Southern African HIV Clinicians Society

3rd Biennial Conference

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Sandton Convention Centre
Johannesburg

Our Issues, Our Drugs, Our Patients

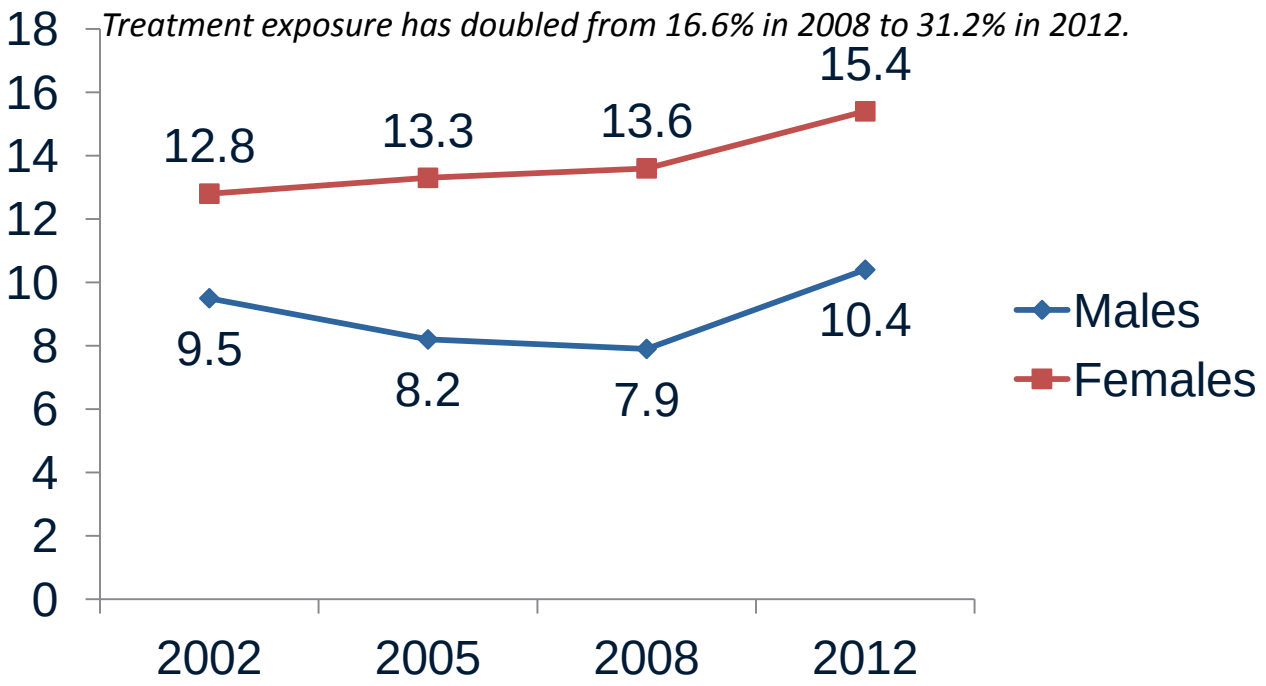
www.sahivsoc.org
www.sahivsoc2016.co.za

MSM and PrEP: PrEP guidelines

Michelle Moorhouse

13 Apr 2016

Ongoing HIV transmission despite expanding access to ART – SA



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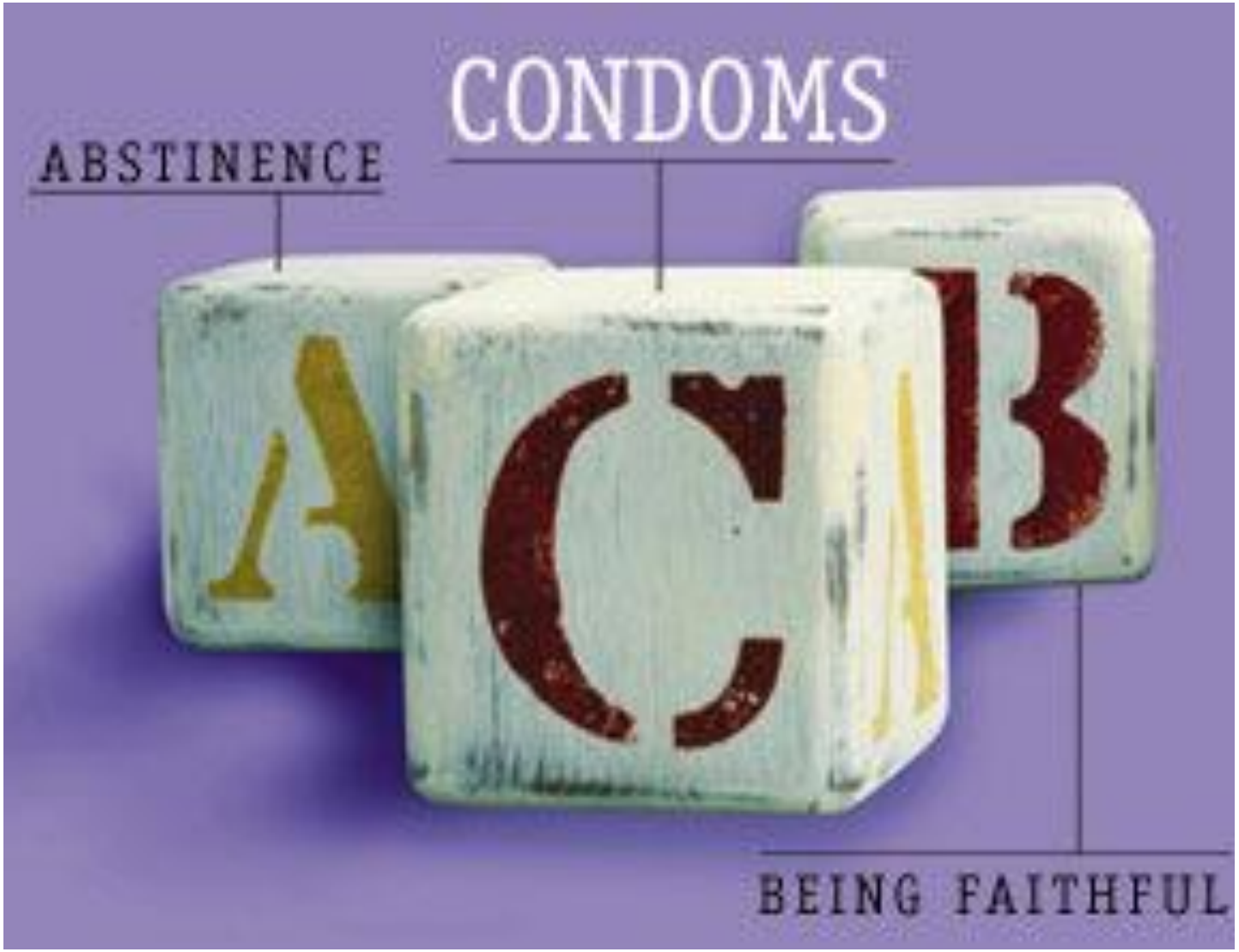

CONDOMS
ABSTINENCE
BEING FAITHFUL

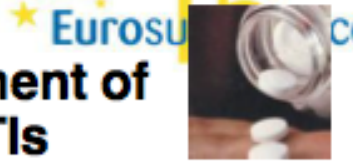
HIV PREVENTION TOOL-KIT

Microbicides for women

Abdool Karim Q, Science 2010

Male circumcision

Auvert B, PloS Med 2005
Gray R, Lancet 2007
Bailey R, Lancet 2007



Treatment of STIs

Grosskurth H, Lancet 2000

Treatment for prevention

Donnell D, Lancet 2010
Cohen M, NEJM 2011

Female Condoms

Male Condoms

Behavioural positive prevention

Fisher J, JAIDS 2004

Oral pre-exposure prophylaxis

Grant R, NEJM 2010 (MSM)
Baeten J , 2011 (Couples)
Paxton L, 2011 (Heterosexuals)

HIV Counselling and Testing

Coates T, Lancet 2000

Behavioural Intervention

- Abstinence
- Be Faithful

Post Exposure prophylaxis (PEP)

Scheckter M, 2002

Vaccines

Rerks-Ngarm S, NEJM 2009

Note: PMTCT, Screening transfusions, Harm reduction, Universal precautions, etc. have not been included – this is focused on reducing sexual transmission

GUIDELINES

Southern African guidelines for the safe use of pre-exposure prophylaxis in men who have sex with men who are at risk for HIV infection

GUIDANCE ON PRE-EXPOSURE ORAL PROPHYLAXIS (PrEP) FOR SERODISCORDANT COUPLES, MEN AND TRANSGENDER WOMEN WHO HAVE SEX WITH MEN AT HIGH RISK OF HIV:
Recommendations for use in the context of demonstration projects

July 2012

World Health Organization

GUIDELINE ON WHEN TO START ANTIRETROVIRAL THERAPY AND ON PRE-EXPOSURE PROPHYLAXIS FOR HIV

US Public Health Service

PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES - 2014

GUIDELINES

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GUIDANCE ON PRE-EXPOSURE ORA
FOR SERODISCORDANT COUPLE
WOMEN WHO HAVE SEX WI
Recommendations for use in th

