Guidelines for the use of post exposure prophylaxis (PEP) following sexual, occupational or non-occupational exposure to HIV

This guidance does not override the individual responsibility of health professionals to make appropriate decision according to the circumstances of the individual patient in consultation with the patient and /or carer. Healthcare professionals must be prepared to justify any deviation from this guidance.

INTRODUCTION

The purpose of the guideline is to ensure the appropriate use of post exposure prophylaxis (PEP) following potential sexual, occupational or other non-occupational exposure to HIV as a method of preventing HIV infection. The guideline offers recommendations on the use of PEP, the circumstances in which it may be recommended, treatment regimens and the use of subsequent diagnostic tests to measure outcome.

THIS GUIDELINE IS FOR USE BY THE FOLLOWING STAFF GROUPS:

The guideline is for use by all those seeing patients in this clinical setting, or those likely to be contacted about such scenarios for example: staff in Sexual Health/A&E/Occupational Health, Consultant Sexual Health (GU) and Infectious Diseases (ID) physicians, Consultant Medical Microbiologists, Pharmacists regarding the prophylactic drugs used.

Lead Clinician(s)

Dr Jacob Okonsukwa	Department of Sexual Health – Herefordshire & Worcestershire Health and Care Trust
Approved by the HIV MDT	6th July 2022
Approved by Medicines Safety Committee	13th July 2022
Review Date: This is the most current document and is to be used until a revised version is available.	13th July 2025

Key amendments to this guideline

Date	Amendment	By:
Feb 2011	Starter pack now contains Truvada 1 tablet once a day for 3 days and Kaletra two tablets bd for 3 days	Dr S Bhaduri
Feb 2011	Starter pack now contains loperamide and domperidone	Dr S Bhaduri
Feb 2011	Similar Algorithm used as per inoculation incident	Dr S Bhaduri
21.02.2011	Approved by Trust Infection Prevention and Control Committee	Dr S Bhaduri
03rd March 2011	Approved by Medicines Safety Committee	Dr S Bhaduri
29/1/2013	Recommendations for PEPSE have changed in source individuals with undetectable viral loads	Dr S Bhaduri
October 2014	Changes to PEPSE regimen	Tina Evans
October 2016	Documents extended for 12 months as per TMC paper approved on 22nd July 2015	TMC
October 2017	Update to section 3 risks of transmission, Section Recommendations for Prescribing PEPSE, Section 8 follow up and Section 10 Monitoring tool	Dr S Bhaduri
December 2017	Sentence added in at the request of the Coroner	
August 2019	Update to sections 3a, 3b, 4a and 8c. Change from trade name “Truvada” to generic nomenclature (Tenofovir disoproxil 245mg/Emtricitabine 200mg combined generic tablet)	Dr S Bhaduri Rachael Leese
May 2022	• Guideline Lead: changed to Dr. Jacob Okonsukwa following retirement to OF Dr Sumit Bhaduri • Title. Title and general content of guideline updated to also reflect occupational and other non-occupational exposures as per updated BHIVA/BASHH guidance 2021. • Section 3. Table 1 content updated as per BHIVA/BASHH guidance 2021 • Section 4. Update to sections 4a and 4b to reflect current recommendations for provision of PEP. • Section 5 and 7. Update to PEP pack contents- now complete 28-day course (extended from 5 day starter pack) issued directly from WAHNHST containing raltegravir 600mg tablets (replacing raltegravir 400mg tablets). • Section 6 contents removed titled ‘previous information on PEP after exposure to HIV’, no longer relevant. Section 6 updated to contain information on baseline monitoring for provision of PEP. • Section 7. Reference made to the Liverpool HIV Interaction checking website and HIVPA patient information leaflet for provision with PEP supplies. • Section 8. Follow up for occupational exposure should be via Occupational Health	Dr S Bhaduri Shane Kailla Rachael Leese
January 2023	• Section 5. Addition of PEP pack access and stock locations within the acute trust	Rachael Leese Dr. Seppings Dr.Okonsukwa

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1. INTRODUCTION

Post exposure prophylaxis (PEP) following potential sexual, occupational or non-occupational exposure to HIV as a potential method of preventing HIV infection. The guideline offers recommendations on the potential use of PEP, the circumstances in which it may be recommended, treatment regimens and the use of subsequent diagnostic tests to measure outcome.

