



**Department  
of Health**



# HIV Pre-Exposure Prophylaxis (PrEP)

June 13, 2017

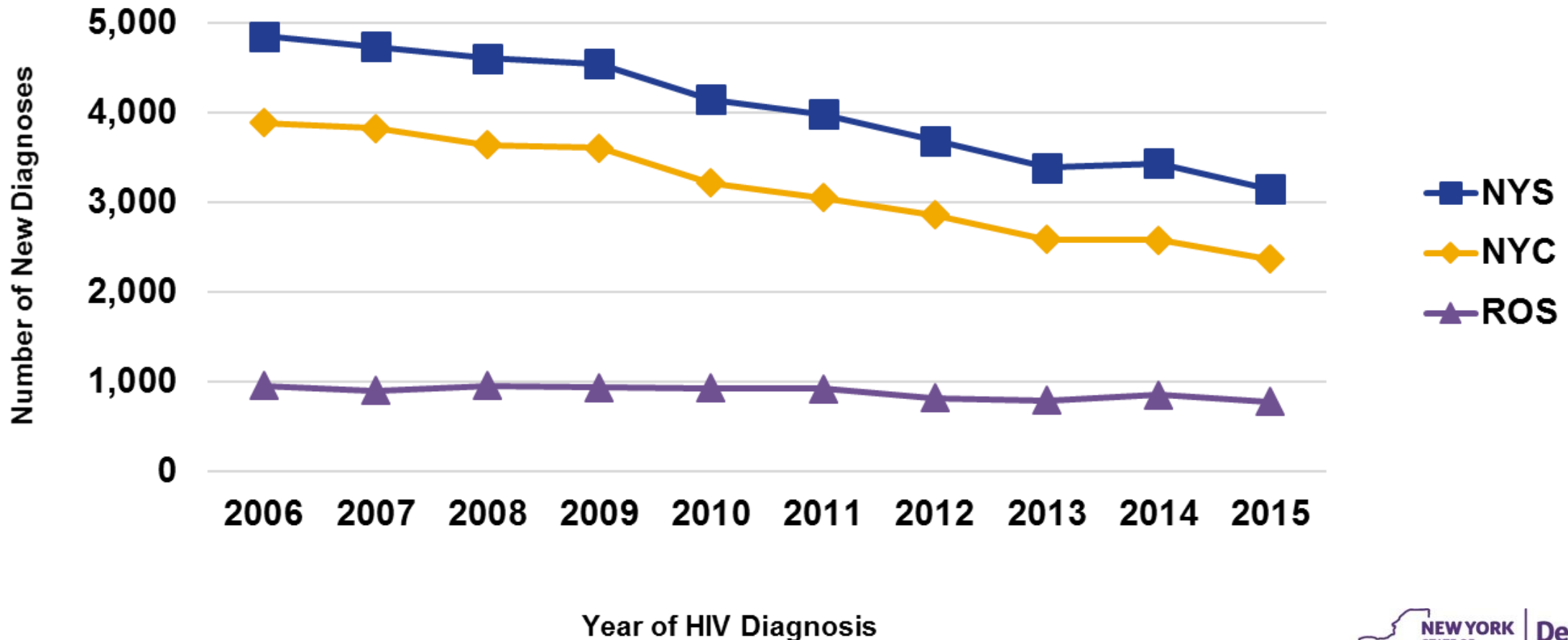
**Douglas Fish, MD**  
Medical Director, Division of Program Development and Management  
Health Home Webinar

# Outline

- **NY State HIV Surveillance data**
- **Ending the Epidemic (EtE)**
- **What is PrEP?**
- **Data supporting PrEP**
- **PrEP guidelines**
- **Increasing client awareness**
- **Increasing provider knowledge**
- **Community Based Organizations**
- **Additional Resources**

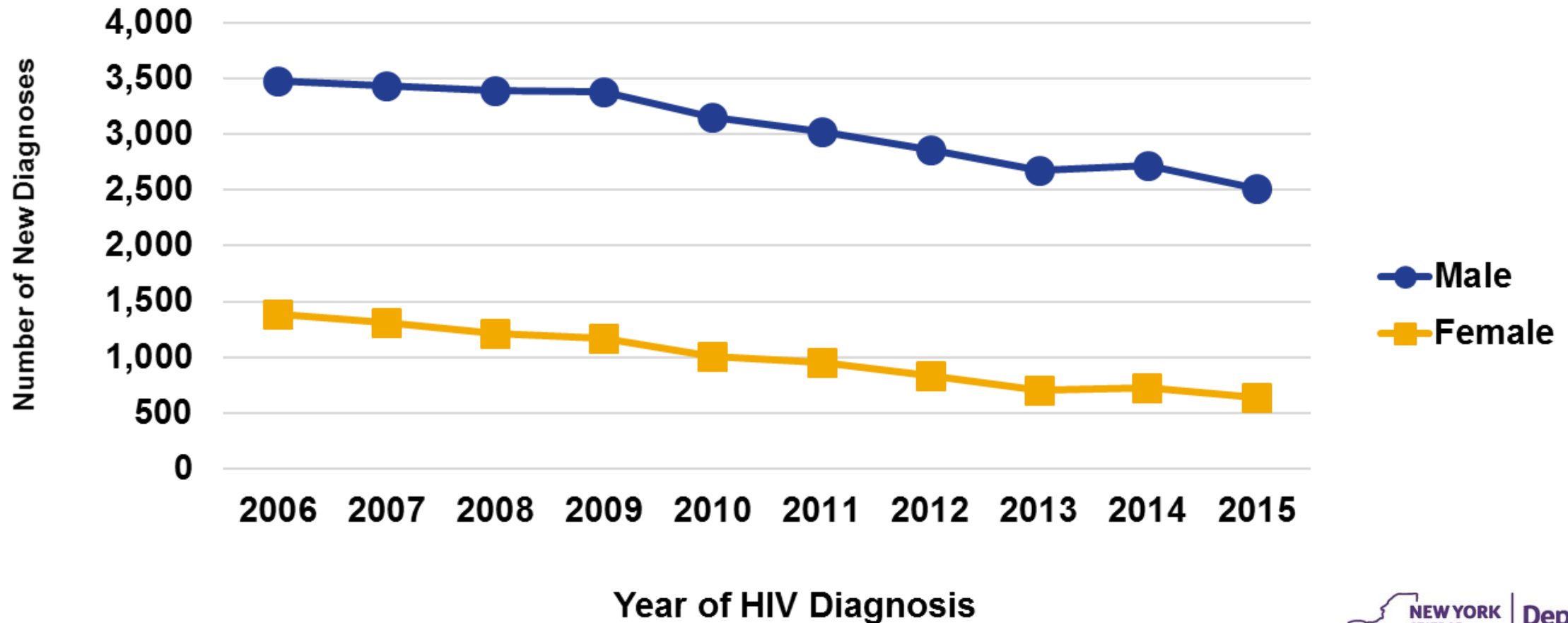
# Newly Diagnosed HIV Cases, 2006-2015 by Region and Selected Characteristics

