

# PEP

## POST-EXPOSURE PROPHYLAXIS IN PRACTICE

Experiences and suggested guidelines for  
PEP provision in the MSM setting

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PART OF ANOVA HEALTH INSTITUTES HEALTH4MEN PROGRAMME

**SIMON NKOLI CENTRE FOR  
MEN'S HEALTH**  
FIRST FLOOR, NEW NURSES HOME,  
CHRIS HANI BARAGWANATH HOSPITAL, SOWETO

**HEALTH  
4MEN**  
*top to bottom*

- Operational since July 2009
- Based in Soweto
- 3314 men in care since opening
- 80 men seen per week



**SIMON NKOLI CENTRE FOR  
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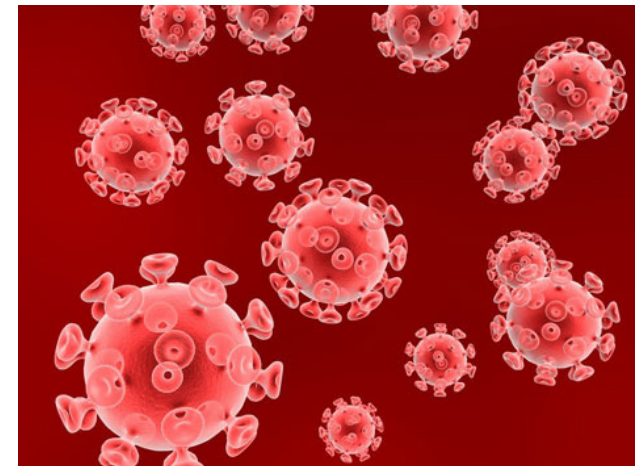
HEALTH  
**4**MEN  
*top to bottom*

- 561 HIV positive men in care
- 200 men currently on ARV medication
- 322 know gay identified MSM
- 1983 of clients are local Soweto men



# SERVICES OFFERED

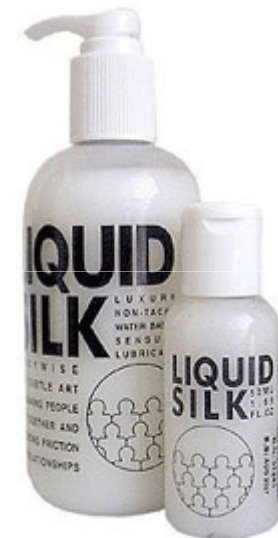
- FREE STI SCREENING, DIAGNOSIS AND TREATMENT
- FREE HIV TESTING AND RAPID RPR
- CD4 COUNTS FOR POSITIVE RESULTS



# SERVICES OFFERED



- FREE ARV PROVISION WITH CLINICAL MONITORING
- CONDOM AND LUBE PROVISION
- PSYCHOSOCIAL SUPPORT
- PEP PROVISION TO ALL CLIENTS





## PEP NUMBERS TO DATE ACROSS BOTH HEALTH4MEN SITES



- 54 MSM Treated
- 100% Completed The PEP Regimen
- Number Of Patients Eligible To Re-test 38
- Number Actually Re-tested For HIV 12
- All Results HIV Negative
- **No HIV Positive Results In This Group To Date**

# MAIN REFERENCES FOR PEP PROTOCOLS



- SAHIVSOC Guidelines 2008 The Southern African Journal Of HIV Medicine
- British Association For Sexual Health And HIV BASHH February 2011 (Draft)
- South African DOH Guidelines 2004
- CDC Guidelines 2005
- Original Research
- Papers Listed At End Of Presentation





# WHAT IS PEP?



PEP IS A COMBINATION OF ANTI-RETROVIRAL DRUGS GIVEN TO AN ELIGIBLE CLIENT WITHIN 72 HOURS OF HIV EXPOSURE FOR A 28 DAY PERIOD WITH THE SPECIFIC INTENT TO AVERT HIV INFECTION IN THE HOST.

