Contraception, Conception and Perinatal Care for Women with HIV

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May 13, 2016

Objectives

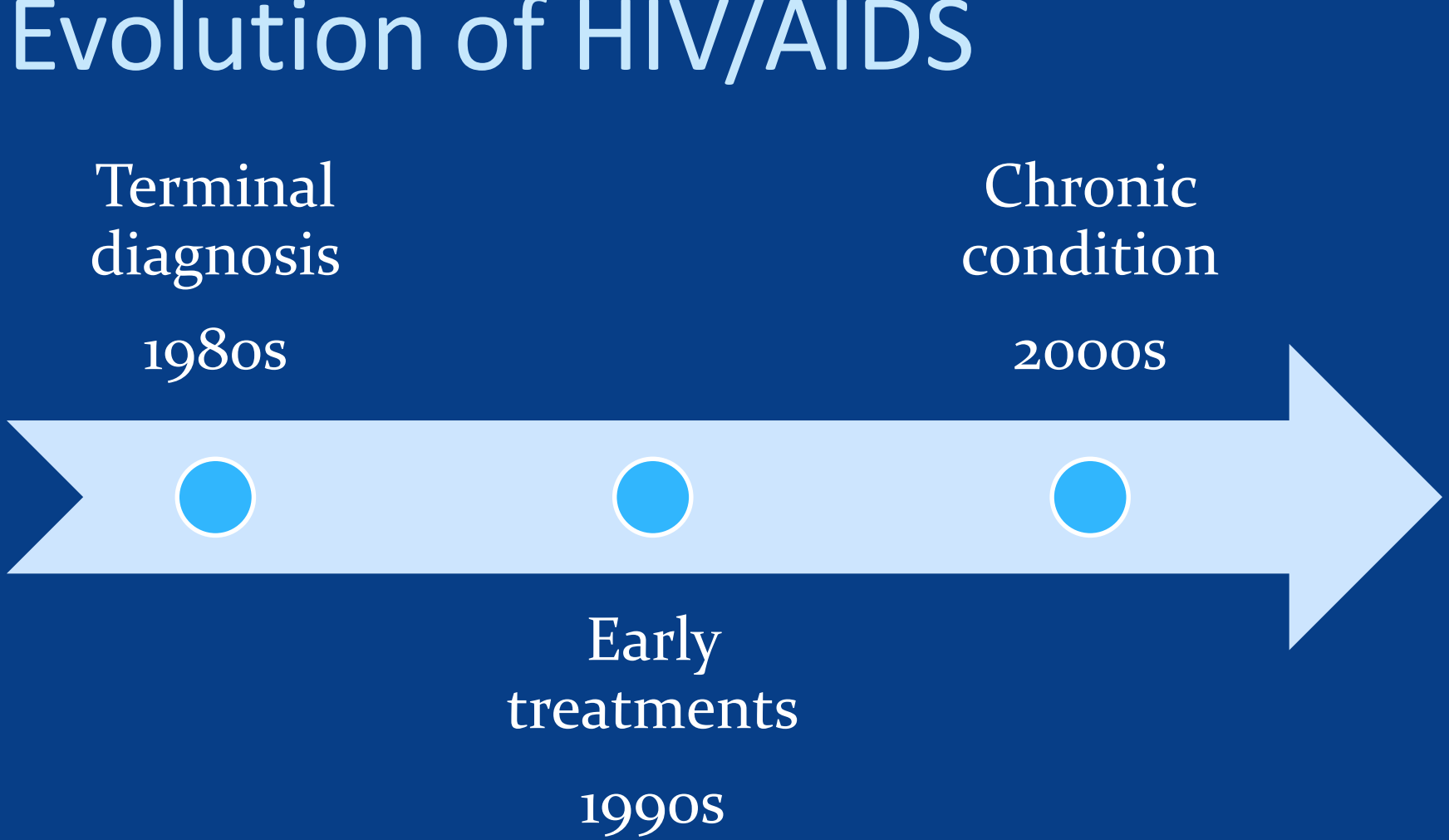
At the conclusion of this presentation, participants will be able to :

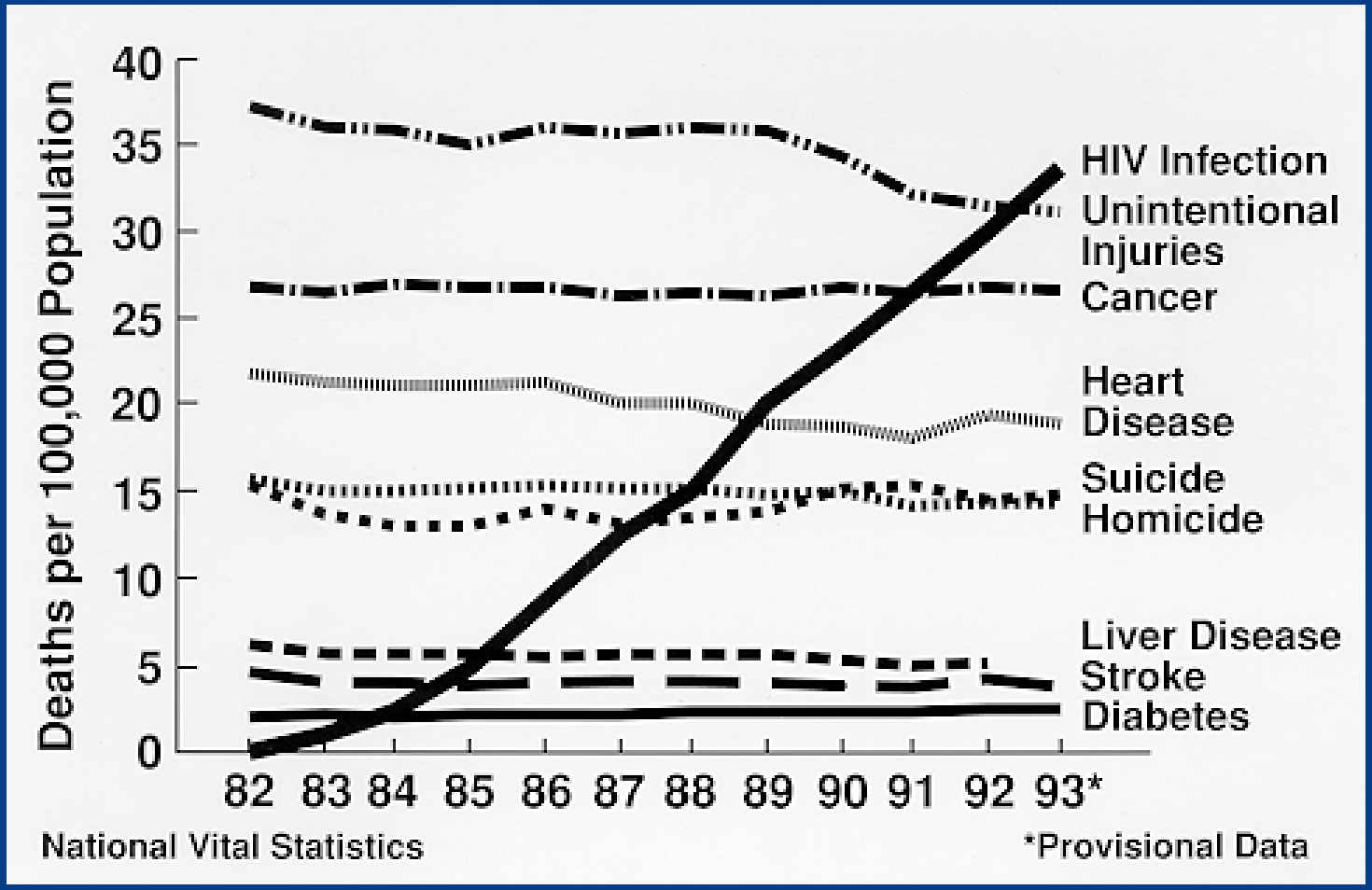
- Provide pre-conception counseling (or referral) for HIV positive women or women with an HIV positive partner
- Counsel HIV positive women regarding contraceptive options.
- Screen and refer for treatment of HIV early in pregnancy to reduce mother to child transmission (or co-manage with team as appropriate)