# Persons Newly Diagnosed with HIV Infection in New York State by Region of Diagnosis, 2006-2015\*



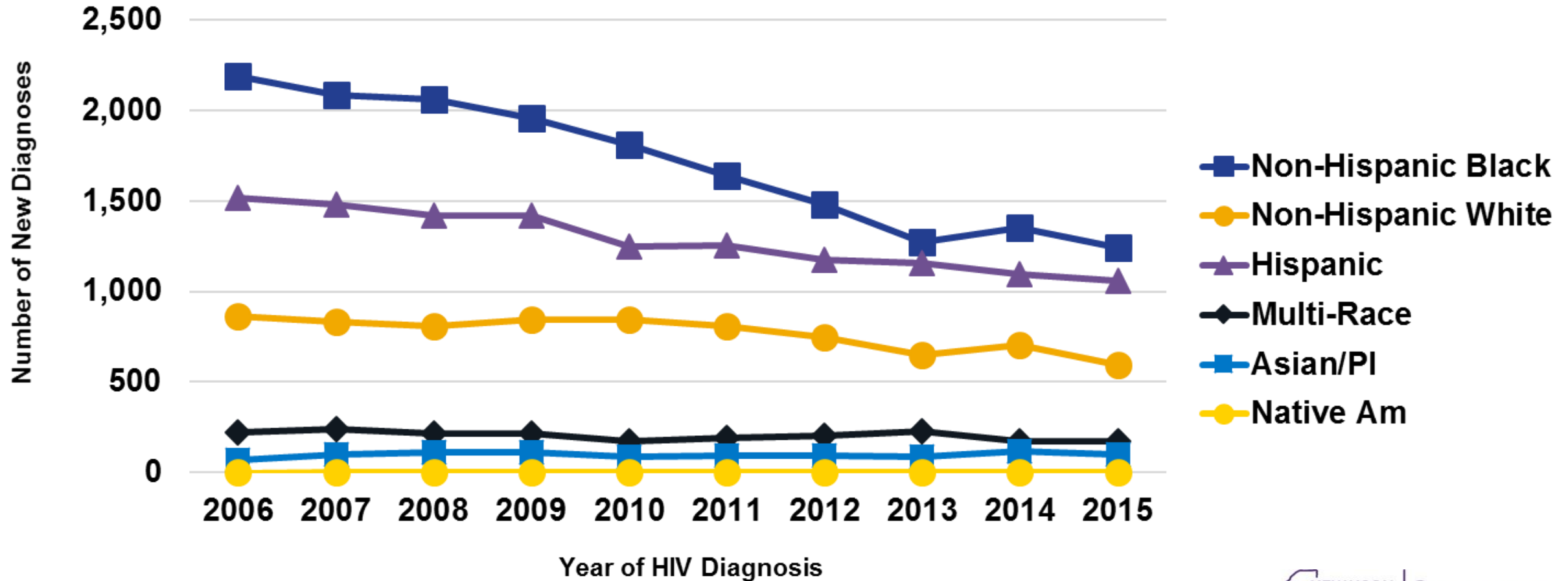
\*Data as of January 2017

# Persons Newly Diagnosed with HIV Infection by Sex Assigned at Birth, NYS, 2006-2015\*



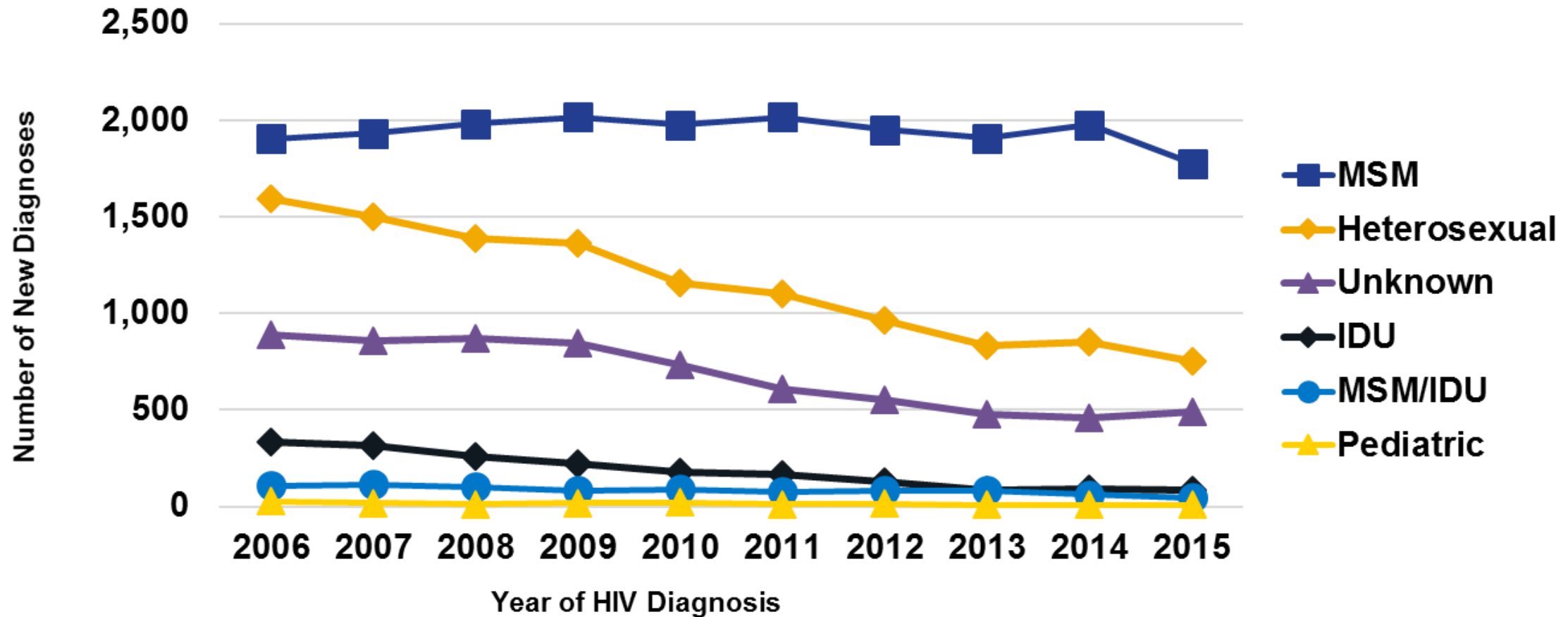
\*Data as of January 2017

# Persons Newly Diagnosed with HIV Infection by Race/Ethnicity, NYS, 2006-2015\*



\*Data as of January 2017

# Persons Newly Diagnosed with HIV Infection by Transmission Risk Group, NYS, 2006-2015\*



\*Data as of January 2017

