Delaware HIV Planning Council

September 22, 2015

12:00-3:00

IN COLLABORATION WITH:

Introductions

- Name
- Organization and/or Location

National HIV/AIDS Strategy for the United States (NHAS)

Update July 2015

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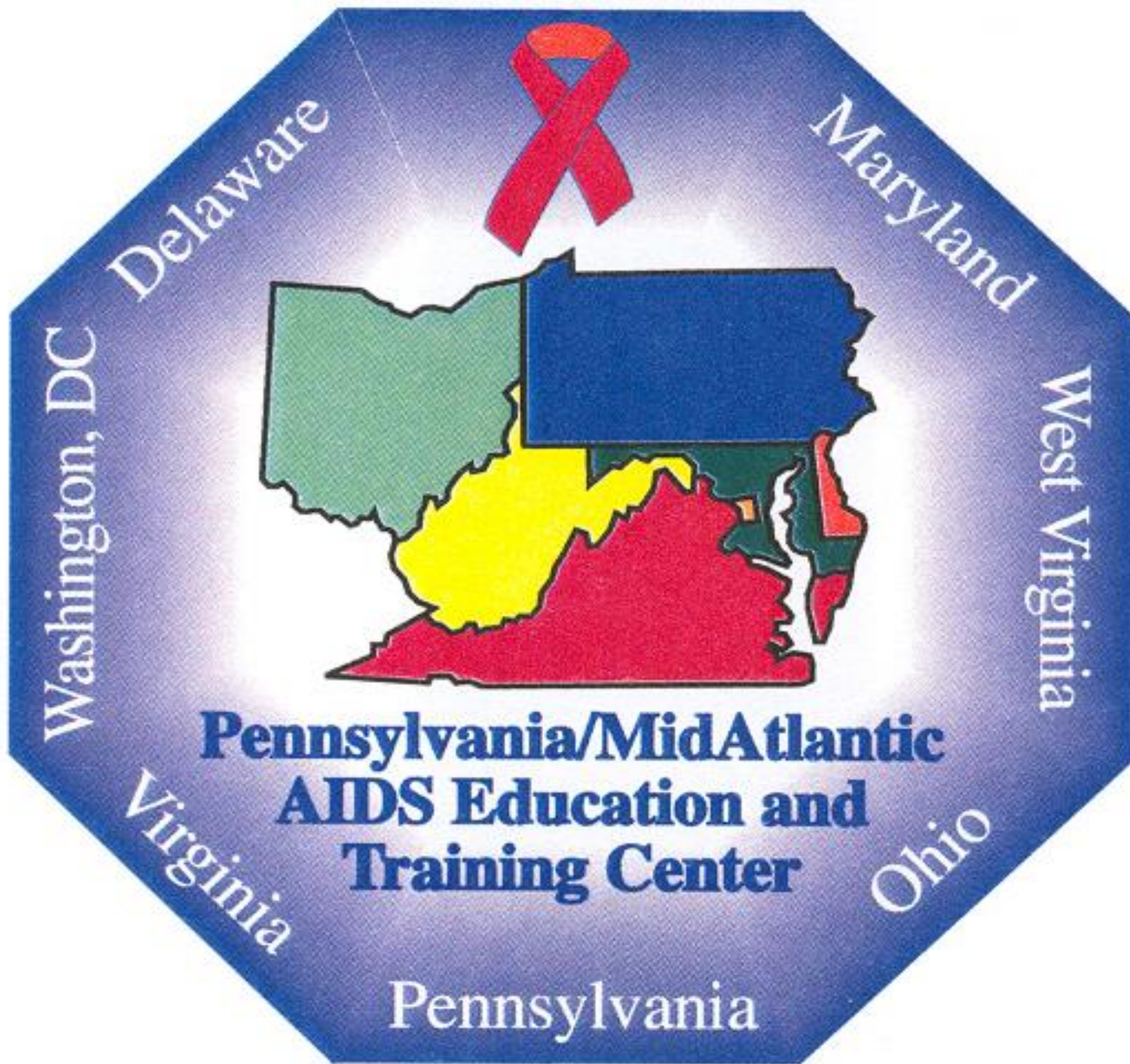
302-320-1404


Delaware
Maryland
Washington, DC
West Virginia
Pennsylvania/MidAtlantic
AIDS Education and
Training Center
Virginia
Ohio
Pennsylvania

Introduction

- The National HIV/AIDS Strategy (NHAS) was released on July 13, 2010
- There were three major goals of the strategy
- The plan will serve as a roadmap for policymakers, partners in prevention, and the public on steps the United States must take to lower HIV incidence, get people living with HIV into care, and reduce HIV-related health disparities.

