Elizabeth Glaser Pediatric AIDS Foundation

Children's National ™

Pre and Post Exposure Prophylaxis for HIV

Natella Rakhmanina, MD, PhD
Professor of Pediatrics
George Washington University
Senior Technical Advisor
Elizabeth Glaser Pediatric AIDS Foundation

HIV Infection Sources

- Exposure to HIV-infected blood, genital secretions, rectal secretions, breast milk or other bodily fluid visibly contaminated with blood through:
  - unprotected sex
  - protected sex with condom failure
  - intravenous drug use
  - sexual assault
  - selected oral mucosa and skin exposures

Estimated Risks for HIV Transmission, USA

Types of exposure	Estimated Risk
Needle-sharing exposure to an infected source	0.67% (1 in 150)
Receptive anal intercourse with an infected source	0.5% (1 in 200) / 3.0% (6 in 200)
Receptive vaginal intercourse with an infected source	0.1% (1 in 1000) / 0.2% (2 in 1000)
Insertive anal intercourse with an infected source	0.065% (1 in 1500)
Insertive vaginal intercourse with an infected source	0.05% (1 in 2000)
Oral sex with ejaculation with an infected source	Conflicting data-however, risk is considered to be low

New York State Department of Health AIDS Institute: HIV Prophylaxis following Non-Occupational Exposure. Albany, NY: Available at: *http://www.hivguidelines.org/wp-content/uploads/2013/09/hiv-prophylaxis-following-non-occupational-exposure.pdf*.

Estimated Risks for HIV Transmission, BHIVA-BASHH,UK

Risk of HIV transmission per exposure from a known HIV-positive individual not on ART.

Type of exposure	Estimated risk of HIV transmission per exposure from a known HIV-positive individual not on ART	References
Receptive anal intercourse	1 in 90	10-16
Receptive anal intercourse with ejaculation	1 in 65	10-17
Receptive anal intercourse no ejaculation	1 in 170	17
Insertive anal intercourse	1 in 666	10,12,13,18
Insertive anal intercourse not circumcised	1 in 161	17
Insertive anal intercourse and circumcised	1 in 909	17
Receptive vaginal intercourse	1 in 1000	10,15,19-15
Insertive vaginal intercourse	1 in 1219	14,15,19-25
Semen splash to eye	<1 in 10,000	26
Receptive oral sex (giving fellatio)	<1 in 10,000	13,20,25,27
Insertive oral sex (receiving fellatio)	<1 in 10,000	12,25
Blood transfusion (one unit)	1 in 1	28
Needlestick injury	1 in 333	27,29,30
Sharing injecting equipment (includes chemsex)	1 in 149	26
Human bite	<1 in 10,000	31,32

ART: antiretroviral therapy.

Pre-Exposure **P**rophylaxis **(PreP)**

- Prevention of mother-to-child transmission (PMTCT)- gold standard - >98% efficient!
- Occupational PreP
- Non-occupational PreP

PreP Quiz

The most effective non-occupational PrEP is (select one correct answer):

a. Not to have sex
b. Not to have sex
c. Not to have sex
d. Not to have sex
e. All of the above

USA

US Public Health Service

PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES - 2014

A CLINICAL PRACTICE GUIDELINE

BHIVA-BASHH, UK

British HIV Association BHIVA

BASHH

BHIVA–BASHH Position Statement on PrEP in UK

Second Update May 2016

Sheena McCormack, Sarah Fidler, Laura Waters, Yusef Azad, Tristan Barber, Gus Cairns, Valentina Cambiano, Dan Clutterbuck, Monica Desai, David Dunn, Julie Fox, Yvonne Gilleece, Margaret Kingston, Charles Lacey, Heather Leake Date, Fabiola Martin, Alan McOwan, Anthony Nardone, Koh-Jun Ong, Roger Pebody, Andrew Phillips, Mags Portman, Killian Quinn, Iain Reeves, Ann Sullivan, George Valiotis

PreP Approaches

- Persons at high risk for HIV based on background incidence (>2%) or recent diagnosis of incident STI
- Individuals who have used PEP > 2 times in the past year
- People who inject drugs and who share injection equipment, inject 1 or more times a day, or inject cocaine or methamphetamines
- **PreP should be part of an integrated risk-reduction strategy**
- **Regular assessment of the patients' risk is required**

