

# Preventing HIV in Adolescents and Adults: PrEP, PEP, and Other Innovative Strategies

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# Disclosure

Dr. Blackwell has no disclosures associated with this presentation.

# Objectives

- At the end of this presentation, participants will identify which factors place adolescents and adults at highest risk for HIV infection.
- At the end of this presentation, participants will outline the two pharmacologic strategies used to prevent HIV infection, including pre-exposure and post-exposure prophylaxis.
- At the end of this presentation, participants will provide at least three examples of non-pharmacologic strategies used to prevent HIV infection.
- At the end of this presentation, participants will articulate the relationships between an HIV-infected individual's HIV RNA level (viral load), CD4 count, and HIV communicability.
- At the end of this presentation, participants will prioritize suggested future research directives in HIV prevention.

# Incidence of HIV Infections & AIDS

- Review of CDC Data: Updated through 2016

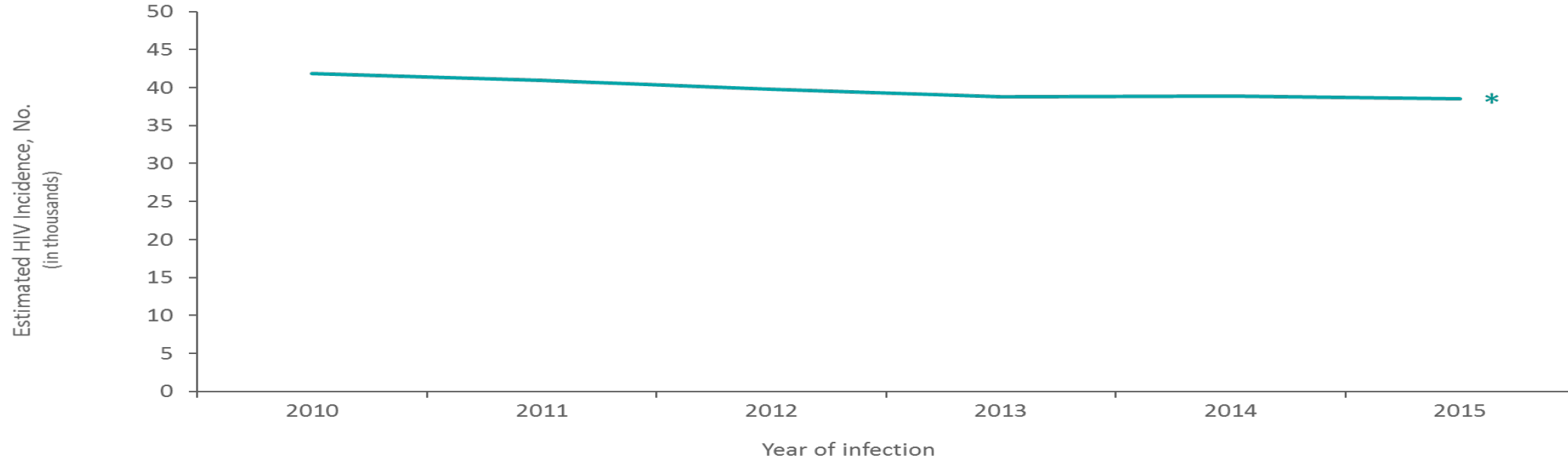


# Incidence of HIV Infection & AIDS: 2011-2016 Take Away Points

- Age Group:
  - From 2011 through 2015, the rate for persons aged 25–29 years increased.
  - The rates for children (aged less than 13 years) and persons aged 13–14, 15–19, 35–39, 40–44, 45–49, 50–54, 55–59, 60–64 years, and 65 years and older decreased.
  - The rates for persons aged 20–24 and 30–34 years remained stable.
  - In 2016, the highest rate was for persons aged 25–29 years (34.8), followed by the rate for persons aged 20–24 years (30.3).

# Incidence of HIV Infection & AIDS: 2011-2016 Take Away Points

- Overall incidence is down, slightly:



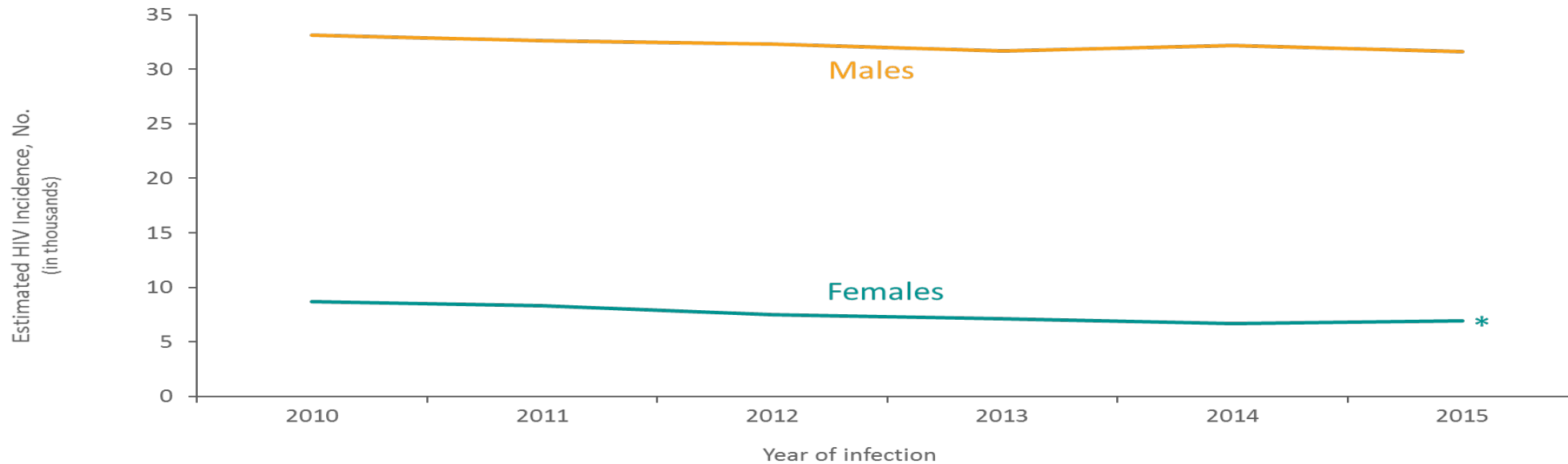
# Incidence of HIV Infection & AIDS: 2011-2016 Take Away Points

- Sex

- From 2011 through 2015, the rates for male and female adults and adolescents decreased.
- In 2016, males accounted for 81% of all diagnoses of HIV infection among adults and adolescents.
- The 2016 rate for male adults and adolescents was 24.3; the 2016 rate for females was 5.4.