# WHAT IS PEP?

- PEP UTILISES ARVS WHICH ARE ALSO THE MAINSTAY OF TREATMENT FOR HIV INFECTION
- ADHERANCE IS KEY
- INITIATION WITHIN 72 HOURS ESSENTIAL

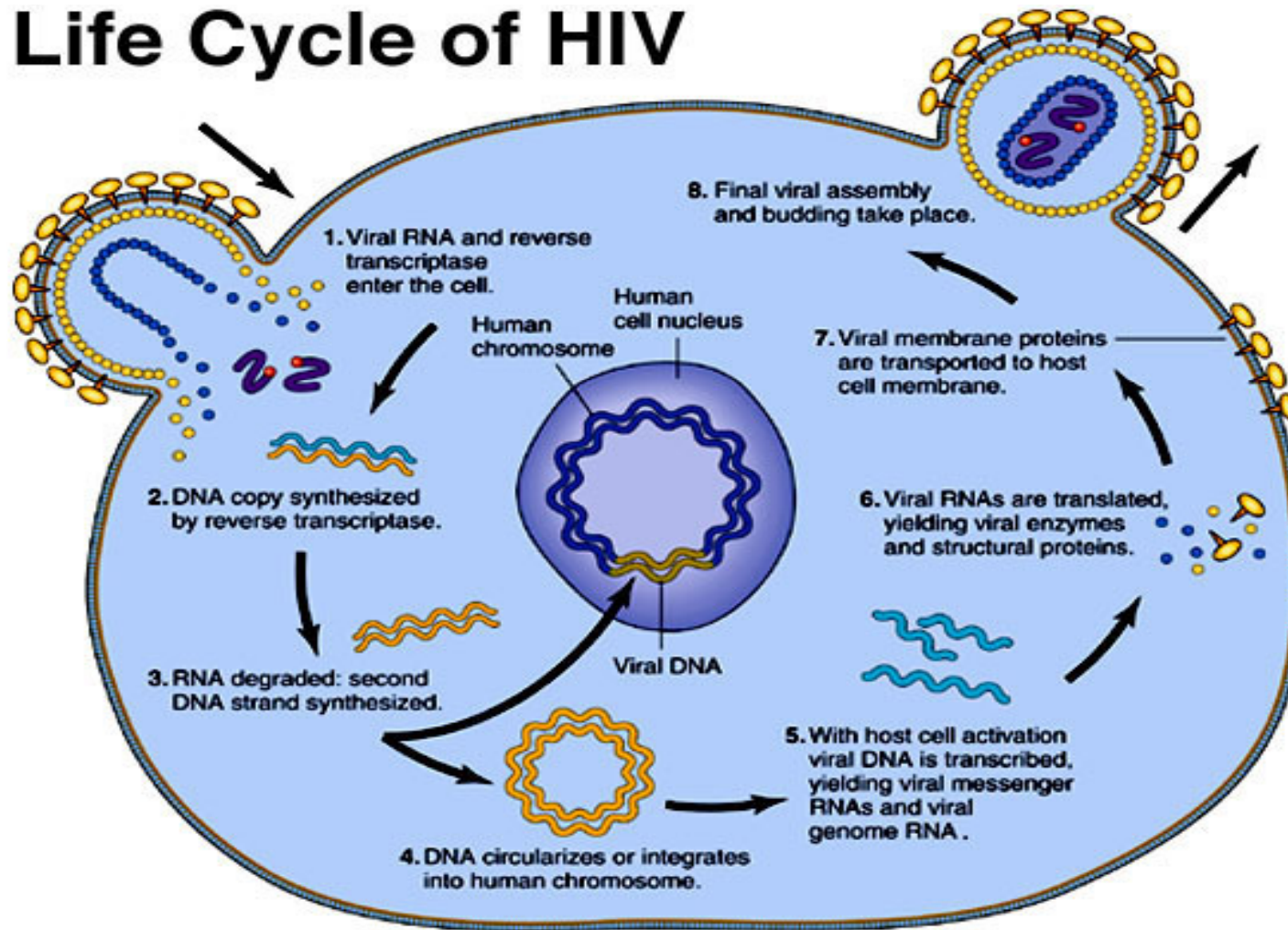
PEP IS NOT JUST A PRESCRIPTION IT IS A SIX MONTH CLINICAL AND PSYCHOLOGICAL PROGRAMME WHICH MUST BE ADHERED TO IN ALL CASES FOR IT TO BE SUCCESSFUL

# HOW DOES PEP WORK?

- PEP IS A COMBINATION OF THREE ARVS
- TWO NRTI DRUGS
- ONE PROTEASE INHIBITOR
- NRTIS WORK BY INHIBITING REVERSE TRANSCRIPTASE PREVENTING HIV VIRAL REPLICATION
- PIS INHIBIT PROTEASE INHIBITOR WHICH PREVENTS VIRAL PARTICLE PRODUCTION

