




**2018 Updates on STD Management:
Practical Approaches to the Most
Common STD Clinic Patient Concerns**

A Monthly Webinar Series



**Webinars occur 12-1 pm EST
One Tuesday per month
January – November 2018**



Learner Objectives

At the conclusion of this webinar series, participants should be able to:

- Accurately identify patients at risk for STIs and then test, diagnose, and treat according to CDC STD Treatment Guidelines.


Continuing Education Accreditation

This activity has been planned and implemented in accordance with the Essential Areas and the Policies of the Accreditation Council for Continuing Medical Education through the joint providership of the University of Alabama School of Medicine and the Sylvie Ratelle STD/HIV Prevention Training Center.

The University of Alabama School of Medicine is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for participants.



The University of Alabama designates this webinar for a maximum of **1.0 AMA PRA Category 1 Credit™**. Participants should claim only the credit commensurate with the extent of their participation in the activity.

These credits are also applicable for registered nurses.



After Today's Webinar

- You will receive an auto-generated email from the National Network of STD Clinical Prevention Training Centers to complete a brief evaluation of today's presentation.
- Within that email, you will find instructions on how to register for and receive CME credits through the University of Alabama School of Medicine.
- Webinars will be archived and available for viewing at www.RatellePTC.org. CME credits will also be available for archived webinars.



2018 STD Webinar Schedule

Date	Title	Speaker(s)	Affiliations
Jan 16	Vaginitis: Bacterial Vaginosis, Yeast Vaginitis, Trichomoniasis	Katherine Hsu, MD, MPH	MDPH/Boston Univ. Med. Ctr.
Feb 20	Cervicitis/PID: Chlamydia, Gonorrhea, <i>M. genitalium</i>	Candice McNeil, MD, MPH	Wakeforest Univ.
Mar 20	Motivational Interviewing for STI/HIV Prevention	Thomas Creger, PhD, MPH	Univ. of Alabama at Birmingham
Apr 24	Pregnancy and STIs	Candice McNeil, MD, MPH	Wakeforest Univ.
May 15	Urethritis/Epididymitis/Proctitis: Gonorrhea, <i>M. genitalium</i> , and Lymphogranuloma Venereum	Candice McNeil, MD, MPH	Wakeforest Univ.
Jun 19	Clinician-Health Department Partnerships: Partner Management, Disease Reporting, Presumptive Treatment	Marjorie Kirsch, MD	FL DOH Wakulla County





2018 STD Webinar Schedule (cont'd)

Date	Title	Speaker(s)	Affiliations
Jul 17	Genital Lesions: HSV, HPV, Syphilis	Nicholas Van Wagoner, MD, PhD	Univ. of Alabama Sch. of Med.
Aug 21	Management of STI/HIV Coinfection	Katherine Hsu, MD, MPH	MDPH/Boston Univ. Med. Ctr.
Sept 11	Genital Dermatology	Nicholas Van Wagoner, MD, PhD	Univ. of Alabama Sch. of Med.
Oct 16	Approaches with Special Populations: Youth, GLBT	Katherine Hsu, MD, MPH and Nicholas Van Wagoner, MD, PhD	MDPH/Boston Univ. Med. Ctr. and Univ. of Alabama Sch. of Med.
Nov 13	Update on PrEP	Jeffrey Beal, MD	Florida Department of Health

Pre-Exposure Prophylaxis (PrEP)




NOVEMBER 12, 2018

Jeffrey Beal, MD, AAHIVS
 Medical Director, HIV/AIDS Section
 The Florida Department of Health
 Bureau of Communicable Diseases

Division of Disease Control and Health Protection
 To protect, promote and improve the health of all people in Florida through integrated state, county and community efforts.


