

Providing PrEP Services to Your Patients

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PrEP Overview

- emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) approved for PrEP in 2012
 - \$14,000 per year
- Only drug approved for this use
 - 1 pill once a day
- CDC issued guidelines for PrEP use in 2014
 - Includes provider supplement
- Combine with other risk reduction strategies
 - 92-99% effective



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PrEP Overview

- Effective for HIV-1 only
 - Not approved for HIV-2
- Quarterly visits
 - Mandatory HIV and kidney function testing
- Hepatitis panel
 - Contraindicated in those with Hepatitis B



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Medication Details

- Manufactured by Gilead
- Emtricitabine/Tenofovir disoproxil fumarate (200/300 mg)
- Non-nucleoside reverse transcriptase inhibitor
- Combined with other drugs for treatment
 - HIV-1
 - Ages 12 and up
- Monotherapy for prevention
- Metabolized in kidneys
 - Monitor kidney function
 - CrCl \geq 60
- Tenofovir disoproxil fumarate treats hepatitis B
 - Immunization status
 - Antibody titer



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Evidence

- iPrEx
- TDF2 Study
- Partners PrEP Study
- Bangkok Tenofovir Study
- FEM-PrEP
- VOICE



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iPrEx

- 2499 MSM and TGF
- Double-blind, placebo controlled, FTC/TDF
- 6 countries (Brazil, Ecuador, Peru, South Africa, Thailand, U.S.)
- 11 sites
- 44% efficacy
- Drug levels compared



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TDF2

- 1200 heterosexual men and women
- Double-blind, placebo controlled, FTC/TDF
- Botswana
- 2 sites
- 62% efficacy
- Drug levels compared
- Efficacy difference between genders



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Partners PrEP

- 4758 serodiscordant, heterosexual couples
- Double-blind, placebo controlled, FTC/TDF, tenofovir
- 2 countries (Kenya, Uganda)
- 75% efficacy-FTC/TDF
- 67% efficacy-tenofovir
- Protection a function of adherence



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Bangkok Tenofovir Study

- 2400 IDU
- Double-blind, placebo controlled, tenofovir
- Thailand
- 17 sites
- 49% efficacy
- 74% efficacy with DOT
- Protection a function of adherence
- Adherence a function of risk



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FEM-PrEP

- 1950 women
- Double-blind, placebo controlled, FTC/TDF
- 3 countries (Kenya, South Africa, Tanzania)
- Study halted early-no effect
- Differences in tissue uptake?
- Adherence? (under 38% with detectable drug in system)
- Interaction with contraceptives?



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VOICE

- 5029 women
- Double-blind, placebo controlled, FTC/TDF, tenofovir, tenofovir gel
- 3 countries (South Africa, Uganda, Zimbabwe)
- 15 sites
- Tenofovir and tenofovir gel halted early-no effect
- FTC/TDF-no effect
- Critically low adherence (50% with no drug in system)