# Plan to End the AIDS Epidemic

## A 3-Point plan announced by the Governor on June 29, 2014

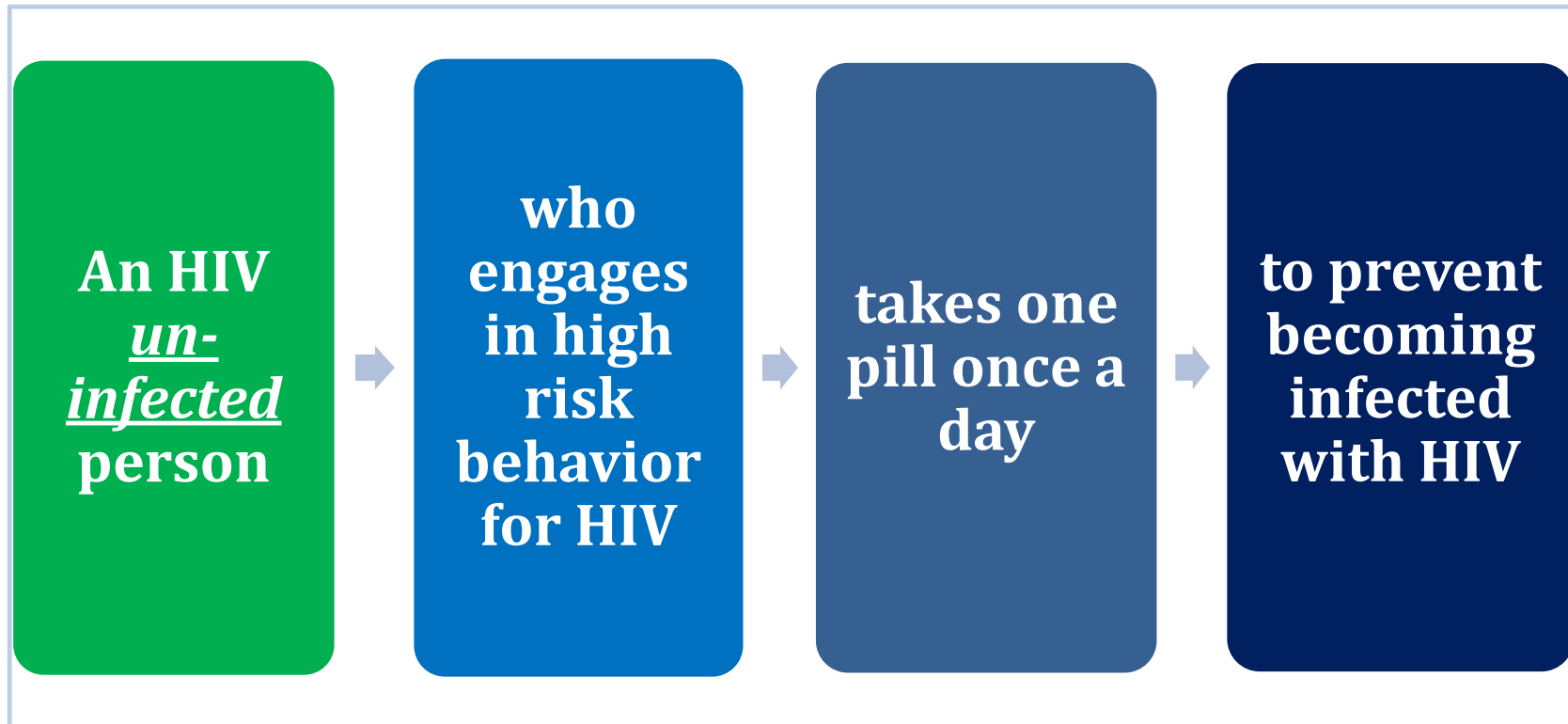
1. Identify all persons with HIV who remain undiagnosed and link them to health care.
2. Link and retain those with HIV in health care, to treat them with anti-HIV therapy to maximize virus suppression so they remain healthy and prevent further transmission.
3. Provide Pre-Exposure Prophylaxis (PrEP) for high risk persons to keep them HIV negative