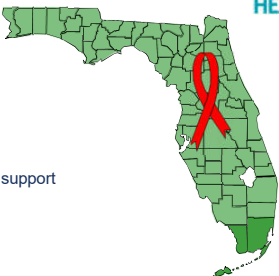
Faculty Disclosure



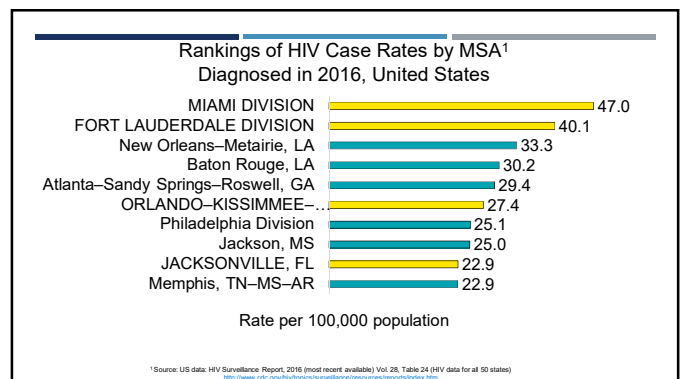
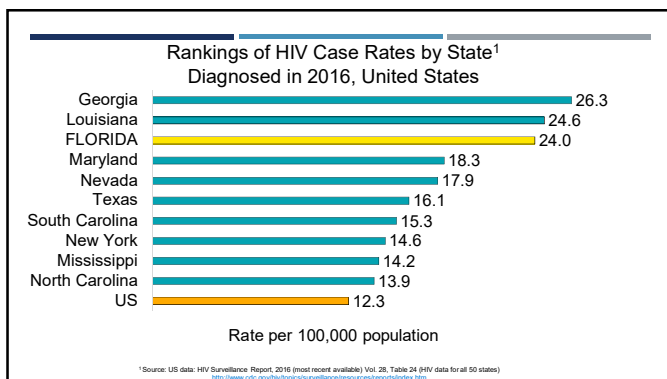
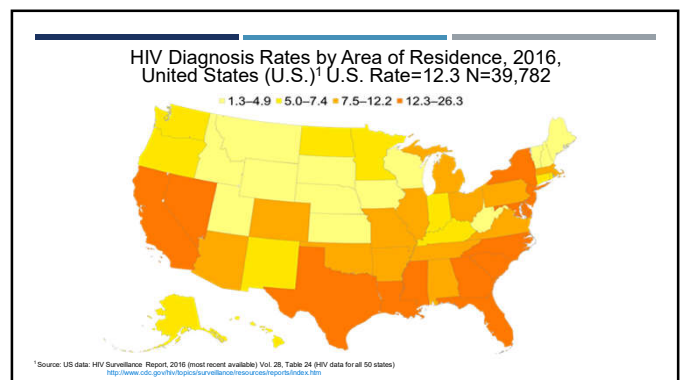
In compliance with Accreditation Council for Continuing Medical Education (ACCME) Guidelines, I hereby declare:

I do not have financial or other relationships with the manufacturer(s) of any commercial service(s) discussed in this educational activity.

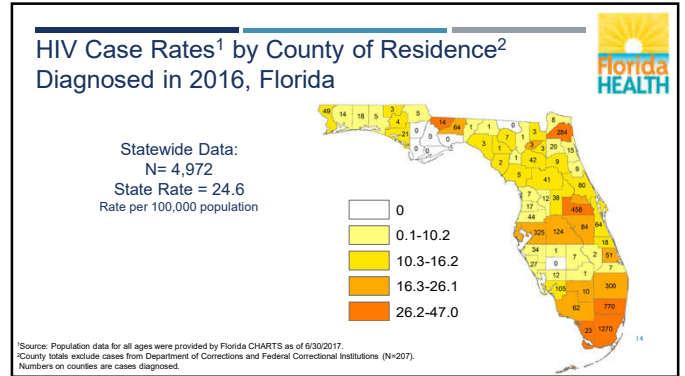
Discussion Topics

- Data review
- Describe PrEP and nPEP
- Outline assessment/management of PrEP/nPEP
- Provide resources for education and support for PrEP and nPEP programs