# Incidence of HIV Infection & AIDS: 2011-2016 Take Away Points

- Sex





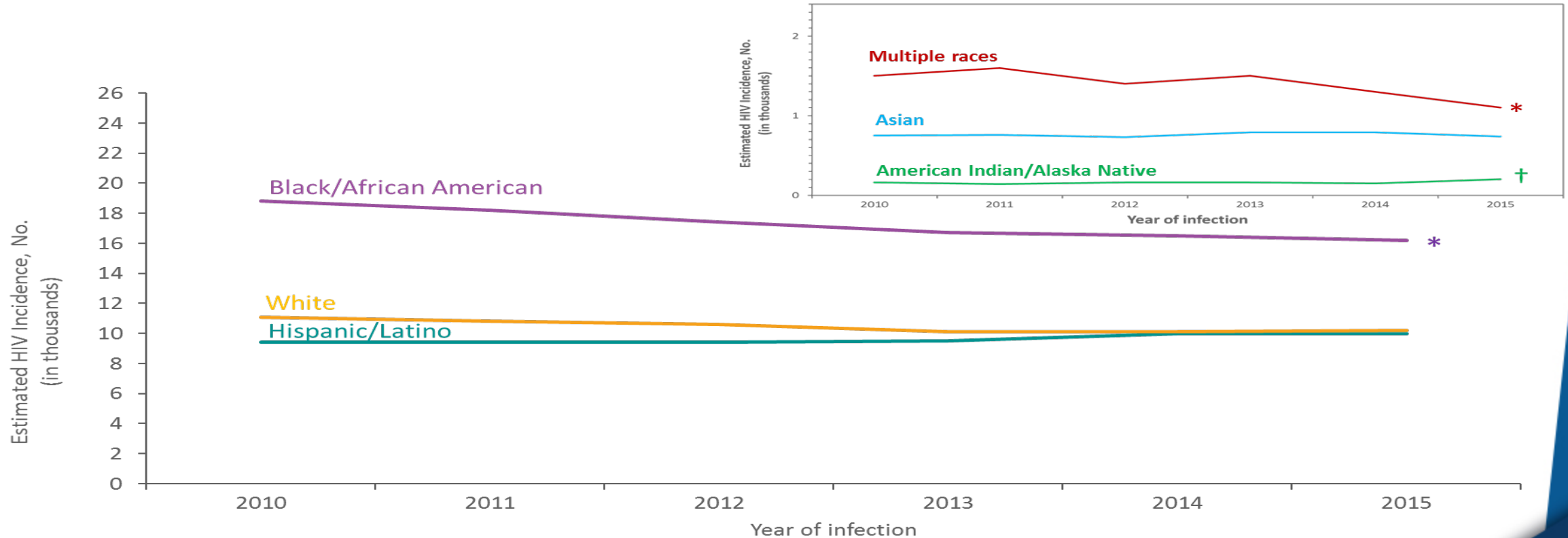
# Incidence of HIV Infection & AIDS: 2011-2016 Take Away Points

- Race/Ethnicity

- From 2011 through 2015, the rates for American Indians/Alaska Natives, Asians, and Native Hawaiians/other Pacific Islanders increased.
- The rates for blacks/African Americans, whites, and persons of multiple races decreased.
- The rates for Hispanics/Latinos remained stable.
- In 2016, the highest rate was 43.6 for blacks/African Americans, followed by 17.0 for Hispanics/Latinos, 12.9 for persons of multiple races, 10.2 for American Indians/Alaska Natives, 8.5 for Native Hawaiians/other Pacific Islanders, 5.5 for Asians, and 5.2 for whites.

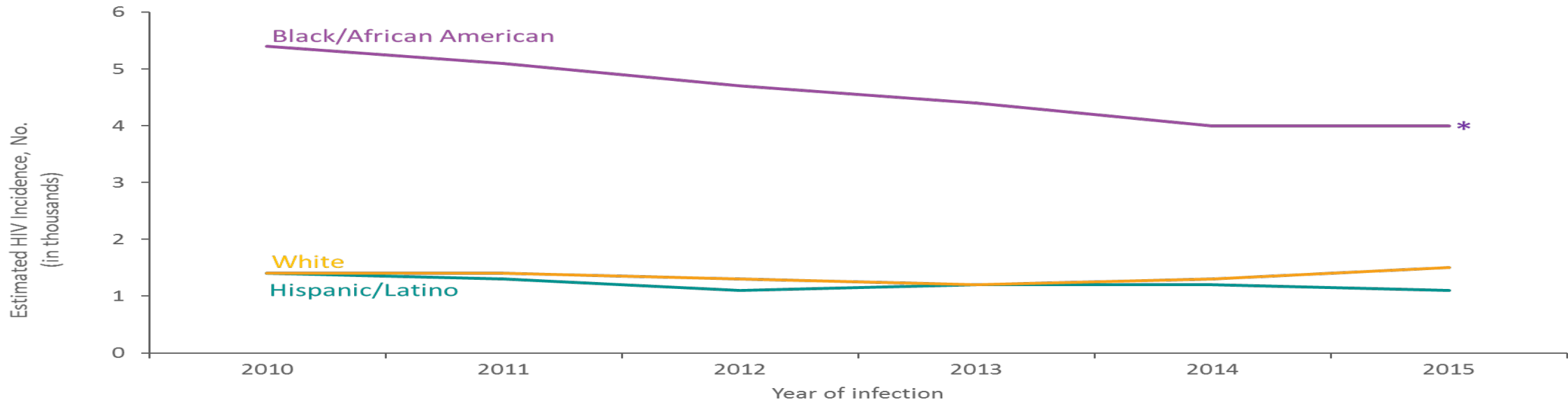
# Incidence of HIV Infection & AIDS: 2011-2016 Take Away Points

- Race/Ethnicity



# Incidence of HIV Infection & AIDS: 2011-2016 Take Away Points

- Race/Ethnicity (Females)

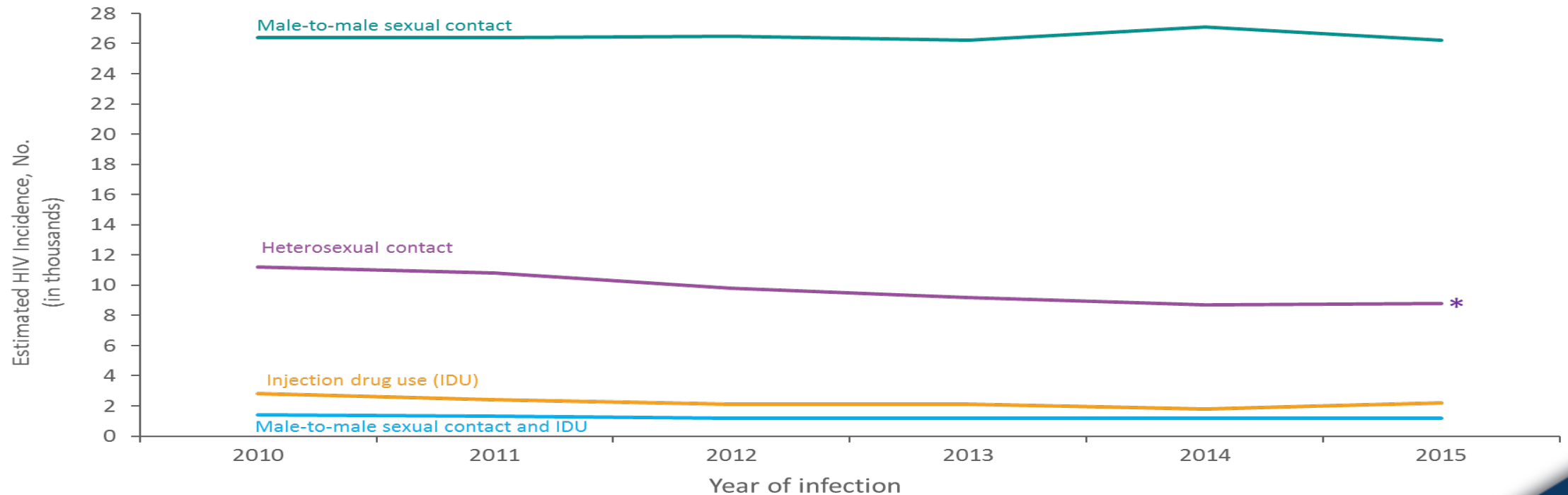


# Incidence of HIV Infection & AIDS: 2011-2016 Take Away Points

- Transmission Category
  - From 2011 through 2015, among male adults and adolescents, the annual number of diagnosed HIV infections attributed to injection drug use, to male-to-male sexual contact *and* injection drug use, or to heterosexual contact decreased.
  - The number of infections attributed to male-to-male sexual contact remained stable.
  - Among female adults and adolescents, the number of infections attributed to injection drug use or to heterosexual contact decreased.
  - In 2016, among all adults and adolescents, the diagnosed infections attributed to male-to-male sexual contact (70%, including male-to-male sexual contact *and* injection drug use) and those attributed to heterosexual contact (24%) accounted for approximately 94% of diagnosed HIV infections in the United States.

