

BASHH GUIDELINE

UK Guideline for the use of post-exposure prophylaxis for HIV following sexual exposure

Martin Fisher FRCP, **Paul Benn** MRCP, **Barry Evans** MD FFPH, **Anton Pozniak** MD FRCP, **Mike Jones** BA, **Suzie MacLean**, **Oliver Davidson** MSc PhD, **Jack Summerside** and **David Hawkins** BSc FRCP, **Clinical Effectiveness Group (British Association for Sexual Health and HIV)**

Summary: We present the British Association for Sexual Health and HIV (BASHH) guidelines for post-exposure prophylaxis after sexual exposure (PEPSE) to HIV. This document includes a review of the current data to support the use of PEPSE, considers how to calculate the risks of HIV infection after a potential exposure, and provides recommendations on when PEPSE would and would not be considered. Other areas included are the possible impact on sexual behaviour, cost-effectiveness, and issues relating to service provision. Throughout the document, consideration is given to the place of PEPSE within the broader context of HIV prevention strategies and sexual health.

Keywords: PEP, HIV, exposure, sexual, BASHH

Introduction and methodology

Scope and purpose

The main objective is to ensure the appropriate use of post-exposure prophylaxis (PEP) following potential sexual exposure (PEPSE) to HIV as a potential method of preventing HIV infection.

This guideline offers recommendations on the potential use of PEPSE, the circumstances in which it may be recommended, the treatment regimens which may be recommended and the appropriate use of subsequent diagnostic tests to measure individual outcome. These guidelines are intended to be complementary to the existing DH/EAGA guidance on PEP.¹

It is aimed primarily at clinicians and policy-makers in sexual health, primary and emergency care within the United Kingdom, who should consider the development of appropriate local pathways. It is likely that this guideline will be used by voluntary sector agencies in providing information for individuals who may potentially be exposed to HIV during sexual activity.

Stakeholder involvement

The development of this guideline included a writing group with representatives from British Association for Sexual Health (BASSH), British HIV Association (BHIVA), Expert Advisory Group on AIDS (EAGA), Society of Sexual Health Advisers (SSHA), Health Protection Agency (HPA), the HIV and Sexual Health Group of the British Psychological Association, the Terrence Higgins Trust (THT) and the National AIDS Trust (NAT).

Patients' perspectives were considered by involvement of THT, NAT and discussion at a stakeholder group organized by THT and the Community HIV and AIDS Prevention Strategy (CHAPS) conference.

Rigour of development

The guideline is based upon a comprehensive review of the literature pertaining to PEPSE. The recommendations are based upon a combination of biological plausibility, cohort studies, data from PEP in other settings, and expert opinion. The recommendations are the result of a series of meetings of the writing committee and the input from the consultation process. Prior to publication the final draft was placed on the BASHH website and copies circulated to THT, BHIVA, and the Department of Health for comment and peer review. After a period of 12 months, any comments

received were reviewed by the guideline authors, and acted upon appropriately, before final authorization by the CEG was given and publication was undertaken.

Background

Pathogenesis studies indicate that there may be a window of opportunity to abort HIV infection by inhibiting viral replication following an exposure. Once HIV crosses a mucosal barrier² it may take up to 48–72 h before HIV can be detected within regional lymph nodes and up to five days before HIV can be detected in blood.^{3,4}

Risks of HIV transmission

The risk of an individual acquiring HIV, following an exposure, is dependant upon the risk that the source is HIV positive where unknown (Table 1) and the risk of the exposure (Table 2):

$$\text{Risk of HIV transmission} = \text{Risk that source is HIV positive} \times \text{Risk of exposure}^*$$

(*including cofactors such as sexually transmitted infections (STIs), high viral load and bleeding).

All risk probabilities are for unprotected sexual exposure; it is assumed that similar risks will exist where condom failure has occurred.

The probability of HIV transmission depends upon the exposure characteristics, the infectivity of

the source and host susceptibility. The following factors may *increase* the risk of HIV transmission:

- A high plasma viral load in the source (this may be particularly relevant during primary HIV infection). Although low or undetectable plasma viral loads probably reduce the risk, transmission may still be possible.^{10,15,19,20}
- Viral loads in the genital tract normally correlate with plasma viral loads (it is, however, possible to have a detectable genital viral load with an undetectable plasma viral load).^{20–32}
- Breaches in the mucosal barrier such as mouth or genital ulcer disease and trauma, following sexual assault or first intercourse may increase the risk of HIV acquisition.^{33–35} Menstruation or other bleeding may also facilitate transmission.
- STIs enhance HIV transmission in epidemiological studies and increase HIV shedding from the genital tract. (This may not be the case in individuals receiving effective antiretroviral therapy.)^{35–44}

Calculating the risk of HIV transmission

Table 3 provides examples of estimates of an individual's risk of HIV transmission if the source is known to be HIV-positive or of unknown status according to type of exposure. Cofactors such as STIs, viral load and bleeding may affect the risk estimate. Knowledge of local HIV prevalence rates will clearly assist in calculating the risk of transmission and therefore developing local policy.

Data supporting the use of PEP against HIV

Animal studies Numerous animal models have been reported. They, however, are not standardized and use different retroviruses, size of inocula and modes of administration. Differences in drug metabolism between human and animals is another limitation to consider when interpreting these studies.

A phase I/II clinical trial using PMPA (tenofovir) for PEP demonstrated that SIV infection was

Table 1 Risk that source is HIV positive

Community group	HIV seroprevalence (%)	
Homosexual men*		
London	20.30	
Scotland	3.20	
Elsewhere	3.60	
Heterosexuals [†] (region of birth)	Male (%)	Female (%)
UK	0.5	0.2
Rest of Europe	2	0.2
North America	2.9	0.1
Central and South America	2.4	0.9
Caribbean	1.2	1.0
North Africa and Middle East	0.5	0.4
Sub-Saharan Africa	6.9	11.3
South Asia	0.5	0.6
East and South East Asia	0.5	0.7
Australasia	0.8	0.1
Injecting drug users*		
London	2.90	
Elsewhere in the UK	0.50	

*HPA data, 2004. Contemporaneous prevalence estimates can be obtained at: www.hpa.org.uk/infections/topics_az/hiv_and_sti

[†]HPA data 2004, HIV prevalence among GUM attendees by world region of birth in 2003. Prevalence rates for exposures outside of the UK or for individuals recently moved to the UK can be obtained at: www.unaids.org

Table 2 The risk of HIV transmission following an exposure from a known HIV-positive individual

