Southern African HIV Clinicians Society
3rd Biennial Conference
13 - 16 April 2016
Sandton Convention Centre
Johannesburg
Our Issues, Our Drugs, Our Patients

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MSM and PrEP: PrEP guidelines

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13 Apr 2016
Ongoing HIV transmission despite expanding access to ART – SA

Treatment exposure has doubled from 16.6% in 2008 to 31.2% in 2012.

Source: HSRC, 2012
ABSTINENCE  CONDOMS  BEING FAITHFUL
**HIV PREVENTION TOOL-KIT**

- **Male circumcision**
  - Gray R, Lancet 2007

- **Treatment of STIs**
  - Grosskurth H, Lancet 2000

- **Female Condoms**

- **Male Condoms**

- **HIV Counselling and Testing**
  - Coates T, Lancet 2000

- **Behavioural Intervention**
  - Abstinence
  - Be Faithful

- **Oral pre-exposure prophylaxis**
  - Grant R, NEJM 2010 (MSM)
  - Baeten J, 2011 (Couples)
  - Paxton L, 2011 (Heterosexuals)

- **Post Exposure prophylaxis (PEP)**
  - Scheckter M, 2002

- **Vaccines**
  - Rerks-Ngarm S, NEJM 2009

- **Treatment for prevention**
  - Donnell D, Lancet 2010
  - Cohen M, NEJM 2011

- **Behavioural positive prevention**
  - Fisher J, JAIDS 2004

- **Microbicides for women**
  - Abdool Karim Q, Science 2010

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

PrEP initiation visit

One month follow up

Three monthly maintenance visits
**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.

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

- GI effects
- ARV resistance
- HBV management
- Renal
- BMD
- Risk compensation
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?

1. Do not be judgemental about patient preferences.
2. Explain that this is a valid choice but there are potentially negative consequences.
3. Stress the importance of discussing the option with the healthcare provider.
4. Confirm that the healthcare provider agrees that the decision is the patient's choice.
5. Vaccination against HIV is recommended.
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 is not a substitute for condoms.
4. Stress that PrEP use increases the risk of bodily harm and death in some circumstances.
5. Confirm a realistic risk assessment.
7. Vaccinate against HIV where possible.

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 this is still highly effective when used intermittently.

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.

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

**BOX 7: Strategies to reduce the likelihood of antiretroviral resistance.**
- Feasibly exclude acute HIV infection before initiating PrEP by:
  - conducting antenatal testing
  - enquiring about sexual exposure
  - considering time period of tests (e.g., screen to detect fever, sore throat, examination)

**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
- Guillain-Barre syndrome
- *Pneumocystis* pneumonia\(^\dagger\)
- cryptococcal meningitis\(^\dagger\)
- oral/oesophageal candidiasis.
And the gifts keep coming
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