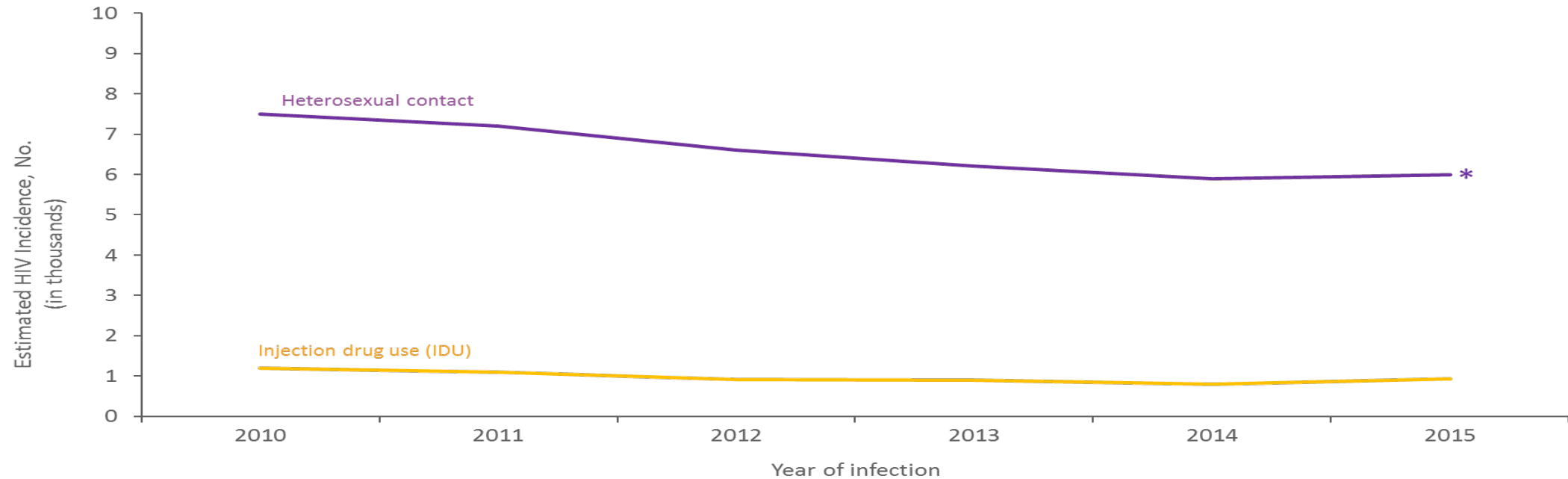
# Incidence of HIV Infection & AIDS: 2011-2016 Take Away Points

- Transmission Category



# Incidence of HIV Infection & AIDS: 2011-2016 Take Away Points

- Transmission Category (Females)

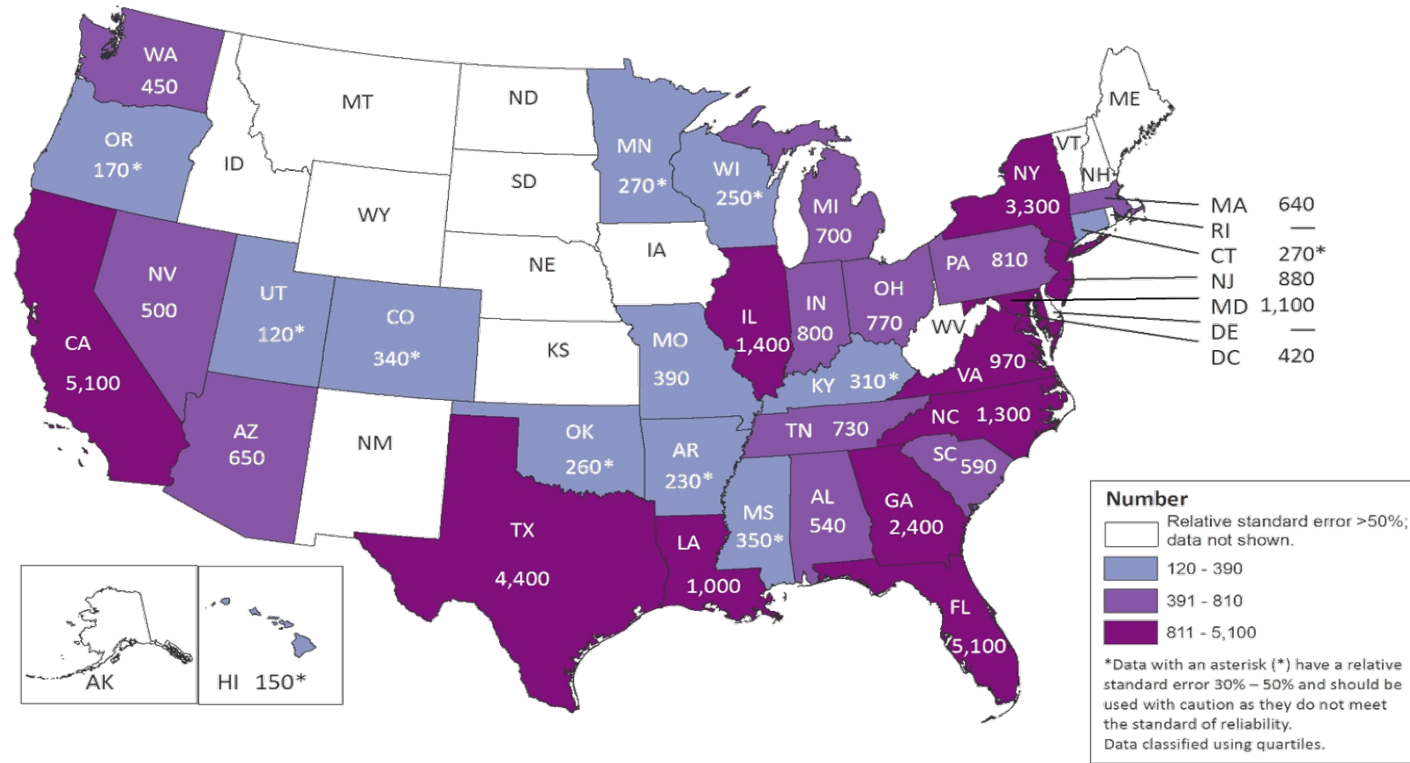


# Incidence of HIV Infection & AIDS: 2011-2016 Take Away Points

- Region: New Dx (2016)
  - From 2011 through 2015, the rates of diagnoses of HIV infection in the Northeast and the South decreased.
  - The rates in the Midwest and the West remained stable.
  - In 2016, rates were 16.8 in the South, 11.2 in the Northeast, 10.2 in the West, and 7.5 in the Midwest.