Type of exposure	Estimated risk of HIV transmission per exposure (%)
Blood transfusion (one unit)	90–100 ⁵
Receptive anal intercourse	0.1–3.0 ^{6,7}
Receptive vaginal intercourse	0.1–0.2 ^{7–12}
Insertive vaginal intercourse	0.03–0.09 ¹⁰
Insertive anal intercourse	0.06 ¹³
Receptive oral sex (fellatio)	0–0.04 ¹³
Needle-stick injury	0.3 (95 CI 0.2–0.5) ^{14–16}
Sharing injecting equipment	0.67 ¹⁷
Mucous membrane exposure	0.09 (95 CI 0.006–0.5) ¹⁸

Table 3 Calculating the risk of HIV transmission

Population group and type of exposure	Risk of HIV transmission (Unknown HIV of source)*	Risk of HIV transmission (source HIV positive)*
Homosexual men		
Unprotected receptive anal intercourse	$15\% \times 3\% = 0.45\%$ 1/222	$1 \times 3\% = 3\%$ 1/33
Heterosexual woman		
Unprotected receptive vaginal intercourse	$0.1\% \times 0.09\% = 0.00009\%$ 1/100,000	$1 \times 0.09\% = 0.09\%$ 1/1111
Intravenous drug user		
Sharing injecting equipment	$4.7\% \times 0.67\% = 0.031\%$ 1/3226	$1 \times 0.67\% = 0.67\%$ 1/149

*Risk is calculated using data from Tables 1 and 2 according to the formula: Risk of HIV transmission = Risk that source is HIV positive \times Risk of exposure. In many circumstances the risk of HIV transmission is clearly greater than that following occupational exposure in which PEP is routinely considered: 1/300 for known HIV+ "source" and based on prevalence where HIV status unknown¹

prevented following an IV inoculation in 100% of macaques if administered within 24 hours and continued for 28 days. As the time to initiation of PEP increased or the duration of PEP reduced, the number of macaques protected declined.⁴⁵ Another study using PMPA (tenofovir) for PEP in macaques showed 100% protection against HIV-2 following an intra-vaginal challenge if administered within 36 hours of the exposure.⁴⁶

These animal studies suggest that PEP is potentially effective and that time to initiation and duration are important. However, not all animal studies demonstrate a protective effect of PEP. A study using a combination of zidovudine, lamivudine and indinavir offered no protection following IV inoculation even if initiated within four hours.⁴⁷

Human studies *Occupational exposure to HIV:* Prospective randomized controlled trials to determine the efficacy of PEP are not feasible, due to (a) the ethical problems of withholding a potentially efficacious treatment and (b) the difficulty in recruiting a high number of participants that would be required for such a study. However, a retrospective case-controlled study among health care workers occupationally exposed to HIV infection, demonstrated that a 28-day course of zidovudine was protective, odds ratio (OR) 0.19 (95% confidence interval [CI] 0.06–0.52%).¹⁵ This study has some limitations including a small number of cases, cases and controls were derived from different countries and details of exposure characteristics of cases were collected retrospectively. Adjustments were needed to take into account the fact that the likelihood of receiving zidovudine was related to the likelihood of transmission (size of inoculum, source patient has AIDS etc.).

These studies suggest that PEP may be protective. However, there are at least 21 instances where PEP has failed to prevent HIV infection following occupational exposure.⁴⁸ In addition, there is no human evidence to support any additional benefit of the use of combination antiretroviral therapy for PEP. However, 'absence of evidence' does

not equal 'evidence of absence' and it is argued that the efficacy of triple therapy in treatment regimens are much more effective at lowering viral load than monotherapy, that triple therapy should be given.

Vertical transmission: Several studies to reduce vertical transmission may also suggest that PEP may be protective. In a subset of women participating in the AIDS Clinical Trials Group (ACTG) 076 study, who did not receive zidovudine prior to delivery, where the neonate was given a six-week course of zidovudine, initiated within 48 hours of delivery, a protective effect was observed.^{49,50}

Data on PEP after sexual exposure: Again, there are no randomized studies, which have investigated the efficacy of PEPSE. However, prospective data are available from sites where PEP has been evaluated in this setting with comparisons made with individuals who did not receive PEP.

In a study of men who have sex with men (MSM) in Brazil, individuals were given PEPSE supplies to commence immediately after sexual exposure. Seroconversions occurred in significantly fewer of those individuals who utilized PEPSE than those who did not (0.6% vs. 4.2%).⁵¹ In a second Brazilian study, individuals who presented within 72 hours following sexual assault were offered PEPSE. HIV seroconversion occurred in no individual who received PEPSE, but did occur in 2.7% of individuals who did not having presented after the 72-hour window.⁵²

Other factors influencing efficacy Other factors may influence the efficacy of PEP in clinical practice. Delays in commencing PEP may adversely its efficacy.^{15,45} Many studies suggest that the time to initiation of PEP is shorter following occupational (two hours) compared with non-occupational exposure (23 hours). This is due to the fact that occupational exposures (needlestick injuries etc.) usually occur in the health care setting where therapy can be accessed quickly. Trust policies and the availability of starter packs may improve time to initiation of PEP. PEP may be less or ineffective if initiated after 72 hours of the

exposure, but may be considered after this time if the exposure is 'high-risk'. In the sexual exposure setting, 'failures' of PEPSE have been attributed to late initiation, poor adherence, and repeated exposure to HIV.⁵³

Reports suggest that the prevalence of antiretroviral resistance among those with primary HIV infection and those chronically infected with HIV is increasing.⁵⁴⁻⁵⁹ Transmission of virus resistant to one or more of the agents used for PEP may reduce its efficacy. If drug resistance is suspected in the source the PEP regimen should be tailored accordingly. Resistance testing of the source may be considered.