PreP CDC Guidelines

PreP should be considered for:

- Sexually-active adult MSM (men who have sex with men) at substantial risk of HIV acquisition **(IA)**
- Adult heterosexually active men and women who are at substantial risk of HIV acquisition **(IA)**
- Adult injection drug users (IDU) at substantial risk of HIV acquisition **(IA)**
- Heterosexually-active women and men whose partners are known to have HIV infection (i.e., HIV-discordant couples) considering conception and pregnancy **(IIB)**

Preexposure Prophylaxis for the Prevention of HIV Infection in the US, 2014 Clinical Practice Guideline

PreP in the USA

- As the first country to approve PrEP in 2012, USA has the most experience to date on PrEP implementation

- PrEP prescriptions in the US show very low initiation of PrEP among youth <25 years - 7.6% of all prescriptions

PreP Choice

- Daily oral PrEP with the fixed-dose combination of **Tenofovir Disoproxil Fumarate (TDF)+Emtricitabine (FTC)** (**Truvada®**) - safe and effective in reducing the risk of sexual HIV acquisition in adults
- Acute and chronic HIV infection must be excluded by symptom history and HIV testing immediately **before** PrEP is prescribed
- HIV infection should be assessed **at least every 3 months** while patients are using PrEP
- Renal function should be assessed **at baseline** and monitored at least **every 6 mon**ths while on PrEP

Sweden – TAF for PreP

Referensgruppen för Antiviral Terapi (RAV)

Antiretroviral behandling av hivinfektion 2016

– *Behandlingsrekommendation*

Referensgruppen för Antiviral Terapi (RAV) och Läkemedelsverket har sedan 2002 regelbundet publicerat nationella rekommendationer för antiretroviral behandling av hivinfektion. I februari 2016 reviderade en arbetsgrupp under ledning av RAV rekommendationerna på nytt.

Väsentliga nyheter i 2016 års behandlingsriktlinjer:

- Sedan föregående uppdatering har tenofovir alafenamid (TAF) godkänts. TAF har fördelar jämfört med tenofovir disoproxil fumarat (TDF) och rekommenderas i de flesta fall framför TDF.
- Förstahandsrekommendationer till tidigare obehandlade individer innefattar dolutegravir, boostrat darunavir eller efavirenz tillsammans med antingen abakavir/lamivudin eller tenofovir (TDF/TAF)/emtricitabin.
- Preexpositionsprofylax (PrEP) rekommenderas till högriskpersoner

Rekommendationerna är som tidigare evidensgraderade och kompletterade med referenser.

Gender matters!

- To build up to protective levels, PrEP takes 20 days in vaginal tissue versus only 7 days in rectal tissue