**Reduce the number of new HIV infections to just 750 [from an estimated 3,000] by 2020**

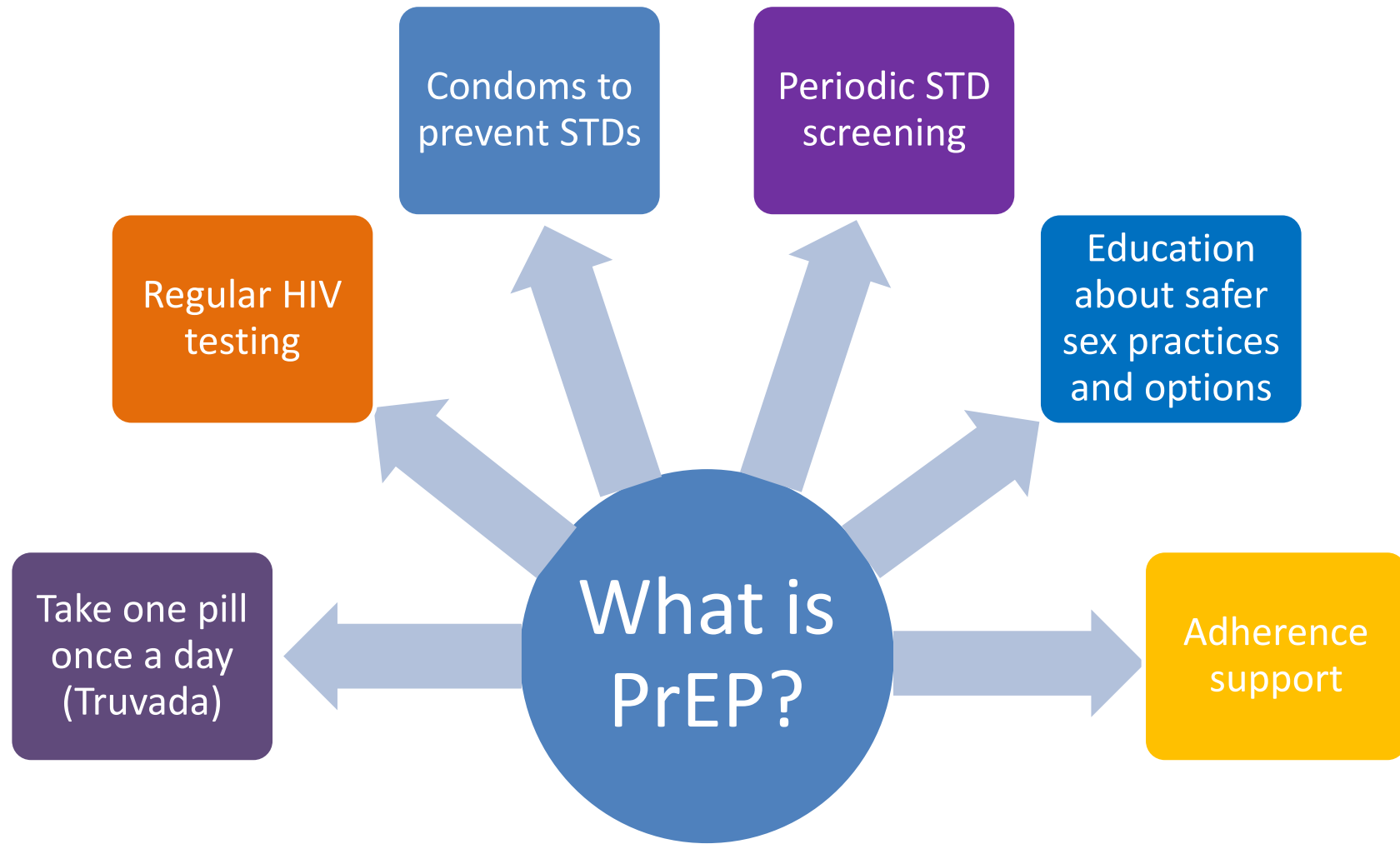


# PrEP is HIV Prevention



# Common Examples of Pre-Exposure Prophylaxis

- A woman taking birth control pills to prevent pregnancy
- A traveler taking anti-malarial medications when going to an area where there is high likelihood of exposure to malaria
- A person taking antibiotics prior to dental surgery to prevent infection
- A person with HIV taking certain medications to prevent an opportunistic infection



# 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 <sup>[1]</sup> (N = 2499)	MSM, transgender women, 11 sites in US, South America, Africa, Thailand	TDF/FTC	36	64	44 (15-63)
Partners PrEP <sup>[2]</sup> (N = 4747)	Serodiscordant couples in Africa	TDF	17	52	67 (44-81)
		TDF/FTC	13		75 (55-87)
TDF2 <sup>[3]</sup> (N = 1219)	Heterosexual males and females in Botswana	TDF/FTC	9	24	62 (21-83)
Thai IDU <sup>[4]</sup> (N = 2413)	Volunteers from 17 drug Thai treatment centers	TDF	17	33	49 (10-72)

- 2 additional trials of PrEP (FEM-PrEP<sup>[5]</sup> and VOICE<sup>[6]</sup>), both conducted among high-risk African women, did not demonstrate protection against HIV; in both trials, PrEP adherence was very low


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. Murrain J, et al. CROI 2013. Abstract 26LB. *Clinical Care Options*

# PrEP Works, but Adherence Is Critical

Study	Efficacy Overall, %	Blood Samples With TFV Detected, %	Efficacy By Blood Detection of TFV, %
iPrEx <sup>[1]</sup>	44	51	92
iPrEx OLE <sup>[2]</sup>	49	71	NR
Partners PrEP <sup>[3]</sup>	67 (TDF) 75 (TDF/FTC)	81	86 (TDF) 90 (TDF/FTC)
TDF2 <sup>[4]</sup>	62	80	85
Thai IDU <sup>[5]</sup>	49	67	74
Fem-PrEP <sup>[6]</sup>	No efficacy	< 30	NR
VOICE <sup>[7]</sup>	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. Murrain J, et al. CROI 2013. Abstract 26LB. *Clinical Care Options*

# IPrEx – Phase 3, Placebo-controlled Study with MSM and Trans-women Who have Sex with Men

Received study drug: 1,251		Received placebo: 1,248	
36 infections for an overall reduction of 42.3%		64 infections	
50% adherence	➔	50.2% reduction	
90% adherence	➔	72.8% reduction	

# Other Important Findings from IPrEx

Concern	Findings
Patients will not tolerate side effects	Medication was well-tolerated
PrEP will lead to decrease in condom use	Participants actually increased condom use
PrEP will lead to increase in risk taking	Participants actually decreased their number of sex partners
PrEP will lead to drug resistance which will complicate treatment	No subsequent drug resistance in those who became infected