Compartmentalization of HIV, in particular within the genital tract may result in separate virus evolution or evolution of resistance which may have implications for transmission. Studies suggest the virus with replicative capacity can be detected within different tissue compartments despite optimal viral suppression.⁶⁰⁻⁶² Pharmacological studies also suggest that antiretrovirals penetrate these compartments, including the genital tract, to varying degrees.⁶³⁻⁶⁵

Adherence and completion rates of four-weeks of PEP among health care workers and individuals exposed non-occupationally are generally poor, which may impact upon its efficacy.⁶⁶⁻⁶⁸ It is unclear whether issues other than pill burden and side effects, such as psychological distress or the re-evaluation of risk over time influence adherence and completion rates. A study among 401 individuals, receiving dual nucleoside therapy for PEP following non-occupational exposure, reported completion rates of 78%. Individuals received three adherence sessions and five risk reduction sessions, which may account for the improved completion rates.⁶⁹

Possible risks of post-exposure prophylaxis

The frequency, severity, duration and reversibility of side effects and potential for as yet unknown long-term complications must be compared with the potential benefit of PEP. Health care workers receiving PEP frequently report side effects. In one study, 6/19 (31.6%) of health care workers taking an indinavir-based regimen required more than two weeks off work.⁶⁷

Protease inhibitors, for example, have been associated with metabolic abnormalities, lipid abnormalities, insulin resistance and diabetes mellitus in addition to gastro-intestinal side effects. Nevirapine has in the past been used for PEP but is now known to be associated with significant toxicity. In one study, almost 10% of individuals receiving a nevirapine-based PEP regimen experienced a grade 3 or 4 elevation in transaminases with or without a rash.⁶⁶ Further more, two health care workers in the USA developed fulminant hepatitis; one required liver transplantation following a nevirapine-based PEP regimen.⁷⁰

In those chronically infected with HIV, adherence to combination antiretroviral therapy is directly related to virological outcome. Poor adherence of PEP regimens theoretically may result in the acquisition of a drug-resistant virus, should the individual become HIV-infected. This has been suggested as a risk for subsequent seroconversion in a retrospective analysis of PEPSE failures.⁵³

Potential behavioural/psychological implications of offering PEPSE

There are concerns that the availability of PEPSE will reduce commitment to primary prevention strategies and consequently result in more frequent high-risk behaviour.⁷¹

Some studies provide evidence that the availability of PEPSE increases risk behaviour. While most gay men in the USA may not intend to use PEPSE, younger, less educated gay men may report greater intentions to use PEPSE, especially if they had engaged in high risk sexual behaviour and had a history of intravenous drug use.⁷²

However, other studies provide evidence that there may be no increase in risk behaviour. The awareness of PEP was reported to have no effect on the condom use in serodiscordant couples participating in a cross-sectional survey,⁷³ while self-reported risk behaviour significantly decreased following PEPSE in a Brazilian cohort of MSM,⁵¹ another comprising Brazilian survivors of sexual assault,⁵² and in two San Francisco Clinics that provided PEPSE to MSM.⁷⁴

Some authors have argued that health-related interventions such as PEPSE may help capitalize on 'close calls' to motivate and sustain risk reduction in individuals who have engaged in risk behaviour.⁷⁵

It is also recognized that individuals may present in a state of acute anxiety following possible exposure to HIV, and that the administration of PEPSE may help to alleviate such anxiety. However, decision-making in this setting needs to consider the potential adverse effects of antiretroviral therapy where the risk of transmission is low.

Recommendations for prescribing PEPSE

The writing committee feel it is crucial to consider PEPSE as only one strategy in preventing HIV infection and, as such, it should be considered as a last measure where conventional, and proven, methods of HIV prevention have failed.

A risk vs benefit analysis should be undertaken for every individual presenting following an exposure and the decision to initiate PEP made on a case-by-case basis. This should consider both the risk of transmission according to coital act (as in Table 2) and the risk of the source being HIV positive (as in Table 1). Consideration should be given to the possibility of the presenting individual

having already been infected with HIV, and the ability to adhere to and tolerate the proposed antiretroviral drug regimen. The potential exposure to other STIs and appropriate management for this needs to be considered alongside consideration of provision of PEPSE. The wishes of the individual should be considered at all times.

Situations in which PEPSE would be considered

The use of PEPSE following potential sexual exposure to HIV is only recommended where the individual presents within 72 hours of exposure. Within that time frame, it is recommended that PEPSE (if given) should be administered as early as possible. All recommendations are for either unprotected sexual exposure or where condom failure has occurred. Recommendations regarding fellatio are where the partner giving fellatio is presenting for PEPSE.

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 eye	Considered
Fellatio without ejaculation	Not recommended
Cunnilingus	Not recommended

Source individual is of unknown status*

*Attempt should be made, where possible, to establish the HIV status of the source individual (according to appropriate guidance on HIV testing and consent) as early as possible. There is growing evidence to suggest that significant cases of PEP can be averted through assertive HIV testing of the source individual.⁷⁶ It is therefore recommended that strong efforts be made to encourage the individual to notify their partner where possible, and for the clinic to arrange urgent HIV testing of that partner, with appropriate guidance on HIV testing and consent, as early as possible.

Source is from a group or area of high HIV prevalence

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

Source is not from a group or area of high HIV prevalence

Receptive anal sex	Considered
Insertive anal sex	Not recommended
Receptive vaginal sex	Not recommended

Insertive vaginal sex	Not recommended
Fellatio with ejaculation	Not recommended

High prevalence groups within this recommendation are those where there is a significant likelihood of the source individual being HIV positive. Within the UK at present, this is likely to be MSM and individuals who have immigrated to the UK from areas of high HIV prevalence (particularly sub-Saharan Africa).

Sexual assault: It is believed that transmission of HIV is likely to be increased following aggravated sexual intercourse (anal or vaginal), such as that experienced during sexual assault. Clinicians may therefore consider recommending PEPSE more readily in such situations. While the routine recommendation of PEPSE is likely to be appropriate in high prevalence situations,⁷⁷ it is likely that the strength of recommendation and subsequent uptake will be lower in UK settings unless the 'donor' is perceived to be from a high-prevalence group.

Other factors which may alter the strength of recommendation: Where factors are present which are believed to influence the probability of HIV transmission – presence of concurrent STI, knowledge of viral load in the 'donor' – the strength of these recommendations may be increased or decreased appropriately.

Recommendations for drug regimens to be used

The choice of drugs to be used for PEP is drawn from those used in established infection. These include the nucleoside reverse transcriptase inhibitors (NRTIs), the non-nucleoside reverse transcriptase inhibitors (NNRTIs) and the protease inhibitors (PIs). In addition the nucleotide tenofovir has shown activity as PEP in an animal (SIV/macaque) model of sexual exposure⁴⁵ and is currently being evaluated in high-risk populations as monotherapy for pre-exposure prophylaxis. Other classes of drugs such as entry inhibitors (T20) will need to be considered as they become available for established infection. Zidovudine (an NRTI) is the only drug to date which has been studied and for which there is evidence of reduction of risk of HIV transmission following occupational exposure. It is for this reason that many consider it to be reasonable that zidovudine is included in all first choice PEP regimens, unless there is evidence that the source virus is resistant to this drug, or that there is significant intolerance. However, it is theoretically likely that alternative nucleosides will be equally effective. Some recent studies^{78,79} suggest that a tenofovir-containing regimen may be better tolerated than zidovudine; therefore, it would be reasonable to offer this as an alternative either at initial presentation or if zidovudine-related side-effects occur.