No disclosures

Newsweek April 2014

Evolution of HIV/AIDS





25-44 years

www.niaid.nih.gov

Prevention of perinatal transmission

- PACTG 076 (from April 1991-December 1993)
- Time of AZT Administration (FDA approved 1987)

  - Antepartum — Oral administration of 100mg AZT 5x/day (300mg BID) initiated at 14-34 weeks gestation and continued throughout the pregnancy

  - Intrapartum — During labor, intravenous administration of AZT in a one-hour initial dose of 2mg/kg body weight/ hour then continuous 1mg/kg IV until delivery

  - Postpartum — Oral administration of AZT to the newborn (AZT syrup at 2mg/kg body weight/dose every six hours) for the first six weeks of life, beginning at 8-12 hours after birth. (Note: intravenous dosage for infants who cannot tolerate oral intake is 1.5 mg/kg body weight intravenously every six hours.)

The New England
Journal of Medicine

Volume 331 NOVEMBER 3, 1994 Number 18

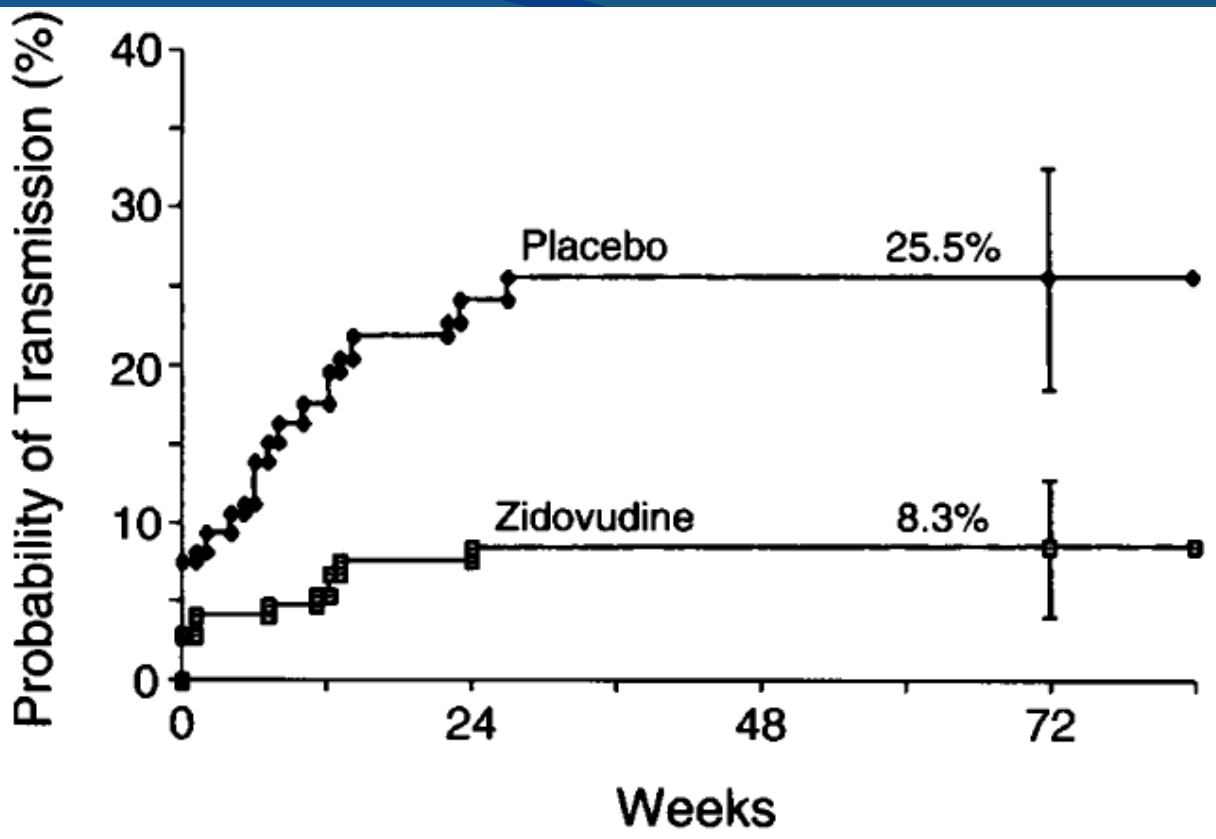
REDUCTION OF MATERNAL–INFANT TRANSMISSION OF HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 WITH ZIDOVUDINE TREATMENT

EDWARD M. CONNOR, M.D., RHODA S. SPERLING, M.D., RICHARD GELBER, PH.D., PAVEL KISELEV, PH.D., GWENDOLYN SCOTT, M.D., MARY JO O'SULLIVAN, M.D., RUSSELL VANDYKE, M.D., MOHAMMED BEY, M.D., WILLIAM SHEARER, M.D., PH.D., ROBERT L. JACOBSON, M.D., ELEANOR JIMENEZ, M.D., EDWARD O'NEILL, M.D., BRIGITTE BAZIN, M.D., JEAN-FRANÇOIS DELFRAISSY, M.D., MARY CULNANE, M.S., ROBERT COOMBS, M.D., PH.D., MARY ELKINS, M.S., JACK MOYE, M.D., PAMELA STRATTON, M.D., AND JAMES BALSLEY, M.D., PH.D.,
FOR THE PEDIATRIC AIDS CLINICAL TRIALS GROUP PROTOCOL 076 STUDY GROUP*

Abstract *Background and Methods.* Maternal–infant transmission is the primary means by which young children become infected with human immunodeficiency virus type 1 (HIV). We conducted a randomized, double-blind, placebo-controlled trial of the efficacy and safety of zidovudine in reducing the risk of maternal–infant HIV transmission. HIV-infected pregnant women (14 to 34 weeks' gestation) with CD4+ T-lymphocyte counts above 200 cells per cubic millimeter who had not received antiretroviral therapy during the current pregnancy were enrolled. The zidovudine regimen included antepartum zidovudine (100 mg orally five times daily), intrapartum zidovudine (2 mg per kilogram of body weight given intravenously over a one-hour period, then 1 mg per kilogram per hour until delivery), and zidovudine for the newborn (2 mg per kilogram orally every six hours for six weeks). Infants with at least one positive HIV culture of peripheral-blood mononuclear cells were classified as HIV-infected.