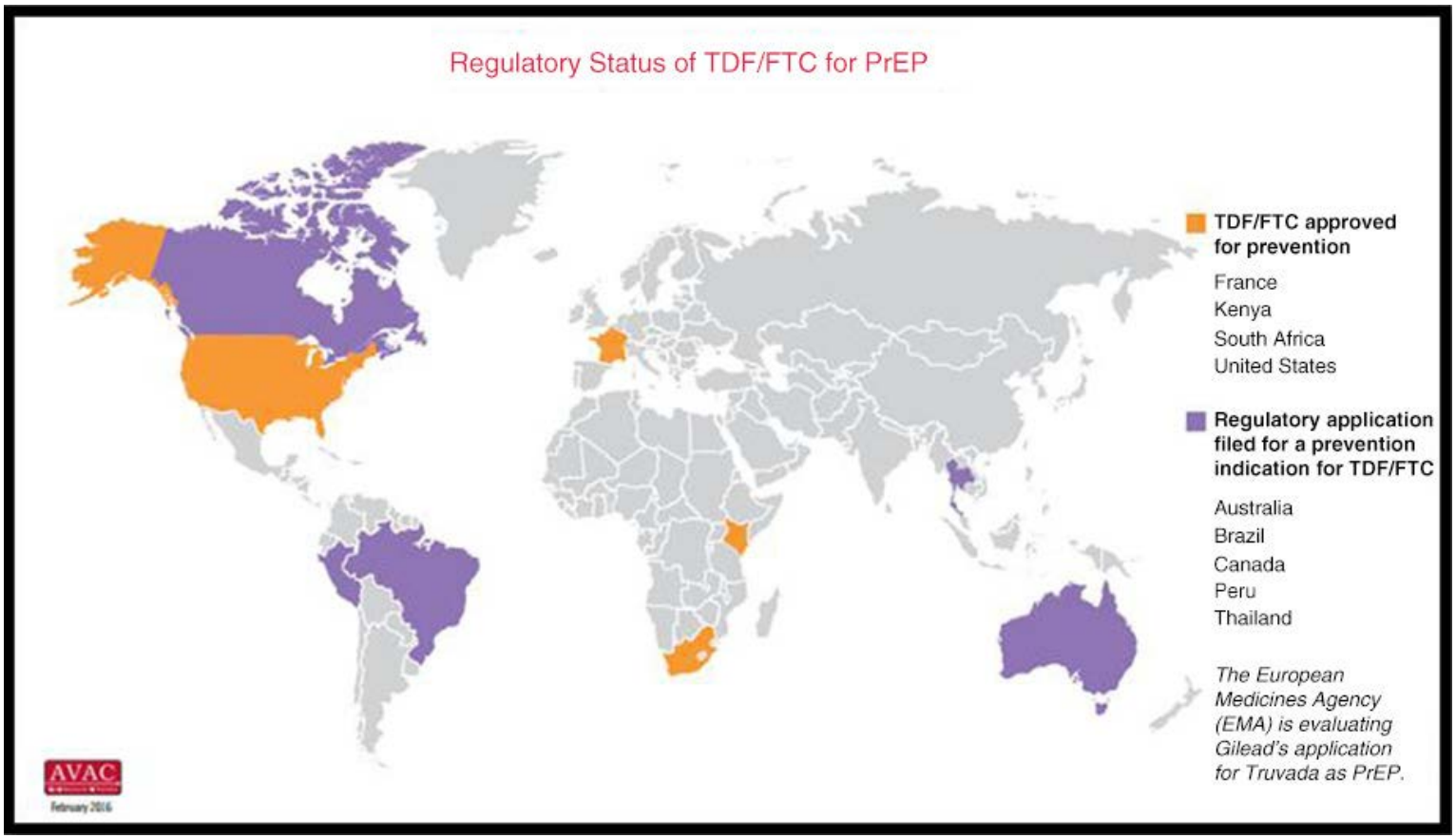
Sun	Mon	Tue	Wed	Thu	Fri	Sat
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21

20 days for vaginal protection

Sun	Mon	Tue	Wed	Thu	Fri	Sat
1	2	3	4	5	6	7

7 days for rectal protection

Truvada® (TDF/FTC) for PreP



J Int AIDS So.j Int AIDS Soc. 2016; 19(7Suppl 6): 21107.

PreP for Adolescents

- Currently the data on the efficacy and safety of PrEP for adolescents < 18 years are limited
- Registration trials on the way in the USA and South Africa for patients<18 yrs of age:
  - ATN 113 (Clinical trial NCT01769456), USA, MSM aged 15-17 yrs
  - CHAMPS PillsPlus (Clinical trials NCT02213328), South Africa, females and males 5-19 years of age
  - HIV Prevention Trials Network (HPTN) 082, women and males 16-25 yrs in South Africa and Zimbabwe
  - IMPAACT 2009, adolescents and women, South Africa, Zimbabwe, Malawi, and Uganda including <18 years of age
- The behavioral intervention as well as ongoing risk reduction counseling sessions have been found to be highly acceptable among a sample of racially diverse YMSM (*J HIV AIDS Soc Serv 2013;12(3-4))*

