(8, 9) However, since these estimates were calculated before the arrival of viral load-reducing treatments, the likelihood of transmission per exposure may now be lower. When an infected partner has a high viral load it is believed the likelihood of infection is much higher. In comparison, only three infections are estimated to occur for every 1,000 occupational needlestick injuries. All commonly judged to be lower risk than receptive anal intercourse are:

- Insertive and receptive vaginal sex (unless accompanied by trauma)
- Insertive anal sex
- Insertive or receptive oral sex.

Under what circumstances is PEP given?

The BASHH guidelines⁽²⁾ provide guidance on the use of PEP following sexual exposure to HIV. The following recommendations assume that the person has presented within 72 hours of exposure and are for either unprotected sexual intercourse or where condom failure has occurred. Recommendations regarding fellatio are where the partner giving fellatio is the one presenting for PEP.

Source individual is known to be HIV positive

Receptive anal sex	Recommended
Insertive anal sex	Recommended
Receptive vaginal sex	Recommended
Insertive vaginal sex	Recommended
Fellatio with ejaculation	Considered
Splash of semen into the eye	Considered
Fellatio without ejaculation	Not recommended
Cunnilingus	Not recommended

If the 'source' is identified as HIV positive, disease stage, treatment history and viral load may be taken into account, where available, as can evidence of drug resistance in the 'source's' virus strain.

Attempts should be made, where possible, to establish the HIV status of the source partner as early as possible, however, except in known sero-discordant relationships, ascertaining the HIV status of the 'source' individual may be problematic. Whether the 'source' came from a high prevalence population or region can be used to judge the likelihood they had HIV. High prevalence groups identified in the BASHH guidelines are MSM and individuals who have emigrated to the UK from areas of high HIV prevalence, particularly sub-Saharan Africa.

If it is not possible to establish the HIV status of the source then the following recommendations apply.

Source individual is from a high risk group and of unknown HIV status

Receptive anal sex	Recommended
Insertive anal sex	Considered
Receptive vaginal sex	Considered
Insertive vaginal sex	Considered
Fellatio with ejaculation	Considered

Source individual is not from a high risk group and of unknown HIV status

Receptive anal sex	Considered
Insertive anal sex	Not recommended
Receptive vaginal sex	Not recommended
Insertive vaginal sex	Not recommended
Fellatio with ejaculation	Not recommended

The following points are also usually considered when assessing PEP eligibility:

- Type of sex act and whether 'insertive' or 'receptive' (vaginal, anal, oral)
- Whether ejaculation into the body occurred
- Whether physical trauma (e.g. bleeding) or violence (e.g. rape) occurred
- Will the person be able to adhere to 28 days of anti-retroviral therapy and possible side effects?
- Will the person consent to HIV testing before PEP starts and for follow-up tests at one, three and six months?

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How does someone get PEP?

PEP can be prescribed by hospitals including A&E departments and GUM or HIV clinics and General Practitioners experienced in treating HIV. Some have suggested that clinics which prescribe PEP appear reluctant to get a reputation for doing so out of concern they will attract large numbers wanting it. As with access to health care in general, PEP access appears easier for the well-informed and well-connected to the medical profession and can depend upon:

- The person knowing about PEP
- Finding a clinic/clinician that has a good understanding of PEP within 72 hours
- Knowing which clinics/clinicians are most likely to prescribe PEP
- Understanding the risk factors that make a clinician more likely to prescribe PEP.

Research also indicates that some people who had a high risk exposure had to 'shop around' until they could find someone who would prescribe PEP while others had to be very assertive before being given the treatment⁽⁷⁾.

In April 2006, the Chief Health Officer, Sir Liam Donaldson sent a letter to all Chief Executives of Primary Care Trusts and Strategic Health Authorities in England addressing the issue of improving the prevention and treatment of sexually transmitted infections, including HIV. In the letter, Sir Liam specifically asked for all PCTs to ensure that PEP was part of the spectrum of sexual health services for local populations. The letter noted that PEP for non-occupational exposure was not a replacement for evidence based HIV health promotion but it had a contribution to make in preventing the transmission of HIV.

Is PEP cost-effective?

The BASHH guidelines⁽²⁾ state that there is no conclusive data regarding the cost effectiveness of PEP. A 28 day course of PEP costs approximately £600 compared to the lifetime costs of treatment for an HIV positive person which is estimated to be between £135,000 and £181,000. Assuming efficacy, PEP is most cost effective for the highest risk exposures.⁽¹⁰⁾ Also, in many cases PEP is prescribed when the 'source' individual will not even have HIV, further reducing cost effectiveness.

Cost effectiveness depends upon how likely the 'source' individual is to be HIV positive and whether the sex act is high risk. In low HIV prevalence populations chances that a 'source' is infected are low enough to make PEP seem not cost effective. This is less true of groups such as gay men or some UK African communities where prevalence rates reach double figures in some areas. Although unethical to some, restricting PEP to those at highest risk, either by group or sexual act, makes both economic and clinical sense. Only if PEP became much cheaper would large scale use make financial sense.