In established HIV infection, combination drug therapy with at least three drugs is more effective than monotherapy or dual drug regimens. It is thus

recommended, when there is considered to be a significant risk of HIV transmission following risk assessment, that a triple agent regimen be advised. Theoretical considerations to support the recommendation of three drugs include the later presentation of patients for PEPSE and giving drugs with different resistance patterns as any resistant virus in the source may be unknown.

As stated above, the use of nevirapine is not recommended due to the high rates of hepatotoxicity and potential for fulminant hepatic failure when used in this setting.^{66,70} Efavirenz has a lower incidence and severity of rash, but this reaction may still cause anxiety and diagnostic confusion. Furthermore efavirenz causes short-term psycho-stimulation, which is possibly less well tolerated in anxious patients receiving PEP than in patients with established HIV infection.

The routine use of abacavir is also not recommended. A hypersensitivity reaction is reported in up to 8% of patients with established infection. Although the risk has not been assessed in HIV negative individuals, it is recommended to reserve the use of abacavir for when first-line treatments are not thought appropriate.

It is recommended that the choice of antiretroviral regimen prescribed should follow consideration of local epidemiology of drug resistance, particularly the incidence of primary resistance which may be increasing in some parts of the UK.⁵⁹

Individuals who are already well informed regarding the safety, tolerability and efficacy profiles of individual antiretroviral agents may have their own individual perspective on which agents they would prefer to take. Such choices should, where possible, be respected but may be affected by the composition of 'starter packs', the possible resistance 'history' of the donor, local HIV primary resistance rates, and must involve consideration of toxicity profiles in the uninfected (as outlined above).

Recommended combinations

2NRTI[#]+PI*(boosted PI⁺)

*Nelfinavir, ⁺Lopinavir or fosamprenavir or saquinavir, [#](AZT & 3TC) or (D4T & 3TC) or (tenofovir & 3TC) or (tenofovir & FTC).

Other triple combinations in use for established infection may also be considered reasonable choices and a number are currently being evaluated in international studies.

If there is evidence that the source patient has current or past history of treatment failure, the PEP antiretroviral therapy should be modified in relation to the drug history and/or to resistance testing if available. Expert advice should be sought.

Starter packs As with the guidelines for occupational exposure,¹ it may be helpful to use a starter pack (3–5 days medication). Should PEP starter packs be used, suitable combinations would be Combivir[®] (zidovudine 300 mg plus lamivudine 150 mg) bd plus nelfinavir 1250 mg bd. An alternative to Combivir would be Truvada[®] (tenofovir 245 mg plus emtricitabine 200 mg). An alternative to nelfinavir would be a boosted PI such as lopinavir/ritonavir 3 capsules bd or fosamprenavir 700 mg bd with ritonavir 100 mg bd (or 1400 mg od with ritonavir 200 mg od). The need for refrigeration of ritonavir and Kaletra[®] may inhibit their use as starter packs; an alternative strategy may be to switch to one of these agents after expert review.

This PEPSE regimen can be continued or modified at initial review within five days, depending on further information about the source virus and the patient's tolerance of the medication.

Side-effects Any of the antiretroviral drugs may have side effects, which appear to be less well tolerated in HIV-negative patients receiving PEP than HIV-positive individuals starting treatment. Many of these can be managed symptomatically, for example the use of anti-nauseants and anti-diarrhoeals with the combination of Combivir and nelfinavir. Close monitoring and follow-up of individuals receiving PEPSE is recommended to manage such side effects and thereby optimize completion rates.

Duration of treatment The optimal duration of PEP is unknown. However, animal studies⁴⁵ and a case-controlled study of health care workers¹⁵ suggest that four weeks is required to minimize the potential for HIV transmission. It is recommended therefore that four weeks of PEP should be utilized in the sexual exposure setting (unless source-testing after initiation of PEPSE determines that the 'donor' is HIV-negative).

Service provision to enable appropriate use of PEPSE

Given that, for optimal efficacy, PEPSE should be commenced as soon as possible after exposure,¹ 24-hour access should be available. As with PEP following occupational exposure, it is recommended that local policies and pathways be established to enable this.

It is therefore likely that A&E departments will be expected to assume significant responsibility for provision of PEPSE, with the need for support and training from areas of local expertise. Such areas are likely to be Departments of Genitourinary (GU) Medicine, HIV Medicine, Infectious Diseases or Virology/Microbiology. The training issues are essentially those outlined comprehensively in the DH/EAGA guidance on HIV PEP.¹

It is recommended that individuals presenting for PEPSE should be referred and seen as early as possible by a clinician experienced in the management of antiretroviral therapy and with expertise in HIV testing and transmission – whether or not PEPSE is offered or accepted. PEPSE should not be withheld until such expertise is available. However, it is recommended that local policies should include 24-hour access to advice from an experienced HIV clinician, particularly for cases where the PEPSE regimen may need to be adjusted to reflect possible drug resistance in the ‘donor’.

Assessment and initial management of the individual presenting for PEPSE

It is essential that an appropriate risk assessment is performed to enable provision of PEPSE according to the recommendations outlined above.

At presentation, and prior to administration of PEPSE, the following issues must be discussed with the individual:

- the rationale for PEPSE
- the lack of conclusive data for the efficacy of PEPSE
- the potential risks and side effects of PEPSE
- the arrangement for early follow-up with an HIV/GUM clinician

The use of a consent form is not considered essential, but documentation must demonstrate that these issues have been discussed.

It is mandatory that individuals for whom PEPSE is provided to undertake an HIV test (with rapid result) prior to, or shortly after initiating therapy. This recommendation reflects the possibility of undiagnosed HIV infection, which would significantly alter the risk-benefit balance of short-course antiretroviral therapy. It may be possible for service providers to obtain results more rapidly by considering newer technologies, such as saliva testing or rapid serum HIV testing. However, such testing should follow the conventional norms of informed consent.

Those presenting for PEPSE must be seen in a GU Medicine/HIV department at the earliest opportunity. It is recommended that the individual be referred to a Health Adviser (or appropriately experienced health care worker), where the following issues can be addressed:

- pre-test discussion (if HIV status as yet unknown)
- the need to continue with a further four-week course of PEPSE if the baseline result is negative
- the need to have a follow-up HIV test at three and six months

- the side effects of the drugs and the support available in the clinic and in the community to help adherence
- the need to utilize generic social support over the following three to six months
- the need for safer sex for the following six months
- issues around disclosure
- coping strategies
- For patients concerned about sexual risk taking health advisers can offer ongoing risk reduction work or referral to psychology if appropriate.