2. BACKGROUND

Studies have indicated that there may be a window of opportunity to prevent HIV infection by inhibiting viral replication following exposure. Once HIV crosses a mucosal barrier it may take up to 48-72 hours before HIV can be detected within regional lymph nodes and up to 5 days before it can be detected in blood.

3. RISK OF TRANSMISSION

This is related to the risk that the source is HIV-positive with a detectable HIV viral load (**Table 1**) and the risk of exposure (**Table 2**) (Risk of HIV transmission = Risk that source is HIV positive with a detectable HIV viral load x risk of exposure).

3a <u>Table 1</u> Number and prevalence of people with detectable (therefore transmissible i.e. HIV viral load >200 copies/ml) levels of HIV per 1000 population aged 15-74 years, England 2018 (PHE data)

Community Group	Est. no of people with detectable virus	Est. population size	Rate per 1000
Gay and Bisexual Men			
England	12,000	518,050	23.00
London	5,000	155,880	32.1
Elsewhere	7,000	361,090	20.9
Heterosexual Men			
Black African	1,900	331,950	5.8
Non-black African	3,480	19,563,630	0.2
Heterosexual Women			
Black African	3,240	373,330	8.7
Non-black African	2,530	20,308,360	0.1
PWID			
All	700	104,470	6.7
Men	400	77,340	5.3
Women	300	26,710	11.5

3b Table 2 Risk of exposure

Type of Exposure	Estimated risk of HIV transmission per exposure from an HIV-positive individual who is NOT on suppressive antiretroviral therapy	
Blood transfusion 1 unit	1 in 1	
Receptive anal intercourse	1 in 90	1 in 65 with ejaculation 1 in 170 without ejaculation
Receptive vaginal intercourse	1 in 1000	
Insertive vaginal intercourse	1 in 1219	
Insertive anal intercourse	1 in 666	1 in 161 not circumcised 1 in 909 circumcised
Receptive oral sex	<1 in 10,000	
Insertive oral sex	<1in 10,000	
Sharing injecting equipment (including chemsex)	1 in 149	
Needlestick injury	1 in 333	
Human Bite	<1 in 10,000	
Semen splash to eye	<1 in 10,000	
Mucocutaneous	1 in 1000	

Other factors that may increase transmission include high plasma viral load (e.g. during primary HIV infection), breaches in the mucosal barrier such as the mouth or genital ulcer disease or trauma (e.g. after sexual assault) or after first intercourse and STIs.

4. RECOMMENDATIONS FOR PRESCRIBING PEP

The use of PEP following potential exposure to HIV is only recommended where the individual presents within 72 hours of exposure and that it be given as early as possible ideally within 24 hours. All recommendations are for occupational or non-occupational exposure and unprotected sexual exposure or where condom failure has occurred.

4a Source Individual is known to be HIV positive:

Exposure	HIV viral load unknown or detectable	HIV viral load undetectable*
Receptive anal sex	Recommended	Not recommended
Insertive anal sex	Recommended	Not recommended
Receptive vaginal sex	Recommended	Not recommended
Insertive vaginal sex	Consider	Not recommended
Receptive oral sex with ejaculation	Not recommended	Not recommended
Receptive oral sex without ejaculation	Not recommended	Not recommended
Splash of semen in eye	Not recommended	Not recommended

Cunnilingus	Not recommended	Not recommended
Sharing of injecting equipment	Recommended	Not recommended
Sharps injury	Recommended	Not recommended
Mucosal splash injury	Recommended	Not recommended
Human Bite	Not recommended	Not recommended

*IF THE HIV VIRAL LOAD FROM SOURCE INDIVIDUAL IS UNDETECTABLE – ALL CATEGORIES OF EXPOSURE ARE NOT RECOMMENDED provided source has good adherence to antiretroviral therapy and confirmed HIV viral load <200 copies/ml for 6 months.