Vision for the National HIV/AIDS Strategy

- “The United States will become a place where new HIV infections are rare and when they do occur, every person, regardless of age, gender, race/ethnicity, sexual orientation, gender identity or socio-economic circumstance, will have unfettered access to high quality, life-extending care, free from stigma and discrimination” President Obama

Coordination of National Response with other efforts across the Administration

- President’s Emergency Plan for AIDS Relief (PEPFAR)
- President’s National Drug Control Strategy
- Federal Strategic Plan to Prevent and End Homelessness
- Office of National Drug Council Policy

National HIV/AIDS Strategy

- The White House Office of National AIDS Policy
- 202-456-4533
- AIDSpolicy@who.eop.gov
- www.whitehouse.gov/onap

NHAS major goals (2010 / 2020)

1) Reducing the number of people who become infected with HIV

2) Increasing access to care and optimizing health outcomes for people living with HIV

3) Reducing HIV-related health disparities.

NEW 4) Achieving a more coordinated national response

2020 Revisions

1. Under each of the goals there are revisions to reflect past progress and activities.
2. The Update contains 10 quantitative indicators to better monitor progress and ensure the Nation is constantly moving in the right direction.

2010 Revisions

3. In addition three areas have been identified as priorities:

PreExposure Prophylaxis (PrEP)

Stigma

HIV among transgender persons

5 Major Changes Since 2010

1. Expansion of toolkit:

   Pre-Exposure Prophylaxis (PrEP)

   Treatment as Prevention (TasP)

2. The Affordable Care Act (ACA) :

   Millions of individuals have health care

   No denial of coverage for pre-existing conditions

   Preventive Services covered without co-pays

   Protection against sex or disability discrimination in health care

5 Major Changes cont'd

3. HIV testing and treatment are recommended: Federal Guidelines recommend routine HIV screening for people age 15 – 65
4. Improving HIV Care Continuum outcomes is a priority: diagnosis, linked to care, retained in care, prescribed combination antiretroviral therapy (cART), virally suppressed

5 Major Changes cont'd

5. Research is unlocking new knowledge and tools:

   Clinical Trials: HPTN 052, SMART

   Starting treatment earlier in infection

   HIV testing technologies

   New HIV medications

Critical Focus for the next 5 years
Right Practices

1. Widespread testing and linkage to care
2. Broad support for people living with HIV to remain in comprehensive care
3. Universal viral suppression
4. Full access to comprehensive Pre Exposure Prophylaxis (PrEP) services.

Thank You

Discussion

- How will the updated NHAS affect Delaware?