# PEP EFFECT ON HIV LIFE CYCLE

## Life Cycle of HIV





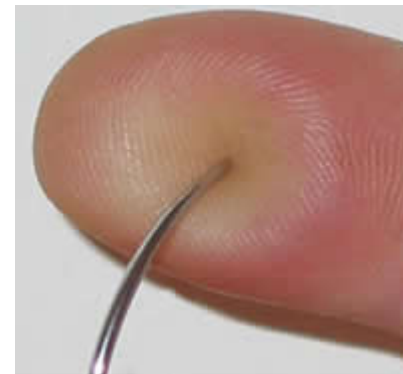
# EVIDENCE FOR PEP

- VERY LITTLE DIRECT PEP DATA ESPECIALLY IN MSM GROUP
- INFECTIVITY IS LOW SO LARGE NUMBERS ARE REQUIRED TO ACHIEVE STATISTICAL POWER
- ETHICAL ISSUES
- ANIMAL STUDIES
- PMTCT EXPERIENCE
- HEALTHCARE WORKERS
- SEXUAL ASSAULT CASES
- SMALL BRAZILIAN OBSERVATIONAL STUDY ON MSM

# SPECIFIC STUDIES EXPLORING PEP EFFICACY



- Experiments On Macaque Monkeys Showed Protective Effect Of PEP *(1,2,3)*
- Human Studies
- Occupational Exposure 81% reduction in those on PEP. Needlestick injuries in health care workers showed AZT to be protective *(4)*



# SPECIFIC STUDIES EXPLORING PEP EFFICACY

- Vertical Transmission (PMTCT)

Study showed protective effect of AZT on exposed neonates (5)



- Data after sexual exposure

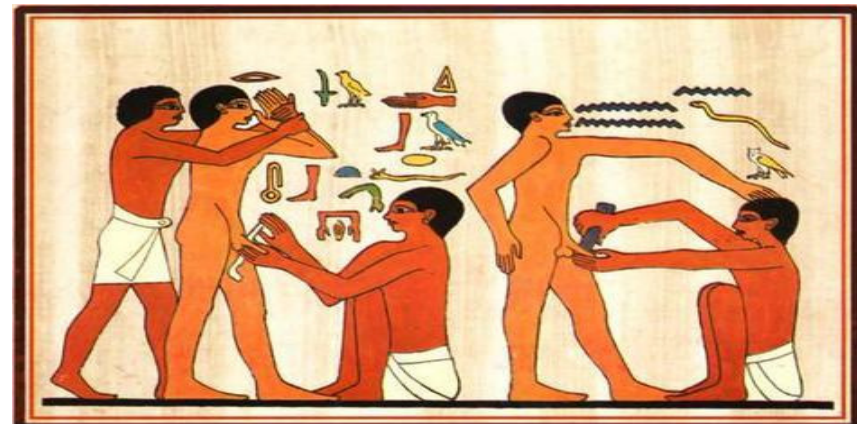
No prospective randomised-controlled trials to determine efficacy of PEP identified

- Observational study undertaken in Brazil showed protective effect of PEP in MSM after sexual exposure (6)



# FACTORS AFFECTING TRANSMISSION

- HIGH VIRAL LOAD IN THE SOURCE (*N.B.HIV prevention trial network HPTN 052 study 2011*)
- Breaches In Mucosal Barrier Such As Mouth Or Genital Ulcer Disease Or Trauma
- STIs Enhance Viral Transmission And Increase HIV Viral Shedding From The Genital Tract
- Risk Greater If Ejaculation Occurs
- Circumcision Little Effect In MSM (7)





# RISK OF HIV TRANSMISSION FOLLOWING AN EXPOSURE FROM A KNOWN HIV POSITIVE INDIVIDUAL



TYPE OF EXPOSURE	ESTIMATED MEDIAN RISK OF HIV TRANSMISSION PER EXPOSURE
RECEPTIVE ANAL INTERCOURSE	1.11% (0.042-3.0%)
INSERTIVE ANAL INTERCOURSE	0.06% (0.06-0.065%)
RECEPTIVE ORAL SEX	0.02% (0-0.04%)
INSERTIVE ORAL SEX	0%
NEEDLE STICK INJURY	0.3% (0.2-0.5%)
SHARING INJECTING EQUIPMENT	0.67%



# RISK OF HIV TRANSMISSION



**RISK OF HIV TRANSMISSION = RISK THAT  
SOURCE IS HIV POSITIVE x THE RISK OF  
EXPOSURE x LOCAL PREVALENCE**

- HIGH LOCAL PREVALENCE AMPLIFIES THE RISK OF HIV TRANSMISSION.
- SOWETO MEN'S STUDY SHOWED A PREVALENCE OF 33.9% HIV POSITIVITY IN GAY IDENTIFIED MSM IN SOWETO (8)