Results. From April 1991 through December 20, 1993, the cutoff date for the first interim analysis of efficacy, 477 pregnant women were enrolled; during the study period, 409 gave birth to 415 live-born infants. HIV-infection status was known for 363 births (180 in the zidovudine group and 183 in the placebo group). Thirteen infants in the zidovudine group and 40 in the placebo group were HIV-infected. The proportions infected at 18 months, as estimated by the Kaplan–Meier method, were 8.3 percent (95 percent confidence interval, 3.9 to 12.8 percent) in the zidovudine group and 25.5 percent (95 percent confidence interval, 18.4 to 32.5 percent) in the placebo group. This corresponds to a 67.5 percent (95 percent confidence interval, 40.7 to 82.1 percent) relative reduction in the risk of HIV transmission ($Z = 4.03$, $P = 0.00006$). Minimal short-term toxic effects were observed. The level of hemoglobin at birth in the infants in the zidovudine group was significantly lower than that in the infants in the placebo group. By 12 weeks of age, hemoglobin values in the two groups were similar.

Conclusions. In pregnant women with mildly symptomatic HIV disease and no prior treatment with antiretroviral drugs during the pregnancy, a regimen consisting of zidovudine given ante partum and intra partum to the mother and to the newborn for six weeks reduced the risk of maternal–infant HIV transmission by approximately two thirds. (N Engl J Med 1994;331:1173-80.)



Placebo	183	84	42	37
Zidovudine	180	105	51	43

Figure 1. Kaplan–Meier Plots of the Probability of HIV Transmission, According to Treatment Group.

The estimated percentages of infants infected at 72 weeks are shown with 95 percent confidence intervals. The numbers of infants at risk at 24, 48, and 72 weeks are shown below the figure.

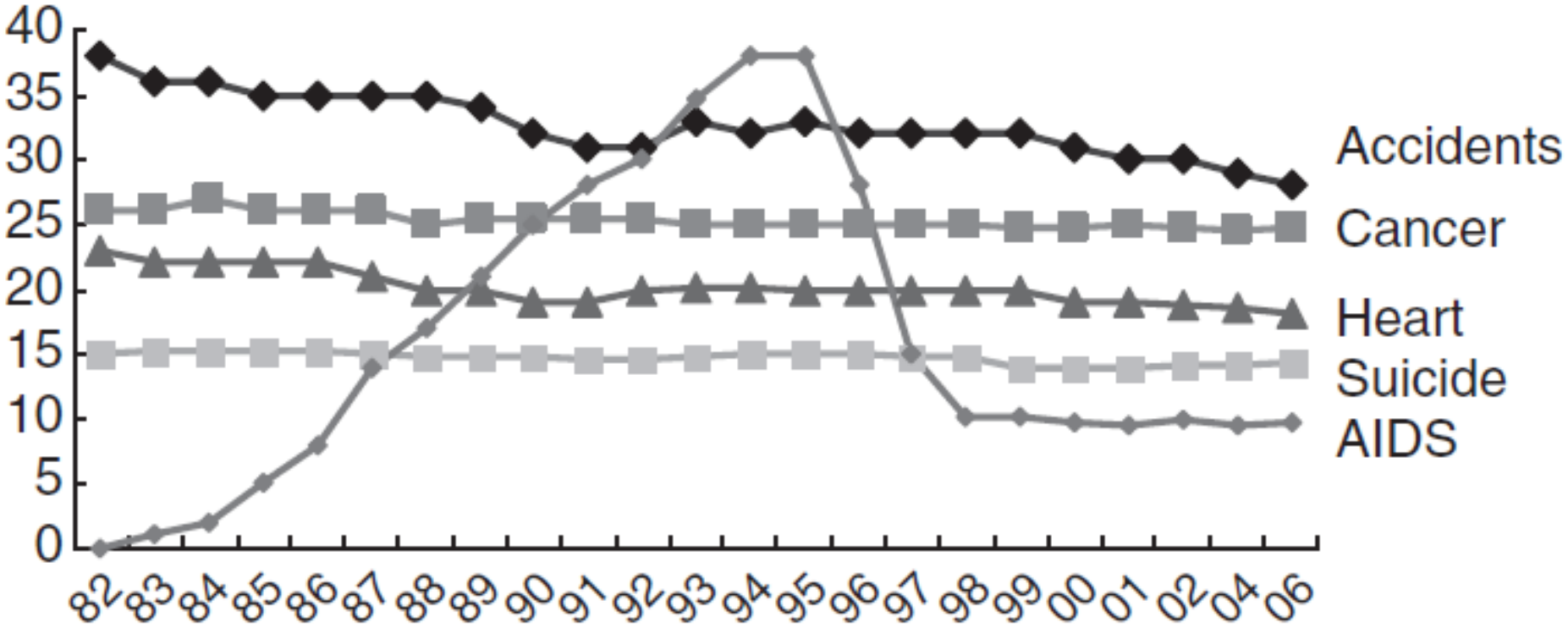
Background

Date	Event
1983	First case of pediatric AIDS in United States described
1985	CDC issues first guidelines for prevention of perinatal HIV transmission including the recommendation that HIV infected women in United States should not breast-feed
1992	Number of reported pediatric AIDS cases peaks in the United States
1994	• PACTG 076 trial findings reported, which indicate a two thirds reduction with an intensive regimen of ZDV given to the mother from the second trimester, intravenously at labor and for 6 weeks to the newborn. • Food and Drug Administration licenses ZDV for perinatal HIV prevention indication • US Public Health Service recommends implementation of ZDV regimen for all HIV-infected pregnant women
1995	CDC recommends voluntary counseling and testing for all pregnant women and offering the ZDV regimen to all HIV-infected women
1998	Institute of Medicine report released, which recommends universal HIV screening with right of refusal for all pregnant women
1999	Congress provides targeted funding for perinatal HIV prevention efforts in high prevalence states
2001	Revised CDC Counseling and Testing Guidelines for Pregnant women supports reducing barriers to offering of prenatal HIV testing to ensure routine universal testing and offering rapid HIV testing at labor/delivery for women whose HIV status is still unknown
2002-2003	CDC reports high uptake of screening of pregnant women using opt-out strategy. Dear Colleague Letter issued recommending opt-out strategy to optimally support routine universal testing of pregnant women.
2006	CDC Revised Recommendations for HIV Testing in Health Care Settings released recommending an opt-out strategy with routine HIV screening of all pregnant women as part of the routine panel of prenatal tests, a second test in the third trimester for women in areas or facilities with elevated incidence of HIV or who are known to be at high risk for HIV, and rapid HIV testing for women whose HIV status is not known at labor/delivery. Additionally, opt-out testing recommended for: all patients aged 13-64 y (annually for those likely to be at high risk for HIV); women as a component of preconception care and all patients with tuberculosis or seeking treatment for a sexually transmitted disease.

