

Breakout 2A:

A Primer on Implementing PrEP for HIV Prevention

Minority AIDS Initiative - Continuum of Care Virtual Meeting

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Topics to be covered

- The science and clinical data behind PrEP
- Clinical guidance
- Components of a comprehensive PrEP program:
Education, Insurance/Payment, Medical, Pharmacy
- Facilitators, barriers and opportunities
- Outreach and educational efforts
- Resources

Objectives

- Gain a basic understanding of PrEP and how it works
- Explore clinical PrEP data
- Explore indicators for PrEP use
- Explore major elements of a comprehensive PrEP program
- Establish a basic understanding of various payer sources
- Explore existing culturally competent outreach and educational efforts
- Inspire

What is PrEP?



PrEP

Pre-Exposure Prophylaxis (PrEP)

- A daily HIV prevention pill that's part of a comprehensive prevention strategy.

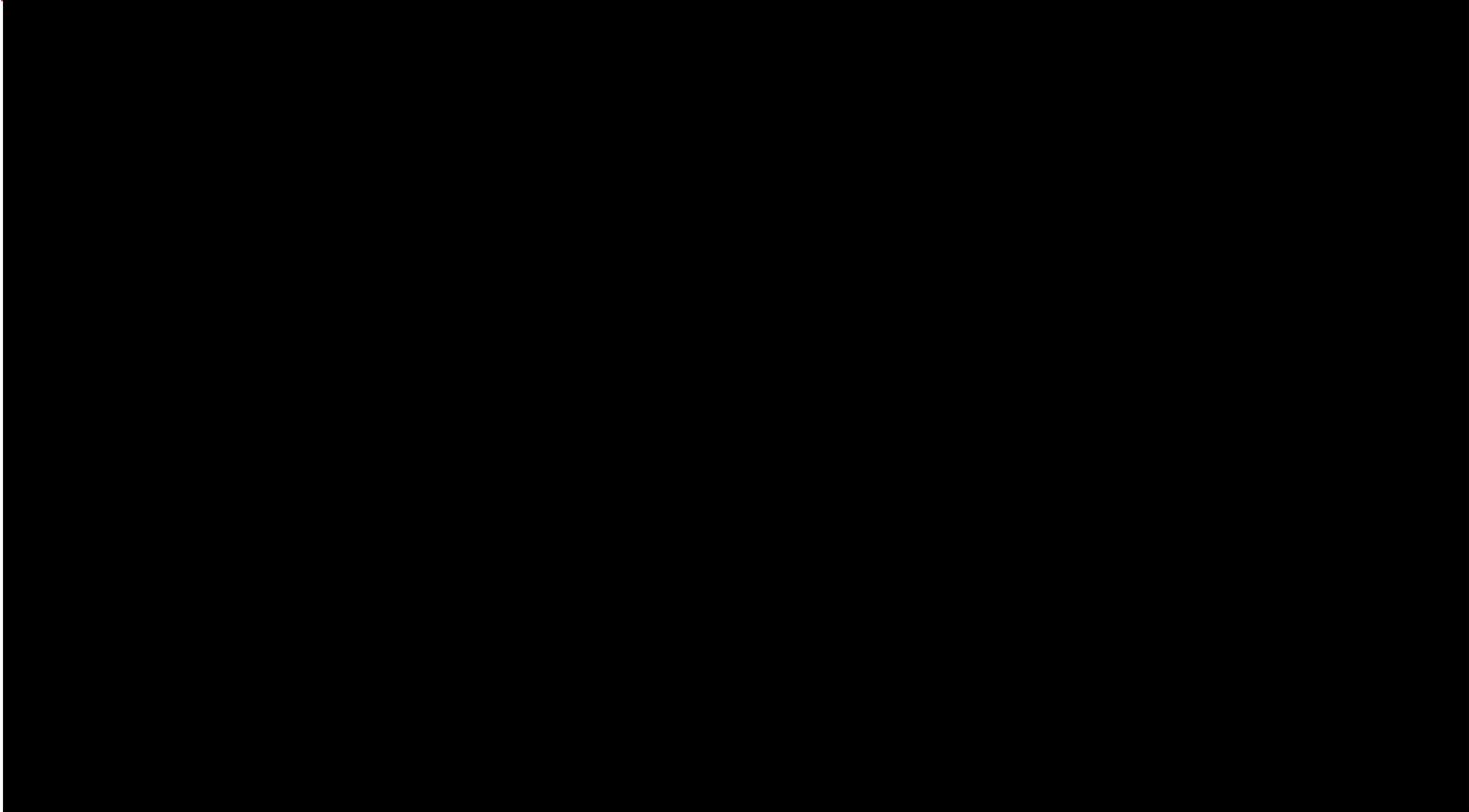
- **Greater than 90% effective at preventing HIV.**
- **Does not protect against STI's or pregnancy.**
- **Can be prescribed by any health care provider.**
- **Some or all costs of the medication can be covered by insurance, Medicaid, and patient assistance programs.**

