Pre-exposure Prophylaxis (PrEP)

Victoria Mobley
Medical Epidemiologist
Wake AHEC requires all speakers to disclose any relevant financial conflicts of interest.

Dr. Victoria Mobley does not have any relevant financial conflicts of interest.
Learning Objectives

• Brief overview of HIV in North Carolina
• HIV Prevention Strategies, to date
• What is PrEP
• How do we know PrEP works
• Who should be considered for PrEP
• Steps to PrEP initiation
• Frequently asked questions
North Carolina HIV Infection Rates Diagnosed Year 2000-2013*

- **Prevalence**
- **New Cases**

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<th>Year</th>
<th>Prevalence</th>
<th>New Cases</th>
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<td>2013</td>
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*Data as of 2013*
Gender Distribution of Newly Diagnosed HIV Infection in North Carolina, 2013

- Male: 78.6%
- Female: 21.4%
Hierarchical Risk for HIV Exposure among Newly Diagnosed Adults/Adolescents in North Carolina, 2013

N = 1,513

MSM 60.5%
Heterosexual 33.0%
MSM/IDU 2.5%
IDU 4.0%
Changing age Distribution of Newly Diagnosed HIV Infection in North Carolina

2007

2014
HIV Prevention Strategies
Post-exposure prophylaxis (PEP)

• HIV drugs taken after a HIV exposure, to prevent infection
  – Effective when started ≤72 hrs (earlier=better)
  – New regimen is much better tolerated

EMTRICITABINE/TENOFOVIR (generic name) 1 tablet daily
PLUS
Raltegravir 1 tablet twice daily

*For 28 days

What is PrEP?

• Taking a drug used to treat HIV infection, once daily to reduce risk of acquiring HIV

• To be used in conjunction with other prevention strategies

• EMTRICITABINE/TENOFOVIR (generic name)
  Well studied
  – Well tolerated
  – Few drug-drug interactions
  – Resistance less likely
Does PrEP Work?
But if you actually take the pill...
Adherence, Adherence, Adherence

Protective efficacy (%)

All participants  High adherers

44 92

62-73  ~95

What if I miss a does or two?

90%  100%

Who should be considered for PrEP?

- Sexually-active adult MSM at substantial risk of HIV acquisition
- Heterosexual adults who are at substantial risk of HIV acquisition
- Adult injection drug users (IDU) at substantial risk of HIV acquisition
- HIV-negative partner in a sero-discordant couple during conception and pregnancy

What are the steps to starting someone on PrEP?
Step 1: Assess HIV status, liver and renal function

Within 30 days
- HBsAg
- HBsAB
- HCV AB

Within 30 days
- Creatinine
- eCrCL

Within 7 days
- Ag/Ab (4th gen)
- Rapid (blood)
- ELISA/EIA

*CAUTION if active HBV
Step 2: Assess for signs/symptoms of acute HIV infection

Must be free of these, within prior 4 weeks:

- Fever (75%)
- Fatigue (68%)
- Skin rash (48%)
- Pharyngitis (40%)
- Cervical adenopathy (39%)

Suspect acute HIV? **Send HIV RNA (viral load)!**
Step 3: Screen for STIs

If not already done in prior 3-6mo
• Syphilis
• Gonorrhea and Chlamydia
  • NAAT preferred
  • Extragenital sites too
Step 4: Counsel the patient

Establish ground rules
• Ongoing relationship – **quarterly** visits
• No HIV test? No prescription!

Warn “Startup syndrome”
• Flatulence, nausea / GI upset, headache
• Symptoms resolve within first 30d, for most

Work with patient on adherence strategies
Step 5: Prescribe & follow up

First Rx: 30 days, no refills

Return to clinic in 30 days
• Adherence
• Side Effects
• Risk behaviors

2nd Rx: 30 days, 2 refills
Step 6: Maintenance & Reassessment

At least every 3 months
- Assess adherence, side effects, risk behavior
- Repeat HIV testing
- Prescription renewal

At least every 6 months
- Check creatinine and eCrCl
- Screen for STIs, if not already done
- Determine need – “seasons of risk”
Frequently Asked Questions
Won’t PrEP encourage riskier sex?

Risk compensation

➢ Repeatedly examined in multiple trials
  ➢ Indices of risk stable or reduced
    • Condomless sex
    • Number of partners
    • Bacterial STIs

How long before I’m protected?

Time to Maximum Intracellular Concentration of Tenofovir Disphosphate (TFV-DP)

Consecutive Days of Oral Dosing

Cervicovaginal

Blood (PBMC)

Rectal

Won’t it be less effective in practice?

Effectiveness is often lower than efficacy

- Condoms (97% → 70-80%)
- Oral contraceptive pills (99% → 90%)

PROUD Study

- 545 MSM, transwomen in English GUM clinics
- Half got PrEP immediately, half waited 1 year
- Stopped early due to strong positive effect

Protective effectiveness 86% (IRR; 95%CI 58, 96)

Can my patient afford PrEP?

Cost to PrEP users

- Out-of-pocket (uninsured) = around $1300/mo.
- Insurance covers (even Medicaid) – **pre-auths**
- Access programs and co-pay assistance
- Potentially free from company that manufactures the brand name of EMTRICITABINE/TENOFOVIR (generic name) if income <$58K

NCATEC has lots of resources
http://www.med.unc.edu/ncaidstraining/prep

• Detailed information on all things PrEP

• Contact information to HIV experts like Dr. Hurt

• Links to CDC and US Public Health Service PrEP guidelines

• Map of North Carolina PrEP providers

Dr. Chris Hurt, from who I shamelessly “borrowed” the majority of these slides
Questions