Some studies take into account the economic cost of HIV-related illness/death (e.g. lost productivity and tax revenue); this results in PEP appearing more cost-effective. Cost effectiveness appears greatest when PEP is restricted to exposure following receptive anal intercourse.⁽¹¹⁾

Does PEP encourage more sexual risk-taking?

Research contradicts the assumption that PEP access increases sexual risk-taking.⁽¹²⁾ No study shows overall increased risk taking among those who have had PEP. Some individuals show greater subsequent risk taking but this is outweighed by reduced risk-taking within the group. PEP offers opportunities for counselling, information and behavioural interventions with potential for reducing risk. The experience of 28 days of anti-retroviral treatment and the related side effects may also result in less risk taking.

In a recent Sigma Research study⁽⁷⁾, no one reported an increase in risk as a result of accessing PEP and there was no change for those who were already careful. For many men in the study, seeking PEP improved their desire to reduce future risk. Quite a few of the men in the study who described themselves as having a somewhat cavalier approach to HIV risk before their experience with PEP, found that having to undergo assessment and medication regimes had dramatically altered their attitudes.

The NONOPEP study⁽⁶⁾ also found no increase in risk behaviour.

Similar findings have also been reported internationally. In a Sydney based study,⁽¹³⁾ PEP was understood and used in the way and for the purpose it was intended – as a risk reduction strategy when other

strategies had failed. After a temporary loss of control over sex, PEP was perceived as a means to restore order and to reclaim control.

In contrast, a separate Sydney study⁽¹⁴⁾ found that men who had accessed PEP continued to be at high risk of subsequent HIV infection and that they were 2.82 times more likely to seroconvert than men who had not received PEP. This would suggest that there is a strong argument for additional behavioural support for people who access PEP.

What else does the social research tell us about PEP?

While knowledge of PEP has significantly increased over the last two years amongst homosexually active men, there is still a significant proportion who do not know about PEP or where or how to access it. Social and sexual networks are still important in disseminating PEP information as are men who have previously used PEP⁽⁷⁾.

There is certainly a real and/or perceived stigma associated with taking PEP, making it difficult for people who are currently on PEP or have used it in the past to tell family and friends⁽⁷⁾.

For many people, taking PEP is an indicator of taking risk, having made a serious mistake, of "being stupid". Social support from close friends was an important reason for telling others and frequently a few close friends were the only people told in an attempt to balance the need for support with the need for privacy.

The experience of enquiring about and receiving PEP in the UK ranges from appalling and discriminatory to positive and supportive.

Some negative experiences people reported were being provided with the wrong information e.g. PEP is not available on the NHS and encountering dismissive and hostile attitudes from A&E staff. Other research participants reported friendly and supportive attitudes from staff, even when the person themselves didn't believe that they deserved it.

There is little research on knowledge and awareness levels of other high risk groups in the UK such as people from African communities. However, in a recent THT report,⁽¹⁶⁾ people from African communities showed no unprompted awareness of PEP, HIV vaccine or any kind of treatment to prevent HIV infection post exposure to the virus. Prompted awareness of PEP was also zero with most participants linking PEP to UK financial products.

Gay men's knowledge about PEP

PEP awareness and knowledge questions were asked in the 2003 Gay Men's Sex Survey (GMSS)⁽⁷⁾ and again in the 2005 survey⁽⁷⁾. This provides information on how many gay men know about PEP and how much awareness has increased over a two year period after a number of PEP awareness programmes were implemented.

The GMSS indicates a significant increase in the number of gay men in the UK who have heard of PEP from 22.2% in 2003 to 38.5% in 2005.

While all areas of the UK reported increases in awareness levels, London and Brighton report the highest level of awareness, presumably due to the large and visible gay communities and the targeted CHAPS campaign in those areas.

Awareness in London increased from approx 34% in 2003 to approx 56% in 2005 and from 31% to 62% in Brighton.

In 2003 and again in 2005 PEP awareness was higher in men:

- In the "white other" ethnic group (rather than other groups)
- In their 30s and 40s (rather than under 30 or over 50)
- With higher incomes (rather than lower incomes)
- Who had tested HIV positive (rather than not)
- Who had more rather than fewer sexual partners.

Campaigns publicising PEP to gay men have been run in other countries, including Australia, Denmark and the US. Knowledge of PEP is therefore widely, but not equally, disseminated. Recent findings in Australia indicate that PEP awareness amongst gay men has reached saturation point^(13,14).

Who has sought or taken PEP?

While the number of people who have either sought PEP or taken it are small, there has been a significant increase from 2003 to 2005. The proportion of men who had ever sought PEP rose from 1.0% to 1.4% between 2003 and 2005. The proportion who had ever taken PEP rose from 0.6 to 1.2% in the same period. It should be noted however, that seeking or taking PEP is still a fairly rare event⁽⁷⁾.

Will PEP use lead to more drug resistant HIV?

