Get prepared: PrEP from all angles

19-20 May 2017
Dolce La Hulpe, Belgium

Belgian PrEP Guidelines
General considerations

- PrEP should be
  - Delivered by an HIV specialist
  - Used during periods of high risks and should be stopped during periods of low or no risks

- Counseling should play a central role

- Community’s help is needed
Eligibility for PrEP

Inclusion criteria

• >18 years-old
• HIV seronegative
• High risk of HIV acquisition
• No suspicion of acute HIV infection

Exclusion criteria

• Suspicion of acute HIV infection
• HIV seropositive or doubtful test
• Estimated creatinine clearance < 60mL/min
• Current use of PEP
Risk factors of HIV acquisition

- Being sexually active in high HIV prevalence population
  - MSM or transgender person
  - Subsaharian population
  - Having an HIV positive sexual partner who has not been on effective therapy for at least 6 months

- **AND** any of the followings
  - Unprotected anal or vaginal intercourse in the past 6 months
  - Past use of PEP
  - Multiple concurrent sex partners
  - History of multiple STIs
  - Use of chemsex
  - Sex workers
Prep is not recommended if

- HIV positive partner on effective HAART with a **sustained undetectable viral load**

- Unprotected heterosexual intercourse not at risk for HIV acquisition
Special situations

- Pregnancy
- Breastfeeding
- Hepatitis B infection
- Recent PEP exposure
# Follow-up

<table>
<thead>
<tr>
<th></th>
<th>Before PrEP</th>
<th>At start</th>
<th>1 month later</th>
<th>3 months later</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Kidney function</strong></td>
<td>X</td>
<td></td>
<td>X</td>
<td>X then every 6 months</td>
</tr>
<tr>
<td><strong>Urine analysis</strong></td>
<td>X</td>
<td></td>
<td></td>
<td>X then every 6 months</td>
</tr>
<tr>
<td><strong>HIV screening</strong></td>
<td>X</td>
<td>X if risk of seroconversion</td>
<td>X</td>
<td>X</td>
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<tr>
<td><strong>HBV/HAV screening and Immunization</strong></td>
<td>X</td>
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<tr>
<td><strong>HCV screening or ALT if previous + serology</strong></td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
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<tr>
<td><strong>Gonococque and Chlamydia screening</strong></td>
<td>X</td>
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<td>X</td>
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<tr>
<td><strong>Syphilis screening</strong></td>
<td>X</td>
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<td><strong>Counseling</strong></td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td><strong>Pregnancy testing</strong></td>
<td>X then if symptoms</td>
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<tr>
<td><strong>Side effects</strong></td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
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<tr>
<td><strong>Medications</strong></td>
<td>X</td>
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</table>
## Follow-up

<table>
<thead>
<tr>
<th>Kidney function</th>
<th>Urea, creatinine, creatinine clearance (CKD-EPI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum electrolytes</td>
<td>Na, Cl, K, HCO3, P</td>
</tr>
<tr>
<td>HIV screening</td>
<td>4th generation test</td>
</tr>
<tr>
<td>Hepatitis C screening</td>
<td>Ac anti-HCV</td>
</tr>
<tr>
<td>Hepatitis A/B screening and immunization</td>
<td>AgHBs, AcHBs, AcHBc, IgG HBA</td>
</tr>
<tr>
<td>Syphilis screening</td>
<td>Screening +/- VDRL +/- TPHA</td>
</tr>
<tr>
<td>Urine analysis</td>
<td>Glycosuria, proteinuria, phosphaturia</td>
</tr>
<tr>
<td>Screening gonocoque/chlamydia</td>
<td>PCR (throat, anus and first pass urine)</td>
</tr>
</tbody>
</table>

Pregnancy test
PrEP regimen

• Emtricitabine 200mg (FTC)+tenofovir (TDF) 245mg (Truvada®)
• Daily is mandatory if:
  ✓ HBV infection
  ✓ Women
• On demand/Event driven
Side effects

Very safe, no side effects for 90% of users

- Dizziness, headache, fatigue
- Gastrointestinal: diarrhea, vomiting, flatulence
- Bone density: decrease of 0.5-1.5% in the first 6 months, no increase in bone fractures, reversible at stop.

Grant et al. NEJM 2010, Molina et al. NEJM 2015, Baeten et al. NEJM 2012
Renal failure

- Increase of creatinine in 1/200 PrEPers, self limiting and resolve in 80% of cases when a second specimen is tested

- What to do?
  - Test on a second specimen
  - If creat clearance < 60mL/min: Stop PrEP
  - If creat clearance worsen 20% but >60mL/min: control at 4 weeks
  - If glucosuria/proteinuria: Rule out Fanconi syndrome and if confirmed => stop PrEP
  - If Fanconi is ruled out: check for another kidney disease and assess risk/benefit of PrEP

*Solomon et al. AIDS 2014, Yacoub et al. Acquis Immune Defic Syndr 2016*
Seroconversion and resistance

Seroconversion
- Preexisting HIV infection
- Inconsistent use of PrEP

Resistance
- Only 3% of users developed TDF resistance
- One case of HIV acquisition while using PrEP despite long term adherence: multidrug resistance was reported

- If seroconversion: HAART should be started as soon as possible
- Drug resistance testing should be performed

Information to prepers

- PrEP is highly effective against HIV infection if you take it correctly
- PrEP do not protect against other STIs
- PrEP has no contraceptive effect
- PrEP does not affect contraceptive effect
- If vomiting occurs at least 30 minutes after intake, no need to retake a second tablet. If one tablet is missed, take it as soon as you remember
- No PrEP interactions with drug use and alcohol
Information to be collected by ARC

- ✓ Number of requests for PrEP
- ✓ Number of effective PrEP users
- ✓ Number of rejected request and reasons
- ✓ Number of seroconversions
- ✓ Number of lost to follow-up
- ✓ Number of PrEP discontinuation and reasons

29.05.17
Information to be collected by ARC

- Sex, age, origin and sexual orientation, exposure to sex workers
- Side effects
- Regimen choice (daily or on demand)
- Drug and alcohol use
- Reason for discontinuation
Any questions?

Thank you for your attention