# Estimated HIV Incidence among Persons Aged $\geq 13$ Years, by Area of Residence, 2015—United States

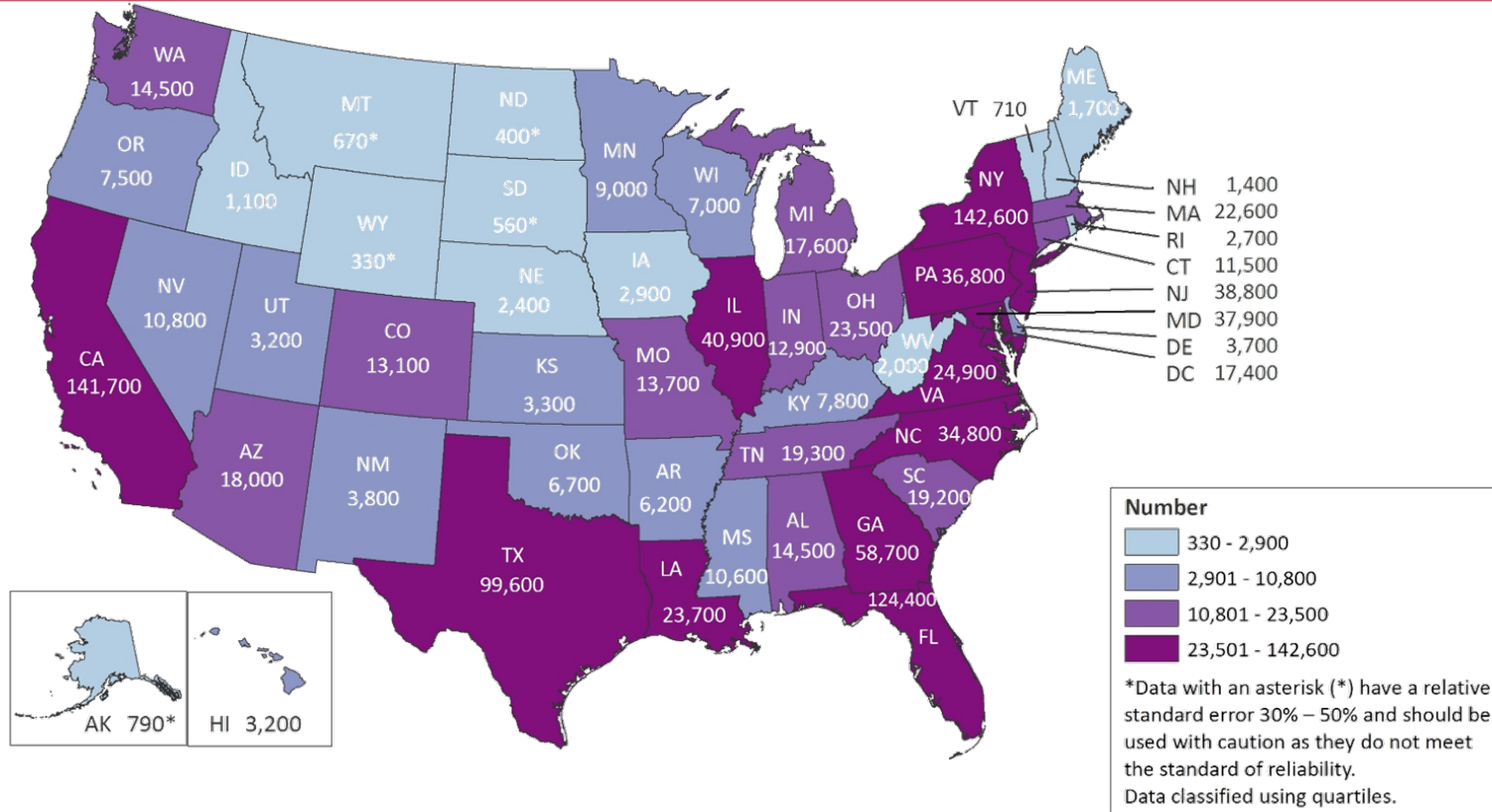
## Total = 38,500



Note. Estimates were derived from a CD4 depletion model using HIV surveillance data. Estimates rounded to the nearest 100 for estimates >1,000 and to the nearest 10 for estimates  $\leq 1,000$  to reflect model uncertainty.



# Estimated HIV Prevalence among Persons Aged ≥13 years, by Area of Residence, 2015— United States Total = 1,122,900

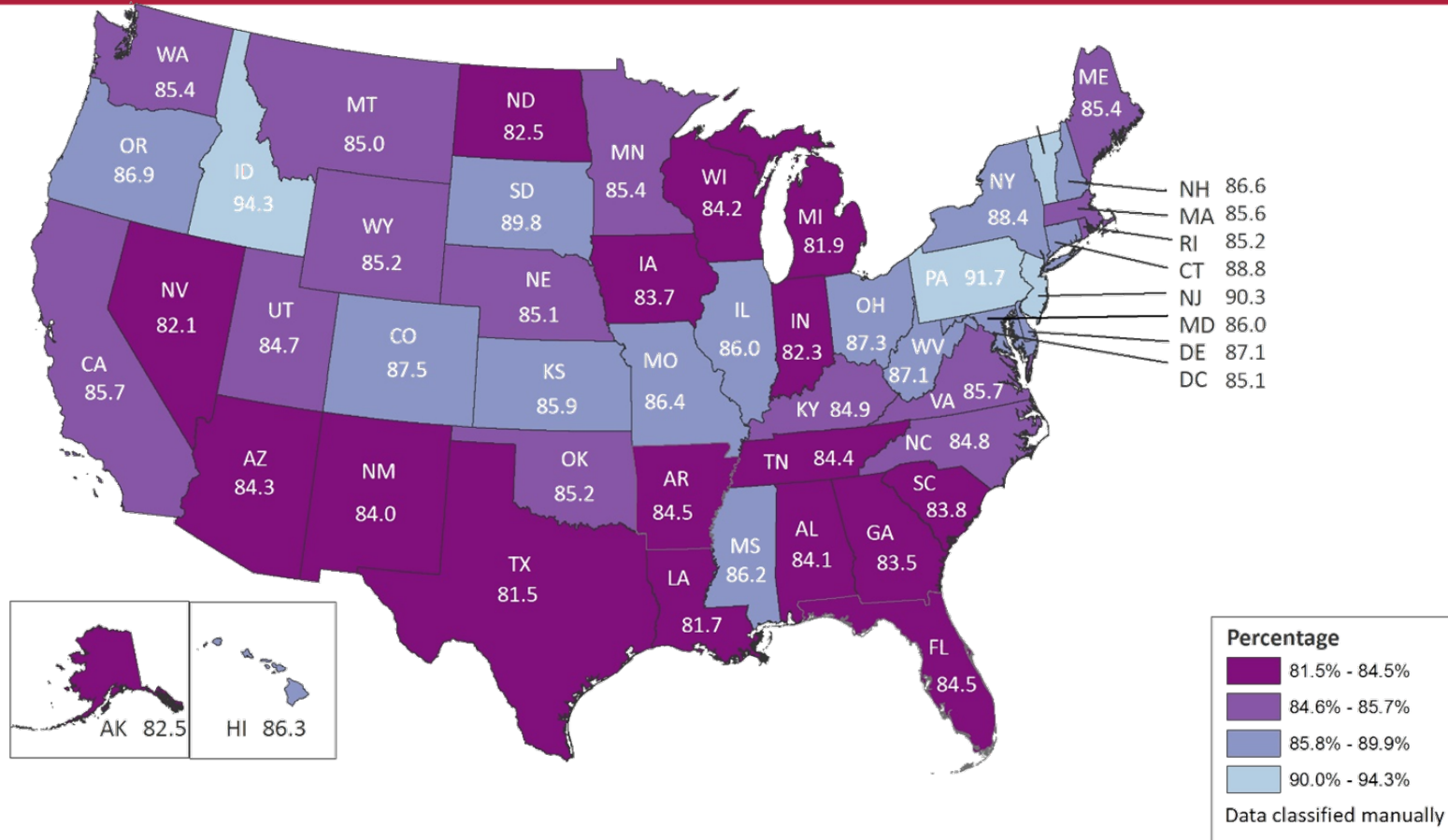


Note. Estimates were derived from a CD4 depletion model using HIV surveillance data. Estimates rounded to the nearest 100 for estimates >1,000 and to the nearest 10 for estimates ≤1,000 to reflect model uncertainty.