PreP Considerations in Adolescents

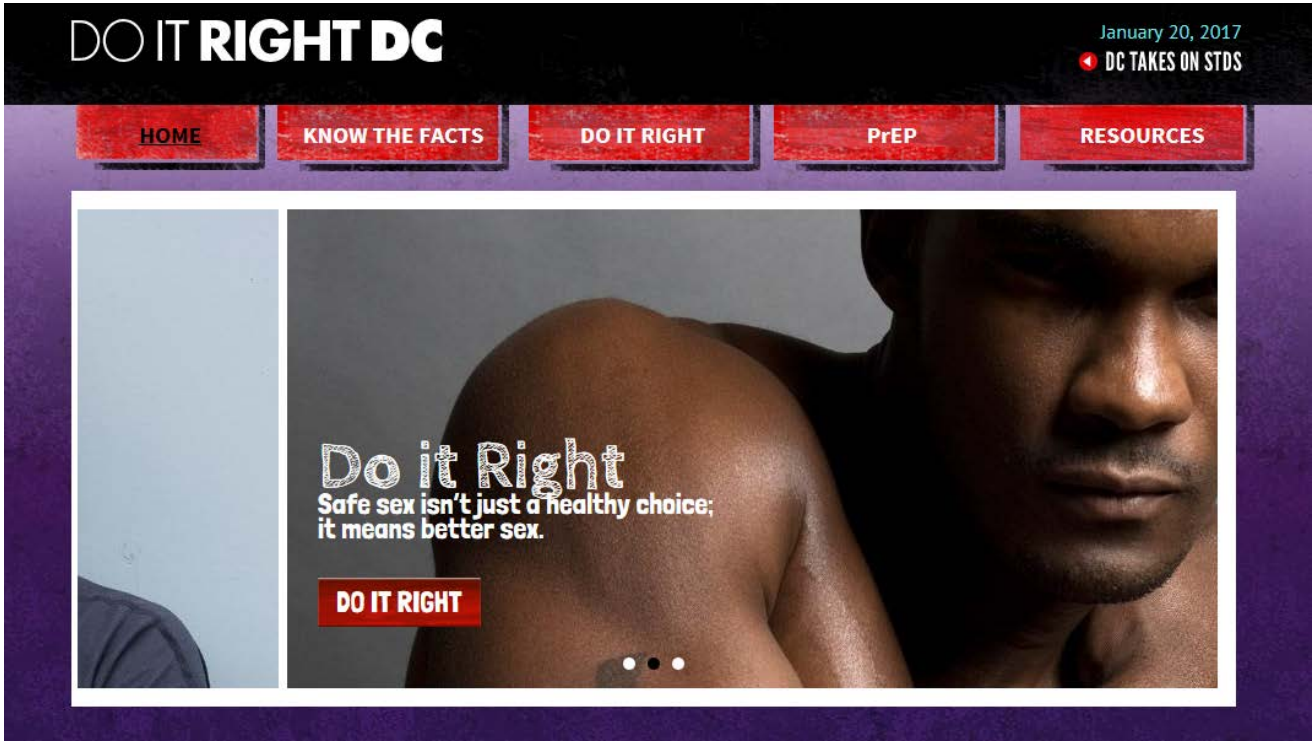
- **18 years old horizontally infected MSM** with history of sustained non-adherence, profound immune suppression, high viremia, untreated perianal warts brings in partner of 2 years for PreP discussion
- **17 years old perintally infected young woman** with excellent control of her disease and undetectable viremia, on oral contraceptives presents with her HIV-negative boyfriend to discuss if they can stop using condoms
- **19 years old young woman** who has a relationship with 19 years old young man living with HIV who has intermittent adherence and moderate degree of HIV viremia, tells you that she wants to have his baby

* All scenarios are adapted from real clinical situations

Challenges and Opportunities

- Registration/Insurance coverage
- Provider/patient readiness/comfort
- Repeat HIV and toxicity testing
- Adherence/compliance support
- Viral resistance testing requirements
- Comprehension prevention package

Do it Right DC



Hot Line Access

http://nccc.ucsf.edu/clinician-consultation/prep-pre-exposure-prophylaxis/

PrEP: Pre-Exposure Prophylaxis

Clinically supported advice on PrEP for healthcare providers

Up-to-date clinical consultation for PrEP decision-making, from determining when PrEP is an appropriate part of a prevention program to understanding laboratory protocols and follow-up tests.