4b Source individual is of unknown status but from a group or area of high HIV prevalence:

(At present in UK- this is likely to be MSM, people who inject drugs from high risk countries and individuals who originate from areas of high HIV prevalence particularly sub-Saharan Africa. Country specific HIV prevalence information can be found at https://aidsinfo.unaids.org/)

Receptive anal sex	Recommended
Insertive anal sex	Consider
Receptive vaginal sex	Generally not recommended
Insertive vaginal sex	Generally not recommended
Receptive oral sex with ejaculation	Not recommended
Receptive oral sex without ejaculation	Not recommended
Splash of semen into eye	Not recommended
Cunnilingus	Not recommended
Sharing of injecting equipment	Generally not recommended
Sharps injury	Generally not recommended
Mucosal splash injury	Generally not recommended
Human Bite	Not recommended
Needlestick from a discarded needle in the community	Not recommended

4c Source is not from a group or area of high HIV prevalence:

Receptive anal sex	Not recommended
Insertive anal sex	Not recommended
Receptive vaginal sex	Not recommended
Insertive vaginal sex	Not recommended
Receptive oral sex with ejaculation	Not recommended
Receptive oral sex without ejaculation	Not recommended
Splash of semen into eye	Not recommended
Cunnilingus	Not recommended
Sharing of injecting equipment	Not recommended
Sharps injury	Not recommended
Mucosal splash injury	Not recommended
Human Bite	Not recommended
Needlestick from a discarded needle in the community	Not recommended

4d If the source is unknown:

Attempts should be made where possible to establish the HIV status of the index case. In all exposures local prevalence of the index case should be considered e.g. where the index case is from a high prevalence area and normally resides outside the UK, PEP should be given where there is doubt. NOTE: where there is deep trauma or bolus of blood in occupational exposure again PEP may be favoured.

4e Sexual Assault:

Transmission of HIV is likely to be increased following aggravated intercourse hence PEP may be considered in this situation but especially so if the assailant is perceived to be from a high prevalence group. NOTE: other factors which may favour PEP where there is doubt in sexual exposure include first intercourse, multiple episodes of sexual exposure over a short period, STI in either partner, individuals at higher risk of acquiring HIV e.g. transgender.

5. ADMINISTRATION OF PEP

5a **ALL CASES FOR POTENTIAL PEP PROVISION WILL REQUIRE IMMEDIATE ATTENTION,** and should be fast tracked for assessment, as treatment may need to be instigated within a very short period of time.

5b If a significant risk of possible HIV infection is identified via the risk assessment of the source and type of exposure the on-call designated person (see below) **MUST** be contacted **IMMEDIATELY** for advice on the appropriate course of treatment / action to be taken.

Designated Persons:-

- **Consultant in Sexual Health (GU - Genitourinary) Medicine**
- **Consultant in Infectious Diseases**
- **Consultant Medical Microbiologist**

All may be contacted via Switchboard

5c Following action should only be taken after consultation with the designated person on call, for example: GU Medicine / Infectious Diseases / Microbiology. It is therefore essential that they are contacted without delay whenever the possibility of HIV exposure is being seriously considered.

5d Prophylactic medication includes the following:

- Tenofovir disoproxil 245mg/Emtricitabine 200mg combined generic tablet daily for 28 days

- Plus Raltegravir 1200mg (2 x 600mg tablets) daily for 28 days

5e Patients will be given a full 28 day supply compared to previous 5 day supplies as evidence suggests this increases compliance, has better cost-effectiveness and drug stability data.

5f Although the full treatment course will be supplied on the first encounter, patients must still be reminded to attend a follow-up with Sexual Health Services (sexual or non-occupational exposures) or Occupational Health (occupational exposure) at the earliest opportunity to assess as to whether they are to continue with treatment.

5g PEP should be initiated **within 72 hours** of the exposure occurring, although undefined benefit may result from initiating therapy after a longer interval in cases of the highest risk exposure. Initiation beyond a 72 hours must be discussed with the designated persons as listed in point 5b.