Fowler MG et al. AJOG September 2007

1999

- IOM issued recommendations calling for universal screening in pregnancy with opt out approach
- Reduction of HIV transmission with scheduled cesarean delivery
  - European Mode of Delivery Collaboration. Elective caesarean-section versus vaginal delivery in prevention of vertical HIV-1 transmission: a randomised clinical trial. *Lancet*. Mar 27 1999;353(9158):1035-1039.
    - 80% reduction (30% rec'd some azt)
  - International Perinatal HIV Group. The mode of delivery and the risk of vertical transmission of human immunodeficiency virus type 1--a meta-analysis of 15 prospective cohort studies. The International Perinatal HIV Group. *N Engl J Med*. Apr 1 1999;340(13):977-987.
    - 10% transmission rate with elective cd without azt vs 19% with other modes of delivery;2% vs 7.3% with AZT



Causes of mortality male and female ages 25-44

R. A. Weiss *Clinical and Experimental Immunology*, **152:** 201–210

Rank[1]	Cause of death (based on ICD–10), race, sex, and age	Number[2]	Percent of total deaths	Death rate[2]
	All races, both sexes, 25–34 years			
...	All causes	45,463	100.0	106.1
1	Accidents (unintentional injuries) (V01–X59,Y85–Y86)	16,209	35.7	37.8
2	Intentional self-harm (suicide) (*U03,X60–X84,Y87.0)	6,348	14.0	14.8
3	Assault (homicide) (*U01–*U02,X85–Y09,Y87.1)	4,236	9.3	9.9
4	Malignant neoplasms (C00–C97)	3,673	8.1	8.6
5	Diseases of heart (I00–I09,I11,I13,I20–I51)	3,258	7.2	7.6
6	Diabetes mellitus (E10–E14)	684	1.5	1.6
7	Chronic liver disease and cirrhosis (K70,K73–K74)	676	1.5	1.6
8	Human immunodeficiency virus (HIV) disease (B20–B24)	631	1.4	1.5
9	Cerebrovascular diseases (I60–I69)	508	1.1	1.2
10	Influenza and pneumonia (J09–J18)	449	1.0	1.0
...	All other causes (residual)	8,791	19.3	20.5
	All races, both sexes, 35–44 years			
...	All causes	69,573	100.0	172.0
1	Accidents (unintentional injuries) (V01–X59,Y85–Y86)	15,354	22.1	38.0
2	Malignant neoplasms (C00–C97)	11,349	16.3	28.1
3	Diseases of heart (I00–I09,I11,I13,I20–I51)	10,341	14.9	25.6
4	Intentional self-harm (suicide) (*U03,X60–X84,Y87.0)	6,551	9.4	16.2
5	Assault (homicide) (*U01–*U02,X85–Y09,Y87.1)	2,581	3.7	6.4
6	Chronic liver disease and cirrhosis (K70,K73–K74)	2,491	3.6	6.2
7	Diabetes mellitus (E10–E14)	1,952	2.8	4.8
8	Cerebrovascular diseases (I60–I69)	1,687	2.4	4.2
9	Human immunodeficiency virus (HIV) disease (B20–B24)	1,246	1.8	3.1
10	Influenza and pneumonia (J09–J18)	881	1.3	2.2
...	All other causes (residual)	15,140	21.8	37.4

