



**PANEL 7: COMMUNITY, PROVIDER,
OPERATIONAL AND REGULATORY
PERSPECTIVES ON PREP IMPLEMENTATION**

Benjamin Young, MD PhD

PROVIDER AND OPERATIONAL ASPECTS

- Who is the PrEP patient?
 - General population
 - At-risk population
 - MSM
 - IDU
 - Women
 - Sex worker
 - Negative partner in magnetic relationship
 - Women desiring pregnancy

PROVIDER AND OPERATIONAL ASPECTS

- Where PrEP is provided has broad implications?
 - General/family practice
 - GLBT medical clinic
 - STI clinic
 - HIV clinic
- Access, entry, retention in care issues

PROVIDER AND OPERATIONAL ASPECTS

- How do at-risk individuals receive information about PrEP?
 - Community program/health worker
 - Peer
 - Clergy
 - Pharmacist
 - Nurse
 - Doctor

PROVIDER AND OPERATIONAL ASPECTS

- Who are the prescribers? How familiar with sexual health and non-stigmatizing practices?
 - General practitioners
 - STI/ID specialists
 - GU specialists
 - HIV specialists

PROVIDER AND OPERATIONAL ASPECTS

- Workforce training issues?
 - How to effectively train the spectrum of care providers on PrEP?
 - PrEP training as part of combination HIV prevention and sexual health
 - Who provides and funds training?

GUIDELINE DEVELOPMENT

CDC Interim Guidance on HIV Pre-Exposure Prophylaxis for Men Who Have Sex with Men

Before initiating PrEP

Determine eligibility

- ▶ Document negative HIV antibody test(s) immediately before starting PrEP medication.
- ▶ Test for acute HIV infection if patient has symptoms consistent with acute HIV infection.
- ▶ Confirm that patient is at substantial, ongoing, high risk for acquiring HIV infection.
- ▶ Confirm that calculated creatinine clearance is ≥ 60 mL per minute (via Cockcroft-Gault formula).

Other recommended actions

- ▶ Screen for hepatitis B infection; vaccinate against hepatitis B if susceptible, or treat if active infection exists, regardless of decision about prescribing PrEP.
- ▶ Screen and treat as needed for STIs.

Beginning PrEP medication regimen

- ▶ Prescribe 1 tablet of Truvada* (TDF [300 mg] plus FTC [200 mg]) daily.
- ▶ In general, prescribe no more than a 90-day supply, renewable only after HIV testing confirms that patient remains HIV-uninfected.
- ▶ If active hepatitis B infection is diagnosed, consider using TDF/FTC for both treatment of active hepatitis B infection and HIV prevention.
- ▶ Provide risk-reduction and PrEP medication adherence counseling and condoms.

Follow-up while PrEP medication is being taken

- ▶ Every 2–3 months, perform an HIV antibody test; document negative result.
- ▶ Evaluate and support PrEP medication adherence at each follow-up visit, more often if inconsistent adherence is identified.
- ▶ Every 2–3 months, assess risk behaviors and provide risk-reduction counseling and condoms. Assess STI symptoms and, if present, test and treat for STI as needed.
- ▶ Every 6 months, test for STI even if patient is asymptomatic, and treat as needed.
- ▶ 3 months after initiation, then yearly while on PrEP medication, check blood urea nitrogen and serum creatinine.

On discontinuing PrEP (at patient request, for safety concerns, or if HIV infection is acquired)

- ▶ Perform HIV test(s) to confirm whether HIV infection has occurred.
- ▶ If HIV positive, order and document results of resistance testing and establish linkage to HIV care.
- ▶ If HIV negative, establish linkage to risk-reduction support services as indicated.
- ▶ If active hepatitis B is diagnosed at initiation of PrEP, consider appropriate medication for continued treatment of hepatitis B.

Abbreviations: STI = sexually transmitted infection; TDF = tenofovir disoproxil fumarate; FTC = emtricitabine

* These recommendations do not reflect current Food and Drug Administration-approved labeling for TDF/FTC.

Source: "Interim Guidance: Pre-exposure prophylaxis for the prevention of HIV infection in men who have sex with men," CDC *Morbidity and Mortality Weekly Report*, January 28, 2011.

OPERATIONAL ASPECTS

- Challenges
 - Additional patient visits for clinic/laboratory monitoring and follow up
 - Adherence counseling
 - Monitoring of retention and follow up
 - Additional costs
 - Acceptance from key stakeholders