Follow-up arrangements for individuals presenting for PEPSE

Regular medical follow-up is necessary for individuals receiving PEPSE to monitor tolerability and possible toxicity of the medications. Close follow-up and encouragement, ideally on a weekly basis at first, is likely to improve adherence to the treatment regimen and allow prompt management of any concerns or complications.

It is recommended that all individuals who receive PEPSE (and those who decline but have had significant risk of exposure to HIV) be re-tested for HIV antibodies at three and six months.

At present there is no prospective monitoring scheme for individuals receiving PEPSE, but it is anticipated this may be developed in conjunction with the Health Protection Agency.

Any adverse events attributed to antiretroviral medications should be reported via the HIV Adverse Drug Reactions Reporting Scheme.

Additional management of individuals after potential sexual exposure to HIV

It is recommended that all individuals presenting for PEPSE be comprehensively screened for other STIs at an appropriate time point, in accordance with the guidelines on screening for STIs (accessible at [www.bashh.org]). It is essential that Hepatitis B vaccination (and immunoglobulin) be considered in addition to PEP in accordance with existing guidance.⁸⁰ Additionally, the opportunity should be taken for appropriate risk-reduction discussion with individuals presenting for PEPSE.

Other issues relating to sexual exposure to HIV

Dissemination of information regarding PEPSE to individuals who may be at risk of HIV transmission

It is recommended that information regarding PEPSE should be proactively provided to individuals diagnosed with HIV infection, particularly if

in a serodiscordant relationship. Furthermore, uninfected individuals with potential for future exposure to HIV, should be provided with information regarding PEPSE in addition to full discussion of other proven risk-reduction strategies. It is recognized that community-based organizations will have a large part to play in providing this information. Consideration should be given to provision of 24-hour helpline access to enable individuals to establish whether presentation to hospital services for PEPSE is appropriate.

Cost-effectiveness of PEP after sexual exposure to HIV

There is no conclusive data regarding the cost-effectiveness of PEPSE. It has been argued that the cost of providing PEP may be effectively spent on other prevention initiatives.⁸¹ However, while the drug cost of a full 28-day course of PEP is approximately £600, the lifetime costs of treatment for an HIV positive individual are estimated to be between £135,000 and £181,000.⁸² A retrospective cost analysis of the San Francisco PEPSE programme has shown it to be cost-effective when used in high-risk exposures and potentially cost saving when used after receptive anal intercourse in MSM.⁸³ Subsequent modelling utilizing data from many US cities⁸⁴ suggests similar levels of cost-effectiveness providing PEPSE is targeted to high-risk exposures consistent with those recommended within these guidelines.

Management of individuals who repeatedly present for PEPSE or with ongoing risk behaviour

There is also a concern regarding repeat users of PEPSE. However, once again, there is no data suggesting that a significant number of individuals will utilize PEPSE repeatedly, perhaps due to the aversive nature of the medications. It is therefore recommended that individuals be considered for repeat courses of PEPSE according to the risk of HIV acquisition at the time of presentation, particularly if their circumstances suggest this to be appropriate (commercial sex workers, serodiscordant couples, inability to control the preventative behaviour of their partners). However, it is also recommended that repeat attenders be strongly encouraged to discuss these issues with a Health Advisor and/or Psychologist.

Individuals who present more than once a year for PEPSE, who do not otherwise have prevailing circumstances for doing so, are of greater concern and should be referred at an early stage for discussions around their safer sex strategies. They should still be considered for PEPSE if the current risk circumstances clearly indicate a need for this, but that this is conditional on their attendance for discussions around future safer sex strategies.

Qualifying statement

The recommendations in this guideline may not be appropriate for use in all clinical situations. Decisions to follow these recommendations must be based on the professional judgement of the clinician and consideration of individual patient circumstances and wishes. It should be acknowledged that use of any antiretroviral agent in this setting is an unlicensed indication.

All possible care has been undertaken to ensure the publication of the correct dosage and route of administration. However, it remains the responsibility of the prescribing physician to ensure the accuracy and appropriateness of the medication they prescribe.

Applicability

The provision of PEP following sexual exposure requires consideration of appropriate pathways of care between GU medicine/HIV clinicians and those providing access to emergency and primary care in order to ensure PEPSE is administered both appropriately and in a timely fashion. This will require local interpretation of this guideline and will most likely involve a degree of organizational change and provision of additional resources.

Auditable outcome measures

- Proportion of PEPSE prescriptions that fit within recommended indications: aim 90%
- Proportion of PEPSE prescriptions administered within 72 h of risk exposure: aim 90%
- Proportion of individuals completing four-week course of PEPSE: aim 75%
- Proportion of individuals completing three- and six-month post-PEP HIV antibody test: aim 60%

Authorship

Martin Fisher, Consultant Physician in HIV/Genitourinary Medicine, Brighton and Sussex University Hospitals NHS Trust

Paul Benn, Consultant in HIV/Genitourinary Medicine, Camden Primary Care Trust

Oliver Davidson, Consultant Clinical Psychologist, Camden Primary Care Trust

Barry Evans, Health Protection Agency

David Hawkins, Consultant in Genitourinary Medicine, Chelsea and Westminster Hospital

Mike Jones, Senior Health Adviser, Royal Free Hospital

Suzie MacLean, National AIDS Trust

Anton Pozniak, Consultant in HIV/Genitourinary Medicine, Chelsea and Westminster Hospital

Jack Summerside, Terrence Higgins Trust

Membership of the Clinical Effectiveness Group:

Chairman: Keith Radcliffe (BASHH); Imytaz Ahmed-Jushuf (BASHH); Mark Fitzgerald (BASHH); Guy Rooney (Royal College of Physicians GU Medicine Committee); Jan Welch (BASHH).