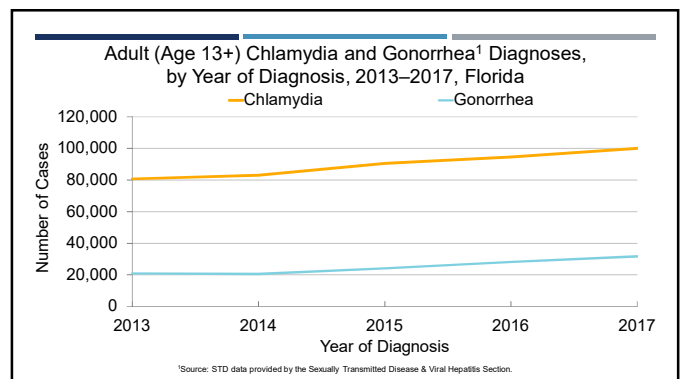
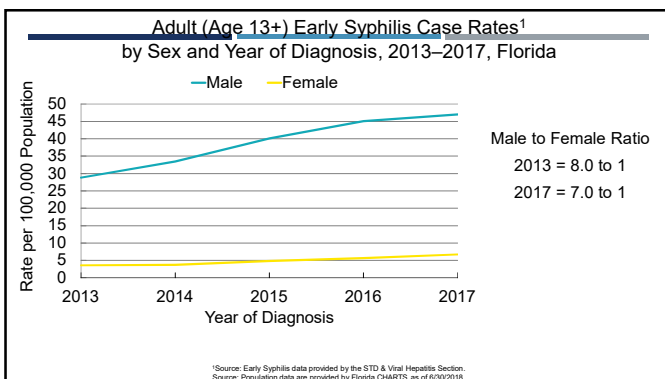


	2016	2017	Trend
Total Population and PLWH Cases			
Population	20,231,092	20,555,728	1.6% increase
Persons Living with an HIV diagnosis (PLWH)	115,266	116,944	1.5% increase
Strategic Long Term Goals			
Reduce the annual number of HIV diagnoses	4,805	4,949	3.0% increase
Increase the percent of PLWH Retained in Care	68.0%	68.3%	0.3% increase
Increase the percent of PLWH with a Suppressed Viral Load	60.5%	61.5%	1.1% increase
Reduce the annual number of babies born in Florida with perinatally acquired HIV to less than 5	8	8	N/A
Additional Indicators			
Reduce annual number of AIDS diagnoses	2,116	2,044	3.4% decrease
Reduced the annual number of HIV-related deaths	864	749	13.3% decrease




- ### One-In-Statements for Adults (Age 13+) Living with HIV in Florida, Year-end 2017
- One in 151 adults in Florida were known to be living with HIV
 - One in 295 Whites were living with HIV
 - One in 49 Blacks were living with HIV
 - One in 155 Hispanics were living with HIV

Florida Sexually Transmitted Infections (STI) Epidemic 2016



Florida's Plan to Eliminate HIV Transmission and Reduce HIV-related Deaths




Four Key Components

1. Implement routine HIV and STI screening in health care settings and priority testing in non-health care settings
2. Provide HIV testing, rapid access to treatment and ensure retention in care
3. Improve access to antiretroviral PrEP and non-occupational nPEP
4. Increase HIV awareness and community response through outreach, engagement and messaging


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Pre-exposure Prophylaxis (PrEP)




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What is PrEP?



- PrEP stands for **Pre-Exposure Prophylaxis**. PrEP is intended to prevent a high risk person from becoming HIV infected if exposure to the virus occurs.
- Truvada® is the FDA approved medication for PrEP, a combination of nucleoside reverse transcriptase inhibitors (NRTIs) emtricitabine 200 mg (FTC) & tenofovir disoproxil fumarate 300 mg (TDF).