- Efficacy was highest (58%) among those at highest risk as measured by self report of unprotected receptive anal intercourse at intake

# FDA Approval for PrEP

- Tenofovir [TDF] 300 mg/emtricitabine [FTC] 200 mg (Truvada) [TRV] approved by FDA, July 2012

<http://www.fda.gov/downloads/NewsEvents/Newsroom/FactSheets/UCM312279.pdf>



# CDC Guidance

- Pre-exposure Prophylaxis for the Prevention of HIV Infection in the United States 2014 – A Clinical Practice Guideline
  - <http://www.cdc.gov/hiv/pdf/PrEPguidelines2014.pdf>
- Pre-exposure Prophylaxis for the Prevention of HIV Infection in the United States 2014 - Clinical Providers Supplement
  - <http://www.cdc.gov/hiv/pdf/PrEPProviderSupplement2014.pdf>

<http://www.cdc.gov/hiv/guidelines/preventing.html>

# New York State Guidance

## Guidance For the Use of Pre-Exposure Prophylaxis (PrEP) to Prevent HIV Transmission (1/14/2014)

### October 2015 Update

- PrEP Payment Options have been compiled by the New York State Department of Health (see [Appendix D](#)). The options include Medicaid, PrEP Assistance Program (PrEP-AP), the Gilead Co-Pay Coupon Card, the Gilead Medication Assistance Program, the Patient Access Network, and most private insurances.
- Updated information about prescribing PrEP for adolescents is provided (see [Section II](#)).
- Updated information about managing patients on PrEP who present with a positive HIV screening test or with symptoms suggestive of acute HIV infection is provided (see [Section VIII](#)).

**INDIVIDUALS WITH WHOM PREP SHOULD BE DISCUSSED**

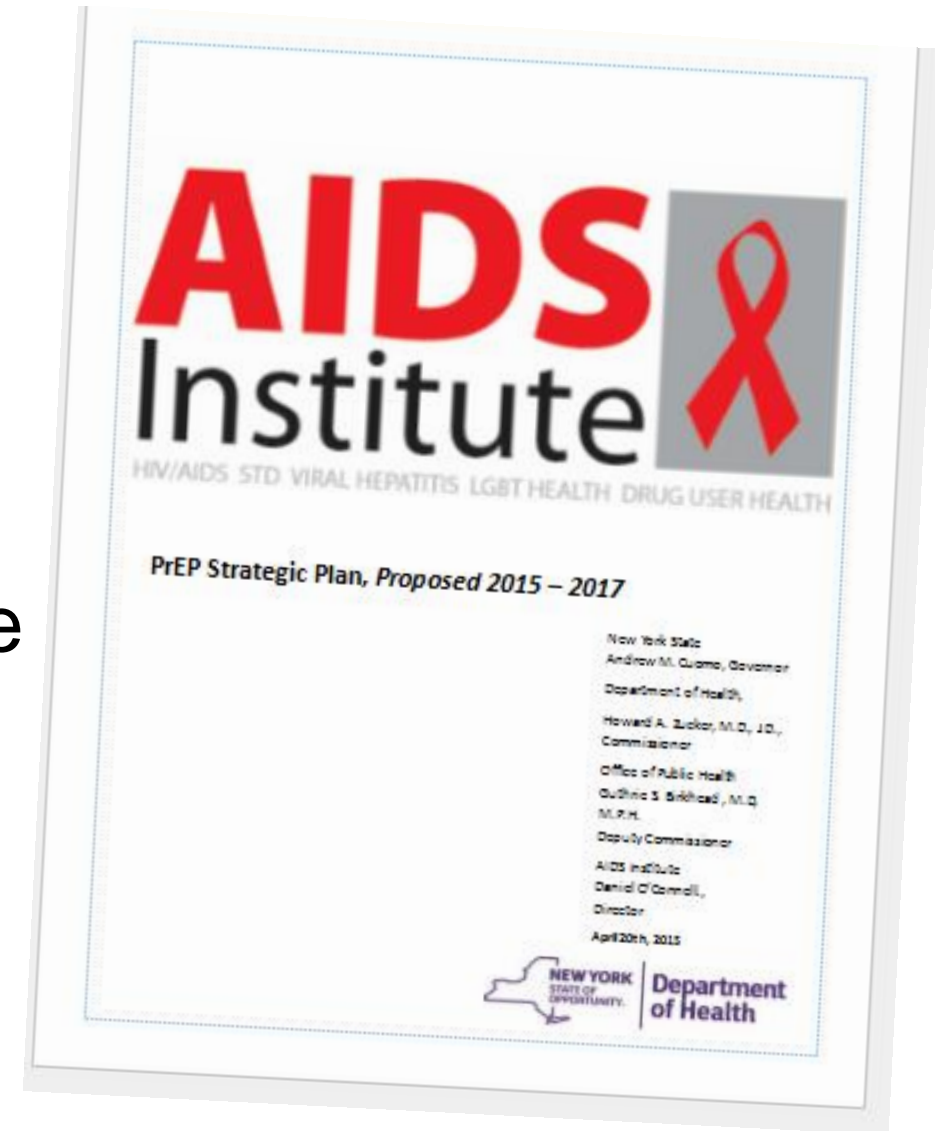
- **Men and transgender women who engage in unprotected anal intercourse with men<sup>14,15,a</sup>**
- **Women or men attempting to conceive with an HIV-infected partner and women at ongoing risk for acquisition of HIV during pregnancy<sup>b</sup>**
- **Individuals who:**
  - **Are in a sexual relationship with a known HIV-infected partner**
  - **Have multiple or anonymous sexual partners**
  - **Engage in sexual activity at sex parties or other high-risk venues**
  - **Are involved in transactional sex, such as sex for money, drugs, or housing, including commercial sex workers and their clients**
  - **Have been diagnosed with at least one sexually transmitted infection (STI) in the last 12 months<sup>16,17</sup>**
  - **Report recreational use of mood-altering substances during sex (e.g. alcohol, methamphetamine,<sup>14,15,18,19</sup> cocaine, and ecstasy)**
  - **Report injecting substances including hormones**
  - **Are receiving non-occupational post-exposure prophylaxis (nPEP) and demonstrate continued high-risk behavior or have used multiple courses of nPEP<sup>20</sup>**

<sup>a</sup> A 7-item screening index has been developed to identify MSM who are at higher risk of HIV seroconversion (see [Appendix A](#)).