References

- 1 HIV Post Exposure Prophylaxis; Guidance from the UK Chief Medical Officers Expert Advisory Group on AIDS. Accessible at [www.doh.gov.uk]
- 2 Miller RJ, Cairns JS, Bridges S, Sarver N. Human immunodeficiency virus and AIDS: insights from animal lentiviruses. *J Virol* 2000;**74**:1787-95
- 3 Pinto LA, Landay AL, Berofsky JA, *et al.* Immune response to human immunodeficiency virus (HIV) in health care workers occupationally exposed to HIV-contaminated blood. *Am J Med* 1997;**102**:21-4
- 4 Spira AI, Marx PA, Patterson BK, *et al.* Cellular targets of infection and route of viral dissemination after an intravaginal inoculation of simian immunodeficiency virus into rhesus macaques. *J Exp Med* 1996;**183**:215-25
- 5 Infection with Human Immunodeficiency Virus Type 1 (HIV-1) among recipients of antibody-positive blood donations. *Ann Intern Med* 1990;**113**:733-9
- 6 Mastro TD, de Vincenz I. Probabilities of sexual HIV-1 transmission. *AIDS* 1996;**10**:575-82
- 7 Royce R, Sena A, Cates Jr W, *et al.* Sexual transmission of HIV. *N Engl J Med* 1997;**336**:1072-8
- 8 Vincenzi I. A longitudinal study of HIV transmission by heterosexual partners. *N Engl J Med* 1994;**331**:341-6
- 9 Anderson RM, May RM. Epidemiological parameters of HIV transmission. *Nature* 1988;**333**:514-19
- 10 Gray R, Wawer MJ, Brookmeyer R, *et al.* Probability of HIV-1 transmission per coital act in monogamous, heterosexual, HIV-1 discordant couples in Rakai, Uganda. *Lancet* 2001;**357**:1149-53
- 11 Leynaert B, Downs AM, de Vincenzi I. Heterosexual transmission of human immunodeficiency virus: variability of infectivity throughout the course of infection. European Study Group on Heterosexual Transmission of HIV. *Am J Epidemiol* 1998;**148**:88-96
- 12 Overbaugh J, Sagar M, Benki S, *et al.* Viral and host factors in HIV-1 transmission and pathogenesis. Program and abstracts of the 9th Conference on Retroviruses and Opportunistic Infections, February 24-28, 2002. Seattle, Washington, DC (abstr. S23)
- 13 Vittinghoff E, Douglas J, Judson F, *et al.* Per-contact risk of human immunodeficiency virus transmission between male sexual partners. *Am J Epidemiol* 1999;**150**:306-11
- 14 Centres for Disease Control. Case-control study of HIV seroconversion in healthcare workers after percutaneous exposure to HIV-infected blood France, United Kingdom and United States, January 1988-August 1994. *MMWR* 1995;**44**:929
- 15 Cardo DM, Culver DH, Ciesielski CA, *et al.* A case-control study of HIV seroconversion in health care workers after percutaneous exposure to HIV-infected blood: clinical and public health implications. *N Engl J Med* 1997;**337**:1485
- 16 Bell DM. Occupational risk of human immunodeficiency virus infection in health care workers: an overview. *Am J Med* 1997;**102**:9-15
- 17 Kaplan EH, Heimer R. A model-based estimate of HIV infectivity via needle sharing. *J Acquir Immune Defic Syndr* 1992;**5**:1116-18
- 18 Ippolito G, Puro V, De Carli G, *et al.*, for the Italian Study group on Occupational Risk of HIV infection. The risk of occupational human immunodeficiency virus infection in health care workers. *Arch Intern Med* 1993;**153**:1451-8
- 19 Quinn TC, Wawer MJ, Sewankambo N, *et al.* Viral load and heterosexual transmission of human immunodeficiency virus type 1. *N Engl J Med* 2000;**342**:921-9
- 20 Deeks SG, Wrin T, Hoh R, *et al.* Virological and immunological evaluation of structured interruptions (STI) in patients experiencing long-term virological failure. 7th Conference on Retroviruses and Opportunistic Infections, 2000. San Francisco (abstr. LB10)
- 21 Chun T, Bocklandt S, McHugh RL, *et al.* Relationship between pre-existing viral reservoirs and the re-emergence of plasma viraemia after discontinuation of highly active anti-retroviral therapy. *Nature Med* 2000;**7**:757-61
- 22 Zhang H, Dornadula G, Beaumont M, *et al.* Human immunodeficiency virus type-1 in the semen of men receiving highly active antiretroviral therapy. *N Engl J Med* 1998;**339**:1803-9
- 23 Eron J, Smeaton LM, Fiscus SA. The effects of protease inhibitor therapy on human immunodeficiency virus type-1 levels in semen (AIDS clinical trials group protocol 850). *J Infect Dis* 2000;**181**:1622-8
- 24 Vernazza L, Troiani L, Flapp MJ, *et al.* Potent antiretroviral treatment of HIV-infection results in suppression of the seminal shedding of HIV. *AIDS* 2000;**14**:117-21
- 25 Nunnari G, Otero M, Dornadula, *et al.* Residual HIV-1 disease in seminal cells of HIV-1 infected men on suppressive HAART: latency without on-going cellular infections. *AIDS* 2002;**16**:39-45
- 26 Choudhury B, Pillay D, Taylor S, *et al.* Analysis of HIV-1 variation in blood and semen during treatment and treatment interruption. *J Med Virol* 2002;**68**:467-72
- 27 Collis T, Calum C, Whittington W, *et al.* Compartmentalization and variability in HIV-1 shedding in blood, semen, rectum and pharynx. 8th Conference on Retroviruses and Opportunistic Infections, February 2001. Chicago, IL, USA (abstr. 396)
- 28 Lampinen TM, Critchlow CW, Kuyypus JM, *et al.* Association of antiretroviral therapy with detection of HIV-1 RNA and DNA in the anorectal mucosa of homosexual men. *AIDS* 2000;**14**:F69-75
- 29 Kotler DP, Shimada T, Snow G, *et al.* Effect of combination antiretroviral therapy upon rectal mucosal RNA burden and mononuclear cell apoptosis. *AIDS* 1998;**12**:597-604
- 30 Kovacs A, Wassermann S, Burns D, *et al.* Determinants of HIV-1 shedding in the genital tract of women. *Lancet* 2001;**358**
- 31 Debiaggi M, Zara F, Spinillo A, *et al.* Viral excretion in cervicovaginal secretions of HIV-1-infected women receiving antiretroviral therapy. *Eur J Clin Microbiol Infect Dis* 2001;**20**:91-6
- 32 Clemetson DB, Moss GB, Willerford DM, *et al.* Detection of HIV DNA in cervical and vaginal secretions: prevalence and correlates among women in Nairobi, Kenya. *JAMA* 1993;**269**:2860-4
- 33 Rothenberg RB, Scarlett M, del Rio C, *et al.* Oral transmission of HIV. *AIDS* 1998;**12**:2095-105
- 34 Haase AT. *Transmission and Propagation of SIV and HIV Infection In Vivo*. Program and abstracts of 9th CROI, 2002. Seattle, Washington, DC (abstr. L9)
- 35 Rottingen JA, Cameron DW, Garnett GP. A systematic review of the epidemiologic interactions between classic STDs and HIV: How much is really known? *Sex Transm Dis* 2001;**28**:579-97
- 36 Laga M, Manoka A, Kivuvu M, *et al.* Non-ulcerative sexually transmitted diseases as risk factors for HIV-1 transmission in women: results from a cohort study. *AIDS* 1993;**7**:95-102
- 37 Hayes R, Mosha F, Nicoll A, *et al.* A community trial of the impact of improved STD treatment on the HIV epidemic in rural Tanzania: randomised controlled trial. *AIDS* 1995;**9**:916-26
- 38 Grosskurth H, Mosha F, Todd J, *et al.* Impact of improved treatment of sexually transmitted diseases on HIV infection

