

Pre-exposure Prophylaxis (PrEP)

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HIV PrEP

2015 CD Conference

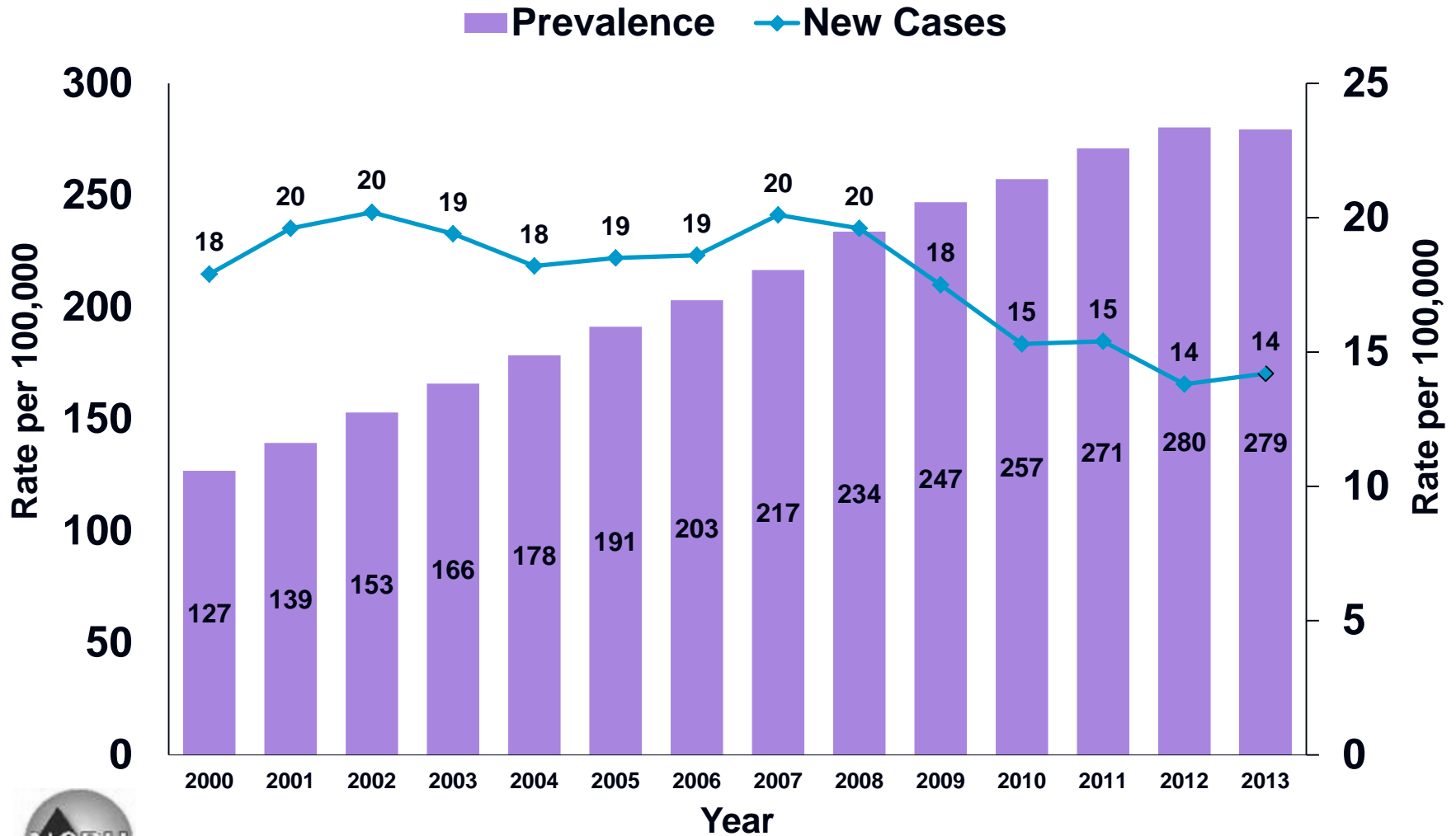
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Dr. Victoria Mobley does not have any relevant financial conflicts of interest.