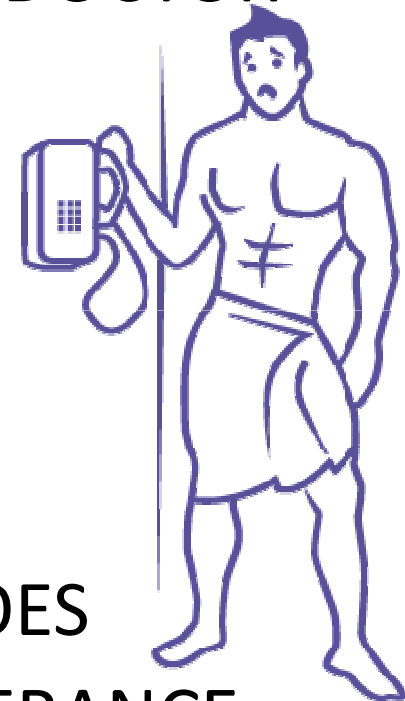


# DOES PEP ENCOURAGE UNSAFE SEX?

- EVIDENCE SUGGESTS THE OPPOSITE (9)
- PEP IS NOT A PLEASANT EXPERIENCE AND MOST USERS WILL AVOID USING IT A SECOND TIME IF AT ALL POSSIBLE
- REQUIRES COMMITMENT, ADHERANCE MEDICALISATION OF SEXUALITY, MONITORING HIV TESTING AND BLOOD TAKING
- ITS EXISTENCE HOWEVER DOES PROVIDE AN IMPORTANT DEFAULT POSITION IF POTENTIALLY EXPOSED

# INITIAL MANAGEMENT OF PATIENT

- IMMEDIATE ACCESS TO PHC NURSE OR DOCTOR
- AFFIRM REASON FOR ATTENDANCE
- ESTABLISH HISTORY OF EXPOSURE
- WHEN DID EXPOSURE TAKE PLACE
- HIV STATUS OF SOURCE IF KNOWN (R)
- HIV STATUS OF CLIENT
- EXPLAIN WHAT PEP IS AND WHAT IT DOES
- EMPHASISE THE IMPORTANCE OF ADHERANCE AND FOLLOW UP





# INITIAL MANAGEMENT OF PATIENT



- EXPLAIN THE NEED FOR HIV TEST WITH CONSENT
- EXPLAIN NEED FOR STI SCREEN ESPECIALLY RPR AND HEPATITIS SEROLOGY IF AVAILABLE
- DISCUSS VALUE OF HEPATITIS B VACCINE IF AVAILABLE
- DISCUSS SIDE EFFECTS OF ARV MEDICATION
- EXPLAIN FOLLOW UP TIMING AND REASONS FOR THIS
- EMPHASIZE UNLIMITED OPEN ACCESS DURING PEP PROGRAMME



# FIRST VISIT CLINICAL INTERVENTIONS



- CONSENT PATIENT FOR PEP AND HIV TEST
- DO HIV TEST, RPR, HEPATITIS SEROLOGY (IF AVAILABLE)  
BASELINE FBC, RENAL AND LIVER FUNCTION
- GIVE FIRST DOSE HEPATITIS B VACCINE IF AVAILABLE
- DISPENSE ARV PACK AND EXPLAIN HOW MANY AND  
HOW EACH DRUG IS TAKEN
- CONSIDER PROPHYLACTIC ANTI-EMETICS OR ANTI-  
DIARRHOEALS
- ARRANGE REVIEW IN ONE WEEK OR PRN IF PATIENT  
NEEDS MORE SUPPORT

# WHICH PEP REGIMEN TO USE

- DUE TO HIGH LOCAL PREVALENCE OF HIV CLINIC USES TRIPLE ARV REGIMEN
- CURRENTLY STAVUDINE+LAMIVUDINE+ ALUVIA
- CONSIDERING CHANGING TO TRUVADA i.e TENOFOVIR+ EMTRACITABINE AND ALUVIA
- AZT AVOIDED AS IT CAUSES DIZZINESS
- NNRTIS AVOIDED BECAUSE OF SIGNIFICANT SIDE EFFECTS
- EFAVIRENZ CAUSES NEUROPSYCHIATRIC EFFECTS
- NEVIRAPINE CAN CAUSE SEVERE SKIN REACTIONS AND IS HEPATOTOXIC
- TWO DOSES BD OF PI CAN BE AVOIDED BY USING ONCE DAILY BOOSTED ATAZANAVIR BUT EXPENSIVE