- The U.S. Food and Drug Administration (FDA) approved Truvada for PrEP use [in 2012](#).
- This medication is taken as a once-daily oral pill, which combines two medicines in one: Emtriva (also called emtricitabine or FTC) and Viread (also called tenofovir disoproxil fumarate or TDF).

- Truvada works by blocking an enzyme called HIV reverse transcriptase. By blocking this enzyme, it prevents HIV from making more copies of itself in the body.

Source: <http://men.prepfacts.org/the-basics/>

What is PrEP?



Source: <http://whatisprep.org/>

Clinical data on side effects

	IPREX TRIAL		PARTNERS PREP TRIAL	
	FTC/TDF (N=1251)	PLACEBO (N=1248)	FTC/TDF (N=1579)	PLACEBO (N=1584)
Gastrointestinal Disorders				
Diarrhea	7%	8%	2%	3%
Abdominal pain	4%	2%	.a	-
Infections and Infestations				
Pharyngitis	13%	16%	-	-
Urethritis	5%	7%	-	-
Urinary tract infection	2%	2%	5%	7%
Syphilis	6%	5%	-	-
Secondary syphilis	6%	4%	-	-
Anogenital warts	2%	3%	-	-
Musculoskeletal and Connective Tissue Disorders				
Back pain	5%	5%	-	-
Nervous System Disorders				
Headache	7%	6%	-	-
Psychiatric Disorders				
Depression	6%	7%	-	-
Anxiety	3%	3%	-	-
Reproductive System and Breast Disorders				
Genital ulceration	2%	2%	2%	2%
Investigations				
Weight decreased	3%	2%	-	-

^aNot reported or reported below 2%.

Clinical Study Data Sheet:

<http://www.projectinform.org/pdf/prepstudydata.pdf>

CDC summary of guidance for PrEP use

Table 1: Summary of Guidance for PrEP Use

	Men Who Have Sex with Men	Heterosexual Women and Men	Injection Drug Users
Detecting substantial risk of acquiring HIV infection	HIV-positive sexual partner Recent bacterial STI High number of sex partners History of inconsistent or no condom use Commercial sex work	HIV-positive sexual partner Recent bacterial STI High number of sex partners History of inconsistent or no condom use Commercial sex work In high-prevalence area or network	HIV-positive injecting partner Sharing injection equipment Recent drug treatment (but currently injecting)
Clinically eligible	Documented negative HIV test result before prescribing PrEP No signs/symptoms of acute HIV infection Normal renal function; no contraindicated medications Documented hepatitis B virus infection and vaccination status		
Prescription	Daily, continuing, oral doses of TDF/FTC (Truvada), ≤90-day supply		
Other services	Follow-up visits at least every 3 months to provide the following: HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, STI symptom assessment At 3 months and every 6 months thereafter, assess renal function Every 6 months, test for bacterial STIs		
	Do oral/rectal STI testing	Assess pregnancy intent Pregnancy test every 3 months	Access to clean needles/syringes and drug treatment services