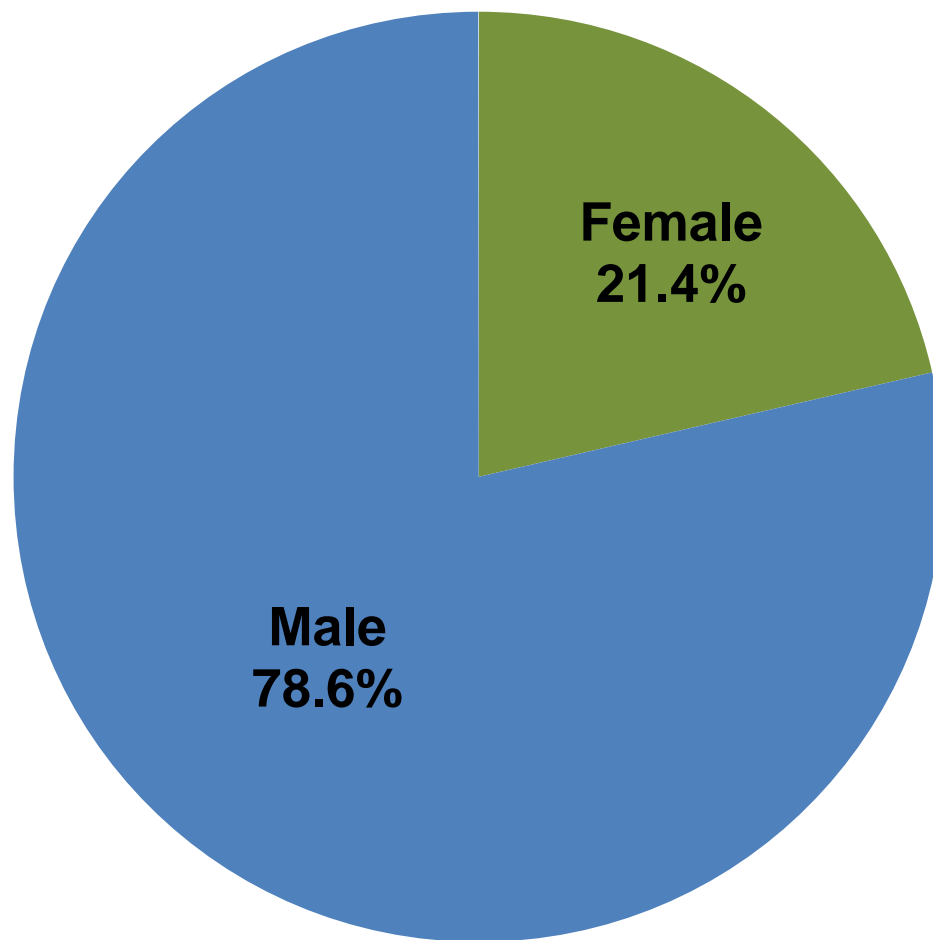
Learning Objectives

- 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*

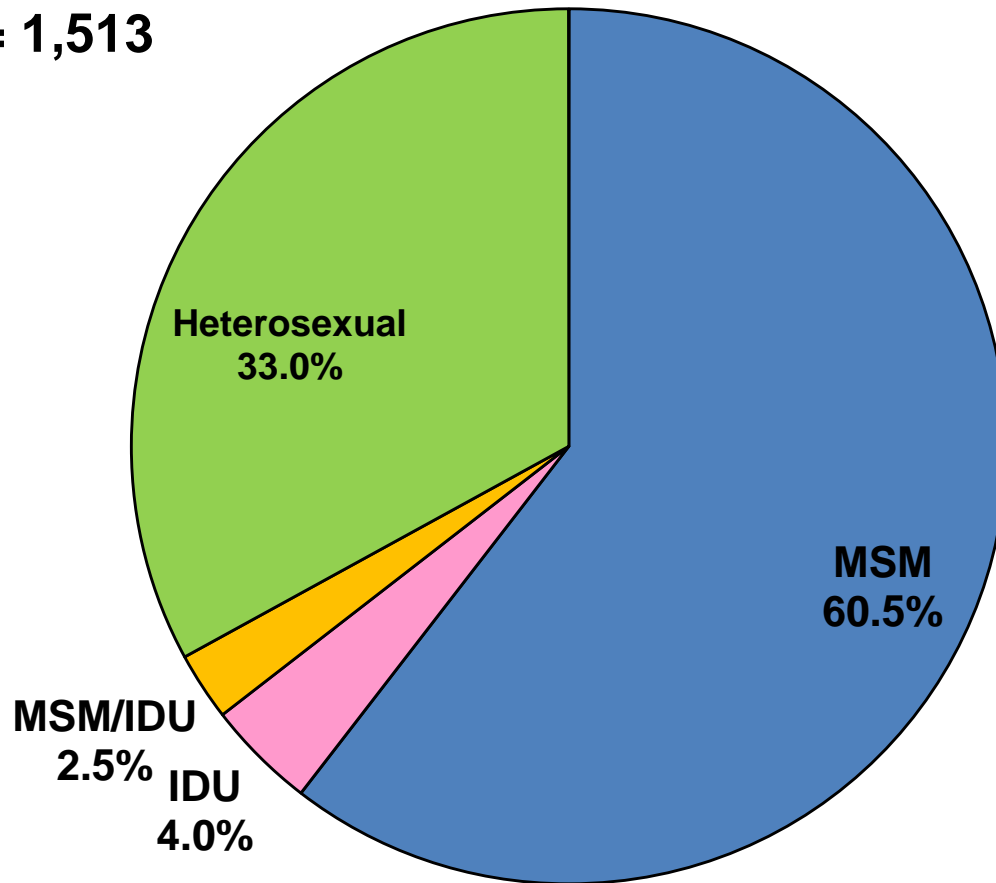


Gender Distribution of Newly