July 2012

Southern African guidelines on the safe use of pre-exposure prophylaxis in persons at risk of acquiring HIV-1 infection

VIRAL
RAPY AND
RE-EXPOSURE
HYLAXIS FOR HIV

S Public Health Service

PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES - 2014

Indications for PrEP

PrEP should be considered for people who are HIV-negative and at significant risk of acquiring HIV infection

1. any sexually active HIV-negative *MSM or transgender person* who wants PrEP
2. *heterosexual* women and men who want PrEP
3. people who inject *drugs*
4. include *adolescents* and *sex workers*
   - especially vulnerable: young MSM

Contra-indications to PrEP

1. HIV-1 infected or evidence of possible acute infection
2. suspicion of window period following potential exposure
3. adolescents <35 kg or <15 years who are not ≥Tanner stage 3
4. poor renal function (creatinine clearance <60 mL/min)
5. other nephrotoxic drugs (eg aminoglycosides)
6. unwilling or unable to return for 3-monthly visits
7. pregnant or breastfeeding women

Risk assessment

In the past 6 months:

1. Have you had sex with men, women or both?
2. How many men have you had sex with?
3. How many times did you have receptive anal sex with a man who was not wearing a condom?
4. How many of your partners were HIV-positive or of unknown HIV status?
5. With these positive/unknown status partners, how many times did you have insertive anal sex without wearing a condom?

Or more simply

In the past 3/6 months:

1. Have you had sex within the past three months?
2. Have you had unprotected (condomless) sex?
3. Have you had sex with partners who are HIV-positive or whose HIV status you did not know?
4. Have you had sex under the influence of alcohol and/or drugs?

Eligibility criteria

- Anyone identified as being at high risk for HIV exposure
- No contraindications to FTC/TDF FDC
- HIV-negative / not thought to be in the window period
- Absence of symptoms of acute HIV infection
- Willing and able to attend 3-monthly visits
- Understands that the protection provided by PrEP is not complete
- Recurrent use of PEP

Starting PrEP

Screening visit

Educate about the risks and benefits of PrEP
Assess risk and eligibility
Conduct HIV counselling and testing, serum creatinine level, hepatitis B and STI screen
Condoms, lubricant and counselling
Arrange follow-up visit

Starting PrEP

TABLE 1: Mandatory baseline investigations for pre-exposure prophylaxis initiation.

Screening	Method
HIV infection	Laboratory ELISA preferably - fourth generation rapid if ELISA not available
Renal function	eGFR > 60 mL/min
Hepatitis B screen	Surface antigen (HBsAg)
	Antibody to surface antigen (HBsAb)
STI screen	Symptomatic screen
	Examination if indicated
	Urine dipstix for urethritis
	Serological screening for syphilis (rapid or laboratory)
	Full STI panel if resources allow

PrEP initiation visit

Conduct HIV counselling and testing
Confirm eligibility (including investigation results and creatinine clearance)
Commence hepatitis B vaccination if indicated
Provide STI treatment if indicated
Educate client about PrEP side-effects and management
Educate client about signs and symptoms of acute HIV infection
Discuss behaviours that promote bone health, such as weight-bearing exercise and avoiding alcohol, tobacco and recreational drugs
Initiate a medication effective use plan
Provide condoms and lubricant
Provide one-month TDF/FTC (FDC) prescription and follow-up date