It’s Time for PrEP

Nicole Johns

Senior Health Planner

Philadelphia Department of Public Health

Office of HIV Planning

September 22, 2015

Outline

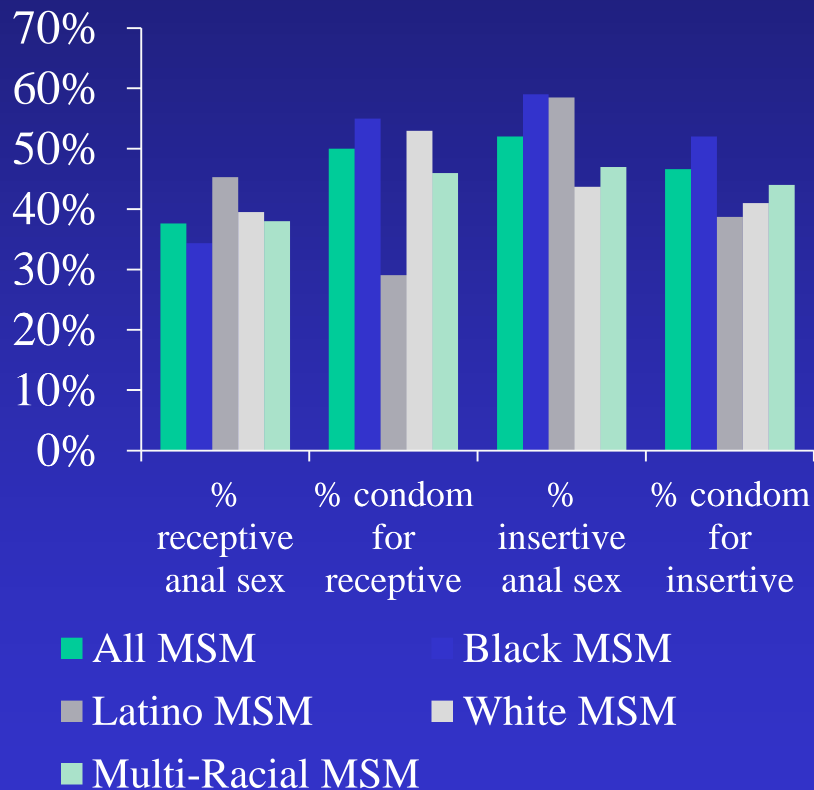
- Need for new preventions strategies
- What is PrEP?
- Data summary on PrEP
- PrEP guidelines
- Resistance
- Risk behaviors on PrEP
- Challenges and Opportunities for implementing PrEP in clinical practice

HIV Prevention: Toolbox for Success

- Safer-sex counseling: understanding risk
- Condoms and lubricant
- Sterile syringes and avoiding sharing “works”
- HIV testing and treatment
- STI testing and treatment
- PEP (postexposure prophylaxis)
- PrEP (pre-exposure prophylaxis)

Need for New Prevention Options NHBS-MSM4, 2014

Condomless Sex



HIV Prevalence

Demographic Group	MSM4 % HIV Positive Tested n=693	MSM4 % New Positives
Total	26.2%	23.3%
Race		
Black	35.3%	23.3%
White	8.8%	18.8%
Latino	26.9%	22.2%
Multi-racial	25.9%	27.3%

Data Source: PDPH/AACO National HIV Behavioral Surveillance among MSM4, 2014

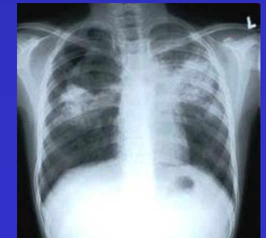
Need for New Prevention Options

- Only 50% of MSM in Philadelphia used a condom the last time they had sex (50% for receptive anal sex and 53% for insertive anal sex)
- Over 25% of MSM in Philadelphia are infected with HIV (26.2%)
  - 35.3% in AA MSM
  - 26.9% in Latino MSM
  - 8.8% in White MSM

Data Source: PDPH/AACO National HIV Behavioral Surveillance among MSM4, 2014

What is pre-exposure prophylaxis?

- Breaking it down
  - Pre-exposure = before an exposure
    - Medication used before an exposure occurs
  - Prophylaxis = prevention
    - Medication used for prevention instead of treatment
- Putting it together
    - Medication used BEFORE an exposure in order to prevent a disease or condition
- Currently being used
  - Malaria (malarone, doxycycline)
  - Tuberculosis (isoniazid)
- HIV prevention
  - Antiretrovirals?



How does PrEP work?

- Steps leading to HIV infection
    1. An infected body fluid comes into contact with a mucous membrane such as the rectum, vagina, or penis
    2. HIV crosses the epithelial barrier and enters underlying tissue
    3. Replicates in the mucous membrane tissue (1-3 days)
    4. Enters the lymphatic and circulatory system and spreads throughout the body

- “Window of opportunity”
    - The time when the amount of virus is small and is replicating at the mucous membrane
    - Antiretrovirals could prevent HIV infection by helping the body clear the virus before it spreads

Antiretrovirals Used in HIV Prevention: The Foundation for PrEP

- Prevention of mother-to-child transmission
  - Antiretrovirals given to the mother during pregnancy, labor, and delivery and to the infant postpartum[1]
  - PMTCT has virtually eliminated perinatal HIV infection in the US and other developed countries
- Postexposure prophylaxis
  - Antiretrovirals given within hrs of a known or suspected HIV exposure (eg, needle stick injury, rape)
  - US public health guidance for PEP is available for both occupational[2] and nonoccupational[3] exposure to HIV

1. DHHS. Perinatal Guidelines. 2014. 2. Kuhar DT, et al. Infect Control Hosp Epidemiol. 2013;34:875-892.
3. MMWR. 2005;54(RR-2):1-20.