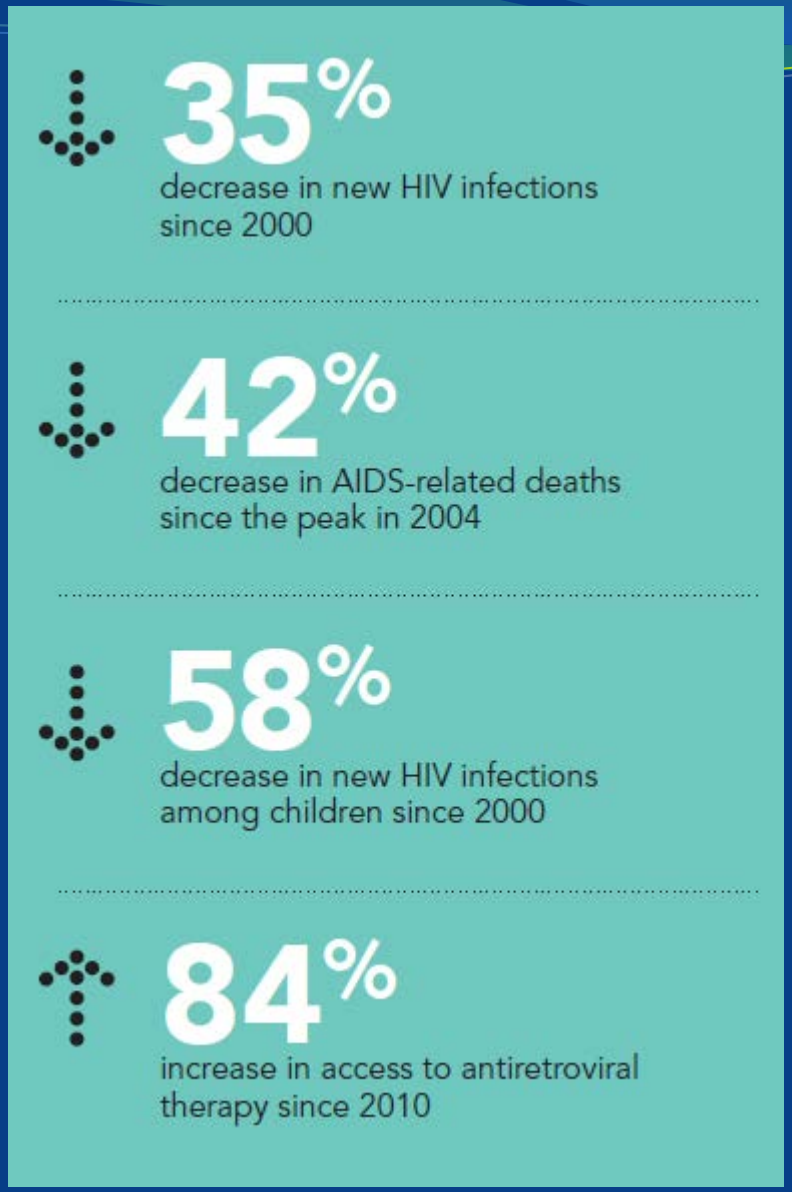
National Vital Statistics Reports

NVSS

Volume 65, Number 2 February 16, 2016

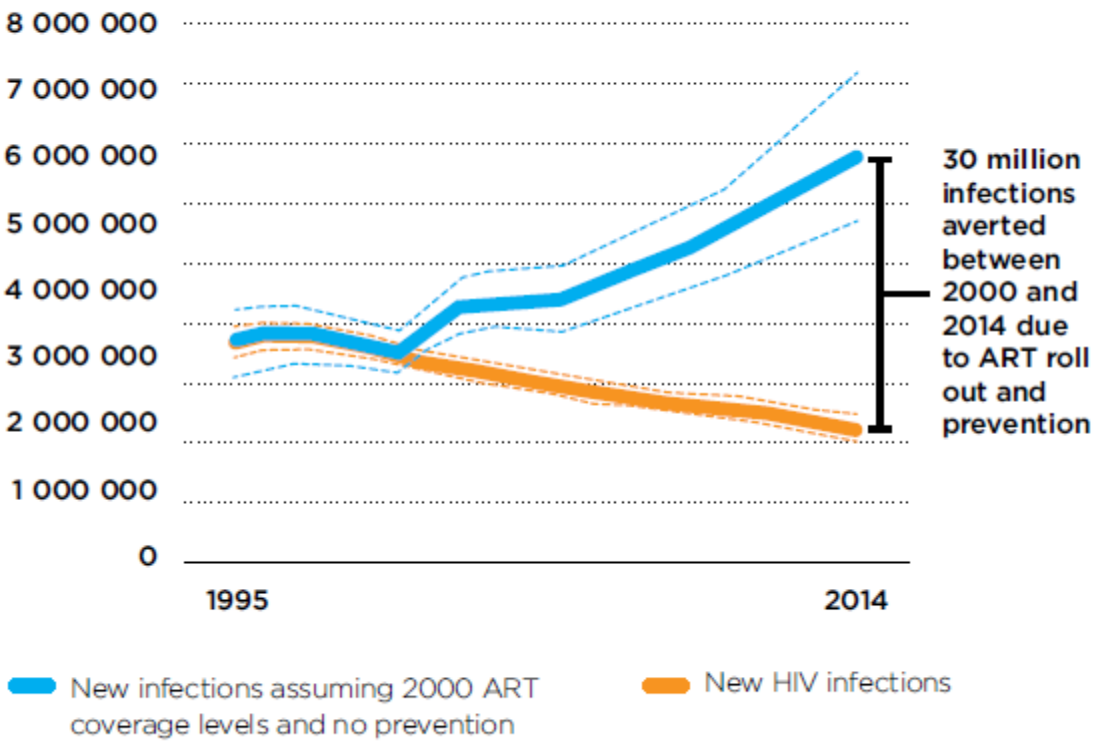
Deaths: Leading Causes for 2013

by Melonie Heron, Ph.D., Division of Vital Statistics



UNAIDS World AIDS Day Report | 2015

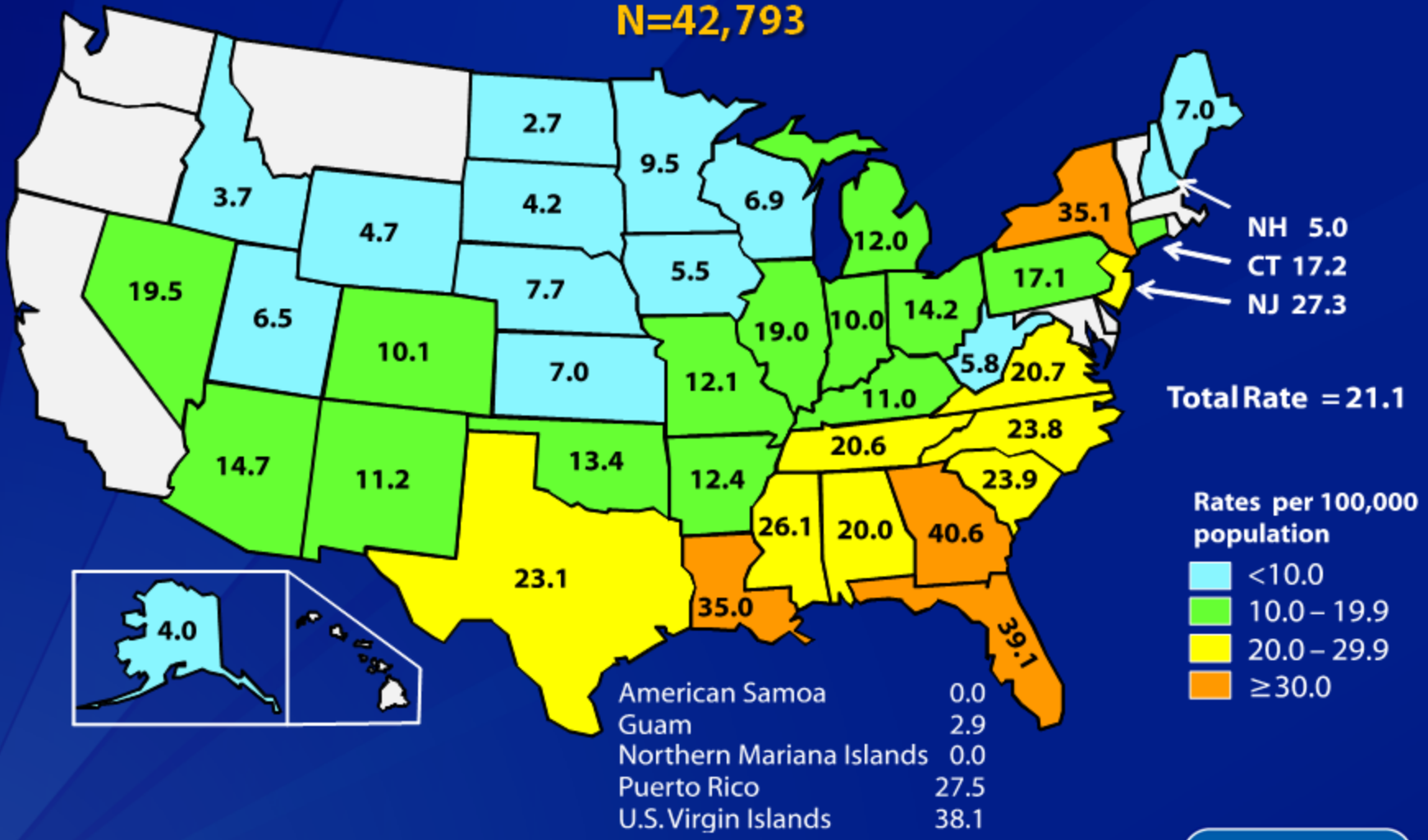
New HIV infections



Sources: UNAIDS 2014 estimates

Rates of Diagnoses of HIV Infection among Adults and Adolescents, 2009—40 states and 5 U.S. Dependent Areas