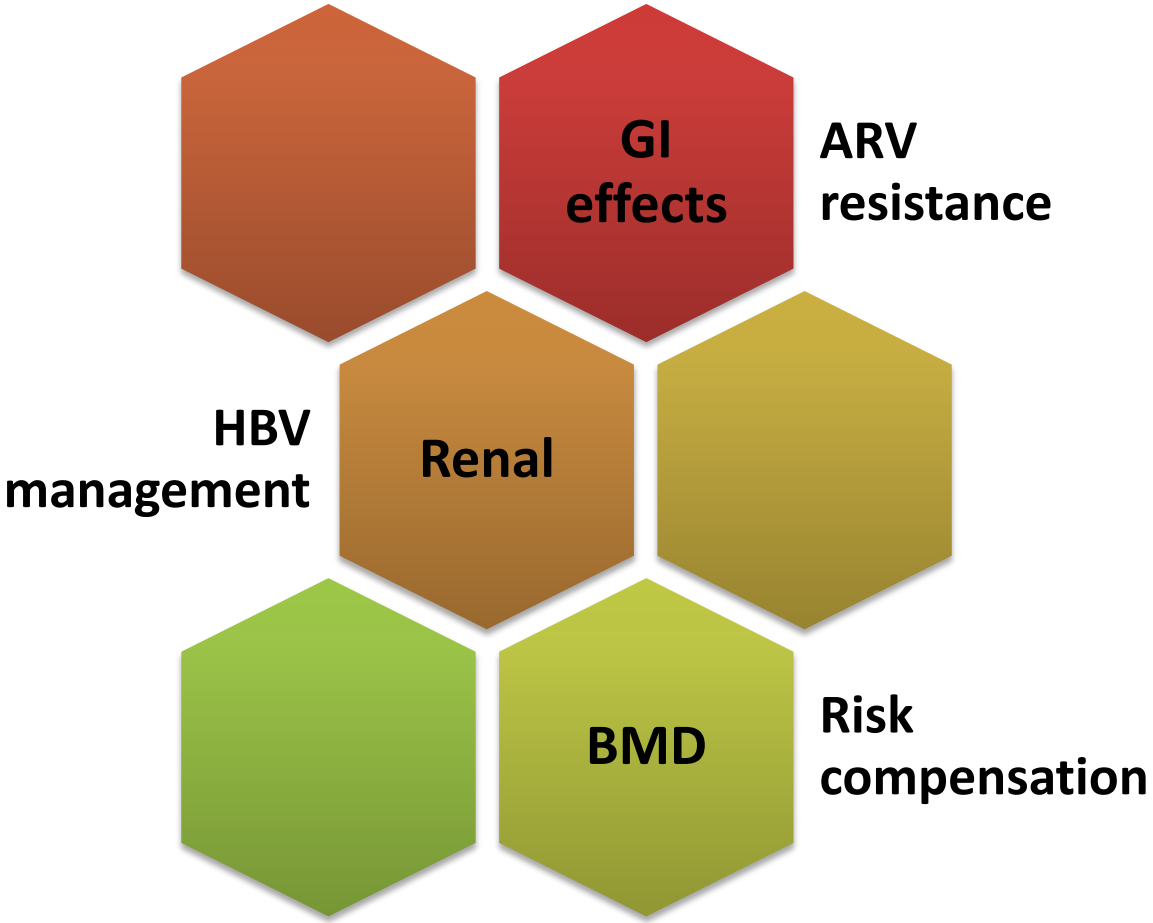
One month follow up

PrEP initiation visit, PLUS:
Assess tolerability, side-effects and effective use
Actively manage side-effects
Measure serum creatinine and calculate creatinine clearance
Provide three-month TDF/FTC (FDC) prescription and follow-up date

Maintenance visits

Repeat procedures done at one-month follow-up
Measure serum creatinine and calculate creatinine clearance at four-month follow-up, and 12-monthly thereafter
Conduct 6-monthly STI screen, including urine dipstix and rapid syphilis test
Complete hepatitis B immunisation at 6 months

Risks and side effects



Stopping PrEP

1. Positive HIV test
2. Request of user
3. Safety concerns
   - Creatinine clearance <60 mL/min
4. Risks outweigh benefits

Cycling on and off PrEP

When starting

- 7 days of daily TDF/FTC to reach adequate tissue levels
- Use other methods of protection

When stopping

- Continue PrEP for 28 days after last potential HIV exposure

Full of little gifts

BOX 4: What if users ask about stopping condom use while on pre-exposure prophylaxis?

1. Do not be judgemental about patient preferences.
2. Explain that this is a valid choice but there are potentially negative consequences.
3. Stress that PrEP prevents HIV but not STIs.
4. Stress that PrEP prevents HIV but not pregnancy.
5. Confirm a regular STI screening and management plan.
6. Confirm an effective and acceptable contraception plan where indicated.
7. Vaccinate against all vaccine-preventable STIs, e.g. hepatitis A and B and HPV where possible.

Full of little gifts

BOX 4: What if users ask about stopping condom use while on pre-exposure prophylaxis?

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BOX 5: 'Adherence' versus 'effective use'.

These guidelines use the term 'effective use' rather than 'adherence'. Adherence is often understood by healthcare workers, especially when applied to ARV treatment adherence, as life-long and at correct dosing intervals to ensure viral suppression. Oral PrEP must be taken, ideally daily, during times of HIV exposure risk, although there are some data suggesting that less than perfect adherence is still highly effective in MSM. There may be times when it would be appropriate to cycle off oral PrEP, for example when MSM move out of 'seasons of risk', or when female sex workers (FSW) return home to visit family, taking a break from sexual activity. If appropriate consistent use of oral PrEP is measured with the same standard as we measure ARV treatment adherence, it may show up as lacking, when in fact the population at risk has used the drug effectively. The term 'effective use' is preferred to when discussing whether ARV-based prevention has been used successfully; this is akin to 'effective use of condoms' as we seldom talk about condom adherence.