Potential PrEP strategies

Route of drug delivery	• Oral (pill) • Topical microbicide(gel) –Rectal –Vaginal • Injection • Intravaginal ring
Dosing schedule	• Daily • Intermittently • Coitally (before/sex)
Number of antiretroviral drugs	• Single • Combination
Choice of antiretroviral drug	• Over 25 available

Tenofovir/Emtricitabine FDA Approved for PrEP

FDA NEWS RELEASE

For Immediate Release: July 16, 2012
Media Inquiries: Erica Jefferson, 301-796-4988, erica.jefferson@fda.hhs.gov
Consumer Inquiries: 888-INFO-FDA

FDA approves first drug for reducing the risk of sexually acquired HIV infection

Evidence-based approach enhances existing prevention strategies

PrEP Trials Have Shown Efficacy in MSM, Heterosexual Men and Women, and IDUs

•

Trial	Population/Setting	Intervention	HIV Infections, n		Reduction in HIV Infection Rate, % (95% CI)
			PrEP	Placebo	
iPrEX[1] (N = 2499)	MSM, transgender women, 11 sites in US, South America, Africa, Thailand	TDF/FTC	36	64	44 (15-63)
Partners PrEP[2] (N = 4747)	Serodiscordant couples in Africa	TDF	17	52	67 (44-81)
		TDF/FTC	13		75 (55-87)
TDF2[3] (N = 1219)	Heterosexual males and females in Botswana	TDF/FTC	9	24	62 (21-83)
Thai IDU[4] (N = 2413)	Volunteers from 17 drug Thai treatment centers	TDF	17	33	49 (10-72)

1. Grant RM, et al. N Engl J Med. 2010;363:2587-2599. 2. Baeten JM, et al. N Engl J Med. 2012;367:399-410. 3. Thigpen MC, et al. N Engl J Med. 2012;367:423-434. 4. Choopanya K, et al. Lancet. 2013;381:2083-2090. 5. Van Damme L, et al. N Engl J Med. 2012;367:411-422. 6. Marrazzo J, et al. CROI 2013. Abstract 26LB.

PrEP Works, but Adherence Is Critical

Study	Efficacy Overall, %	Blood Samples With TFV Detected, %	Efficacy By Blood Detection of TFV, %
iPrEx[1]	44	51	92
iPrEx OLE[2]	49	71	NR
Partners PrEP[3]	67 (TDF) 75 (TDF/FTC)	81	86 (TDF) 90 (TDF/FTC)
TDF2[4]	62	80	85
Thai IDU[5]	49	67	74
Fem-PrEP[6]	No efficacy	< 30	NR
VOICE[7]	No efficacy	< 30	NR

1. Grant RM, et al. N Engl J Med. 2010;363:2587-2599. 2. Grant RM, et al. Lancet Infect Dis. 2014; 14:820-829. 3. Baeten JM, et al. N Engl J Med. 2012;367:399-410. 4. Thigpen MC, et al. N Engl J Med. 2012;367:423-434. 5. Choopanya K, et al. Lancet. 2013;381:2083-2090. 6. Van Damme L, et al. N Engl J Med. 2012;367:411-422. 7. Marrazzo J, et al. CROI 2013. Abstract 26LB.

PrEP Trials

- PrEP Trials Have Shown Efficacy in MSM, Heterosexual Men and Women, and IDUs
  - Efficacy ranged from 44% to 75%[1-6]
- PrEP Works, but Adherence Is Critical
  - Efficacy ranged from 74% to 92% in persons who had detectable drug levels[1-6]
- In an implementation study mimicking the real world, efficacy was 86%[7]

1. Grant RM, et al. N Engl J Med. 2010;363:2587-2599. 2. Baeten JM, et al. N Engl J Med. 2012;367:399-410. 3. Thigpen MC, et al. N Engl J Med. 2012;367:423-434. 4. Choopanya K, et al. Lancet. 2013;381:2083-2090. 5. Van Damme L, et al. N Engl J Med. 2012;367:411-422. 6. Marrazzo J, et al. CROI 2013. Abstract 26LB. 7. McCormack t al. CROI 2015. Abstract 22LB.