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Others

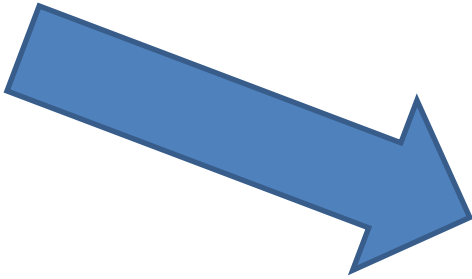
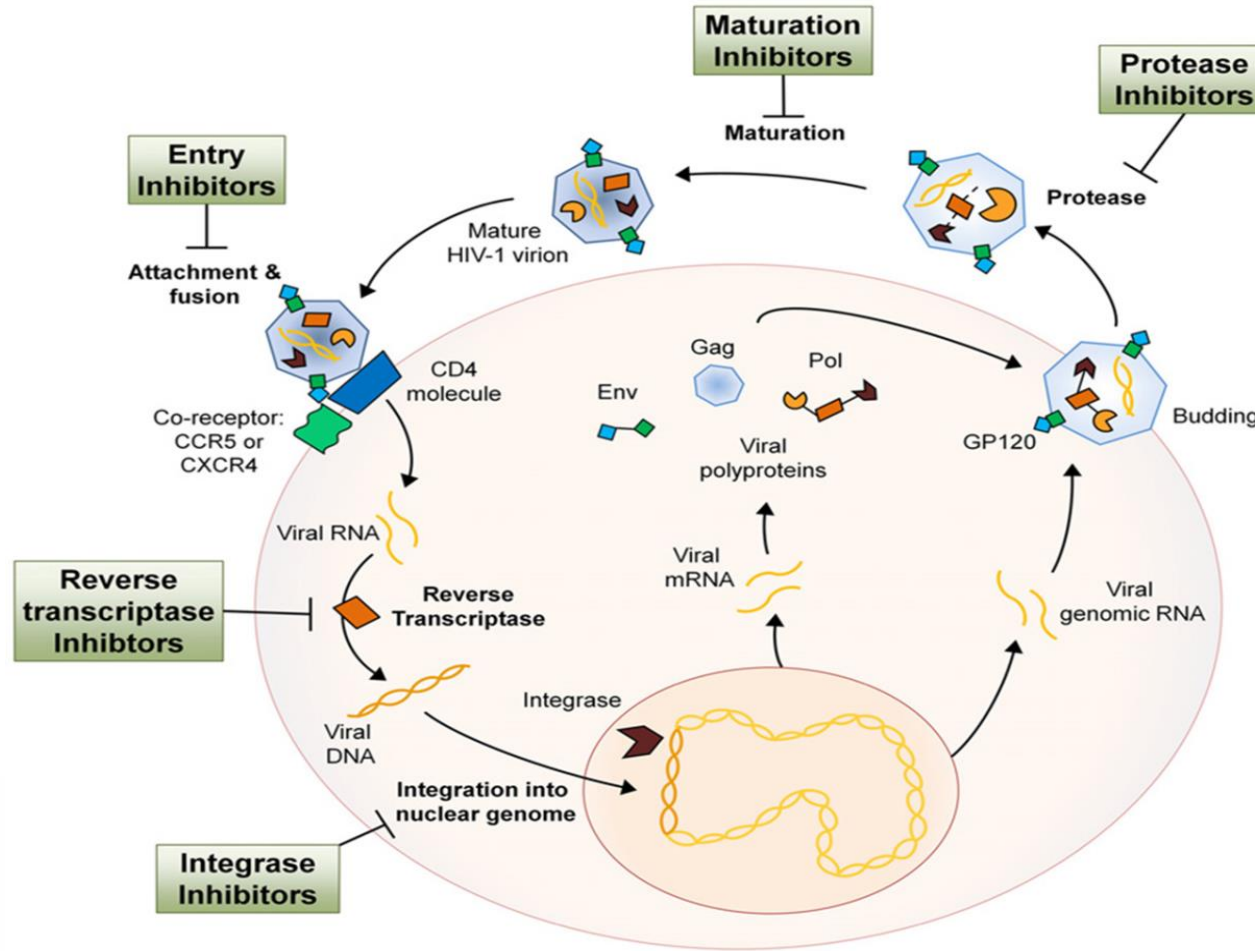
Ipergay

- 400 MSM
- Double blind, placebo controlled, FTC/TDF
- Canada and France
- On-demand PrEP
- 2-1-1 regimen 2-24 hours before sex
- 86% risk reduction
- Not indicated at present

PROUD

- 500 MSM
- Immediate start vs. delayed start
- England
- Cost efficacy
- Halted early due to high efficacy
- NHS made funding available to support PrEP as a primary HIV prevention strategy

Site of Action



Risk Reduction

- Use condoms
 - Male
 - Female
- Limit number of partners
- Test frequently
 - Up to monthly for some patients
- Reduce/eliminate substance abuse
 - Counseling
 - Rehab programs (AA, NA, inpatient, etc.)
- Behavioral /mental health
 - Counseling
 - Medication



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Eligible Patients

- Men who have sex with men
 - 1:2 African American
 - 1:4 Latino
 - 1:11 Caucasian
- Commercial sex workers
- Intravenous drug users
- High risk heterosexuals
- HIV negative partner in serodiscordant relationship



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Determining Eligibility

- Sexual preference
 - Men
 - Women
 - Both
- Number of partners
 - Monthly
 - Quarterly
 - Semi-annually
- Meeting partners
 - Apps/other online sources
 - Friends
 - Bars/social outings
- Sexual activities
 - Oral
 - Anal
 - vaginal
- Substance use
 - Alcohol
 - Illegal/illicit drugs
 - Routes (IN, IV, PR)
- Trading sex for commodities
- Immunization status
- **YOU MUST ASK THE QUESTIONS!**