STI: sexually transmitted infection

Source: <https://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf>

Reminder

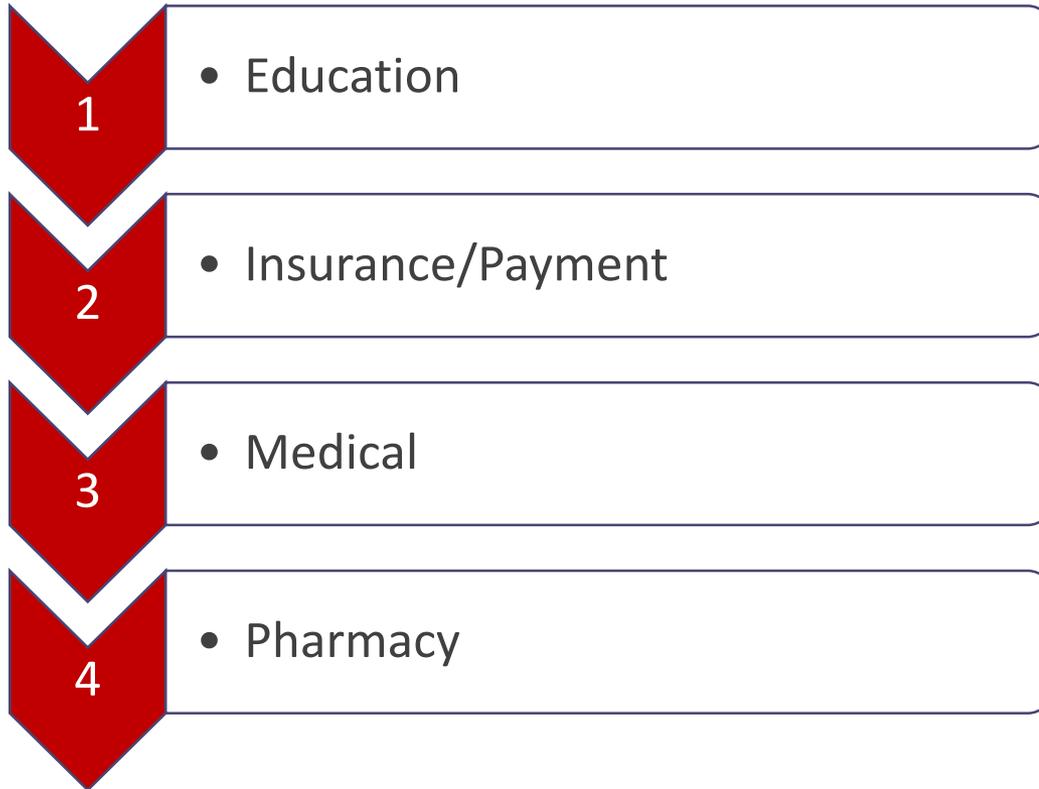
- Not all patients will self-identify as being part of certain “risk groups”
- Not all patients will be completely honest about sexual behaviors
- Inclusion/exclusion categories will eventually be determined by medical protocols and medical direction
- Ultimately, a licensed medical provider will be the final decision maker

Clinical Evidence Summary

- Twelve trials of the effectiveness of oral PrEP have been conducted among serodiscordant couples, heterosexual men, women, MSM, people who inject drugs and transgender women. These trials took place in Africa, Asia, Europe, South America and the United States.
- PrEP has an excellent safety profile. Across 10 randomized controlled trials, rates of any adverse event did not differ between PrEP and a placebo.
- Risk of drug resistance is low, occurring in approximately 1 in 1000 PrEP users in clinical trials.
- PrEP can be used with hormonal contraception. Recommended PrEP regimens do not appear to alter the effectiveness of hormonal contraception.
- PrEP can be used during pregnancy. No increase occurred in adverse pregnancy-related events among women taking PrEP in early pregnancy. This is important because both mother and infant are more vulnerable to HIV acquisition during pregnancy and breastfeeding.

Source: http://apps.who.int/iris/bitstream/10665/197906/1/WHO_HIV_2015.48_eng.pdf?ua=1