5h PEP packs are stocked in both acute trust pharmacy departments and are also located as follows: A&E Worcestershire Royal Hospital and Alexandra Hospital, Minor Injuries Unit Kidderminster Treatment Centre, Emergency Drug Cupboard Worcestershire Royal Hospital and Alexandra Hospital. Or out of hours PEP packs can also be accessed by contacting the on-call pharmacist.

6. BASELINE MONITORING FOR THE PROVISION OF PEP

6a *All exposures* must have the following baseline monitoring undertaken: U+E, LFTs (to include ALT), HIV-1 Ag/Ab, Hepatitis B serology (HepBsAg, HepBsAb, HepBcAb)

6b *Sexual exposures* in addition to tests listed in point 6a must have the following additional baseline monitoring undertaken: chlamydia/ gonorrhoea PCR (urine sample in males, vulvo-vaginal swab in females), Hepatitis C screening (Hep C Ab) in MSM and others if deemed at risk of Hepatitis C

6c *Occupational exposures* in addition to tests listed in point 6a must have the following additional baseline monitoring undertaken: Hepatitis C screening (Hep C Ab)

NB: A pregnancy test should be performed for all women of child bearing age where PEP is being considered.

7. FACTORS FOR CONSIDERATION

Any drug regimen will have to take into account the following factors:

- whether the exposed patient is allergic to one of these drugs
- whether the patient is pregnant or breast feeding
- interactions with other medication
  (refer to https://www.hiv-druginteractions.org/checker)
- whether there is a possibility that the virus may be resistant to one or more of the drugs prescribed for PEP

In all these circumstances expert advice should be sought.

The drugs discussed above have all been licensed for the treatment of HIV infection but only tenofovir disproxil/emtricitabine for it's prevention. For this reason they may be prescribed only for PEP on "a named patient basis".

At present the first line drugs for PEP are Tenofovir disoproxil 245mg/Emtricitabine 200mg combined generic tablet and Raltegravir 600mg tablets, they should be taken for **28 days.**

Check **PEP pack contains:**

- 30 x Tenofovir disoproxil 245mg/Emtricitabine 200mg combined generic tablet labelled “take one tablet once a day”

and

- 60 x Raltegravir 600mg tablets labelled “take two tablets once a day”

and

- PEP patient information leaflet. Copies can be accessed via the HIVPA website if necessary https://hivpa.org/patient-information-leaflets-pils/

The PEP pack is taken for 28 days. Patients should be instructed to discard the remaining tablets as due to instability of ‘packed down’ commercially available preparations a 30 day supply in original packaging is provided.

7a Short term toxicity with the agents are listed as follows:

Tenofovir disoproxil 245mg/Emtricitabine 200mg combined generic tablet:
Diarrhoea, nausea, vomiting
Rash
Headache, dizziness, abnormal dreams, insomnia
Hypophosphataemia
Hyperglycaemia, hypertriglyceridaemia
Neutropenia
Renal impairment

Raltegravir: Gastrointestinal symptoms
Hepatic dysfunction
Rash, pruritus, Stevens Johnson syndrome
Headache, dizziness, abnormal dreams, insomnia, vertigo
Metabolic disturbance
Decreased appetite
Fatigue, Asthenia, pyrexia, paraesthesia, myalgia, myositis, Rhabdomyolysis.
Pancreatitis, hepatitis, gastritis, taste disturbance
Interacts with antacids, multivitamins and iron supplements (refer to https://www.hiv-druginteractions.org/checker)

7b Use of Drugs in Pregnancy and Breast Feeding

There is limited data on the safety of Tenofovir disoproxil 245mg/Emtricitabine 200mg combined generic tablet and Raltegravir in pregnancy and breast feeding

Further discussion with Microbiology / GU Medicine / Infectious Diseases Consultant required.