So How Many People Need to Take PrEP?

- Number needed to treat
  - the average number of patients who need to be treated to prevent one additional bad outcome

- PrEP = 13 to prevent 1 HIV infection

- Statins = 100 to prevent 1 cardiovascular event

CDC PrEP Guideline: For Which Patients Is PrEP Recommended?

- PrEP is recommended as one prevention option for the following adults at substantial risk of HIV acquisition
  - Sexually active MSM
  - Heterosexually active men and women
  - Injection drug users

	MSM	Heterosexual Women and Men	Injection Drug Users
Potential indicators of 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)

CDC. PrEP Guideline. 2014.

CDC Guideline: Follow-up and Monitoring

Follow-up	At Least Every 3 Mos	After 3 Mos and at Least Every 6 Mos Thereafter	At Least Every 6 Mos	At Least Every 12 Mos
All patients	▪ HIV test ▪ Medication adherence counseling ▪ Behavioral risk reduction support ▪ Adverse event assessment ▪ STI symptom assessment	▪ Assess renal function	▪ Test for bacterial STIs	▪ Evaluate need to continue PrEP
Women	▪ Pregnancy test (where appropriate)			
HBsAg+			▪ HBV DNA by quantitative assay*	

*Every 6-12 mos.

CDC. PrEP Guideline. 2014.

Pregnancy

- PrEP use at conception and during pregnancy by the uninfected partner may offer an additional tool to reduce the risk of sexual HIV acquisition[1]
- Data directly related to the safety of PrEP use for a developing fetus are limited
- Potential risks and limited information should be discussed
- TDF and FTC are classified as FDA Pregnancy Category B medications[2]

1. CDC. PrEP Guideline. 2014. 2. DHHS. HIV Perinatal Guideline. 2014.

Resistance

- Data from the Proud study[1]
  - 3 of 6 individuals who were seroconverting around the time they started PrEP developed resistance with a M184V/I (resistance to one component in Truvada)
- Data from iPrex[2]
  - 2 of 2 individuals who were seroconverting around the time they started PrEP developed resistance with a M184V/I (resistance to one component in Truvada)
- Highlights the need to rule out acute infection prior to starting PrEP in high risk populations

1. McCormack t al. CROI 2015. Abstract 22LB. . 2. Liegler, T., et al. JID. 2014;210:1217-1227.

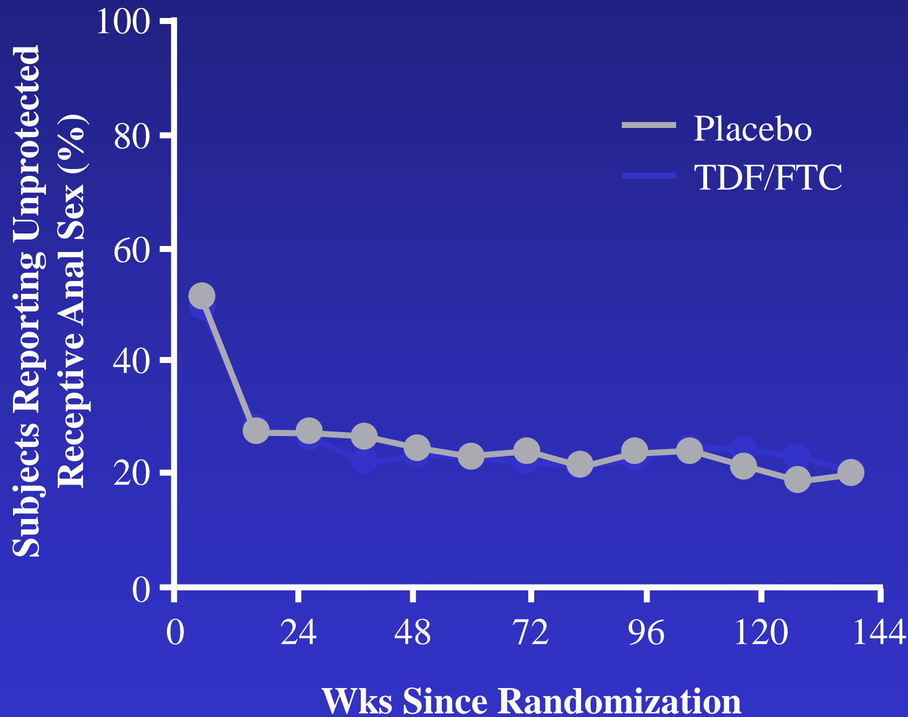
Reported sexual behaviour (preliminary)