PrEP IS A NEW HIV PREVENTION METHOD IN WHICH PEOPLE WHO DO NOT HAVE HIV INFECTION TAKE A PILL DAILY TO REDUCE THEIR RISK OF BECOMING INFECTED.

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www.aids.gov/hiv-aids-basics/prevention/your-risk/pre-exposure-prophylaxis/truvadapreps.com/online-training

Antiretrovirals Used in HIV Prevention: The Foundation for PrEP




- Prevention of mother-to-child transmission (PMTCT)
 - Antiretrovirals given to the mother during pregnancy, labor and delivery and to the infant postpartum¹
 - PMTCT has virtually eliminated perinatal HIV infection in the U.S. and other developed countries
- Non-human primate studies demonstrating protection^{2,3}
- Observational data⁴

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1. DHHS. Perinatal Guidelines, 2014.
 2. Am. J. Med. 1997;102(5B):39-44.
 3. J. Virol. 1998;72(5):4265-73
 4. NEJM. 1997;337(21):1485-90

Modified from Clinical Care Options: www.clinicaloptions.com/hiv

PrEP– Key Points




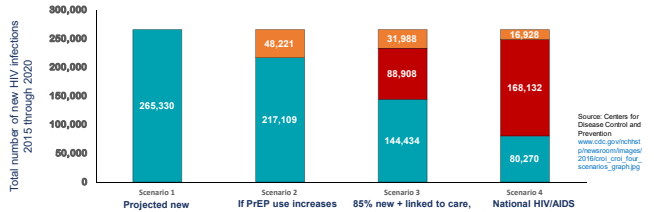
- Truvada® (TDF/FTC) is a combination of tenofovir disoproxil fumarate 300 mg (TDF) & emtricitabine 200 mg (FTC)
- Approved by the FDA in 2012 for the use of PrEP
- TDF/FTC works by inhibiting HIV from replicating when it enters the body
- PrEP is one component of a comprehensive prevention strategy that includes safer sex practices



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Image credit: www.walshirelax.com/hiv-prevention-drug-truvada220671/

Four Scenarios of the Potential Impact of Expanded HIV Testing, Treatment and PrEP in the U.S., 2015–2020





Scenario	Total New HIV Infections (2015-2020)
Scenario 1: Projected new infections by 2020	265,330
Scenario 2: If PrEP use increases	217,109
Scenario 3: 85% new + linked to care, 60% viral suppression, PrEP use	144,434
Scenario 4: National HIV/AIDS Strategy (NHAS) goals	80,270

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Source: Centers for Disease Control and Prevention www.cdc.gov/nchdnl/preventionstrategies/2016/04/04/2016/04/04_four_scenarios_graph.jpg

Who Should Be Offered PrEP? CDC Guidelines




“Substantial risk of HIV Infection”

MSM	Heterosexual Women and Men	IDU
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	HIV-positive injecting partner Sharing injection equipment Recent drug treatment (but currently injecting)

Center for Disease Control and Prevention Guidelines 2014 www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf


Clinical Assessment for PrEP Use




Categories	Men Who Have Sex with Men	Heterosexual Women and Men	Injection Drug Users
Clinically eligible	Documented negative HIV test result before prescribing PrEP No signs/symptoms of acute HIV infection Normal renal function; no contraindicated medications Documented hepatitis B virus infection and vaccination status		
Prescription	Daily, continuing, oral doses of TDF/FTC (Truvada®), ≤90-day supply		
Other Services	Follow up visits at least every three months to provide the following: HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, STI symptom assessment, at three months and every six months thereafter, assess renal function every six months, test for bacterial STIs		
	Do oral/rectal STI testing	Assess pregnancy intent Pregnancy test every three months	Access to clean needles/syringes and drug treatment services

www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf

Considerations When Prescribing




- Counsel patients on the importance of adherence to the prescribed medication regimen—TDF/FTC effectiveness is strongly correlated with consistent adherence
- Seven days for protective TDF/FTC drug levels for receptive anal sex, 20 days for blood, vaginal sex and insertive anal sex
- Side effects: nausea, vomiting, stomach pain, diarrhea, headache, dizziness, depression and joint pain