8. FOLLOW UP

For those patients prescribed PEP, follow up at Sexual Health Services (sexual and non-occupational exposures) or Occupational Health (occupational exposure) should be arranged at the earliest opportunity with a view to:

a) Review continuation of PEP
b) Review of baseline monitoring undertaken for provision of PEP (see Section 6)
c) Follow up monitoring for any potential toxicities (including U&E, LFT, urinalysis for proteinuria at 14 days if any baseline abnormality)
d) Follow up HIV testing from 45 days after the completion of PEP
e) Follow up STI testing as appropriate: gonorrhoea, chlamydia, syphilis and for other blood borne viruses 8-12 weeks post exposure

9. DOCUMENTATION

Documentation should be completed as a record of issues discussed and actions taken as per the standard inoculation injuries pro forma.

10. MONITORING TOOL

Page/ Section of Key Document	Key control:	Checks to be carried out to confirm compliance with the policy:	How often the check will be carried out:	Responsible for carrying out the check:	Results of check reported to: *(Responsible for also ensuring actions are developed to address any areas of non-compliance)*	Frequency of reporting:
	WHAT?	**HOW?**	**WHEN?**	**WHO?**	**WHERE?**	**WHEN?**
	Patients are reviewed fortnightly if taking PEP	Audit of guideline	3 yearly	Consultants in Sexual Health	This will be via Herefordshire & Worcestershire Health and Care Trust audit process	3 yearly
	Patients have a baseline HIV test within 72 hours of presenting for PEP	Audit of guideline	3 yearly	Consultants in Sexual Health	Herefordshire & Worcestershire Health and Care Trust	3 yearly
	Patients complete 28 day course of PEP	Audit of guideline	3 yearly	Consultants in Sexual Health	Herefordshire & Worcestershire Health and Care Trust	3 yearly
	Patients have an HIV test 10.5 weeks (45 days after completion of PEP)	Audit of guideline	3 yearly	Consultants in Sexual Health	Herefordshire & Worcestershire Health and Care Trust	3 yearly

11. REFERENCES

Fisher M. Benn P (2006). *UK Guideline for the use of post-exposure prophylaxis for HIV following sexual exposure* International Journal of STD & AIDS; **17:** 81–92

BHIVA/BASHH. UK Guideline for the use of HIV Post Exposure Prophylaxis 2021. Post consultation version. https://www.bhiva.org/file/6183b6aa93a4e/PEP-guidelines.pdf

HIVPA patient information leaflet for HIV post exposure prophyaxis – generic tenofovir/emtricitbaine with once daily raltegravir https://hivpa.org/wp-content/uploads/2021/04/HIVPA-PEP-PIL-April-2021-generic-TDF-FTC-RAL-OD-Final.pdf

12. CONTRIBUTION LIST

Key individuals involved in developing the document (previous versions and May 2022 update)

Name	Designation
Dr Sumit Bhaduri	Consultant GU Physician
Dr Jane Stockley	Consultant Microbiologist (May 2022 - no longer a WAHNHST employee)
Tina Evans	Clinical Pharmacy Team Leader
Lara Bailey	Senior Infection Prevention Nurse
Rachael Leese	Lead Pharmacist – HIV and Hepatitis C
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Circulated to the following individuals for comments (May 2022 update)

Name	Designation
Dr Mark Roberts	Consultant in Infectious Diseases
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Emma Carrington	Clinical Nurse Specialist in Sexual Health
Samantha Green	Clinical Nurse Specialist in HIV
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Anita Griffiths	Clinical Nurse Specialist in HIV
Dr Ross Hodson	Consultant Emergency Medicine
Tina Evans	GEMS Practitioner & Team Lead Pharmacist for Urgent Care and Pharmacist ACPs
Dr Emma Yates	Consultant Microbiologist & Co-Infection Control Doctor
Zeshan Riaz	Lead Pharmacist Antimicrobial Stewardship
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Circulated to the chair of the following committee's / groups for comments (May 2022 update)

Name	Committee / group
Vicky Morris	Medicines Safety Committee
Vicky Morris	Trust Infection Prevention & Control Committee

Supporting Document 1 – Equality Impact Assessment form

To be completed by the key document author and included as an appendix to key document when submitted to the appropriate committee for consideration and approval.