# Diagnosed Infection among Persons Aged $\geq 13$ Years Living with Diagnosed or Undiagnosed HIV Infection, 2015—United States

Total = 85.5%



Note. Estimates were derived from a CD4 depletion model using HIV surveillance data.



# Incidence of HIV Infection & AIDS: 2011-2016 Take Away Points

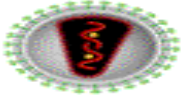
- Dx of Stage III (AIDS):
  - 2011-2015 = Overall decrease with current rate of 5.6
  - The number of persons in the United States whose diagnosed HIV infection was classified as stage 3 (AIDS) in 2016 was 18,160.
  - Of these, 13,851 stage 3 (AIDS) classifications were among adult and adolescent males, 4,271 were among adult and adolescent females, and 38 were among children younger than 13.
  - The cumulative number of persons in the United States with diagnosed HIV infection ever classified as stage 3 (AIDS) at year-end 2016 was 1,232,346.
- Deaths:
  - From 1987 (the first year HIV was listed as a cause of death on death certificates) through 2015, 507,351 people died from HIV disease.
  - In 2015, 6,465 people died from HIV disease.
    - 2015 HIV any-cause death rate was 4.8 (calculated from all cause)

# Incidence of HIV Infection & AIDS: 2011-2016 Take Away Points

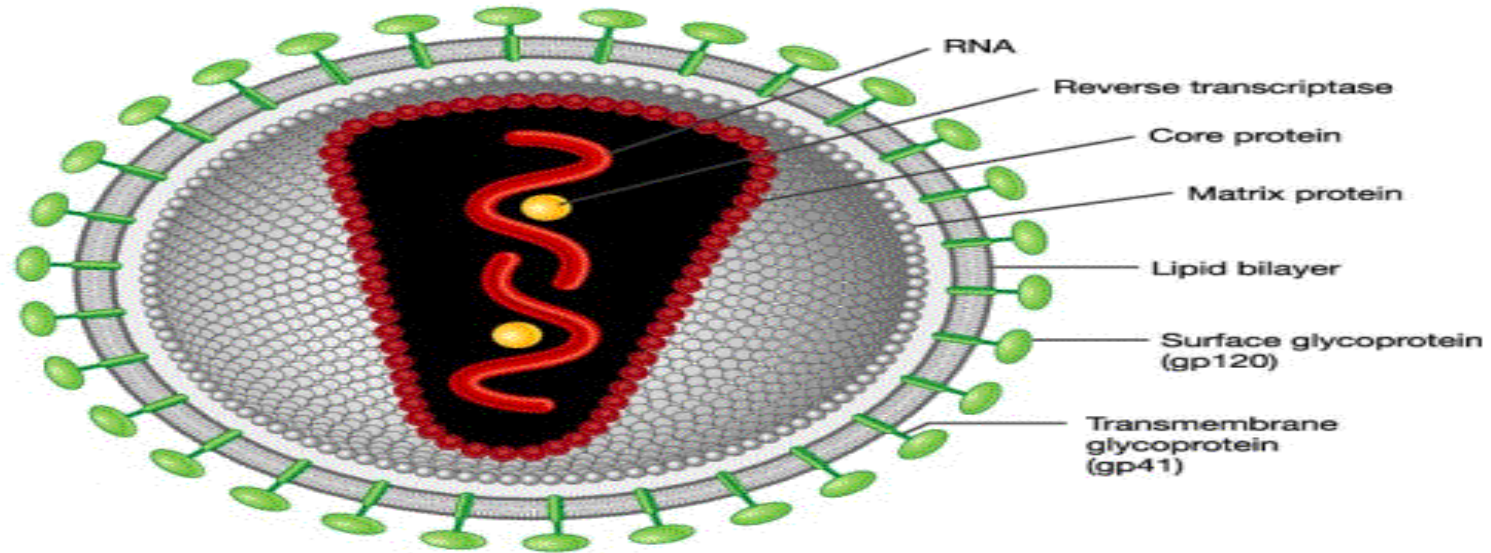
- Estimated annual HIV infections in the United States declined 8% from 2010 to 2015.
- From 2011 through 2015, among male adults and adolescents, the annual number of diagnosed HIV infections attributed to male-to-male sexual contact remained stable.
- In 2016, among male and female adults and adolescents, the diagnosed infections attributed to male-to-male sexual contact (70%, including male-to-male sexual contact *and* injection drug use) and those attributed to heterosexual contact (24%) accounted for approximately 94% of diagnosed HIV infections in the United States.
- Females MUCH higher heterosexual transmission (61% vs 9% in males [2016]).
- African Americans HIGHEST rates (57%), followed by Hispanics (35%).
- Progression to AIDS and related deaths decreased.

**TAKE AWAY**

# HIV



## HIV



# Pathophysiology of HIV Infection

- HIV is a retrovirus, transcribing RNA-containing genetic material into DNA of the host cell nucleus by using an enzyme called reverse transcriptase.
- Glycoproteins allow HIV to attach to CD4 Cell and incorporate its RNA into the cell membrane, which then transcribes the RNA to DNA using reverse transcriptase.
- This is then integrated into the CD4 nucleus using integrase. Integrated viral genes then transcribe back into genomic RNA and messenger RNA, which are translated to viral proteins.
- These proteins then are cleaved with protease into new HIV particles, which release to infect other cells.
- HIV progresses to AIDS.
- Seroconversion (HIV- → HIV+) typically occurs in 2-12 weeks post-exposure.

# Pathophysiology of HIV Infection

- After seroconversion, HIV antibody titers decrease as infected cells are sequestered in the lymph nodes.
- This is the latent period, lasting up to 10 years.
- During this period, CD4 cell lines drop as a result of infection and lysis of healthy T-Helper cells.

# Pathophysiology of HIV Infection

- As CD4 cells continue to decline, the patient becomes susceptible to opportunistic infections, malignancies, and neurological diseases. AIDS develops.
- A very few HIV+ individuals are termed “Non-Progressors”



# Pathogenic Process of HIV/AIDS

- Exposure to HIV
- HIV Infection
- Seroconversion
- Latency Period
- Initial Symptoms of Immunodeficiency and Declining Immune Function
- Immune System Failure and AIDS
- Severe Immune Deficiency

# Pathogenic Process of HIV/AIDS

- Important Points:
- Transmission of HIV is possible at any stage of the disease process.
- Risk to health workers is overall small.
- With blood product screening emerging in 1985, transfusion-related HIV transmission decreased dramatically.
- Since the introduction of maternal antiretroviral therapy, HIV transmission from mom to child has decreased.
- *Practically Preventable.*

# Prevention of HIV Transmission

- Sexual Transmission:
  - Alteration in Sexual Behaviors
  - Women more susceptible via vaginal mucosa compared to male penis.
  - Anal intercourse (regardless of orientation) also risky secondary to rectal trauma, tearing, and fistula formation.
  - Oral sex is actually very low risk.
  - Viral Load is NOT a determinant of degree of safeness (theoretically)—CDC (2017) issued new statement about this.