Modified from: www.truvadapreps.com/online-training
Image credit: www.hivandhepatitis.com/Recent/2010/11/23_2010_4.html

Considerations When Prescribing, continued




- A negative HIV test must be confirmed immediately before starting a regimen of TDF/FTC
- HIV screenings should be repeated every three months along with STI and adherence assessments and counseling for behavior change
- If symptoms of acute HIV infection occur, discontinue TDF/FTC until negative status can be confirmed



Modified from: www.truvadapreps.com/online-training
Image credit: www.hivandhepatitis.com/Recent/2010/11/23_2010_4.html

Warnings, Precautions and Adverse Events




Renal Impairment

- Do not administer TDF/FTC with or following recent use of nephrotoxic drugs
- Offer alternatives to nonsteroidal anti-inflammatory drugs (NSAIDs) for patients with renal impairment
- Discontinue use if creatinine clearance (CrCl) < 60 mL/min
- In patients at risk of renal dysfunction, monitor estimated glomerular filtration rate (eGFR), serum phosphorus, urine glucose and urine protein before and during therapy

www.truvadapreps.com/online-training

Warnings, Precautions and Adverse Events, continued



- All patients should be tested for chronic Hepatitis B (HBV) before beginning TDF/FTC
- Assess bone mineral density (BMD) if history of pathologic fracture or risk factors for osteoporosis

www.truvadapreps.com/online-training

Prescribing and Monitoring



- One tablet daily with or without food
- Time to achieving maximum protection (adequate tissue levels of tenofovir diphosphate):
 - 20 days for insertive anal sex, vaginal sex and IDU
 - Seven days for receptive anal sex

Gilead Truvada® Package Insert
Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2014 Clinical
Practice Guideline
www.cdc.gov/hiv/basics/prep.html

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Prescribing and Monitoring, continued



Clinical follow-up

- Every three months
 - Fourth generation HIV testing; signs/symptoms of acute HIV infection; assess STI symptoms
 - Pregnancy testing for women who may become pregnant
 - Assess for signs/symptoms of acute HIV infection and STI
 - Counsel regarding adherence and risk reduction

Gilead Truvada® Package Insert
Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2014 Clinical
Practice Guideline
www.cdc.gov/hiv/basics/prep.html

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Prescribing and Monitoring, continued



Clinical follow-up

- Every six months
 - Estimated CrCl testing
 - STI testing
- Every 12 months evaluate need to continue PrEP

Gilead Truvada® Package Insert
Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2014 Clinical
Practice Guideline
www.cdc.gov/hiv/basics/prep.html

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Pregnant Women

- While there have been no well-controlled trials of the use of TDF/FTC during pregnancy, it should be used only if a need is clearly indicated
- A pregnancy registry is available for pregnant women on TDF/FTC for PrEP

Call 1-800-258-4263

Breastfeeding Women

- The components of TDF/FTC are excreted in breastmilk
- Risk to the infant is unknown at this time; therefore, women on TDF/FTC should not breastfeed

www.truvadapreps.com/online-training

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Reducing Risk of HIV Acquisition



- Safer sex/needle practices
- Knowledge of their own HIV status as well as the status of their partner(s)
- Regular HIV testing of self and partner(s)
- Medication compliance

www.truvadapreps.com/online-training
www.cdc.gov/hiv/basics/prep.html

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Acute HIV Infection



Signs/symptoms of acute HIV infection include:

- Fever (75%)
- Fatigue (68%)
- Myalgia (49%)
- Skin rash (48%)
- Headache (45%)
- Pharyngitis (40%)
- Cervical adenopathy (39%)
- Arthralgia (30%)
- Night sweats (28%)
- Diarrhea (27%)

www.truvadapreps.com/Content/pdf/Safety_Information_Fact_Sheet.pdf
www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf [2016 CDC PrEP update]
www.truvadapreps.com/online-training