<sup>b</sup> Ongoing risk for sero-discordant couples during pregnancy includes lack of consistent use of barrier protection, lack of complete viral suppression in the HIV-infected partner for at least 6 months, or both.

# New York State Priorities

- ✓ Increase client awareness
- ✓ Increase clinical provider knowledge
- ✓ Increase number of clinicians prescribing PrEP
- ✓ Increase access to PrEP and healthcare
- ✓ Develop a system that can incorporate future developments
- ✓ Research



# Increasing Client Awareness

## PrEPforSex.org



- Resources for Consumers
- Materials
- Women's Information Tab
- Videos
  - Beginning the Process
  - Affordability
  - Remembering to take PrEP
  - Condom Use
  - Why PrEP?
  - Side Effects
  - PrEP and Emotions

# Increase Clinical Provider Knowledge

- **Clinical Education Initiative**

- ceitraining.org
- 20 minute video
- Webinars
- Nametag information card

- **CEI Line**

- 1-866-637-2342

- **Voluntary Provider Directory**

- **To Sign Up**

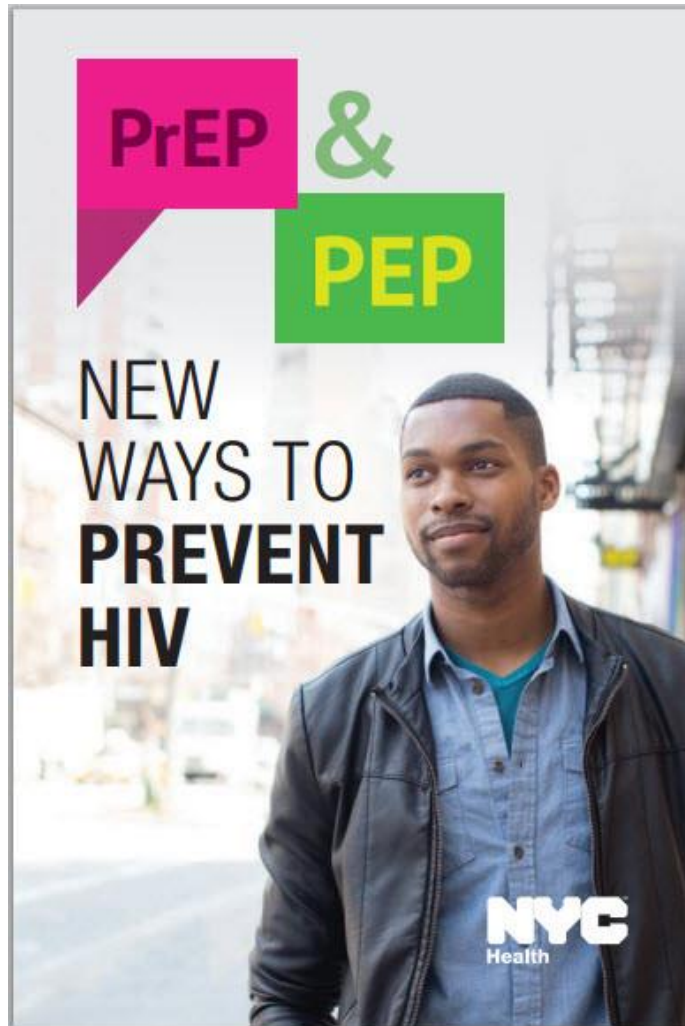
<https://www.surveymonkey.com/s/S329ZK5>

- **To Access Directory**

<http://www.health.ny.gov/diseases/aids/general/prep/docs/directory.pdf>

The screenshot displays the CEI website interface. At the top, the logo for CEI (Clinical Education Initiative) is shown alongside the text 'HIV, HCV & STD Clinical Education Initiative' and 'New York State Department of Health • AIDS Institute'. Navigation links include 'Home', 'CE Courses', 'Learning Modules', 'Mobile Tools', 'Resources', and 'Support'. A search bar is located on the right. The main content area features a video player for 'HIV Prevention with Pre-Exposure Prophylaxis' (Resource ID: CM342). The presenter is identified as Demetre Daskalakis, MD, MPH, Associate Professor of Medicine and Medical Director of the HIV Program at Mt. Sinai School of Medicine, New York City. A list of supporting documents is provided, including 'Potential Candidates for PrEP', 'HRI-MSM Risk Index', 'Pre-Prescription Assessment Checklist', and 'Guidance for the Use of Pre-Exposure Prophylaxis (PrEP) to Prevent HIV Transmission'. A presenter bio for Dr. Daskalakis is also included, detailing his background and role at the New York City Department of Health and Mental Hygiene.

# Increase Clinical Provider Knowledge



## PrEP DETAILING

- Targeting 500 providers outside of NYC
- Provide PrEP Detailing Kit
- 175 providers have received PrEP Detailing visits to date
- 125 registered with the NYSDOH PrEP Voluntary Provider Directory

# Increase Non-Clinical Provider Knowledge

## Education and Training Initiative

### Topics

- Role of CBO's in Promoting Pre-Exposure Prophylaxis for HIV
- Role of Non-clinicians in Promoting PrEP
- HIV Testing in NYS
- Healthy Sex! Linking Gay Men and MSM to Sexual Health Services
- Achieving and Sustaining Viral Suppression Among Women  
(ETE series – PrEP module)

<http://www.hivtrainingny.org/>



# Relevance to Health Homes/Care Management Agencies

- **HIV Infection is a HH qualifying condition.**
- **Awareness of promotion of efforts to End the Epidemic**
- **Awareness and promotion of PEP and PrEP services**
- **Assisting with consumer advocacy and navigation**
- **Each one of us has an HIV status – Do you know yours?**