# Prevention of HIV Transmission

- Pharmacologic: PrEP and PEP
- Parenteral Transmission:
  - Proper cleaning of drug paraphernalia:
    - (filled and flushed with water → filled with bleach and then shaken for 1 min.);
    - participation in needle exchange programs.



# Prevention of HIV Transmission

- Perinatal Transmission:
  - HIV transmission thought to occur transplacentally in utero, intrapartally during exposure to blood and vaginal secretions during childbirth, or postpartally through breast milk.

# Prevention of HIV Transmission

- Perinatal Transmission (Ctd):
- Review of prior HIV-related illnesses and past CD4 T lymphocyte (CD4) cell counts and plasma HIV RNA levels;
- Current CD4 cell count;
- Current plasma HIV RNA copy number;
- Assessment of the need for prophylaxis against opportunistic infections such as *Pneumocystis jirovecii* pneumonia and *Mycobacterium avium* complex (see Adult and Adolescent Opportunistic Infections Guidelines)



# Prevention of HIV Transmission

- Perinatal Transmission (Ctd):
- Screening for hepatitis C virus and tuberculosis in addition to standard screening for hepatitis B virus (HBV) infection;
- Assessment of the need for immunizations per guidelines from the American College of Obstetricians and Gynecologists, with particular attention to hepatitis A, HBV, influenza, pneumococcus, and Tdap immunizations;
- Complete blood cell count and renal and liver function testing;
- HLA-B\*5701 testing if abacavir (Ziagen®) use is anticipated;
- History of prior and current antiretroviral (ARV) drug use, including prior ARV use for prevention of perinatal transmission or treatment of HIV and history of adherence problems

# Prevention of HIV Transmission

- Perinatal Transmission (Ctd):

## Key Points

- Pregnant women with HIV receive HIV medicines during childbirth (also called labor and delivery) to reduce the risk of **mother-to-child transmission of HIV**.
- Recommendations on the use of HIV medicines during childbirth consider whether a woman is already taking HIV medicines when she goes into labor and the level of HIV in her blood (**HIV viral load**).
- Women who are already taking HIV medicines should continue taking their HIV medicines as much as possible during childbirth. Women who have a high or unknown HIV viral load near the time of delivery should receive **zidovudine** (brand name: Retrovir) by **intravenous (IV) injection**.
- A scheduled **cesarean delivery** (sometimes called a C-section) at 38 weeks of pregnancy (2 weeks before a woman's expected due date) to reduce the risk of mother-to-child transmission of HIV is recommended for women with a high or unknown HIV viral load near the time of delivery.



# Screening for HIV

- ELISA → Western Blot (99.5% accurate)
  - Newer guidelines (CDC, 2014) are calling for substitution of Western Blot with antigen tests that differentiate HIV1 from HIV2.
- Confidentiality is **INCREDIBLY** important (i.e. no phone messages, personal names, etc.).
- Pre-Test and Post-Test Counseling can be valuable, but is NOT CDC recommended as a requirement any longer.
  - Check your state regulations for guidance
- General consent for Tx implies consent for HIV.

# Screening for HIV

- Antibody tests are specifically designed for the routine testing of HIV in adults, are inexpensive, and are very accurate
- Antibody tests give false negatives results during the *window period* of between three weeks and six months from the time of HIV infection until the immune system produces detectable amounts of antibodies
- Much screening done as POS (OraSure® or OraQuick® testing methods)

# Screening for HIV

- The vast majority of people have detectable antibodies after three months
- A six month window is extremely rare with modern antibody testing
- During this window period an infected person can transmit HIV to others, without their HIV infection being detectable using an antibody test
- ART during the window period can delay the formation of antibodies and extend the window period beyond 12 months.

# Screening for HIV

- The specificity of Rapid Antibody Tests in low-risk populations has not been evaluated
- Designed for high-risk individuals
  - OraQuick is an antibody test that provides results in 20 minutes. The blood, plasma or oral fluid is mixed in a vial with developing solution, and the results are read from a sticklike testing device
  - Orasure is an HIV test which uses mucosal transudate from the tissues of cheeks and gums. It is an antibody test which first employs ELISA, then Western Blot
  - There is also a urine test; it employs both the ELISA and the Western Blot method
  - Home Access Express HIV-1 Test is a FDA-approved home test: the patient collects a drop of blood and mails the sample to a laboratory; the results are obtained over the phone

# Screening for HIV

- **Antigen tests:**

- The **p24 antigen test** detects the presence of the p24 protein of HIV (also known as CA), a major core protein of the virus
- This test is now used routinely to screen blood donations, thus reducing the window to about 16 days

- **Nucleic acid based tests:**

- Nucleic acid based tests amplify and detect a 142 base target sequence located in a highly conserved region of the HIV *gag* gene
- Since 2001, donated blood in the US has been screened with nucleic acid based tests, shortening the window to about 12 days
- Since these tests are relatively expensive, the blood is screened by first pooling some 10-20 samples, testing these together, and if the pool tests positive, each sample is retested individually

# HIV/ AIDS Surveillance and Dx

- CD4 Testing:
  - Declining CD4 T-cell counts are considered to be a marker of the progression of HIV infection.
  - In HIV+ people, AIDS is officially diagnosed when the count drops below 200 cells or when certain opportunistic infections occur; CDC guidelines recommend beginning ART AT TIME OF Dx (2015)
  - Low CD4 T-cell counts are associated with a variety of conditions, including many viral infections, bacterial infections, parasitic infections, sepsis, tuberculosis, coccidioidomycosis, burns, trauma, intravenous injections of foreign proteins, malnutrition, over-exercising, pregnancy, normal daily variation, psychological stress, and social isolation

# HIV/ AIDS Surveillance and Dx

- CD4 Testing:
  - Generally speaking, the lower the number of T cells, the lower the immune system's function will be
  - Normal T4 counts are between 500 and 1500 CD4+ T cells per microliter and the counts may fluctuate in healthy people, depending on recent infection status, nutrition, exercise and other factors -- even the time of day
  - Women tend to have somewhat lower counts than men

# HIV/ AIDS Surveillance and Dx

- Viral Load Testing:
  - Evidence shows that keeping the viral load levels as low as possible for as long as possible decreases the complications of HIV disease and prolongs life
  - Most recent public health guidelines state that treatment should be considered for asymptomatic HIV-infected people AT TIME OF Dx
  - There are several methods for testing viral load; results are not interchangeable so it is important that the same method be used each time
  - Keep viral loads undetectable = decrease/ eliminate transmission



# Prophylactic Prevention of HIV Infection: Post-Exposure

- Although large-scale studies about PEP are lacking, PEP is clinically effective (80%) and recommended (Landovitz & Currier, 2009) when:
  - The source is known to be HIV+
  - The source is of unknown serostatus (test source in occupational exposure)
  - The source has an increased likelihood of being HIV+:
    - MSM, MSM/W, commercial sex workers, history of incarceration, residence in a county with a seroprevalence rate  $\geq 1\%$
  - The behavior has an increased ( $\geq 1\%$ ) likelihood of transmitting HIV:
    - Receptive Anal Intercourse = 1%-30% chance of infection
    - Insertive Anal Intercourse = .1-10% chance of infection
    - Receptive Vaginal Intercourse = .1-10% chance of infection
    - Insertive Vaginal Intercourse = .1-1% chance of infection
    - Oral Intercourse: Few documented cases
    - Needle Sharing: .67% per needle-sharing event
- Ideally, begin PEP within 36 hours but no more than 72 hours after exposure
- Treat with zidovudine-lamivudine (Combivir®) PO BID or tenofovir-emtricitabine (Truvada®) PO QD for 28 days (see supplemental Rx handout for precautions and other prescribing-related information).