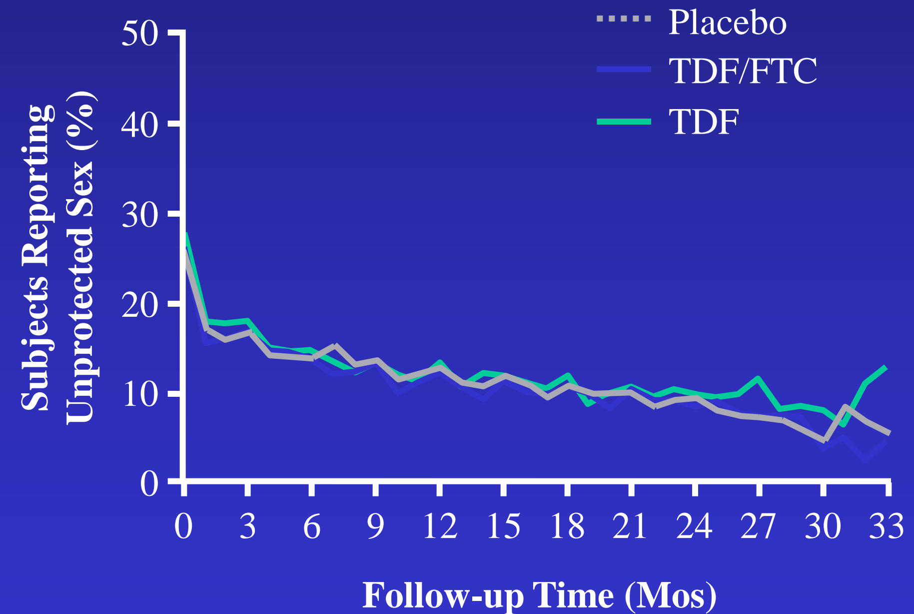
Anal sex partners in last 90 days **BASELINE n=539**	**Immediate** Median (IQR)	**Deferred** Median (IQR)
Total number of partners	10.5 (5-20)	10 (4-20)
Condomless partners, participant receptive	3 (1-5)	2 (1-5)
Condomless partners, participant insertive	2.5 (1-6)	3 (1-7)

Anal sex partners in last 90 days **MONTH 12 n=349**	**Immediate** Median (IQR)	**Deferred** Median (IQR)
Total number of partners	10 (3-24)	8 (3-15)
Condomless partners, participant receptive	3 (1-8)	2 (1-5)
Condomless partners, participant insertive	3 (1-8)	3 (1-6)

McCormack t al. CROI 2015. Abstract 22LB.

PrEP Trials Found *Decreasing* Risk Behavior Over Time





1. Grant RM, et al. N Engl J Med. 2010;363: 2587-2599.
2. Baeten JM, et al. N Engl J Med. 2012;367:399-410.

Unintended Consequences

- Resistance[1, 2]
  - To date, resistance has been identified in some of the individuals who were seroconverting around the time they started PrEP (5/8 persons in iPrex and Proud)
  - Highlights the need to rule out acute infection prior to starting PrEP in high risk populations
- Sexual Risk Behavior[3, 4]
  - Multiple studies have shown that there is no significant increase in HIV risk behaviors (STIs or condomless sex) in persons taking PrEP

1. McCormack t al. CROI 2015. Abstract 22LB. . 2. Liegler, T., et al. JID. 2014;210:1217-1227.
3. Grant RM, et al. N Engl J Med. 2010;363: 2587-2599. , 4. Baeten JM, et al. N Engl J Med. 2012;367:399-410.