<http://www.hivtrainingny.org/>

# Toolkit for Community Based Organizations

Action Steps for Community Based Organizations	
<i>At the Organizational Level</i>	<i>At the Programmatic Level</i>
✓ Agency leadership and governing board should be well informed about PrEP	✓ Integrate messages about PrEP into all prevention services
✓ Train your staff about PrEP	✓ Provide community presentations on PrEP
✓ Highlight PrEP on your agency website	✓ Integrate messages about PrEP into HIV testing services
✓ Include PrEP in your agency's social media messaging	✓ As appropriate, link high risk, HIV- clients to providers who prescribe PrEP
✓ Provide links on key pages of your agency's website to the NYS PrEP campaign at: <a href="http://www.prepforsex.org">www.prepforsex.org</a>	✓ Assist clients with accessing financial assistance for PrEP
✓ Be familiar with medical providers who prescribe PrEP in your region by reviewing the NYSDOH Voluntary Directory or PrEP/PEP providers at: <a href="http://www.health.ny.gov/diseases/aids/general/prep/">http://www.health.ny.gov/diseases/aids/general/prep/</a>	✓ Establish linkage agreements with medical providers to provide their PrEP patients with prevention and supportive services
✓ Take an active role encouraging medical providers in the region to prescribe PrEP	✓ Partner with CBOs, local health departments and DOH regional offices to link high risk HIV- individuals to PrEP services
✓ Address community misconceptions about PrEP	✓ Offer support services and/or education for clients on PrEP
	✓ Create an environment where clients can openly consider if PrEP is an option for them

# Increase Access to PrEP and Healthcare Voluntary Provider Directory

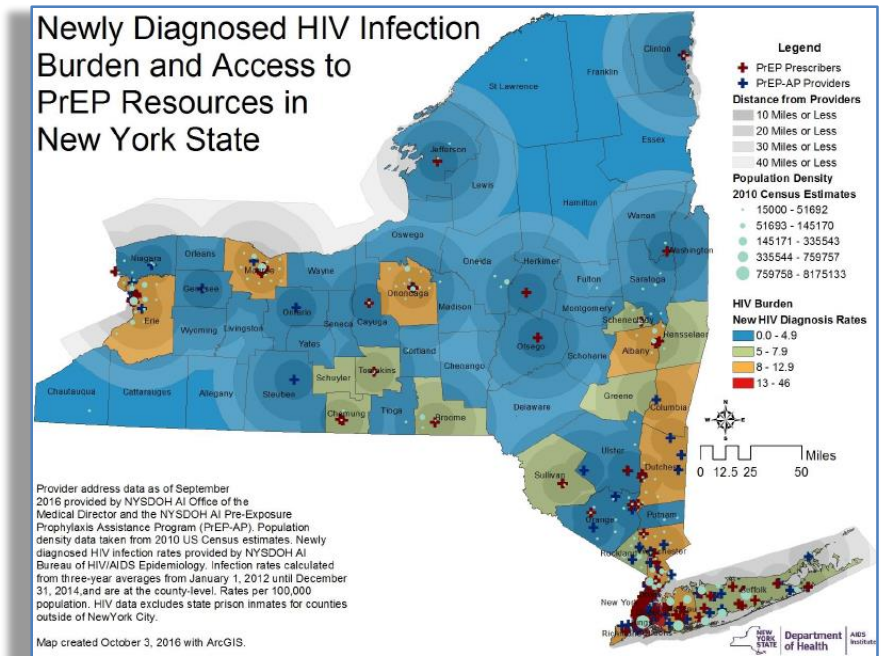
- PrEP prescribers are present in areas of the state with the highest risk, thus highest need, of PrEP.
- 350 registered PrEP prescribers (2/22/17)
  - 25% increase compared to October
  - 47 counties (up from 39 counties in October)

## To Sign Up

<https://www.surveymonkey.com/s/S329ZK5>

## To Access Directory

<http://www.health.ny.gov/diseases/aids/general/prep/docs/directory.pdf>



# Increase Access to PrEP and Healthcare Payment Options

## Payment Options for Pre-Exposure Prophylaxis (PrEP)

Health Coverage and New York State Department of Health Sponsored Programs	
Private Insurance	<ul style="list-style-type: none"> <li>Most private insurances cover PrEP.</li> <li>Coverage varies based on plan. There may be deductibles and co-payments.</li> </ul>
Medicaid	<p><a href="http://www.health.ny.gov/diseases/aids/general/prep/truvada.htm">www.health.ny.gov/diseases/aids/general/prep/truvada.htm</a></p> <ul style="list-style-type: none"> <li>PrEP prescription costs, medical appointments, and lab tests covered.</li> <li>Prior approval is required and renewed every 3 months.</li> </ul>
PrEP Assistance Program (PrEP-AP)	<p><a href="http://www.health.ny.gov/diseases/aids/general/resources/adap/">www.health.ny.gov/diseases/aids/general/resources/adap/</a></p> <p><b>PrEP-AP- (800)-542-2437 (Hotline)</b></p> <ul style="list-style-type: none"> <li>PrEP-AP serves HIV-negative persons who are residents of New York State who are uninsured or underinsured. Financial eligibility is based on 435% of the Federal Poverty Level (FPL).</li> <li>Covers costs of doctor's visits and lab testing for uninsured and underinsured individuals. Services include HIV, STI/STD testing, counseling, and supportive primary care services consistent with clinical guidelines for PrEP.</li> <li>PrEP medication will be provided to uninsured or underinsured individuals through the manufacturer patient assistance programs (PAP) (listed below).</li> <li>Providers that are enrolled in the New York State Medicaid Program are eligible to enroll in PrEP-AP. Please contact the ADAP Provider Relations Section at (518) 459-1641 or email <a href="mailto:damaris.feliciano@health.ny.gov">damarys.feliciano@health.ny.gov</a> for more information on becoming a PrEP-AP provider.</li> <li>Providers are responsible for assisting patients with the PAP application to receive Truvada as indicated for PrEP.</li> <li>PrEP-AP is available for all at risk individuals regardless of age.</li> </ul>
Medication Assistance Programs	
Gilead Co-Pay Coupon Card	<p><a href="http://www.gileadcopay.com">www.gileadcopay.com</a> - (877)-505-6986</p> <ul style="list-style-type: none"> <li>Covers up to \$300/month in prescription co-payments.</li> <li>Patient must have insurance.</li> <li>Patient must NOT be enrolled in Medicare or Medicaid.</li> <li>No income eligibility requirement.</li> <li>Not available for patients under 18 years of age</li> <li>Not available for patients under 18 years of age</li> </ul>
Gilead Truvada for PrEP Medication Assistance Program	<p><a href="http://www.start.truvada.com/individual">www.start.truvada.com/individual</a> - (855)-330-5479</p> <ul style="list-style-type: none"> <li>Covers prescription costs.</li> <li>Patient must be uninsured or their insurance does not cover any prescription cost.</li> <li>Patient must have annual income less than 500% FPL</li> <li>Not available for patients under 18 years of age</li> </ul>