- in rural Tanzania: randomised controlled trial. *Lancet* 1995; **346**:530-6
- 39 Wald A, Link K. Risk of human immunodeficiency virus infection in herpes simplex virus type 2-seropositive persons: a meta-analysis. *J Infect Dis* 2002;**185**:45-52
- 40 Mbopi-Keou FX, Gresenguet G, Mayaud P, et al. Interactions between herpes simplex virus type 2 and human immunodeficiency virus type 1 infection in African women: opportunities for intervention. *J Infect Dis* 2000;**182**:1090-6
- 41 Cohen Ms, Hoffmann IF, Royce RA, et al. Reduction of concentration of HIV-1 in semen after treatment of urethritis: Implications for prevention of sexual transmission of HIV-1. *Lancet* 1997;**349**:1868-73
- 42 Sadiq T, Taylor S, Kaye S, et al. The effects of antiretroviral therapy on HIV-1 RNA loads in seminal plasma in HIV-positive patients with and without urethritis. *AIDS* 2002; **16**:219-25
- 43 Laga M, Manoka A, Kivuvu M, et al. Non-ulcerative sexually transmitted diseases as risk factors for HIV-1 transmission in women: results from a cohort study. *AIDS* 1993;**7**:95-102
- 44 Ghys PD, et al. The associations between cervicovaginal HIV shedding, sexually transmitted diseases and immunosuppression in female sex workers in Abidjan, Cote d'Ivoire. *AIDS* 1997;**11**:F85-93
- 45 Tsai CC, Fransen K, Diallo MO, et al. Effectiveness of post-inoculation PMPA Treatment For Prevention of Persistent SIV Infection Depends Critically on Timing of Initiation and Duration of Treatment. *J Virol* 1998;**72**:4265-73
- 46 Otten RA, Smith DK, Adams DR, et al. Efficacy of postexposure prophylaxis after intravaginal exposure of pig-tailed macaques to a human-derived retrovirus (human immunodeficiency virus type 2). *J Virol* 2000;**74**:9771-5
- 47 Le Grand R, Vaslin B, Llargero L, et al. Post-exposure prophylaxis with HAART could not protect macaques from inoculation with SIV/HIV chimera. *AIDS* 2000;**14**:1846
- 48 Jochimsen EM. Failures of zidovudine postexposure prophylaxis. *Am J Med* 1997;**102**:52-5
- 49 Sperling RS, Shapiro DE, Coombs RW, et al. Maternal viral load, zidovudine treatment and the risk of transmission of human immunodeficiency virus type-1 from mother to infant. *N Engl J Med* 1996;**335**:1621-9
- 50 Wade NA, Birkhead GC, Warren BL, et al. Abbreviated regimens of zidovudine prophylaxis and perinatal transmission of the human immunodeficiency virus. *N Engl J Med* 1998;**339**:1409-14
- 51 Praca Onze Study Team. Behavioural impact, acceptability, and HIV incidence amongst homosexual Men with access to postexposure chemoprophylaxis for HIV. *J Acquir Immune Defic Syndr* 2004;**35**:519-25
- 52 Schecter M. Occupational and sexual PEP – benefit/risk? 6th International Conference on Drug Therapy in HIV Infection, 2002. Glasgow, UK (abstr. PL 6.1)
- 53 Roland M, Neilands TB, Krone MR. *Seroconversion following non-occupational post-exposure prophylaxis*. *Clin Infect Dis* 2005;**41**:1507-13
- 54 Williams IG, Kaye S, Williams DI, et al. *Antiretroviral drug-resistant genotypic mutations in HIV-infected persons at first diagnosis (1988-1997) (Abstract 116)*. Programme and abstracts of 2nd International Workshop on HIV Drug Resistance & Treatment Strategies 1998. Italy, 80
- 55 Mayers DL. Prevalence and incidence of resistance to zidovudine and other antiretroviral drugs. *Am J Med* 1997; **102**:70-5
- 56 Yerly S, Kaiser L, Race E, et al. Transmission of antiretroviral-drug resistance HIV-1 variants. *Lancet* 1999;**354**:729
- 57 Hecht FM, Gant RM, Petropoulos CJ, et al. Sexual transmission of an HIV-1 variant resistant to multiple reverse transcriptase and protease inhibitors. *N Engl J Med* 1998;**339**:307
- 58 Boden D, Hurlley A, Zhang L, et al. HIV-1 drug resistance in newly infected individuals. *JAMA* 1999;**282**:1177
- 59 Pillay D, Porter K, Cane P, et al. Analysis of prevalence of HIV-1 drug resistance in primary infections in the United Kingdom. *BMJ* 2001;**322**:1087-8
- 60 Ibanez A, Puig T, Elias J, et al. Quantification of integrated and total HIV-1 DNA after long-term highly active antiretroviral therapy in HIV-1-infected patients. *AIDS* 1999;**13**:1045-9
- 61 Poles M, Elliott J, Vingerhoets J, et al. Despite high concordance, distinct mutational and phenotypic drug resistance profiles in human immunodeficiency virus type 1 RNA are observed in gastrointestinal mucosal biopsy and peripheral blood mononuclear cells compared with plasma. *J Infect Dis* 2001;**183**:00
- 62 Andreoni M, Borisi SG, Sarmati L, et al. Cellular proviral HIV-DNA decline and viral isolation in naive subjects with <5000 copies/ml of HIV-RNA and >500 × 10⁶/l CD4 cells treated with highly active antiretroviral therapy. *AIDS* 2000;**14**:23-9
- 63 Kashuba AD, Dyer J, Eron JJ, Kramer LM, Raasch RH, Cohen MS. Antiretroviral-drug concentrations in semen: implications for sexual transmission of human immunodeficiency virus type 1. *Antimicrob Agents Chemother* 1999;**43**:1817-26
- 64 Hosseinipour M, Cohen MS, Vernazza PL, Kashuba ADM. Can antiretroviral therapy be used to prevent sexual transmission of human immunodeficiency virus type 1? *Clin Infect Dis* 2002;**34**:1391-5
- 65 Pereira AS, Kashuba AD, Fiscus SA, et al. Nucleoside analogues achieve high concentrations in seminal plasma: relationship between drug concentration and virus burden. *J Infect Dis* 1999;**180**:2039-43
- 66 Benn P, Mercey D, Brink NJ, et al. Post-exposure prophylaxis using a nevirapine based regimen. *Lancet* 2001;**357**:687-8
- 67 Parkin JM, Murphy M, Anderson J, et al. Tolerability and side-effects of post-exposure prophylaxis for HIV infection. *Lancet* 2000;**355**:722-34
- 68 Evans B, Duggan W, Baker J, et al. Exposure of healthcare workers in England, Wales, and Northern Ireland to blood borne viruses between 1997 and June 2000: analysis of surveillance data. *BMJ* 2001;**322**:397-8
- 69 Kahn J, Martin JN, Roland ME, et al. Feasibility of post-exposure prophylaxis (PEP) against HIV Infection after Sexual or Injecting Drug Use Exposure: The San Francisco PEP Study. *J Infect Dis* 2001;**183**:707-14
- 70 Serious adverse events attributed to Nevirapine regimens for Post-Exposure Prophylaxis after HIV exposures-worldwide, 1997-2000. *Morbid Mortal Wkly Rep* 2001;**49**:1153-6
- 71 Lert F. Advances in HIV Treatment and Prevention: should treatment optimism lead to prevention pessimism? *AIDS Care* 2000;**12**:745-55
- 72 Kalichman S. Post-exposure prophylaxis for HIV infection in gay and bisexual men; Implications for the future of HIV Prevention. *Am J Preventive Med* 1998;**15**:120-7
- 73 Van der stratten A, Gomez CA, Saul L, et al. Sexual risk behaviours among heterosexual serodiscordant couples in the era of post-exposure prevention and viral suppressive therapy. *AIDS* 2000;**14**:F47-54
- 74 Martin JN, Roland ME, Neilands TB, et al. Use of postexposure prophylaxis against HIV infection following sexual exposure does not lead to increases in high-risk behaviour. *AIDS* 2004;**18**:787-92
- 75 Waldo CR, Franses F, Dillon B, In: Chesney MA, Antoni MH. (eds.), *Innovative Approaches to Health Psychology: Prevention and Treatment Lessons From AIDS*, 2002. Washington: APA
- 76 Greuba G, Gallanta S, Zumb P, et al. Spare non-occupational post exposure prophylaxis by active contacting and testing of the source person. *AIDS* 2002;**16**:1171-6
- 77 Kim JC, Martin LJ, Denny L. Rape and HIV post-exposure prophylaxis: addressing the dual epidemics in South Africa. *Reprod Health Matters* 2003;**11**:101-12
- 78 Mayer K, Goldhammer H, Cohen D, et al. *Tenofovir/3TC for non-occupational post-exposure prophylaxis: improved tolerability and adherence compared to AZT/3TC*. 3rd IAS Conference 2005. Rio de Janeiro, Brazil (abstr. WePe10.3P08)

