Box 1: Benefits and Risks of TDF/FTC as PrEP

<table>
<thead>
<tr>
<th>Benefits</th>
<th>Risks and Challenges</th>
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| • 99% effective in reducing the risk of HIV acquisition when used as prescribed [CDC 2019]:  
  - MSM: No seroconversions with therapeutic blood levels and a 92% risk reduction through sexual activity if detectable drug levels in blood [Grant, et al. 2010].  
    o No seroconversions in MSM who took >4 doses per week [Grant, et al. 2014].  
  - Injection drug use: 74% effective in reducing risk when detectable levels of TDF present [Choopanya, et al. 2013].  
  - Heterosexual men and women: 78% effective in the as-treated analysis, with only 2 seroconversions with any detectable drug levels [Thigpen 2012].  
  - Regimen is a single tablet taken daily.  
  - TDF/FTC has a good safety profile in people who do not have HIV [Tetteh, et al. 2017; Pilkington, et al. 2018].  
  - Minimal side effects, most of which resolve fairly quickly or can be managed [Tetteh, et al. 2017].  
  - Appears to be safe for use during attempts to conceive and during pregnancy [AIDSinfo 2018].  
  - Can decrease anxiety regarding HIV acquisition.  
  - Engages sexually active at-risk individuals in care who are then screened regularly for STIs. | • Safety concerns for individuals with impaired kidney function [FDA 2016].  
• Uncertainty about time to protection after initiation (see section on Time to Protection in this guideline).  
• Protection is correlated with adherence to the dosing schedule [Dimitrov, et al. 2016].  
• No protection against STIs other than HIV.  
• May be associated with reversible decreases in bone density in younger individuals [Havens, et al. 2017].  
• Continued use after undiagnosed HIV infection may result in development of drug-resistant virus [Lehman, et al. 2015].  
• Requires additional monitoring in patients with chronic hepatitis B virus (see Box 3: Important Clinical Considerations When Prescribing TDF/FTC as PrEP in this guideline).  
• Cost. |

Abbreviations: FTC, emtricitabine; MSM, men who have sex with men; PrEP, pre-exposure prophylaxis; STI, sexually transmitted infection; TDF, tenofovir disoproxil fumarate.

REFERENCES