Diagnosed HIV Infection in North Carolina, 2013



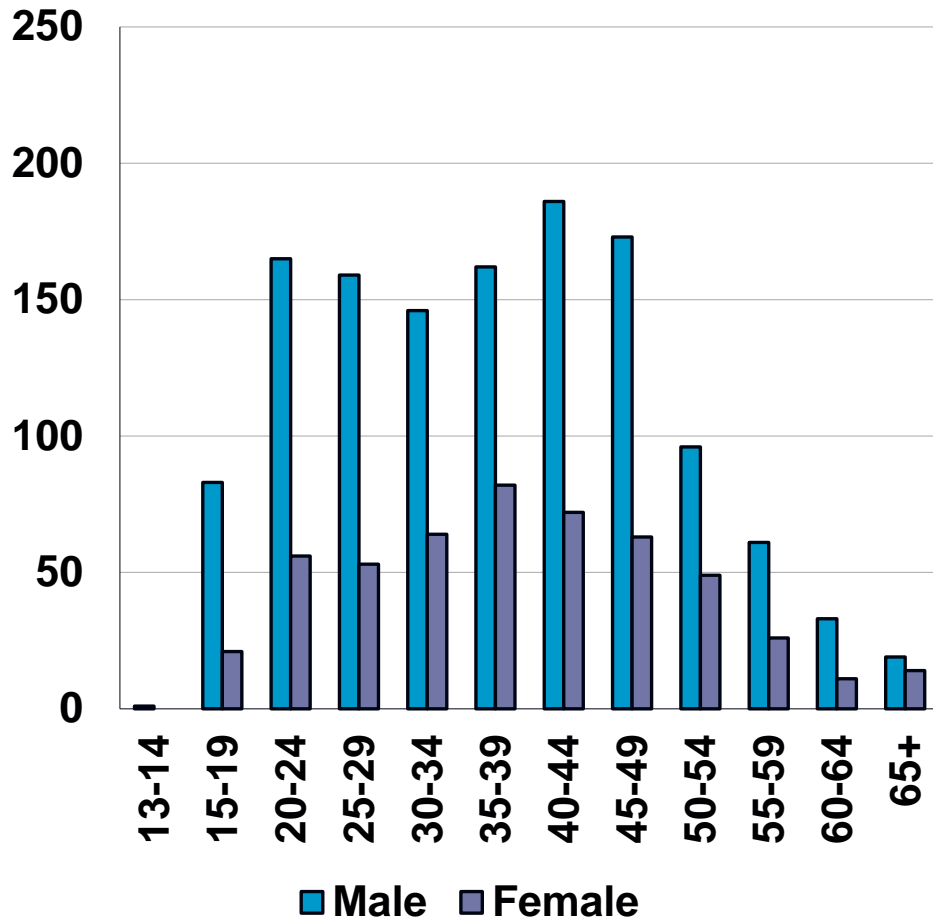
Hierarchical Risk for HIV Exposure among Newly Diagnosed Adults/Adolescents in North Carolina, 2013