Local PrEP Awareness Among MSM

- 32% of NHBS-MSM4 participants knew someone in Philadelphia who had taken PrEP
- 6% of HIV negative men had taken PrEP
- 59% of HIV negative MSM were willing to take PrEP
  - 62% of AA, 71% of Latino and 54% of whites
- Major reasons for not wanting to take PrEP
  - Low risk (37%), questions about side effects (35%), need to take daily (19%)

Data Source: PDPH/AACO National HIV Behavioral Surveillance among MSM4, 2014

Challenges to Implementing PrEP

- **Lack of knowledge about PrEP**
  - Providers aren’t sure how to prescribe it
  - Highest risk populations do not know about it
- Prescribing PrEP can be resource-intensive
  - Monitoring adherence
  - Coverage of Truvada
- Potential for stigma to undermine success

Primary Care Providers

- What it takes to prescribe PrEP well:
  - Conversation about risk
  - Baseline laboratory testing
  - * Write the prescription (insured patients)
  - Paperwork for patient assistance (uninsured)
  - At least q3 month follow-up and HIV test
  - Retention in care for highest risk groups
  - Ongoing conversation about risk

What Providers Think

- Felt current models of care would have to change
  - To accommodate the need for adherence counseling
  - To address mental health, case management, substances
- Felt screening/eligibility protocols are needed
- Need clarification of insurance reimbursement rates
- Need training of existing staff +/- new staff
- Recognized need for community recruitment campaigns to recruit those at highest risk

Arnold EA et al, PLoS One 2012

Challenges to Implementing PrEP

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  - Coverage of Truvada
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Medication Coverage

- Everyone (mostly) has access to PrEP
  - Uninsured: Gilead Patient Assistance Program
  - Insured (Medicaid): Covered ($3 co-pay)
  - Insured (Private Insurance): Variable co-pays, Co-pay card covers up to $250
- Patient Assistance time-consuming, which limits incorporation into PCP offices and utilizes valuable resources in all settings

Challenges to Implementing PrEP

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  - Monitoring adherence
  - Coverage of Truvada
- **Potential for stigma to undermine success**

AIDS pill as party drug?

Some HIV-negative men are using tenofovir instead of condoms, hoping it provides protection. Physicians say the practice could lead to more infections.

By DANIEL COSTELLO
Times Staff Writer

"Taking a T." That's what HIV-negative gay men call the growing practice of downing the AIDS drug tenofovir and, with fingers crossed, hoping it protects them from the virus during unprotected sex.

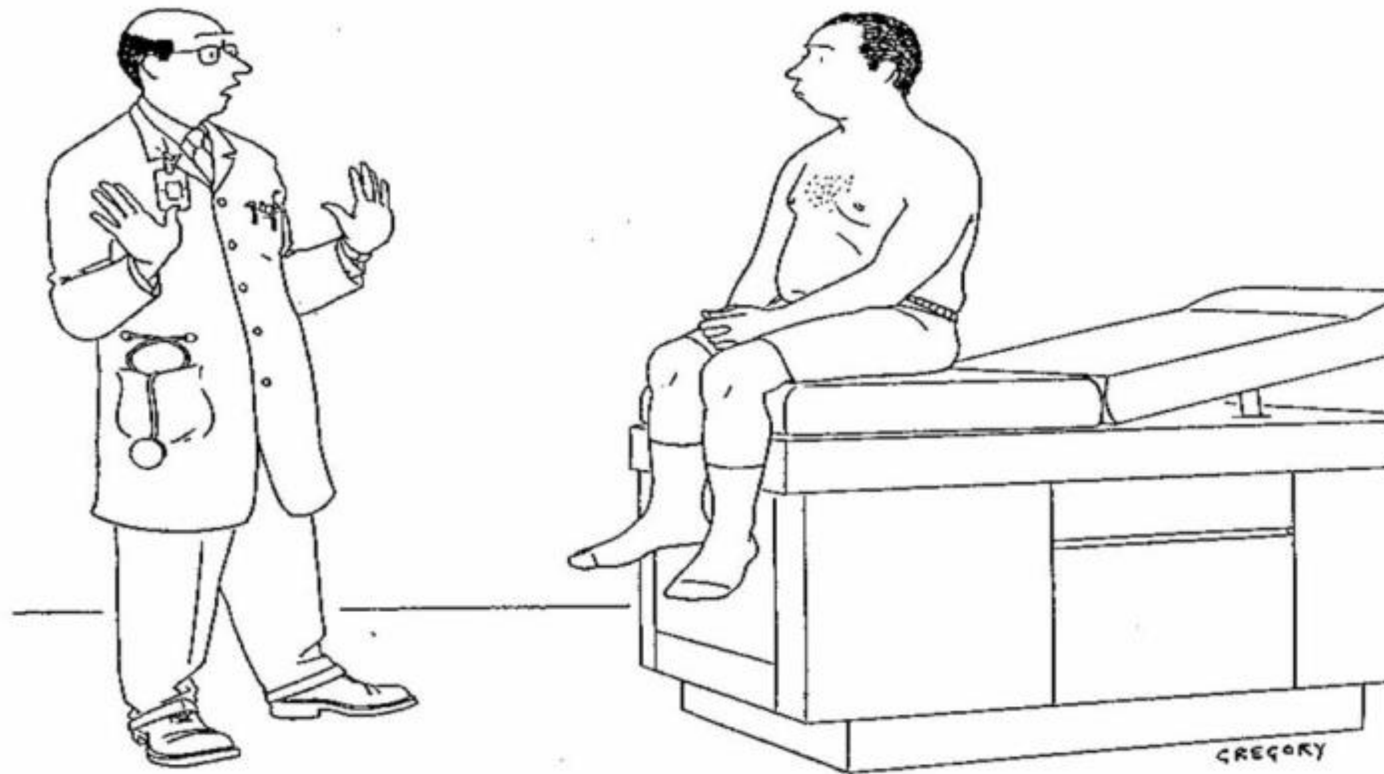
It's being sold in packets along with Viagra and Ecstasy in gay dance clubs — and even prescribed by physicians, say doctors and AIDS prevention experts. The trend has alarmed