Call for a Phone Consultation

(855) 448-7737 or **(855) HIV-PrEP**
Monday – Friday, 11 a.m. – 6 p.m. EST

CALL

We advise on all aspects of pre-exposure management (PrEP), including:

- Administering medications
- Addressing adherence issues
- Initial and follow-up laboratory evaluations
- Follow-up and testing protocols
- Transitioning from PEP to PrEP
- Managing PrEP as a safer conception tool

Advice for providers from national experts in PrEP

Related Information

Get testing and prevention tools

Do you need information and resources to guide you in implementing HIV testing in your practice?

> Find testing FAQs, recommendations,

Post **E**xposure **P**rophylaxis - **PEP**

PEP considered for following exposures:

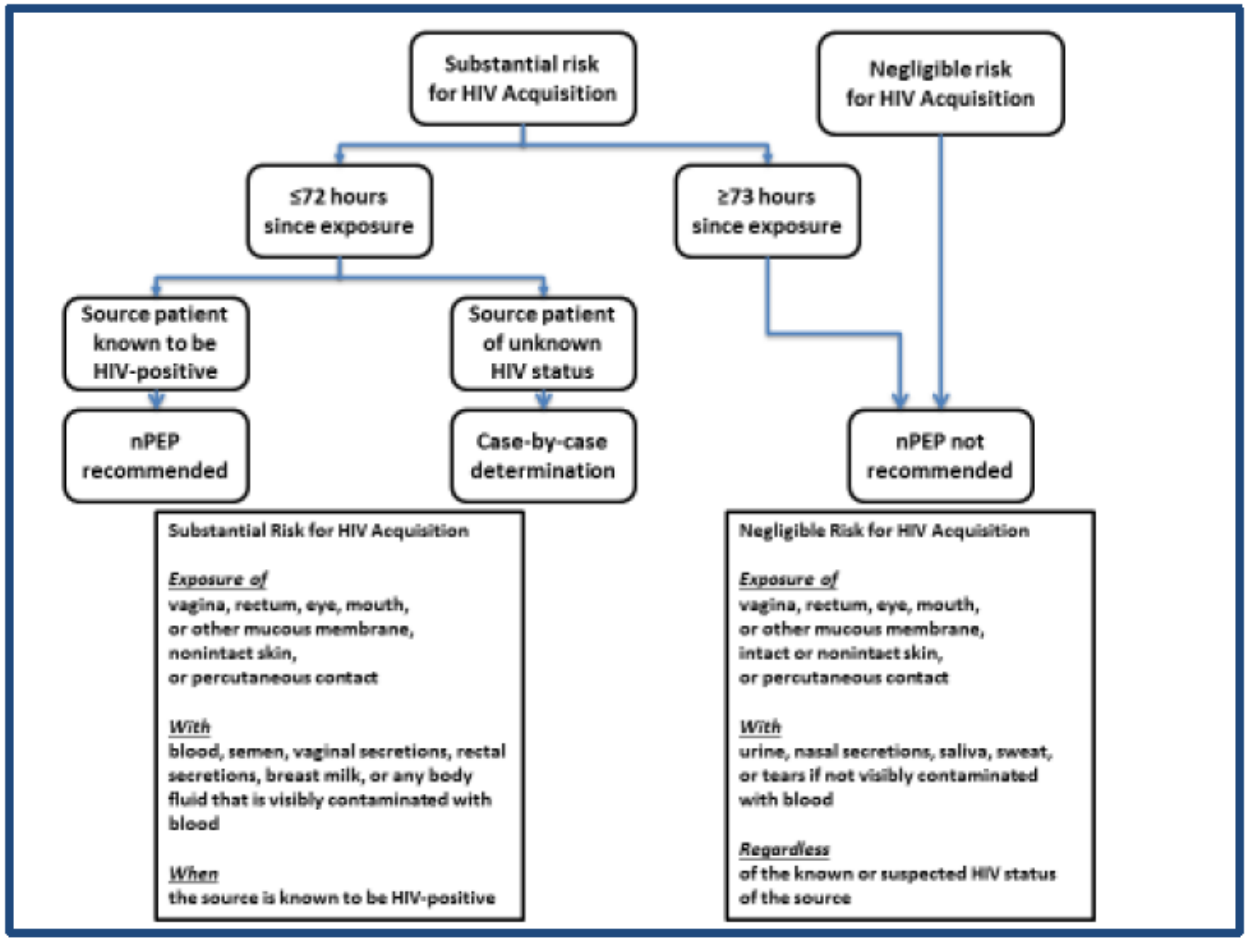
- Occupational (OPEP)
- Non-occupational (NPEP)