N = 1,513

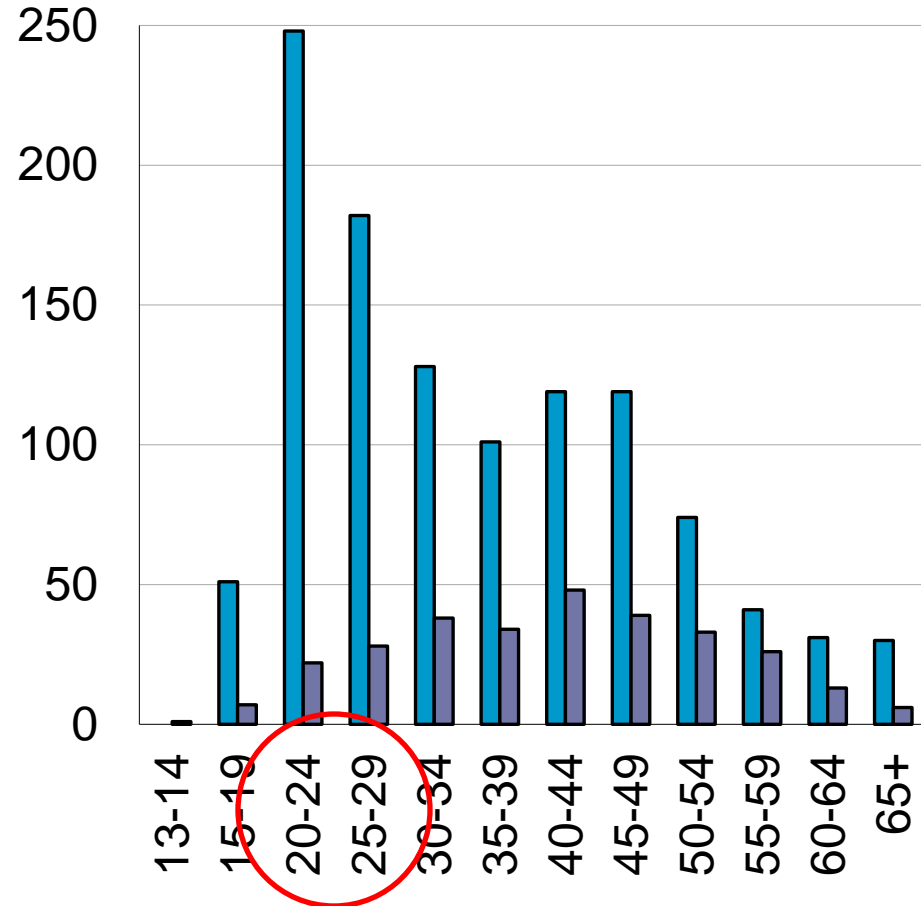


Changing age Distribution of Newly Diagnosed HIV Infection in North Carolina

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

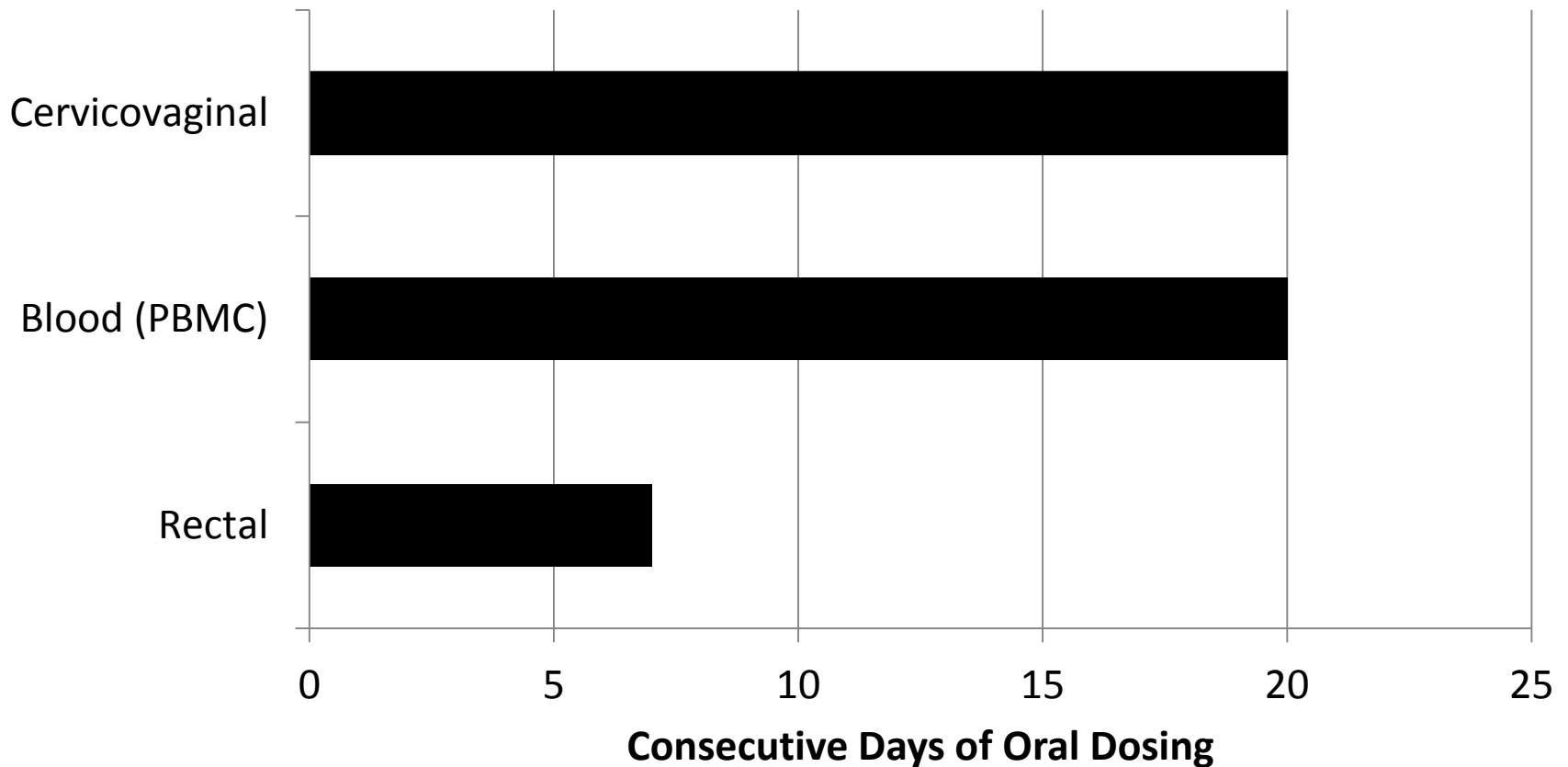
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How long before I'm protected?

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



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