Guidelines

Clinically eligible	<p>Documented negative HIV test result before prescribing PrEP</p> <p>No signs/symptoms of acute HIV infection</p> <p>Normal renal function; no contraindicated medications</p> <p>Documented hepatitis B virus infection and vaccination status</p>		
Prescription	Daily, continuing, oral doses of TDF/FTC (Truvada), ≤90-day supply		
Other services	<p>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</p> <p>At 3 months and every 6 months thereafter, assess renal function</p> <p>Every 6 months, test for bacterial STIs</p>		
	Do oral/rectal STI testing	<p>Assess pregnancy intent</p> <p>Pregnancy test every 3 months</p>	Access to clean needles/syringes and drug treatment services

TCPH Adult Health Services Example

- Started May 2, 2016
- Initial investment \$35,000
 - CMP machines for both clinics
 - CLIA waived
 - Reimbursable
- DSHS support for CDD contract
 - Uninsured hepatitis panels
- HIV NAAT support
- Incorporated into STI services
- Grant award January 2017
 - No money for drug
 - Additional personnel
 - Supplies
 - Advertising



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Personnel

- 2 NPs
- 4 RNs
- 2 LVNs
- 4 CSAs
- 2 Clerks
- Staff split between 2 locations
 - Monday-Friday
 - Tuesday-Saturday
- Outreach staff
- DIS



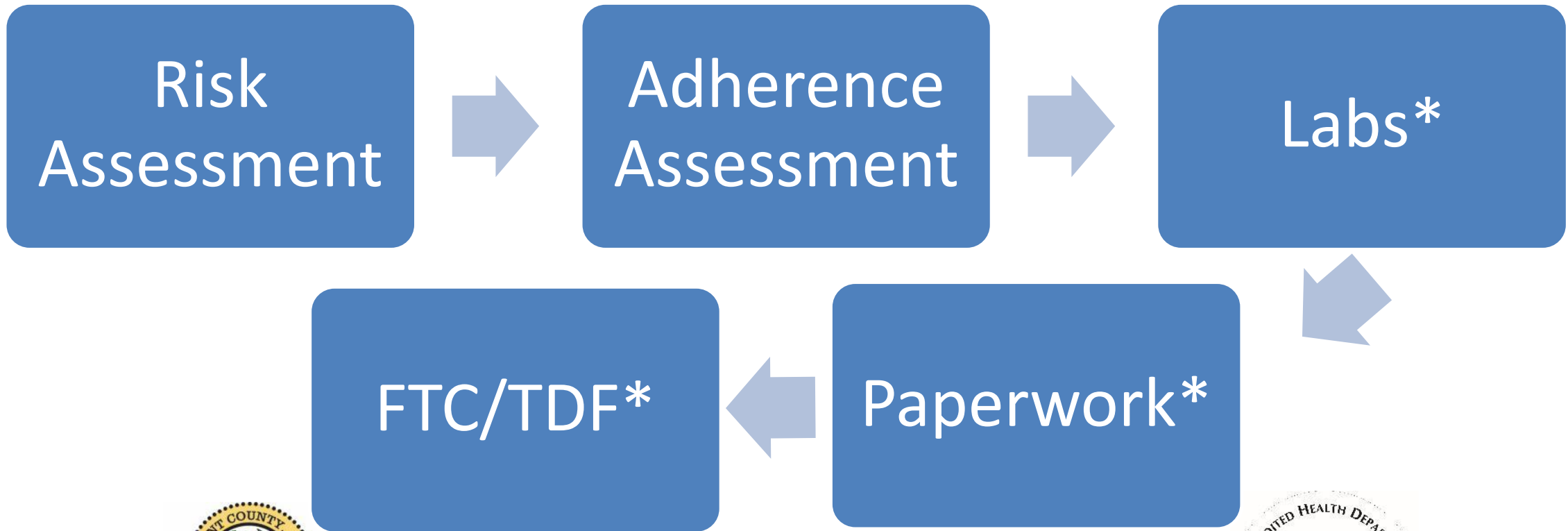
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TCPH Adult Health Services

- Initial PrEP appointments with NP
- All patients receive risk assessment
- All patients receive PrEP education
- Adherence assessment
 - Able to take a daily pill
 - Strategies to remember