# Prophylactic Prevention of HIV Infection: Post-Exposure

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- Ideally, begin PEP within 36 hours but no more than 72 hours after exposure

# Prophylactic Prevention of HIV Infection: Post-Exposure

**Table 1. Estimated per-act risk for acquiring human immunodeficiency virus (HIV) from an infected source, by exposure act<sup>a</sup>**

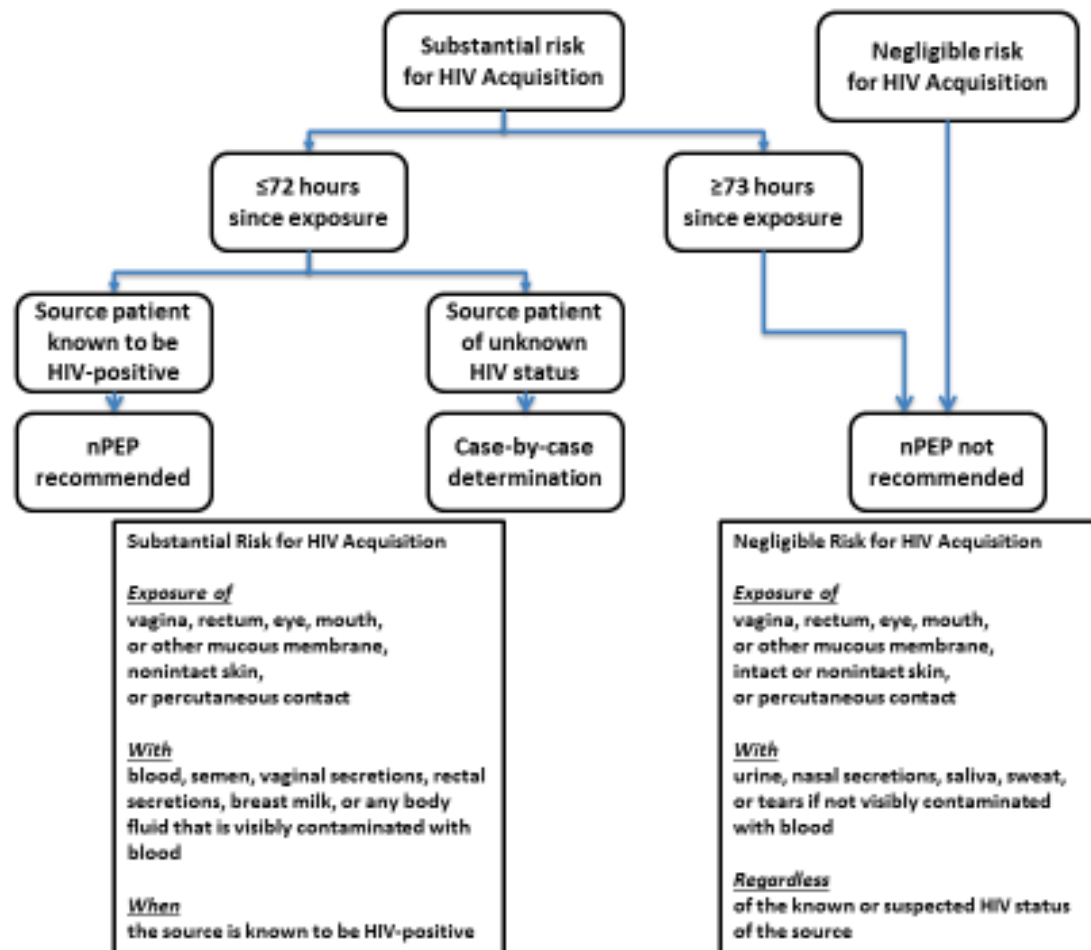
Exposure type	Rate for HIV acquisition per 10,000 exposures
<b>Parenteral</b>	
Blood transfusion	9,250
Needle sharing during injection drug use	63
Percutaneous (needlestick)	23
<b>Sexual</b>	
Receptive anal intercourse	138
Receptive penile-vaginal intercourse	8
Insertive anal intercourse	11
Insertive penile-vaginal intercourse	4
Receptive oral intercourse	Low
Insertive oral intercourse	Low
<b>Other<sup>b</sup></b>	
Biting	Negligible
Spitting	Negligible
Throwing body fluids (including semen or saliva)	Negligible
Sharing sex toys	Negligible

Source: <http://www.cdc.gov/hiv/policies/law/risk.html>

<sup>a</sup> Factors that may increase the risk of HIV transmission include sexually transmitted diseases, acute and late-stage HIV infection, and high viral load. Factors that may decrease the risk include condom use, male circumcision, antiretroviral treatment, and preexposure prophylaxis. None of these factors are accounted for in the estimates presented in the table.

<sup>b</sup> HIV transmission through these exposure routes is technically possible but unlikely and not well documented.

# Prophylactic Prevention of HIV Infection: Post-Exposure



# Prophylactic Prevention of HIV Infection: Post-Exposure

Table 5. Preferred and alternative antiretroviral medication 28-day regimens for nPEP<sup>a,b</sup>

Age group	Preferred/ alternative	Medication
Adults and adolescents aged $\geq 13$ years, including pregnant women, with normal renal function (creatinine clearance $\geq 60$ mL/min)	Preferred	A 3-drug regimen consisting of tenofovir DF 300 mg <b>and</b> fixed dose combination emtricitabine 200 mg (Truvada <sup>c</sup> ) once daily <b>with</b> raltegravir 400 mg twice daily <b>or</b> dolutegravir 50 mg once daily
	Alternative	A 3-drug regimen consisting of tenofovir DF 300 mg <b>and</b> fixed dose combination emtricitabine 200 mg (Truvada) once daily <b>with</b> darunavir 800 mg (as 2, 400-mg tablets) once daily <b>and</b> ritonavir <sup>b</sup> 100 mg once daily
Adults and adolescents aged $\geq 13$ years with renal dysfunction (creatinine clearance $\leq 59$ mL/min)	Preferred	A 3-drug regimen consisting of zidovudine <b>and</b> lamivudine, with both doses adjusted to degree of renal function <b>with</b> raltegravir 400 mg twice daily <b>or</b> dolutegravir 50 mg once daily
	Alternative	A 3-drug regimen consisting of zidovudine <b>and</b> lamivudine, with both doses adjusted to degree of renal function <b>with</b> darunavir 800 mg (as 2, 400-mg tablets) once daily <b>and</b> ritonavir <sup>b</sup> 100 mg once daily

# Prophylactic Prevention of HIV Infection: Post-Exposure

**Table 2. Recommended schedule of laboratory evaluations of source and exposed persons for providing nPEP with preferred regimens**

Test	Source	Exposed persons			
	Baseline	Baseline	4–6 weeks after exposure	3 months after exposure	6 months after exposure
	For all persons considered for or prescribed nPEP for any exposure				
HIV Ag/Ab testing <sup>a</sup> (or antibody testing if Ag/Ab test unavailable)	✓	✓	✓	✓	✓ <sup>b</sup>
Hepatitis B serology, including: hepatitis B surface antigen hepatitis B surface antibody hepatitis B core antibody	✓	✓	—	—	✓ <sup>c</sup>
Hepatitis C antibody test	✓	✓	—	—	✓ <sup>d</sup>
	For all persons considered for or prescribed nPEP for sexual exposure				
Syphilis serology <sup>e</sup>	✓	✓	✓	—	✓
Gonorrhea <sup>f</sup>	✓	✓	✓ <sup>g</sup>	—	—
Chlamydia <sup>f</sup>	✓	✓	✓ <sup>g</sup>	—	—
Pregnancy <sup>h</sup>	—	✓	✓	—	—
	For persons prescribed tenofovir DF+ emtricitabine + raltegravir or tenofovir DF+ emtricitabine + dolutegravir				
Serum creatinine (for calculating estimated creatinine clearance <sup>i</sup> )	✓	✓	✓	—	—
Alanine transaminase, aspartate aminotransferase	✓	✓	✓	—	—
	For all persons with HIV infection confirmed at any visit				
HIV viral load	✓	✓	✓	✓ <sup>j</sup>	✓
HIV genotypic resistance	✓	✓	✓	✓ <sup>j</sup>	✓

Abbreviations: Ag/Ab, antigen/antibody combination test; HIV, human immunodeficiency virus; nPEP, nonoccupational postexposure prophylaxis; tenofovir DF, tenofovir disoproxil fumarate.