Please complete assessment form on next page;

Herefordshire & Worcestershire STP - Equality Impact Assessment (EIA) Form
Please read EIA guidelines when completing this form

Section 1 - Name of Organisation (please tick)

Herefordshire & Worcestershire STP		Herefordshire Council		Herefordshire CCG	
Worcestershire Acute Hospitals NHS Trust		Worcestershire County Council		Worcestershire CCGs	
Worcestershire Health and Care NHS Trust		Wye Valley NHS Trust		Other (please state)	

Name of Lead for Activity	

Details of individuals completing this assessment	**Name**	**Job title**	**e-mail contact**
Date assessment completed			

Section 2

Activity being assessed (e.g. policy/procedure, document, service redesign, policy, strategy etc.)	**Title:**			
What is the aim, purpose and/or intended outcomes of this Activity?				
Who will be affected by the development & implementation of this activity?	❑ Service User ❑ Patient ❑ Carers ❑ Visitors		❑ Staff ❑ Communities ❑ Other _____	
Is this:	❑ Review of an existing activity ❑ New activity ❑ Planning to withdraw or reduce a service, activity or presence?			
What information and evidence have you reviewed to help inform this assessment? (Please				

name sources, eg demographic information for patients / services / staff groups affected, complaints etc.	
Summary of engagement or consultation undertaken (e.g. who and how have you engaged with, or why do you believe this is not required)	
Summary of relevant findings	

Section 3

Please consider the potential impact of this activity (during development & implementation) on each of the equality groups outlined below. **Please tick one or more impact box below for each Equality Group and explain your rationale**. Please note it is possible for the potential impact to be both positive and negative within the same equality group and this should be recorded. Remember to consider the impact on e.g. staff, public, patients, carers etc. in these equality groups.

Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Age				
Disability				
Gender Reassignment				
Marriage & Civil Partnerships				
Pregnancy & Maternity				
Race including Traveling Communities				
Religion & Belief				
Sex				
Sexual Orientation				
Other Vulnerable and Disadvantaged Groups (e.g. carers; care leavers; homeless; Social/Economic deprivation, travelling communities etc.)				
Health Inequalities (any preventable, unfair & unjust differences in health status				

Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
between groups, populations or individuals that arise from the unequal distribution of social, environmental & economic conditions within societies)				

Section 4

What actions will you take to mitigate any potential negative impacts?	Risk identified	Actions required to reduce / eliminate negative impact	Who will lead on the action?	Timeframe
		.		
How will you monitor these actions?				
When will you review this EIA? (e.g in a service redesign, this EIA should be revisited regularly throughout the design & implementation)				

Section 5 - Please read and agree to the following Equality Statement

1. Equality Statement

1.1. All public bodies have a statutory duty under the Equality Act 2010 to set out arrangements to assess and consult on how their policies and functions impact on the 9 protected characteristics: Age; Disability; Gender Reassignment; Marriage & Civil Partnership; Pregnancy & Maternity; Race; Religion & Belief; Sex; Sexual Orientation

1.2. Our Organisations will challenge discrimination, promote equality, respect human rights, and aims to design and implement services, policies and measures that meet the diverse needs of our service, and population, ensuring that none are placed at a disadvantage over others.

1.3. All staff are expected to deliver services and provide services and care in a manner which respects the individuality of service users, patients, carer's etc, and as such treat them and members of the workforce respectfully, paying due regard to the 9 protected characteristics.

Signature of person completing EIA	
Date signed	
Comments:	

Signature of person the Leader Person for this activity	
Date signed	
Comments:	

Supporting Document 2 – Financial Impact Assessment

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

	Title of document:	Yes/No
1.	Does the implementation of this document require any additional Capital resources	no
2.	Does the implementation of this document require additional revenue	no
3.	Does the implementation of this document require additional manpower	no
4.	Does the implementation of this document release any manpower costs through a change in practice	no
5.	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programmes or allocated training times for staff	no
	Other comments:	

If the response to any of the above is yes, please complete a business case and which is signed by your Finance Manager and Directorate Manager for consideration by the Accountable Director before progressing to the relevant committee for approval