Examples of NPEP in Pediatric Practice

- **17 years old boy** tells his mother that he was at the private tattoo party yesterday, where needle was reused, and now has two new tattoos
- **18 years old girl** reports that she was raped by last night by her older cousin and she just heard that he might be HIV positive
- **14 years old boy** is referred because there are multiple syringes with needles found at home from his visiting uncle who is using IV drugs daily, he has been stuck by one of them this morning

* All scenarios are adapted from real clinical situations

CDC PEP Guidelines, 2016



NPEP Guidelines

- **Tenofovir+Emtricitabine (Truvada®) plus Raltegravir or Dolutegravir** - need to be started within 72 hours after exposure!!!!
- Superior effectiveness of three drugs in reducing chances for viral replication and establishment of reservoir
- Concerns about HIV drug resistance to commonly used HIV medications

**CDC HIV Postexposure Guidelines, 2016.*

Conclusions

- Thorough history and evaluation of risk factors are crucial for PreP
- Individualized approach is very important
- PEP and PreP both require close follow up and repeat testing and evaluations
- Recurrent PEP and PreP both need enhanced counseling on risk reduction

PrEP and Sexual Health Education

Veronica Urquilla, MSW

DC Department of Health/HAHSTA

Youth and Young Adults STD Programs Manager

WE ARE WASHINGTON DC

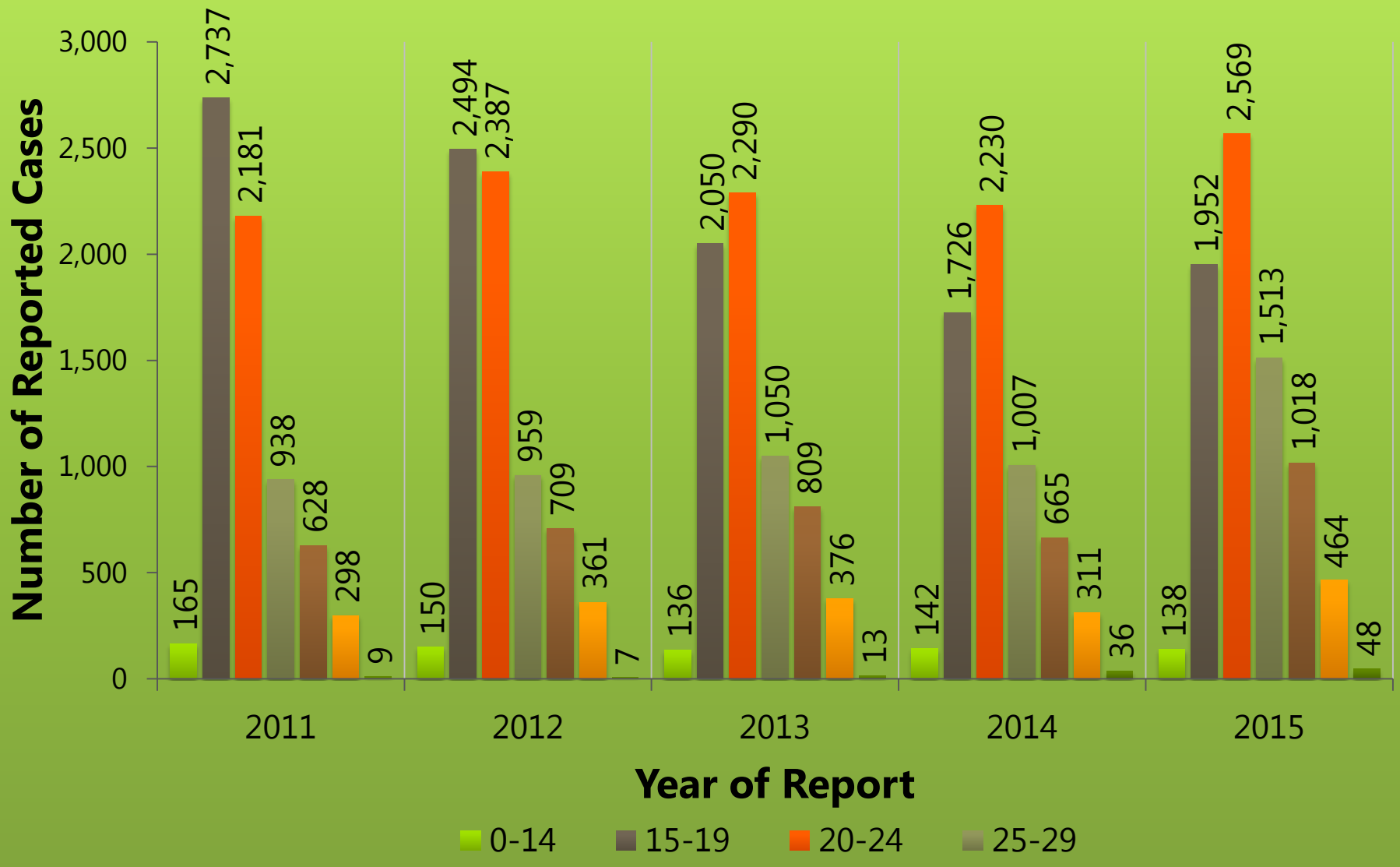
GOVERNMENT OF THE DISTRICT OF COLUMBIA
DOH
DEPARTMENT OF HEALTH
Promote. Prevent. Protect.