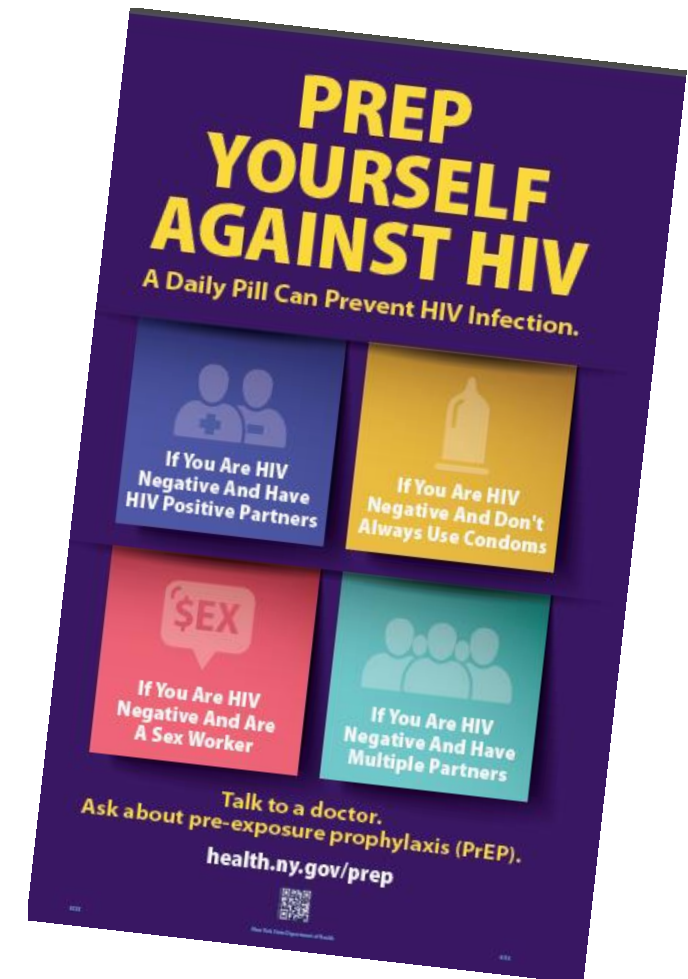
New York State Department of Health AIDS Institute - Updated April 2016



# Increase Access to PrEP and Healthcare

## Models of Care

- PrEP Specialist
- Local Health Department STD Clinic
- Syringe Exchange Programs
- Planned Parenthood
- Telemedicine



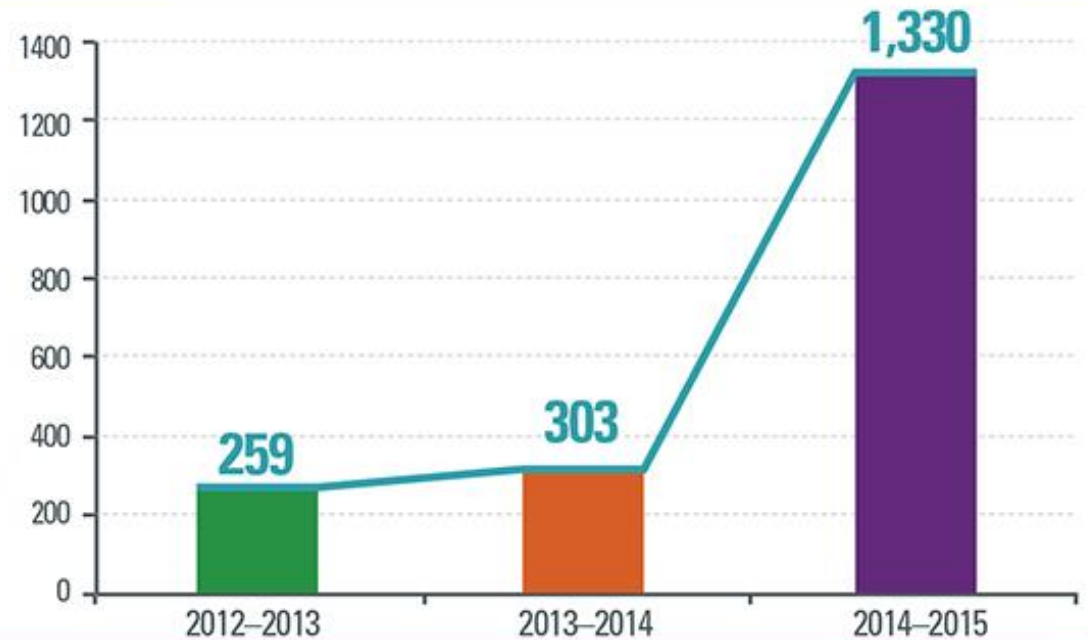
## Increasing PrEP Use

### A focused effort by New York State

to increase PrEP uptake started  
in June 2014 and included:

1. **Provider Training**
2. **Raising Awareness**
3. **Ensuring Medicaid Coverage**

Number of  
New York  
State Medicaid  
beneficiaries  
receiving PrEP.



SOURCE: NYS Medicaid Data Warehouse (based on Medicaid data loaded through July 2015).

## New York State and PrEP

- ✓ At the 2016 21<sup>st</sup> International AIDS Conference in Durban, South Africa Keith Rawlings, MD presented data on the number of people in the US on PrEP.
- ✓ **We're proud to say that New York State had the most people on PrEP per capita.**

**GET TESTED.  
TREAT EARLY.  
STAY SAFE.**

**End AIDS.**



[health.ny.gov/ete](http://health.ny.gov/ete)

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