There is an erroneous belief that, after taking anti-retrovirals as part of PEP, an individual can become resistant to these drugs. But after PEP, the anti-viral drugs disappear from the body, leaving no 'memory' behind that would interfere with HIV treatment later. Someone who has successfully taken PEP is, just like any other HIV negative individual, incapable of exhibiting any kind of drug resistance.

Drug resistance can arise:

- If the person given PEP already has HIV. PEP may not be sufficient therapy to suppress viral reproduction, potentially allowing the virus to develop resistance to the drugs used in the PEP combination
- If PEP fails to prevent an infection. Then the virus has encountered the drugs, survived and may develop resistance. This is possible if someone does not complete the PEP course or does not take PEP as instructed
- Alternately, if the strain of HIV entering the body is already resistant to any of the drugs in the PEP combination, PEP is more likely to fail and the person will be infected with this drug-resistant strain. As drug-resistant HIV strains become more common it will increasingly impact on PEP's effectiveness and the need for resistance-testing of 'source' individuals.

Won't demand for PEP be huge?

Demand for PEP has slightly increased over the last 3 years^(6,7), however the majority of people who have been prescribed PEP fall within the BASHH guidelines. The GMSS⁽⁷⁾ survey also found that although PEP awareness has increased, a lot more men know about PEP than men seeking it. Concern about HIV infection is low outside populations seen as 'high risk' and those from low risk groups requesting PEP are unlikely to meet the prescribing criteria. Among exposed health care workers, the one high risk group with easy access to PEP, take-up is low. Members of high risk groups are most likely to seek out PEP. In San Francisco where dedicated PEP clinics for sexual exposure have been operating, HIV incidence is high and the population of gay men is large, 401 requests were received in 15 months, with 309 people completing a course of PEP.

Where will the money for PEP come from?

Although seen as a preventative measure, PEP involves prescribing medicines to eradicate a virus inside the body and is therefore paid for out of treatment budgets. It remains to be seen whether in future a proportion of HIV prevention funds will be allocated to cover the cost of PEP.

Will people become repeat users of PEP?

Most studies show those who have used PEP once may subsequently take fewer sexual risks.^(6,7,13) although there are a few exceptions to this.^(7,14) Some PEP prescribing clinics set a limit on how often an individual is entitled to be receive PEP. The BASHH guidelines recommend that PEP should be considered according to the risk of HIV at the time of presentation, not on how many times someone has used it previously. It is also likely that those requesting PEP more often than some clinics allow will simply go to another clinic or area to get it.

The repeated use of PEP may be appropriate in certain situations and repeated presentation for PEP should not be morally judged. For example in sero-discordant relationships where condom failure may occur periodically, or for gay men who for a range of reasons, find consistent condom use difficult.

People who repeatedly present for PEP should be offered or referred to counselling and/or a support programme to help them address the issues that make it difficult for them to maintain safer sex practices.

What has been done to support the implementation of PEP?

The CHAPS partnership has implemented a range of interventions to improve gay men's knowledge of PEP. A knowledge and awareness campaign targeting gay men in London and Brighton was released in 2004 and included mass media in gay and positive press, information resources, an internet micro-site and outreach knick knacks. The campaign was later rolled out across other areas of the UK.

A comprehensive sector development programme was also developed and implemented to compliment the PEP awareness campaign. The programme consists of a number of elements including:

- A briefing paper released in June 2005
- A PEP frequently asked questions fact sheet
- A summary of the draft BASHH guidelines
- Information for service providers on establishing PEP locally
- Training and development of HIV sector workers on PEP
- Information for health promotion staff on how to support the CHAPS PEP Programme.

A campaign to raise awareness of PEP for African communities and their sexual partners has also been developed and launched in November 2006 including mass media in *'The African Eye'*, an information booklet and a micro-site.

What else needs to be done?

Recent research, HIV epidemiology and anecdotal evidence suggests that there are still things that need to be done to improve awareness of and access to PEP. This includes work with staff in the health system to improve access to PEP and work with high risk communities to improve awareness and knowledge of PEP and the skills required to get it if necessary.

Specific work needs to be done with staff working in the health service, particularly those working in Accident and Emergency departments regarding the protocols of PEP and high risk situations for HIV exposure. Further training on the BASHH guidelines may be appropriate as well as additional sensitivity training on working with gay men and people at greater risk of HIV infection. Additional work in facilitating meetings between GU clinics and Accident and Emergency Departments (A&E) is also important in improving access to PEP in A&E.

There also appear to be information gaps for staff working for telephone advice lines. Additional training on PEP protocols, especially on where and how to access PEP may be appropriate. Particular emphasis should be given to the importance of the 72 hour time period related to PEP efficacy and high risk sexual exposure.

Knowledge that PEP exists is not the only information gap that exists for gay men about PEP. As the qualitative research suggests, gay men would benefit from additional information on where PEP is dispensed, their rights to treatment and what to do if a valid request for PEP is denied. It is also important the message that PEP is more effective the sooner it is taken continues to be highlighted in educational messages as well as information on how to best identify a high risk exposure.

"Recent research, HIV epidemiology and anecdotal evidence suggests that there are still things that need to be done to improve awareness of and access to PEP."

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