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TDF/FTC: STI



PrEP Demo Project, San Francisco Cohen Conference on Retroviruses and Opportunistic Infections (CROI) 2016 #870

- September 2012–January 2014
- 557 men and women with quarterly screening
- 51% had an STI during follow up
- 20–41% of STI missed with every six month screening
- Conclusion: quarterly screening

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PrEP – A Cautionary Tale



43 year-old man from Toronto

- On TDF/FTC PrEP X 24 months (pharmacy records, dried blood spots with TFV-DP ~2300 fmol/punch)
- Found p24 Ag+, HIV antibody (-), HIV RNA ~28K

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Knox CROI 2016 #169aLB

PrEP – A Cautionary Tale, continued



- Drug resistant virus
 - NRTI: 41L, 67G, 69D, 70R, 184V, 215E
 - NNRTI: 181C
 - II: 51Y, 92Q; phenotypic resistance to all II
- Phylogenetic analysis: narrow range
- Conclusion: PrEP failure with multi-drug resistance (MDR)

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Knox CROI 2016 #169aLB

Case Report: Wild-Type (WT) HIV-1 Infection in MSM Adherent to PrEP



- 50 year-old MSM using daily oral FTC/TDF PrEP in Amsterdam Pre-Exposure Prophylaxis project
 - Reported drug use during sex, excellent PrEP adherence
 - Median number of condomless anal sex partners per day in each month following PrEP initiation ranged from two to five
 - Tested positive for rectal STIs - gonorrhea (twice) and chlamydia

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Hoomenborg E, et al. CROI 2017. Abstract 953.

Slide credit: www.clinicaloptions.com

WT HIV Infection while Adherent to PrEP



- First reported case of WT HIV infection in person with protective TFV-DP levels
- Seroconversion pattern atypical: no HIV DNA in bulk peripheral blood mononuclear cells (PBMCs), no HIV DNA or RNA in three sigmoid biopsies at time of seroconversion

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Hoomenborg E, et al. CROI 2017. Abstract 953.

Slide credit: www.clinicaloptions.com

WT HIV Infection while Adherent to PrEP, continued



- Hypothetical mechanisms of infection
 - High number of repeated HIV exposures with or without mucosal damage?
 - Decreased TDF and/or FTC levels in rectal mucosa?
- Highlights importance of periodic HIV testing during PrEP use and awareness of potential for atypical seroconversion patterns

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PrEP TDF/FTC Versus TAF/FTC



- TAF/FTC protects monkeys¹
- Tenofovir levels in human tissue comparing TAF to TDF²
 - Cervical and vaginal tissue levels two-fold lower with TAF
 - Rectal tissue levels ten-fold lower with TAF

1 Messoud I et al., CROI 2016, Boston, Abstract 107
2 Garrett KL, et al., CROI 2016, Boston, Abstract 100LB

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New HIV Health Management System (HMS) Program Codes



PrEP

- Codes 5701–5703
- May be seen through STD or Family Planning

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Patient Assistance Programs



Truvada® (tenofovir + emtricitabine):
 Gilead's Advancing Access Program – for PrEP & nPEP
 1-800-226-2056

www.nccsc.edu/wp-content/uploads/2014/04/CCC_PEP_Quick_Guide_Alternative_Regimen_and_Dosing_and_Toxicity_Tables.pdf

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Patient Assistance for PrEP: When the Patient Has Insurance



Patient Advocate Foundation (PAF) Co-Pay Relief:

If the patient has health insurance and the insurance covers medications for which patient needs assistance

PAF CareLine 1-800-532-5274

Gilead's Co-Pay Coupon Program:

If the patient has commercial insurance, he/she may contact or be referred to Gilead's Co-Pay Coupon Program

1-877-505-6986

The patient is given an authorization number to present with the prescription and other insurance at the pharmacy