# ONE WEEK FOLLOW UP

- ENQUIRE AS TO ANY SIDE EFFECTS
- CHECK ADHERANCE TO PEP
- RPT RPR. IF POSITIVE ADMINISTER IM PENICILLIN
- ENQUIRE ABOUT OTHER STI SYMPTOMS AND TREAT EMPIRICALLY IF INDICATED
- PSYCHOLOGICAL SUPPORT

# FOUR WEEK FOLLOW UP

- ESTABLISH PEP COURSE HAS BEEN COMPLETED
- SECOND HIV TEST MAY BE DONE AT THIS STAGE IF REQUESTED THOUGH WILL NOT BE CLINICALLY CONCLUSIVE. MAY BE REASSURING
- SECOND HEPATITIS B VACCINE GIVEN IF AVAILABLE
- MAKE APPOINTMENT FOR THREE MONTHS FROM PEP COMPLETION DATE



# 12 WEEK AND 6 MONTH POST PEP FOLLOW UP



- Repeat HIV Test At 12 Weeks
- Reflect On PEP Experience And Re-enforce Safer Sex Advice.
- Provide Condoms And Lube As Necessary
- Arrange To Review At Six Months
- At Six Months Repeat HIV Test And Give Final Hepatitis B Vaccine If Available.
- Patient Can Be Discharged From Care



# DOCUMENTATION



- VERBAL CONSENT IS OBTAINED FOR PEP AND DOCUMENTED IN THE PATIENTS FILE
- WRITTEN CONSENT GIVEN FOR ALL HIV TESTING
- ALL PATIENTS RECEIVING PEP ARE DOCUMENTED IN CLINIC PEP REGISTER



# VARIOUS ADHERANCE ISSUES

- ADHERANCE PROBLEMS RELATING TO SIDE EFFECTS.

## **FOREWARNED IS FOREARMED**

- OPEN ACCESS TO ADDRESS SIDE EFFECTS AS THEY ARISE.
- PROPHYLACTIC ANTI-EMETICS OR ANTI-DIARRHOEALS EG METOCLOPRAMIDE CYCLIZINE OR LOPERAMIDE
- STOP PI IF NECESSARY

# VARIOUS ADHERANCE ISSUES

- If One Day Is Missed Patient Advised To Continue With Pack As Half Life Of The NRTI'S Allows For Sustained Blood Levels And Hence Efficacy
- If More Than Three Days Are Missed Then PEP Can Be Stopped
- Unsafe Sex Whilst On PEP Advise Patient To Continue As PEP In This Case Is Also Acting As PrEP

# PEP CONSULTATION



# PEP SUMMARY

- PEP IS A COMBINATION OF THREE ARVS GIVEN FOR 28 DAYS WITHIN 72 HOURS OF POTENTIAL EXPOSURE TO HIV
- PATIENTS FOLLOWED UP AT ONE, FOUR, 16 AND 30 WEEKS
- IN HIGH PREVALENCE SETTINGS WITH HIGH RISK ACTIVITY ALL PATIENTS AT CLINIC CURRENTLY RECEIVE TRIPLE PEP THERAPY

**PEP IS PART OF A HIV PREVENTION STRATEGY AND DOES NOT TAKE THE PLACE OF CONDOM USE OR OTHER BEHAVIOURAL INTERVENTIONS**



# SPECIFIC HIVSOC GUIDELINES 2008

## SOME GENERAL POINTS



- Triple ARV Treatment For All Exposures
- Hepatitis B Must Be Part Of Any PEP Assessment
- AZT And PI's Have Significant Side Effects And Are Therefore Best Avoided
- D4T Is Extremely Well Tolerated In PEP Due To The Short Duration Of Intervention
- PCR Testing Not Indicated In PEP Due To High False Positive Rates

# HOW MUCH DOES PEP COST

- A ONE MONTH SUPPLY OF CURRENT PEP REGIMEN COSTS **R389.55**

ALUVIA – R267.97 pcm

STAVUDINE- R36.24 pcm

LAMIVUDINE- R85.34



- A TEN YEAR SUPPLY OF THE DOH FIRST LINE ARV REGIMEN TDF+3TC+EFV WOULD COST **R43801.20**  
NOT FACTORING IN ANNUAL COST INCREASE OR COSTS OF MANAGING CONDITIONS AND REGULAR MONITORING OF CD4, VIRAL LOAD AND BLOOD WORK

# MARKETING



**wet dream or cold**  
**REALITY?**

PEP stands for **Post Exposure Prophylaxis** – anti-retroviral medication to reduce your risk of HIV infection if you've been exposed to the virus.  
 PEP is given to HIV-negative people after they've been exposed to the virus.  
 PEP is available to HIV negative gay men if they've had a very risky encounter.  
 PEP must be initiated within **72 hours** of exposure to the virus.