Comprehensive PrEP program



- Don't overthink it!
- Leverage current resources available at your clinic

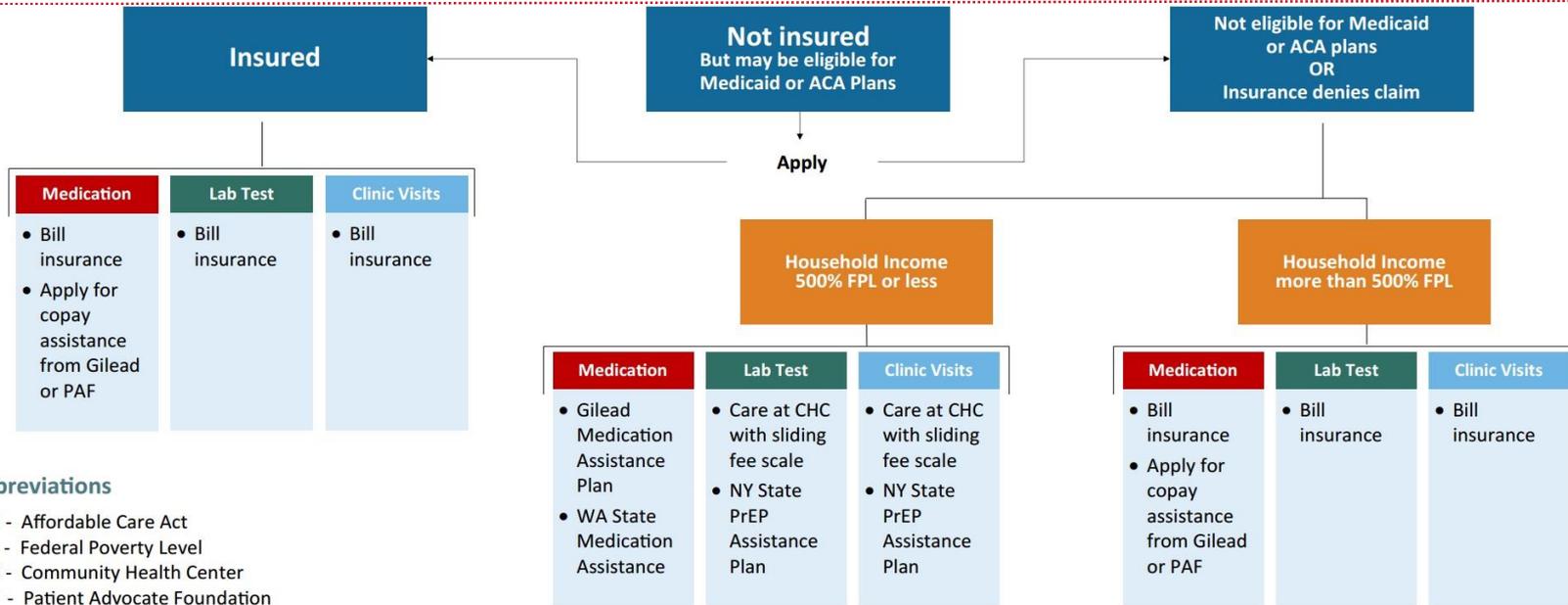
Reminder

- Truvada as PrEP can be prescribed by any licensed medical provider
- HIV-negative patients do not require specialty care
- Establish realistic expectations and timeline for patients
- Assess your patients readiness and commitment
- Assess your clinic capacity and capabilities

1. Education

- HIV 101 (provider/patient)
- PrEP 101 (provider/patient)
- Brochures/palm cards (keep it simple)
- Various online resources
- Targeted culturally competent outreach to at-risk communities
- Identification of gatekeepers and existing social networks
- Staff involved should aim for successful linkage and follow-up
- The goal is to provide enough correct information to lead patient to next step

Paying for PrEP



Abbreviations

ACA - Affordable Care Act
 FPL - Federal Poverty Level
 CHC - Community Health Center
 PAF - Patient Advocate Foundation

Definitions:

PrEP: Daily pill to prevent HIV infection (pre-exposure prophylaxis)

Co-pay: Fixed amount to be paid by insured person per prescription

Co-insurance: Fixed percentage of prescription cost to be paid by insured person

Deductible: Amount of health care cost (including prescriptions) that must be paid by the insured person before insurance begins to cover costs

PrEP Medication Assistance Program

(Gilead Sciences)

People eligible for this program must:

- Be 18 years of age or older
- Be without insurance or have payment declined by their insurance carrier
- Be resident in the US (social security number not required)
- Have family income ≤ 500% of the federal poverty level

Once enrolled in this program:

- Medication will be sent to the provider, a pharmacy, or the patient's home
- Patients can get their medication at no charge from their provider or pharmacy for as long as they are eligible
- Eligibility must be confirmed every 6 months by the provider

PrEP Medication Assistance Program

Family Size 500% Federal Poverty Level Household
 Annual Income must be less than:

1	\$58,850
2	\$79,650
3	\$100,450
4	\$121,250
5	\$142,050
6	\$162,850

Reminder

- Medicaid should cover Truvada and PrEP related services

David Evans, the director of research advocacy at [Project Inform](#), told Healthline, “We are unaware of any private health insurance carrier who is not covering PEP (post-exposure prophylaxis) or PrEP. Some have prior authorization restrictions, but these hurdles can typically be gotten over. All Medic aids are obligated to cover both PEP and PrEP, though some have prior authorization restrictions—usually just confirmation of a negative HIV diagnosis.”