N=42,793

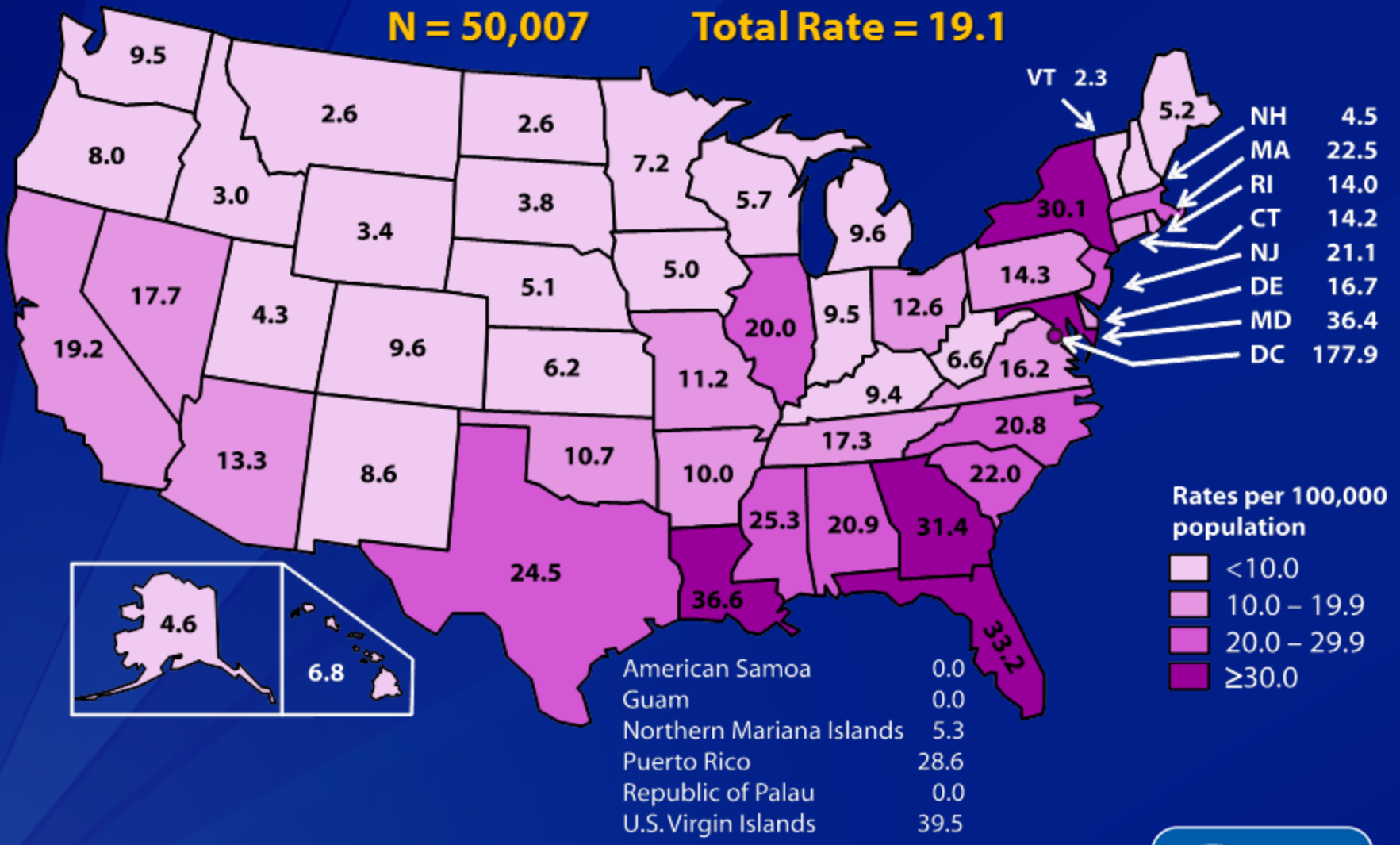


Note. Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays, but not for incomplete reporting.

CDC

Rates of Diagnoses of HIV Infection among Adults and Adolescents, 2011—United States and 6 Dependent Areas

N = 50,007 Total Rate = 19.1

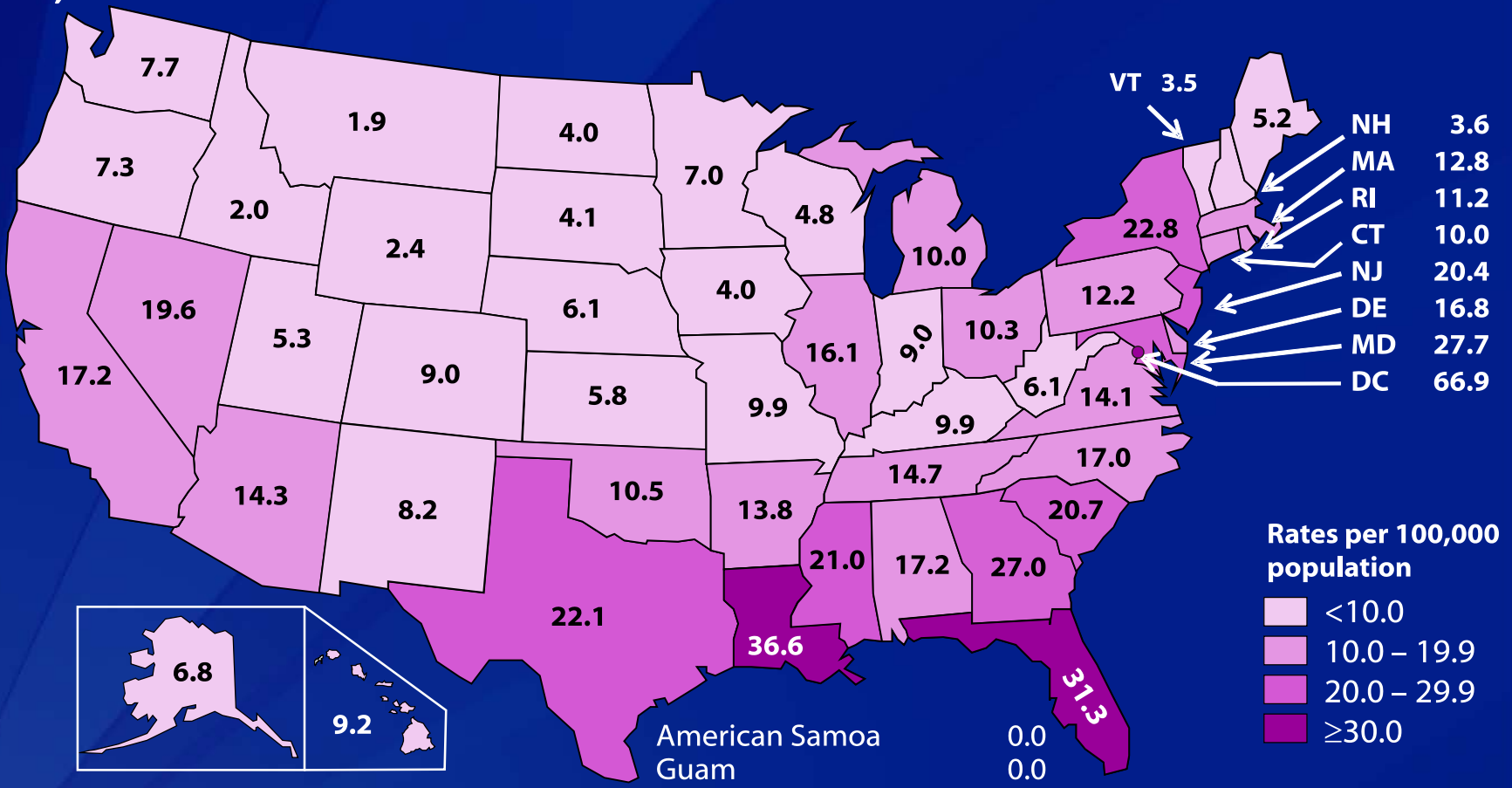


American Samoa	0.0
Guam	0.0
Northern Mariana Islands	5.3
Puerto Rico	28.6
Republic of Palau	0.0
U.S. Virgin Islands	39.5

Note. Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays, but not for incomplete reporting.