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Additional Resources: PrEP and nPEP



PrEP Help Lines, continued



For **PrEP** advice and inquiries, please call the PrEP line:

1-855-448-7737

or

1-855-HIV-PrEP

Monday through Friday, 11 a.m.–6 p.m. ET

Provides free, expert advice about PrEP to clinicians across the country

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Common ICD-10 Billing Codes: PrEP and PEP

- Z72.5 High-risk sexual behavior
- Z20.82 Contact with and (suspected) exposure to other viral communicable diseases
- Z20.6 Contact with and (suspected) exposure to human immunodeficiency virus (HIV)
- W46.0 Contact with hypodermic needle (hypodermic needle stick NOS)

For additional information about ICD-10 coding, as well as access to additional HIV ICD-10 codes, visit: www.aapc.com/icd-10/faq.aspx

Southeast AIDS Education & Training Center (SEAETC) Pocket Guide for PEP, PrEP and nPEP

The SEAETC brochure is available from their website or downloaded in PDF form. The pocket guide expands on PrEP, PEP and nPEP.

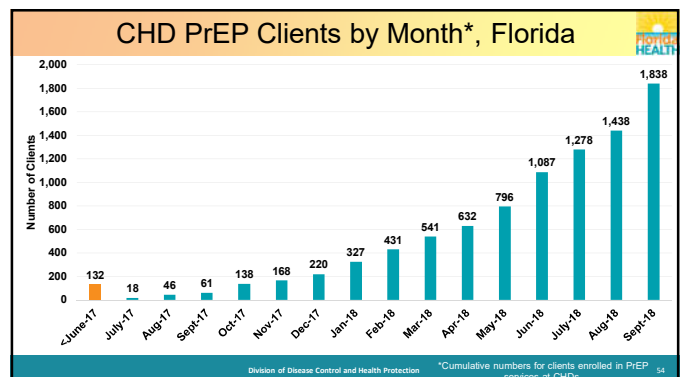
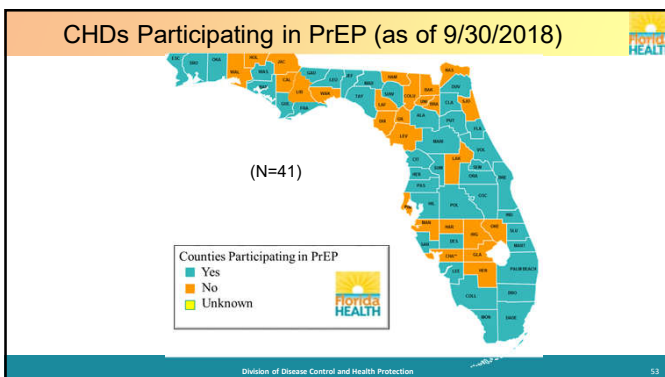
PrEP and nPEP Implementation in CHDs

- Integration of PrEP services in all 67 county health department (CHD) STD and Family Planning clinics by December 2018
- Technical assistance to CHDs for nPEP service delivery
 - Expedited nPEP delivery challenged by CHD hours of operation
 - Collaborative nPEP delivery models

PrEP and nPEP Implementation in CHDs, continued

- As of September 30, 2018, 41 of 67 (61%) CHDs are providing PrEP services
 - Over 1,800 PrEP clients have been served to-date*
- An additional 19 of 67 (28%) CHDs report making nPEP available
 - Over 100 nPEP clients have been served to-date*

* Cumulative number of clients enrolled in PrEP at the CHDs. DOH-Okaloosa began providing PrEP services in 2015; and DOH-Miami-Dade began providing PrEP services in 2016. DOH Health Management System (HMS) PrEP and nPEP codes were initiated in July 2017.



PrEP/nPEP Provider Toolkits, continued

Division of Disease Control and Health Protection 55

PrEP/nPEP Provider Toolkits, continued

Division of Disease Control and Health Protection 56

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