Why are we teaching this to students?

- Purpose of health education is to promote positive health behaviors
- Sexual health education should provide students with all the options they *can* choose from to stay healthy
- Patient and their clinician will decide if PrEP is right for them- so educate all youth about it
- PrEP is a highly effective tool in preventing HIV transmission
- High rates of STIs indicate youth are having unprotected sex

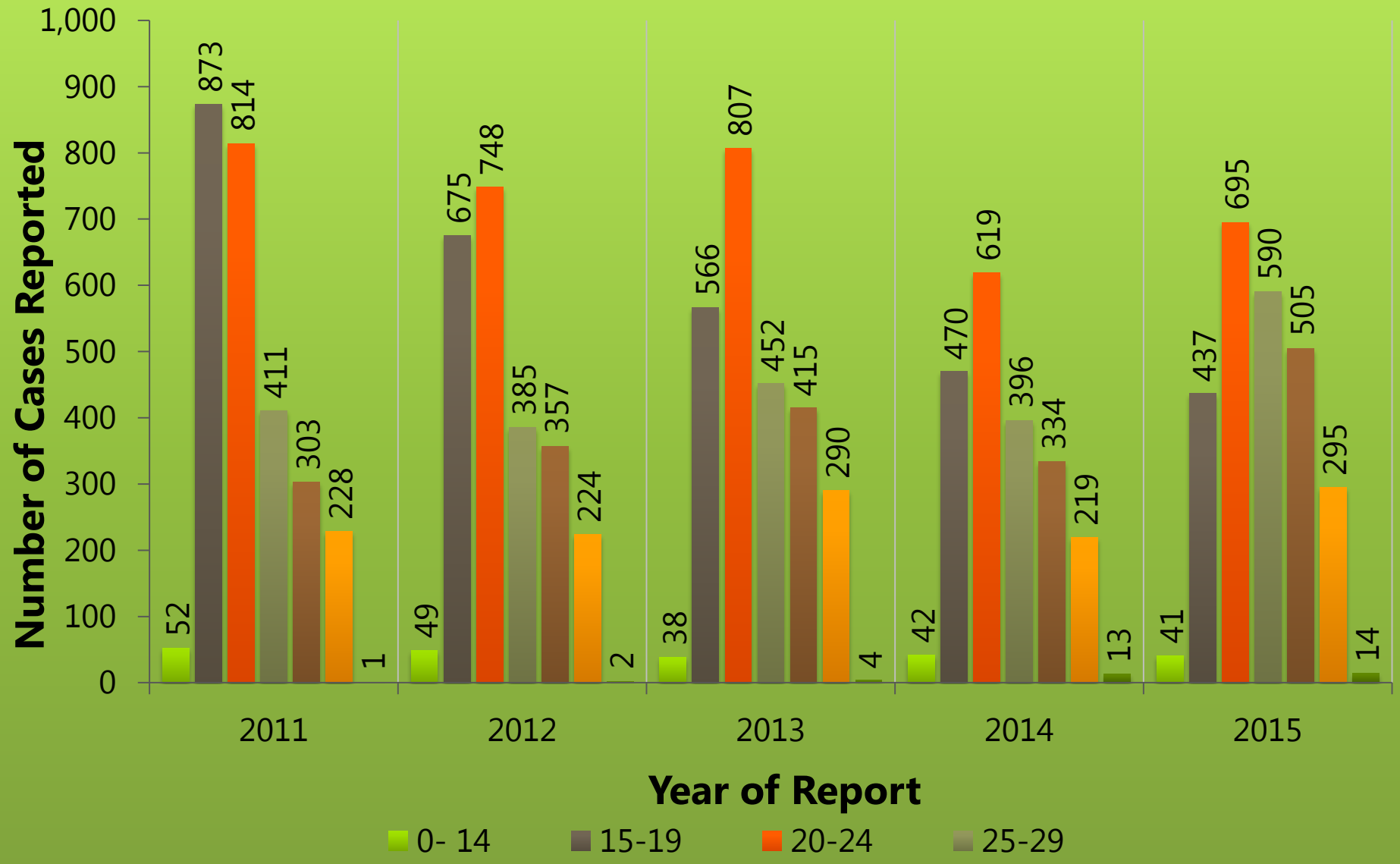
Reported Number of Chlamydia Cases by Year of Report and Age at Diagnosis