I can't remember... was there a condom?!  
**HOW SAFE WAS IT?**

Damn! Did he top me bareback?  
**WHERE DID HE CUM?!**

OK, I need PEP - from Health4Men

**HEALTH4MEN SUPPLIES FREE PEP TO GAY MEN!**  
 WORRIED ABOUT HIV INFECTION? CALL US ON 021 447 2844  
 Reducing your number of sexual partners and always using condoms with water-based lube remain your best defence against HIV and STIs.



**WET DREAM? OR COLD**  
**REALITY?**

HEALTH 4 MEN  
top to bottom

PEP stands for **Post Exposure Prophylaxis**... medication to reduce your risk of HIV infection if you've been exposed to the virus.

PEP is given to women if they've been raped and to men if they've pricked themselves with a used needle.

PEP is available to HIV negative gay men if they've had a very risky encounter.

PEP must be initiated within **48 hours** of exposure to the virus.

I can't remember... was there a condom?!  
**HOW SAFE WAS IT?**

Damn! Did he top me bareback?  
**WHERE DID HE CUM?!**

OK, I need PEP - from Health4Men

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 Reducing your number of sexual partners and always using condoms with water-based lube remain your best defence against HIV and STIs.  
 Worries about HIV infection? CALL us on 021 421 6127



**WHATEVER YOUR GAME**

**WINNERS ALWAYS PLAY RESPONSIBLY!**  
 Consistent use of condoms with water-based lube, and reducing your number of sexual partners, are your best defence against STIs and HIV.

If you're HIV negative and exposed to the virus, you need PEP!

PEP (post exposure prophylaxis) uses ARVs (anti-retroviral medication) in HIV negative people to reduce the risk of them becoming infected if they've been exposed to the virus.  
 You'll take PEP for one month after someone has ejaculated directly inside your anus, inside your mouth or eye, or on your broken skin.  
 Importantly, PEP must be initiated within 72 hours!

**HEALTH4MEN PROVIDES FREE PEP TO GAY MEN!**  
 Call our clinics on 021 447 2844 (Cape Town) or 011 989 9726 (Soweto) for an appointment



- POSTERS AND LEAFLETS IN THE CLINIC
- OUTREACH TEAM PROMOTING PEP
- AVAILABILITY AT EVENTS AND SPECIFIC MSM VENUES
- HEALTH4MEN CLINIC BANNERS ON INTERNET
- DATING SITES EG MAMBAONLINE/GAYDAR?
- SIMON NKOLI CLINIC FACEBOOK PAGE
- HEALTH4MEN WEBSITE
- INFORMATION TO MEDIA
- ADVERTS IN GAY PAPERS

[www.h4m.mobi](http://www.h4m.mobi)

# REFERENCES

- SAHIVSOC GUIDELINES 2008
  - BASHH DRAFT GUIDELINES 2011
1. *Tsai CC et al J Virol 1998*
  2. *Otten et al j Virol 2000*
  3. *Garcia-lerma JG et al Sci Transl Med jan 2010*
  4. *Cardo DM et al N Engl J Med 1997*
  5. *Sperling RS et al N Engl J Med 1996 Wade NA et al N Engl J Med 1998*
  6. *Praca Onze Study Team . J Acquir Immune Defic Syndr 2004*
  7. *Meta Analysis Millet GA et al JAMA 2008*
  8. *Tim Lane et al, SOWETO MENS STUDY. AIDS Behav 2009*
  9. *Mauro Schechter et al J AIDS april 15 2004*





# LAST WORD FROM SAHIVSOC PEP GUIDELINE 2008



*As a public health intervention equal access to (PEP) of persons who might otherwise not have been considered to have been raped, but who have definitely sustained a high-risk exposure, is essential to equality of therapy and minimisation of HIV transmission.*



**THANKS**

QUESTIONS PLEASE