Los Angeles Times

Monday, December 19, 2005

SHAKEN OR

STIRRED?



"Whoa—<u>way</u> too much information."

So who should know about PrEP?

EVERYONE

Questions/Discussion

The NHAS needs to guide all national and local HIV community planning efforts.

- How should the Delaware HIV Planning Council like to proceed with the research, discussion, and adoption of PrEP into our community planning efforts and/or HIV prevention toolbox?

Staff Report

Committee Report

MEMBERSHIP & COMMUNITY ENGAGEMENT (MCE) WORKING GROUP

CHRIS SKIVERS
MCE WORKING GROUP CHAMPION

Membership & Community Engagement Working Group

- **TASK**: Develop an evaluation process and create the documents needed
- Evaluation Process
  1. HPC support staff presentation of New Member Evaluation process and HPC need.
  2. Work group members will be provided a binder
  3. Each MCE work group member will score each applicant individually using developed score sheet.
  4. After all membership applications are evaluated, all applicant scores will be tallied and re-ordered using three point rating system.
  5. Discussions about any applicants will be held after all scoring is done.
  6. Submit a report to the Executive Committee Co-chairs with recommended applicants for membership to the DHPC.
- **NEXT STEPS:** A designated meeting solely for the purpose to evaluated each membership application.
  - Thursday, October 8, 2015

Committee Report

TESTING AND LINKAGE TO CARE (TLC)
RETENTION AND VIRAL SUPPRESSION (RVS)

Committee Report

SPECIAL COMMITTEE ON BYLAW AMENDMENTS

Synopsis of the Suggested Bylaw Edits with the Greatest Impact

1. Article III § 5. Voting Member Qualifications.
2. Article III § 11. Attendance.
3. Article III § 12. Member Removal.
4. Article IV § 3. Community Co-Chairs.
5. Article IV § 4. Election of Community Co-Chair.
6. Article V § 5. Annual Meeting.

Committee Recommendations

- Motion to amend something previously adopted: General Revision of the Bylaws (motion to accept the findings from the Special Committee on Bylaw Amendments).

Executive Committee Elections

Member Discussion

EMERGING TRENDS IN HIV PREVENTION/CARE IN DE

Announcements

- AIDS Walk Delaware
  - September 26, 2015
- Delaware HIV Planning Council Meeting
  - November 3, 2015
- Mem. & Com. Engagement WG Meeting
  - October 8, 2015
- Testing & linkage to Care WG Meeting
  - October 13, 2015
- Retention & Viral Suppression WG Meeting
  - TBD
- Systems of Care WG Meeting
  - TBD