District of Columbia, 2011-2015



Reported Number of Gonorrhea Cases by Year of Report and Age at Diagnosis

District of Columbia, 2011-2015



Where do I fit PrEP into health education?

MS Category 3: Human Body and Personal Health

- **Accessing Information**

  3.3.13

  Identify school, medical, and community based support services for sexual health services, including STI/HIV testing/ treatment, contraception, and abortion.

- **Decision Making**

  3.5.17

  Analyze the short-term and long-term consequences of adolescent sexual activity including the various costs of STI/HIV testing/ treatment, unplanned pregnancy, and parenting.

MS Category 3: Human Body and Personal Health

- **Healthy Behaviors**
  - 3.7.27**

  Define and describe STI/HIV, protection methods (e.g., male/insertive and female/receptive condoms; dental dams; finger cots; and **PreExposure Prophylaxis**), symptoms, confidential testing, treatment, risks, and modes of transmission.

High School Category 3

- **Accessing Information**
  - 3.3.14

    Identify and locate community health clinics, private health clinics, urgent care facilities and hospital emergency rooms. Analyze the cost and accessibility thereof.

- **Communication**
  - 3.4.17

    Adapt health messages and communication techniques to promote prevention, treatment, and testing for STIs and HIV for high school-aged youth.

High School Category 3

- **Decision Making**

  3.5.19

  Demonstrate the ability to select professional health services based on the type of care needed, the nature of the problem, and the kinds of questions that need answering

- **Healthy Behaviors**

  3.7.23

  Identify and recommend behaviors that enhance and support the optimal functioning of bodily systems, including the functions of the body's immune system

- **Advocacy**
  3.8.28
- Research DC minor consent laws, compare and contrast these laws to other states, and describe adolescent sexual health rights generally

- **Advocacy**
3.8.29

- Analyze the data on STI and HIV rates among youth. Discuss barriers to prevention, testing, and treatment including legal, economic, and cultural barriers.

Examples

- Have students use the PrEP locator to find locations near them
- Brainstorm benefits and barriers to taking a pill everyday
- Review PrEP studies
- Don't set PrEP aside integrate it into discussion around prevention
- Discussion possible progression from PrEP pill similar to oral contraception to other forms of birth control (depo, nuva ring, IUD with horomone)

Need some help?

- Learn more about PrEP
  - https://doitrightdc.com/prep/
  - https://www.cdc.gov/hiv/basics/prep.html

- DOH, CNMC, Planned Parenthood and other community based organizations can help with introducing PrEP to youth

Thank you!