<sup>a</sup> Any positive or indeterminate HIV antibody test should undergo confirmatory testing of HIV infection status.

<sup>b</sup> Only if hepatitis C infection was acquired during the original exposure; delayed HIV seroconversion has been seen in persons who simultaneously acquire HIV and hepatitis C infection.

<sup>c</sup> If exposed person susceptible to hepatitis B at baseline.

<sup>d</sup> If exposed person susceptible to hepatitis C at baseline.

<sup>e</sup> If determined to be infected with syphilis and treated, should undergo serologic syphilis testing 6 months after treatment.

<sup>f</sup> Testing for chlamydia and gonorrhea should be performed using nucleic acid amplification tests. For patients diagnosed with a chlamydia or gonorrhea infection, retesting 3 months after treatment is recommended.

- For men reporting insertive vaginal, anal, or oral sex, a urine specimen should be tested for chlamydia and gonorrhea.
- For women reporting receptive vaginal sex, a vaginal (preferred) or endocervical swab or urine specimen should be tested for chlamydia and gonorrhea.
- For men and women reporting receptive anal sex, a rectal swab specimen should be tested for chlamydia and gonorrhea.
- For men and women reporting receptive oral sex, an oropharyngeal swab should be tested for gonorrhea.

<http://www.cdc.gov/std/tg2015/tg-2015-print.pdf>

<sup>g</sup> If not provided presumptive treatment at baseline, or if symptomatic at follow-up visit.

<sup>h</sup> If woman of reproductive age, not using effective contraception, and with vaginal exposure to semen.

<sup>i</sup> eCrCl = estimated creatinine clearance calculated by the Cockcroft-Gault formula; eCrClCG = [(140 – age) × ideal body weight] ÷ (serum creatinine × 72) (× 0.85 for females).

<sup>j</sup> At first visit where determined to have HIV infection.

# Pre-Exposure Prophylaxis

- PrEP therapy is indicated for patients considered high risk for sexually acquired HIV
- Examples of such individuals might include a non-HIV-infected partner of an HIV infected individual



## **Initiation of PrEP: Pretreatment evaluation<sup>3,13</sup>**

Prior to initiation of therapy, perform the pretreatment evaluation to determine eligibility for therapy.

- Document HIV-negative antibody test:
  - Test for HIV if patient reports unsafe sex with an HIV-infected partner
  - Test for HIV if patient reports symptoms of acute HIV infection (symptoms include fever, chills, malaise, anorexia, nighttime diaphoresis, lymphadenopathy, dysphagia, nausea, emesis, diarrhea, and/or myalgia)
- In females, document a negative urine pregnancy test
- Provide education regarding possible risks of using PrEP during pregnancy
- Do not prescribe PrEP for female patients who are breastfeeding
- Confirm creatinine clearance of 60 mL/min or greater (use Cockcroft-Gault formula)
- Assess status of care in HIV-infected partners and provide referral as needed
- Screen for hepatitis B and initiate treatment when indicated
- Screen for and treat any sexually transmitted infections



# Pre-Exposure Prophylaxis

- The PrEP dosage is one tablet (emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg)
- The drug is taken orally with or without food and should be prescribed with a frequency of once daily
- In addition to the medication, which should be prescribed in no more than a 90-day supply, the patient should be educated about risk reduction strategies, particularly consistent use of condoms during every sexual encounter



## Treatment monitoring recommendations<sup>3</sup>

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- Document HIV-negative antibody test every 2 to 3 months
  - Review adherence and provide safer sex counseling at each follow-up visit
  - Screen for bacterial STIs, even if asymptomatic, every 6 months
  - In females, document a negative urine pregnancy test and counsel pregnant patient regarding possible risks if PrEP is continued
  - Assess creatinine clearance 3 months after treatment initiation and then every 6 months while on PrEP
-

# Pre-Exposure Prophylaxis

- The financing of antiretrovirals for PrEP is emerging as an important healthcare policy issue
- A 2011 cost-effectiveness model by the CDC estimated the daily cost of PrEP at \$22, which equals \$8,030 per year
- Additional monitoring and screening costs per person were estimated to be \$1,300 per year.
- Most private insurance companies cover PrEP



# Pre-Exposure Prophylaxis

- The Patient Protection and Affordable Care Act requires insurers to cover preventive services with an A or B rating from the United States Preventive Services Task Force (USPSTF)
- Therefore, a significant step toward private insurance coverage for PrEP in the United States should occur with June 2019 USPTF A Rating for PrEP!



# Pre-Exposure Prophylaxis

- PrEP therapy with the use of FTC/TDF is a newly approved approach to preventing HIV in individuals at high risk for sexually acquired infection
- The once-daily regimen has been shown as significantly effective at preventing HIV in both men and women including heterosexual and bisexual persons



# Pre-Exposure Prophylaxis

- Evaluating patient appropriateness for PrEP, performing pretreatment evaluations prior to initiation of treatment, and close monitoring of therapy are all responsibilities NPs will assume as this treatment becomes more widespread in the U.S. healthcare system.
- Cost of the therapy is also a major blockade to its implementation, and this will continue to be a prevalent issue in the foreseeable future

# Pre-Exposure Prophylaxis

Blackwell, C.W. (2014). Pre-exposure prophylaxis: An emerging clinical approach to preventing HIV in high-risk adults. *The Nurse Practitioner: The American Journal of Primary Healthcare* 39(9), 50-53. DOI: 10.1097/01.NPR0000452976.92052.fa.

<http://drchristopherblackwell.com/research>

# Moving Forward

- Community and Public Health Outreach
- Prevention Education in the Clinical Setting
- Future Research and the Responsibility of the Nurse Practitioner



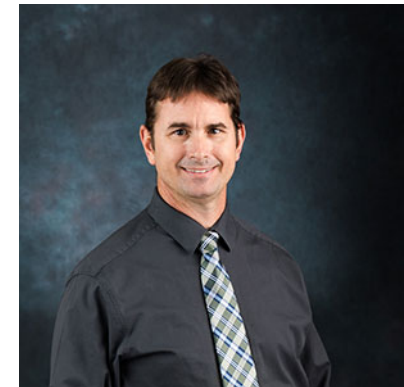
# References

Please see the supplemental handout, which includes a bibliography and additional resources for more information.

Go to <https://guides.ucf.edu/CONLibBibliographies/Prep> access the online bibliography!



Bibliography Compiled by:  
Andrew Todd, MLIS, BSN, RN  
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# Preventing HIV in Adolescents and Adults: PrEP, PEP, and Other Innovative Strategies

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