Source: <http://www.healthline.com/health-news/hiv-prevention-truvada-prep-covered-by-most-insurers-050814#1>

- Medicaid: If your patient does not qualify for Medicaid you can **still** find access points. It will require using multiple payer sources:
 1. Truvada covered through Gilead Advancing Access
 2. Doctor visits/labs covered on sliding fee scale and/or local STI programs

2. Insurance/Payment

- Credentials to enroll into Medicaid & state marketplace
- Verify all costs associated with health care policy:
Premiums, medical visit, lab and medication co-pays, deductibles
- Knowledge of managed care plans accepted at your clinic
- Knowledge of patient assistance programs:

Gilead Co-Pay Card

\$3,600 for use with commercial plans (including ACA) on pharmacy co-pays and pharmacy deductibles
(No income limit)

<http://www.truvada.com/truvada-patient-assistance>

Gilead Advancing Access

Free medication covered on a 6 months basis to those who qualify (Patient may re-apply every 6 months)

http://services.gileadhiv.com/content/pdf/gilead_enrollment_form.pdf

Patient Advocate Foundation

\$7,500 Per Year to those who qualify (as of May 2nd, 2016)

<https://www.copays.org/diseases/hiv-aids-and-prevention>

3. Medical

- There should be a medical protocol in place for prescribing PrEP that aligns with your current clinic flow
- Protocol should outline lab tests **required** for baseline/follow up:
Kidney function, STI panel, HIV test, Hep B/C, etc.
- Protocol should outline inclusion/exclusion criteria for patients
- Adjust clinic flow for increased lab/nurse visits
- Establish system for adherence support
- Psychosomatic patients
- Patients in need of behavioral health

4. Pharmacy

- Advise your pharmacy to stockpile Truvada
- Advise the pharmacy manager that you will be sending new *HIV-negative* patients
- Advise pharmacy staff that patients will be utilizing co-pay cards. Confirm that they are accepted and can be easily processed
- Keep an open line of communication with your pharmacy and staff
- Elect point people to handle PrEP Patients

Facilitators

- HIV/STI testing clients
- Clients who are currently in sero-discordant relationships
- Patients who exhibit health-seeking behavior
- Utilizing PrEP screeners for new and current primary care patients at your clinic
- On site health educators/patient navigators

Opportunities

- New skill set/training required
(Suggested solution: HR portal, online training)
- Clear funding stream for PrEP navigators
- Providers still uncomfortable prescribing Truvada
- Cultural/Language barriers
- Stigma (patient and provider)

Barriers

Outreach and Education

- Consult with the community-
Examples: CAB meetings, Town Halls, Survey Monkey, Google docs.
- Culturally appropriate
- Culturally relevant
- Visuals and language matter
- Strategic planning: *Where can we have the most effective reach?*
- Outreach to consumers vs. Outreach to health care providers
- We can lead the horse to the water...

Clinical Resources

PrEPARE for Life: NMAC's PrEP Education and Awareness program:

<http://nmac.org/prepareforlife/>

CDC Clinical Practice Guideline:

<http://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf>

NASTAD's Billing and Coding Guide for HIV Prevention:

<https://www.nastad.org/resource/billing-coding-guide-hiv-prevention>

New CDC/DHAP PrEP brochures: Paying for PrEP brochure:

<http://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-paying-for-prep.pdf>

PrEP medication adherence brochure:

<http://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-adherence.pdf>

Project Inform PrEP Flow Chart:

http://www.projectinform.org/pdf/PrEP_Flow_Chart.pdf

Project Inform PrEP clinical data sheets:

<http://www.projectinform.org/pdf/prepstudydata.pdf>

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Questions

Feedback for Session