Full of little gifts

BOX 4: What if users ask about stopping condom use while on pre-exposure prophylaxis?

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BOX 6: Tips to support effective use.

Include user-focused effective use counselling at each contact. Provide a clear explanation of the benefits of effective use. In a neutral manner, ask if the user has any challenges that may make taking PrEP difficult. Also explore possible facilitators to pill taking. Include identified facilitators when developing strategies to improve effective use of PrEP.[42]

Options to improve daily pill taking:

- Use reminders (cellphone, alarm clock, diary, partner reminder).
- Link with daily activity (breakfast, brushing teeth).
- Use a pillbox.
- Food is **NOT** required for pill taking.
- Join an on-line support group, e.g. Facebook: PrEP Rethinking HIV Prevention or #wethebrave.

And the gifts keep coming

BOX 7: Strategies to reduce the likelihood of antiretroviral resistance.

Feasibly exclude acute HIV infection before initiating PrEP by:
• conducting antibody HIV testing before commencing or re-prescribing PrEP
• enquiring about pill taking patterns and whether any pills were missed
• among persons with a negative HIV antibody test, conducting a clinical screen to detect signs and symptoms of acute HIV infection – history of fever, sore throat, rash, joint pain, cough in the past month and a targeted examination (temperature, ENT and skin exam) (see Acute HIV infection text box)
• considering time period between last potential HIV exposure and window period of tests being used
• If symptoms or signs of acute HIV infection found: ▪ At screening: postpone PrEP until symptoms subside and rapid antibody test remains negative at 2–4 weeks' follow-up ▪ At screening: do not initiate PrEP until follow-up HIV antigen/antibody testing (2–4 weeks) complete ▪ At follow-up: may elect to continue PrEP while awaiting results of follow-up HIV antigen/antibody testing (2–4 weeks) or may decide to withhold PrEP until follow-up tests available ▪ Note that, if PrEP has been taken consistently, breakthrough infection is unlikely. Withholding PrEP may put an effective user at greater risk for HIV acquisition
• Support client to maximise effective use and include effective use counselling at each visit
• Stop PrEP should requirements for PrEP eligibility not be fulfilled or if client recognises risk profile has altered or wishes to use a different combination of prevention
• Counsel client that recommencement will require all of the above steps again.

And the gifts keep coming

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- Support client t each visit
- Stop PrEP shou recognises risk prevention
- Counsel client t

BOX 8: Acute HIV-infection.

Severity of the syndrome ranges from mild non-specific 'viral' or 'flu-like' symptoms to a severe infectious mononucleosis-like illness with immune dysregulation and transient profound CD4 depletion.[47,48]

Symptom:

- malaise
- anorexia
- myalgias
- headache
- sore throat
- sore glands
- rash.

Sign:

- fever, sweating
- generalised lymphadenopathy
- hepatosplenomegaly
- non-exudative pharyngitis
- orogenital herpetiform ulceration
- truncal rash (maculopapular or urticarial)
- viral meningitis
- Guillian-Barre syndrome
- *Pneumocystis* pneumonia†
- cryptococcal meningitis†
- oral/oesophageal candidiasis.

And the gifts keep coming

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BOX 9: HIV prevention for pre-exposure prophylaxis users.

General factors to consider:

- accessibility of condoms and compatible water-based lubricant should be addressed
- no single HIV risk reduction intervention is likely to suit all users
- combinations of prevention options, tailored to address specific risks, should be offered ('menu of prevention choices'), inclusive of biomedical and psychosocial/ behaviour change interventions
- prevention options are likely to increase as new evidence becomes available.

Biomedical:

- male or female condoms and compatible lubrication
- access to frequent HIV testing
- early access to ART
- post-exposure prophylaxis
- pre-exposure prophylaxis
- voluntary medical male circumcision
- STI screening and treatment
- needle syringe exchange and opioid substitution therapy for people who inject drugs.

Psychosocial:

- education: risk and safer sex practices
- regular HIV counselling and screening
- reducing number of sex partners
- reducing alcohol and substance abuse
- addressing mental health needs
- couple counselling and programming
- harm reduction counselling and support for clients who use drugs.

Some final thoughts

- PrEP is seasonal
- PrEP isn't for everyone
- Role of PrEP in serodiscordant couples
- Risk reduction counselling
- PrEP users are NOT patients
- Frequent HIV testing

Acknowledgements

- SA HIV Clinicians Society