79 Winston A, McAllister J, Amin J, *et al.* The use of a triple nucleoside-nucleotide regimen for non-occupational HIV post-exposure prophylaxis. *HIV Med* 2005;**6**:191-7

80 *Management of Viral Hepatitis*. CEG of MSSVD/AGUM (now BASHH); accessible at [www.bashh.org]

81 Pinkerton SD, Holtgrave DR. How treatment advances affect the cost-effectiveness of prevention. *Med Decision Making* 2000;**20**:89-94

82 Beck E, Mandalia S, Power A, *et al.* *Reduced HIV disease progression and mortality due to CART in English NPMS-HCC clinics*. 13th International AIDS Conference, 2000. Durban, South Africa (Po TuPeC3331)

83 Pinkerton SD, Martin JN, Roland ME, *et al.* Cost effectiveness of postexposure prophylaxis after sexual or injection-drug exposure to human immunodeficiency virus. *Arch Intern Med* 2004;**164**:46-54

84 Pinkerton SD, Martin JN, Roland ME, *et al.* Cost-effectiveness of HIV postexposure prophylaxis following sexual or injection drug exposure in 96 metropolitan areas in the United States. *AIDS* 2004;**18**:2065-73

(Accepted 1 November 2005)

Appendix: Example of PEPSE proforma (courtesy of Paul Bena, Camdan Primary Care Trust)

Patient
Sticker

PEPSE DISCUSSION PRO FORMA

NameDoB /..... /.....

Address.....

Date of PEP discussion /..... /.....

Name of Health Adviser

Name of Senior Doctor

INCLUSION CRITERIA

Date of sexual exposure /..... /.....

If No then patient should be informed that PEP is unlikely to be effective this long after exposure, but refer to Dr if patient wishes to continue.

- Type of exposure.....
- Was it protected? Yes / No
- Was the sexual partner HIV positive? Yes / No / Unknown / High risk category

If No then PEP is unlikely to be needed as the likelihood of actual risk of HIV transmission is low see table.

- Did unprotected anal, vaginal sex, or receptive oral sex to ejaculation occur? Yes / No

If No then PEP is unlikely to be needed as the risk of HIV transmission with most oral sex or non-penetrative sex is small.

2. Details of risk partner:

- HIV status of risk partner:
 - [] Definitely known HIV + (well known to patient or partner here and confirms status)
 - [] Probable HIV + (patient told by contact by someone else)
 - [] Unknown HIV status but high risk group, specify
 - [] Probably HIV negative (patient told by contact)
 - [] Known HIV negative (Patient knows partner and is certain he/she is HIV negative)
 - [] Unknown HIV but low risk, specify

- Does the partner attend MMC Yes / No – if **Yes** request notes for senior doctor

Name of risk partnerDoB / /

MMC Clinic Ref. Of partner (or address)

.....

RISK ASSESSMENT

2. Prior HIV risk of patient:

- Has the patient tested HIV negative in the past? Yes / No
- **If Yes** give date of last test / /
.....
- Approximate number of partner with which patient has had UPSI since last HIV negative test (or even if no prior HIV test)
0 1 2 3 4 5 6-10 11-20 20+
- Most recent date of UPSI (excluding that for which PEP considered) / /
- Has the patient ever been at risk of HIV Infection via blood to blood contact (e.g. sharing needles, accidents, etc.) since last HIV test? Yes / No

3. Nature of Contact

If there is more than one date of potential exposure within the last 7 days, or more than one partner, please give details for each on a separate form

Sexual activity	Condom intact	Condom accident	No condom used	Internal ejaculation
Oral sex, patient insertive				
Oral sex, patient receptive				
Vaginal sex, patient insertive				
Vaginal sex, patient receptive				
Anal sex, patient insertive				
Anal sex, patient receptive				
Other perceived risk				