Guidelines for the use of post exposure prophylaxis for HIV following sexual exposure

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 exposure (PEPSE) to HIV as a potential method of preventing HIV infection. The guideline offers recommendations on the potential use of PEPSE, 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 – Staff in Sexual Health and A/E, Consultant Medical Microbiologists, Sexual health and ID physicians. Pharmacists regarding the prophylactic drugs used.

Lead Clinician(s)

Dr Sumit Bhaduri	Dept of Sexual Health – Worcestershire Health and Care Trust
Approved by TIPCC	16th December 2019
Approved by Medicines Safety Committee	4th November 2019
Review Date	16th December 2022

This is the most current document and is to be used until a revised version is available.

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

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1. INTRODUCTION

Exposure prophylaxis (PEP) following potential sexual exposure (PEPSE) to HIV as a potential method of preventing HIV infection. The guideline offers recommendations on the potential use of PEPSE, 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 window of opportunity to abort 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 risk that the source is positive where unknown (**Table 1**) and the risk of exposure (**Table 2**) (Risk of HIV transmission = Risk source positive x risk of exposure).

3a Table 1 Risk that source is positive

HIV Seroprevalence		
Community Group	**Male**	**Female**
Men having sex with Men (MSM) London	12.5%	
Elsewhere	3.8%	
UK	5.9%	
Heterosexuals		
Sub-Saharan Africa	4.1%	7.1%
Elsewhere	0.06%	
Injecting Drug Users	0.67%-1.1%	0.67-1.1%

3b Table 2 Risk of exposure

Type of Exposure	**Estimated risk of HIV transmission per exposure**	
Blood transfusion 1 unit	1 in1	
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	1in 333	
Human Bite	<1 in 10,000	

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 PEPSE

The use of PEPSE 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. All recommendations are for either unprotected sexual exposure or where condom failure has occurred.

4a Source Individual is known to be HIV positive:

Receptive anal sex	Recommended
Insertive anal sex	Recommended
Receptive vaginal sex	Recommended
Insertive vaginal sex	Consider
Receptive oral sex with ejaculation	Not recommended
Splash of semen in eye	Not recommended
Receptive oral sex without ejaculation	Not recommended
Oral sex (m on f)	Not recommended
Sharing of injecting equipment	Recommended
Human Bite	Not recommended

IF THE HIV VIRAL LOAD FROM SOURCE INDIVIDUAL IS UNDETECTABLE – ALL CATEGORIES ARE NOT RECOMMENTED provided source has 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 and individuals who originate from areas of high HIV prevalence particularly sub-Saharan Africa)

Receptive anal sex	Recommended
Insertive anal sex	Consider
Receptive vaginal sex	Consider
Insertive vaginal sex	Consider
Receptive oral sex with ejaculation	Not recommended
Receptive oral sex without ejaculation	Not recommended
Splash of semen into eye	Not recommended
Sharing of injecting equipment	Consider
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
Sharing of injecting equipment	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 HIV status of the source

4e Sexual Assault:

Transmission of HIV is likely to be increased following aggravated intercourse hence PEPSE may be considered in this situation but especially so if the assailant is perceived to be high prevalence group.

5. ADMINISTRATION OF PEPSE

5a ALL CASES OF POTENTIAL PEPSE 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 Medical Microbiologist**
- **Consultant in GU Medicine**
- **Consultant in Infectious Diseases**

All may be contacted via Switchboard

NB: A pregnancy test should be performed for all females if pregnancy is possible and PEP is to be considered.

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

5d Prophylactic treatment should include the following:

- Tenofovir disoproxil 245mg/Emtricitabine 200mg combined generic tablet for 5 days

- Plus Raltegravir for 5 days

5e The prophylaxis should ideally be initiated **within 72 hours** of the incident occurring, although undefined benefit may result from initiating therapy after a longer interval in cases of the highest risk exposure.

6. PREVIOUS INFORMATION ON POST EXPOSURE PROPHYLAXIS (PEP) AFTER EXPOSURE TO HIV

6a In a recent retrospective case-control study among healthcare workers (HCW's) Zidovudine post exposure prophylaxis was associated with a 79% decrease in the risk for HIV sero-conversion after percutaneous exposure to HIV infected blood.

6b Failures of Zidovudine PEP have occurred.

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
- interactions with other medication
- when there is a possibility that the virus may be resistant to one or more of the drugs.

Normally, in all these circumstances expert advice should be sought.

The drugs discussed above have all been licensed for the treatment of HIV infection but not for its prevention. For this reason they may be prescribed only for PEP on "a named patient basis". As more anti-retroviral drugs are developed it is likely that other drugs or combinations of drugs will become the preferred regimen for PEP.

At present the drugs for PEP are Tenofovir disoproxil 245mg/Emtricitabine 200mg combined generic tablet and Raltegravir and should be taken for **4** weeks

Check **PEP pack contains:**

- 5 x Tenofovir disoproxil 245mg/Emtricitabine 200mg combined generic tablet labelled "take one tablet once day"

and

- 10 x Raltegravir 400mg tablets
  labelled "take one tablet twice a day"

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: GIT symptoms
Hepatic dysfunction
Rash, pruritus, Stevens Johnson syndrome
Headache, dizziness, abnormal dreams, insomnia, vertigo
Lipodystrophy
Metabolic disturbance
Decreased appetite
Fatigue, Asthenia, pyrexia, paraesthesia, myalgia, myositis, rhabdomyolysis.
Pancreatitis, hepatitis, gastritis Taste disturbance
May also interact with omeprazole

7b Use of Drugs in Pregnancy

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

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

8. FOLLOW UP

For those patients prescribed PEPSE, follow up at GU medicine / Infectious disease should be arranged at the earliest opportunity with a view to

a) Continuation of PEPSE
b) Monitoring of any potential toxicities (including baseline U&E, LFT, urinalysis for proteinuria and at 14 days if any baseline abnormality)
c) HIV / STI testing as appropriate (baseline and 8-12 weeks post exposure for HIV and/or other blood borne viruses and/or syphilis)

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 post exposure prophylaxis	Audit of policy	3 yearly	Consultants in sexual health	This will be via Worcestershire health and care trust audit process	3 YEARLY
	Patients have a baseline HIV test within 72 hours of presenting for PEPSE	Audit of policy	3 yearly	Consultants in sexual health	Worcestershire health and care trust	3 yearly
	Patients complete 4 week course of PEPSE	Audit of policy	3 yearly	Consultants in sexual health	Worcestershire health and care trust	3 yearly
	Patients have an HIV test 8-12 week post exposure	Audit of policy	3 yearly	Consultants in sexual health	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

12. CONTRIBUTION LIST

Key individuals involved in developing the document

Name	Designation
Dr Sumit Bhaduri	Consultant GU Physician
Dr Jane Stockley	Consultant Microbiologist (No longer Trust Employee)
Tina Evans	Clinical Pharmacy Team Leader (No longer Trust Employee)
Lara Bailey	Senior Infection Prevention Nurse
Rachael Leese	Lead Pharmacist – HIV and Hepatitis C

Circulated to the following individuals for comments

Name	Designation
Dr Mark Roberts	Consultant in Infectious Diseases

Circulated to the chair of the following committee's / groups for comments

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;

NHS Worcestershire Acute Hospitals NHS Trust

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				

Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Inequalities (any preventable, unfair & unjust differences in health status 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