TCPH Adult Health Services



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* Indicates differences between insured and uninsured



Initial Labs

Insured

- HIV NAAT (Dallas County Lab)
- Routine HIV (North Texas Regional Lab)
- Rapid HIV (for same day PrEP)
- Syphilis IgG (North Texas Regional Lab)
- GC/CT (North Texas Regional Lab)
 - Urine
 - Swabs
- CMP (onsite)
- Hepatitis panel (Quest, LabCorp)
- Wet mount for biological females (onsite)

Uninsured

- HIV NAAT (Dallas County Lab)
- Routine HIV (North Texas Regional Lab)
- Rapid HIV (if requested)
- Syphilis IgG (North Texas Regional Lab)
- GC/CT (North Texas Regional Lab)
 - Urine
 - Swabs
- CMP (onsite)
- Hepatitis panel (CDD)
- Wet mount for biological females (onsite)

Navigation

- Applications completed during appointment
 - Prescription Assistance Program
 - Co-pay card
 - Patient Advocate Foundation
- Refill calls/emails
- Progress emails
- Direct line access
- Lab review
- Contract pharmacy
- Referrals from PCPs



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Paperwork

Insured

- Gilead Co-pay card
 - Online application
 - Card activation
 - \$4800 per year
 - Co-pays, coinsurance, deductible
- Prior Authorization
- Patient Advocate Foundation
 - Online application
 - Supporting documents
 - Up to \$7500 per year
 - Co-pays, coinsurance, deductible

Uninsured

- Gilead Prescription Assistance Program
 - Up to 6 months FTC/TDF at no cost to patient
 - Must reapply every 6 months
 - Proof of income or signed income statement

Medication Counseling

- Expected side effects
 - Nausea
 - Headache
 - Minor
 - Short-lived
- With or without food
- 4-8 hours away from GERD meds
- Preliminary data suggests
 - Safe in pregnancy
 - Safe in breastfeeding
- Discontinue if signs of allergy
- Discontinue if HIV positive
- Discontinue if CrCl < 60



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Prescription

Insured

- Same day with negative HIV result
- #90 with 3 refills

Uninsured

- A week after submission of completed PAP application
- #30 with 5 refills



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Quarterly Follow Up Labs

Insured

- Routine HIV (North Texas Regional Lab)
- Syphilis IgG (North Texas Regional Lab)
- GC/CT (North Texas Regional Lab)
 - Urine
 - Swabs
- CMP (onsite)
- Wet mount for biological females (onsite)
- Additional testing based on exposures

Uninsured

- Routine HIV (North Texas Regional Lab)
- Syphilis IgG (North Texas Regional Lab)
- GC/CT (North Texas Regional Lab)
 - Urine
 - Swabs
- CMP (onsite)
- Wet mount for biological females (onsite)
- Additional testing based on exposures

Current Stats

- 508 patients on FTC/TDF
- Overwhelmingly MSM
 - 54 women
- 6 cases acute HIV identified
- 1 case active Hepatitis C identified
- No discontinuations due to side effects
- No discontinuations due to kidney issues
 - 2 not started secondary to poor kidney function



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Clinic Payment Structure

- Private insurance/ACA Plans
- Medicare/Medicaid
- Sliding fee scale (200% FPL)
- Waivers for DIS/some minors
- 340b
- Grant



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Information and Referral Sources

- Waiting rooms x 2
- Exam rooms x 8
- Counseling rooms x 4
- Community Events
- Community partners
- Local primary care providers
- Website
- PrEP locator sites
- Social Media



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Special Considerations: Adolescents

Insured

- EOB going to primary insured
- Lack of health insurance literacy
- Parent/guardian support
- Lack of support without parent/guardian signature

Uninsured

- Lack of support without parent/guardian signature
- FTC/TDF not approved in under 18 for PrEP



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Special Considerations: Income Potential

- Third-party billing
- Cash pay
- Quarterly visits
- Adding primary care activities to visits
 - Immunizations
- 340b program income for qualified programs
 - HRSA program
 - Drug rebates
 - Contract pharmacy
- Additional services possible from additional clinical information and labs



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Lessons Learned

- Health insurance literacy
 - Staff
 - Patients
- Navigators critical
 - Paperwork
 - Follow up calls



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Questions?



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