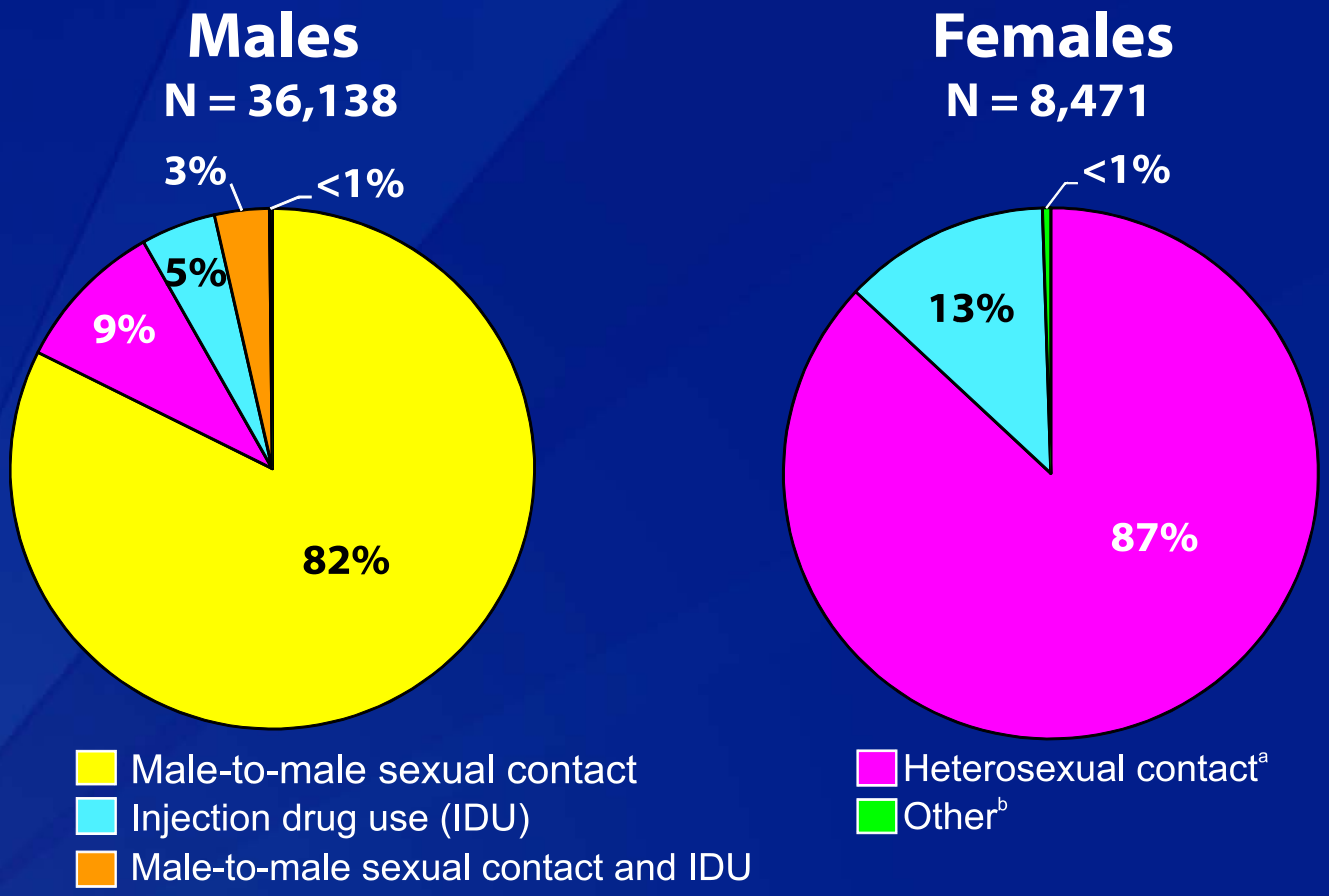
Rates of Diagnoses of HIV Infection among Adults and Adolescents, 2014—United States and 6 Dependent Areas

N = 44,609 **Total Rate = 16.6**



Note. Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays, but not for incomplete reporting.

Diagnoses of HIV Infection among Adults and Adolescents, by Sex and Transmission Category, 2014—United States and 6 Dependent Areas



Note. Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays and missing transmission category, but not for incomplete reporting.

a Heterosexual contact with a person known to have, or to be at high risk for, HIV infection.

b Includes hemophilia, blood transfusion, perinatal exposure, and risk factor not reported or not identified.

TREATMENT AS PREVENTION

- Viral load most important risk factor for transmission
  - 2.4x increased risk for every 1 $\log_{10}$ increase
  - Reduction in VL of 0.7 $\log_{10}$ estimated to reduce transmission by 50%
- September 2006 CDC recommendations for universal routine HIV screening; yearly for high risk

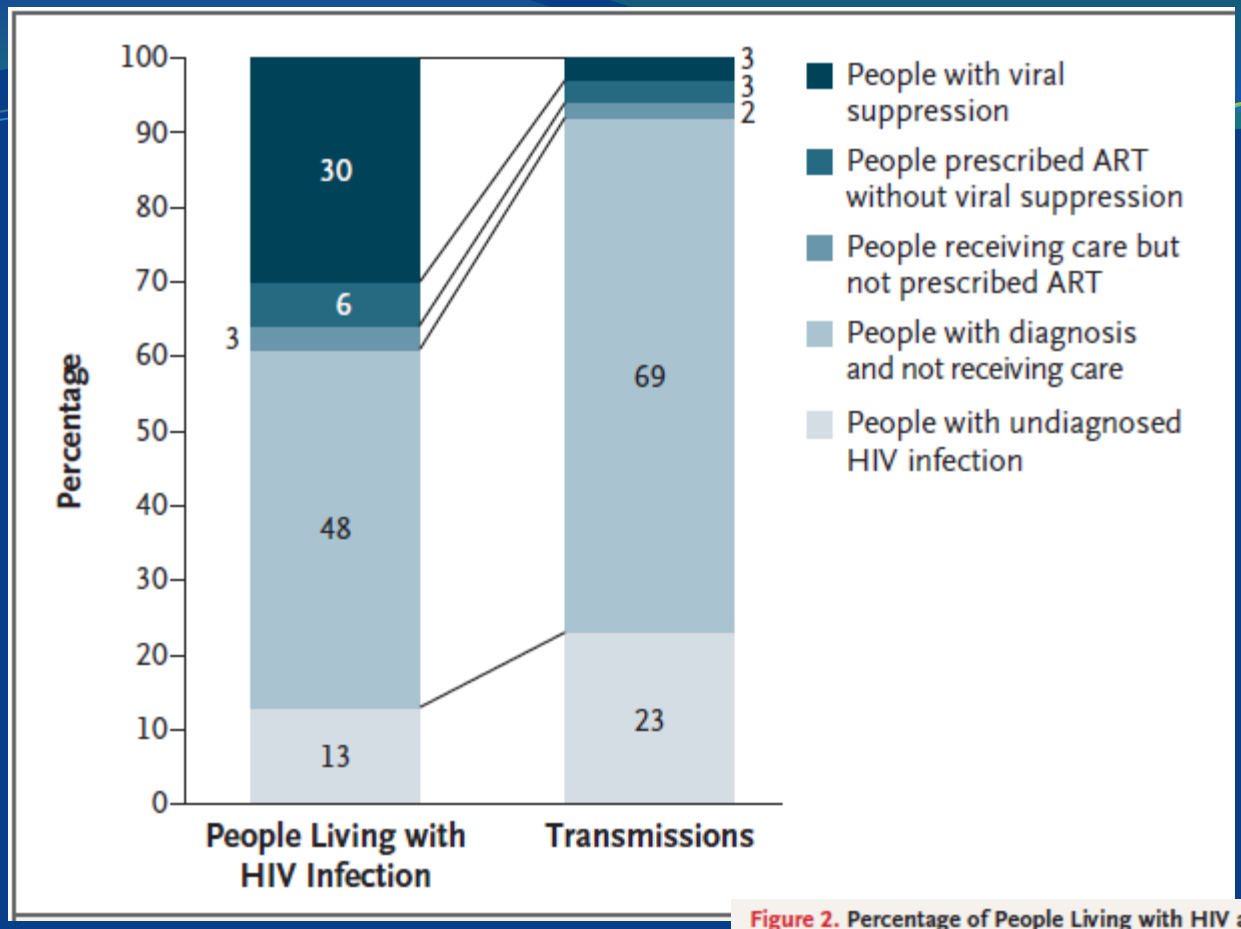


Figure 2. Percentage of People Living with HIV and Percentage of HIV Transmissions at Each Stage of the Care Continuum, United States and Puerto Rico, 2012.

National HIV Surveillance System data were used to estimate the number of people 13 years of age or older who were living with diagnosed or undiagnosed HIV infection (prevalence) in the United States at the end of 2012. Data from the Medical Monitoring Project were used to estimate the number of people 18 years of age or older who received medical care for HIV infection between January and April 2012, the number who received prescriptions for ART, and the number whose most recent viral load in the previous year was undetectable or less than 200 copies per milliliter. The percentage of transmissions from each group was estimated by applying transmission rates from Skarbinski et al.[30] to 2012 surveillance data. There were about 10,000 transmissions from people with undiagnosed HIV infection, 31,000 from those with diagnosed infection who were not in care, 900 from those in care but not prescribed ART, 1300 from those prescribed ART but without viral suppression, and 1500 from those with viral suppression.

Applying Public Health Principles to the HIV Epidemic — How Are We Doing?

Thomas R. Frieden, M.D., M.P.H., Kathryn E. Foti, M.P.H., and Jonathan Mermin, M.D., M.P.H.

N ENGL J MED 373;23 NEJM.ORG DECEMBER 3, 2015

CBS/AP / April 28, 2015, 8:38 AM

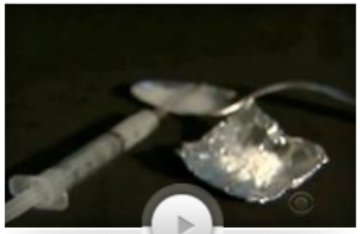
Sudden spike in HIV cases draws CDC alert in Indiana

INDIANAPOLIS - An Indiana county is experiencing nearly daily increases in new HIV infections tied to intravenous drug use, and health officials hope the situation prompts other states to closely track their hepatitis C and HIV rates to identify potential clusters of the diseases.

Indiana state health officials said Friday that the number of positive HIV tests so far this year has jumped to 142 in Scott County, which saw just three new HIV cases between 2009 and 2013, and has never seen more than five cases in a year, health officials said.

The new number includes 136 confirmed cases and 6 preliminary positives in the county, about 30 miles north of Louisville, Kentucky.

"We literally have new cases being reported every day," said Dr. Jerome Adams, the state's health commissioner.



Play VIDEO

Indiana tries to curb HIV crisis linked to drug abuse

When CBS News first met 49-year-old Kevin Polly this month, he showed us the needles he used to inject Opana three to five times a day. Polly was able to get clean syringes from a needle exchange set up by the state. But for months he had been sharing contaminated needles with other users and is now diagnosed with HIV.

Dr. Joan Duwve, chief medical consultant for the Indiana State Department of Health, said four out of five people infected in the outbreak have acknowledged using injectable drugs, mostly the painkiller Opana.

Federal health officials helping to contain the outbreak issued an alert to health departments nationwide on Friday, urging them to take steps to identify and track HIV and hepatitis C cases in an effort to prevent similar outbreaks elsewhere

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http://emergency.cdc.gov/han/han00377.asp

HAN HEALTH ALERT NETWORK

This is an official
CDC HEALTH ADVISORY

This information is *for historic and reference purposes only.* Content has not been updated since the last updated date at the bottom of this page.

Distributed via the CDC Health Alert Network
April 24, 2015, 11:00 ET (11:00 AM ET)
CDCHAN-00377

Summary

The Indiana State Department of Health (ISDH) and the Centers for Disease Control and Prevention (CDC) are investigating a large outbreak of recent human immunodeficiency virus (HIV) infections among persons who inject drugs (PWID). Many of the HIV-infected individuals in this outbreak are co-infected with hepatitis C virus (HCV). The purpose of this HAN Advisory is to alert public health departments and healthcare providers of the possibility of HIV outbreaks among PWID and to provide guidance to assist in the identification and prevention of such outbreaks.

Background

http://emergency.cdc.gov/han/han00377.asp

Background

From November 2014 to January 2015, ISDH identified 11 new HIV infections in a rural southeastern county where fewer than 5 infections have been identified annually in the past. As of April 21, 2015, an on-going investigation by ISDH with assistance from CDC has identified 135 persons with newly diagnosed HIV infections in a community of 4,200 people; 84% were also HCV infected. Among 112 persons interviewed thus far, 108 (96%) injected drugs; all reported dissolving and injecting tablets of the prescription-type opioid oxymorphone (OPANA® ER) using shared drug preparation and injection equipment.[1]

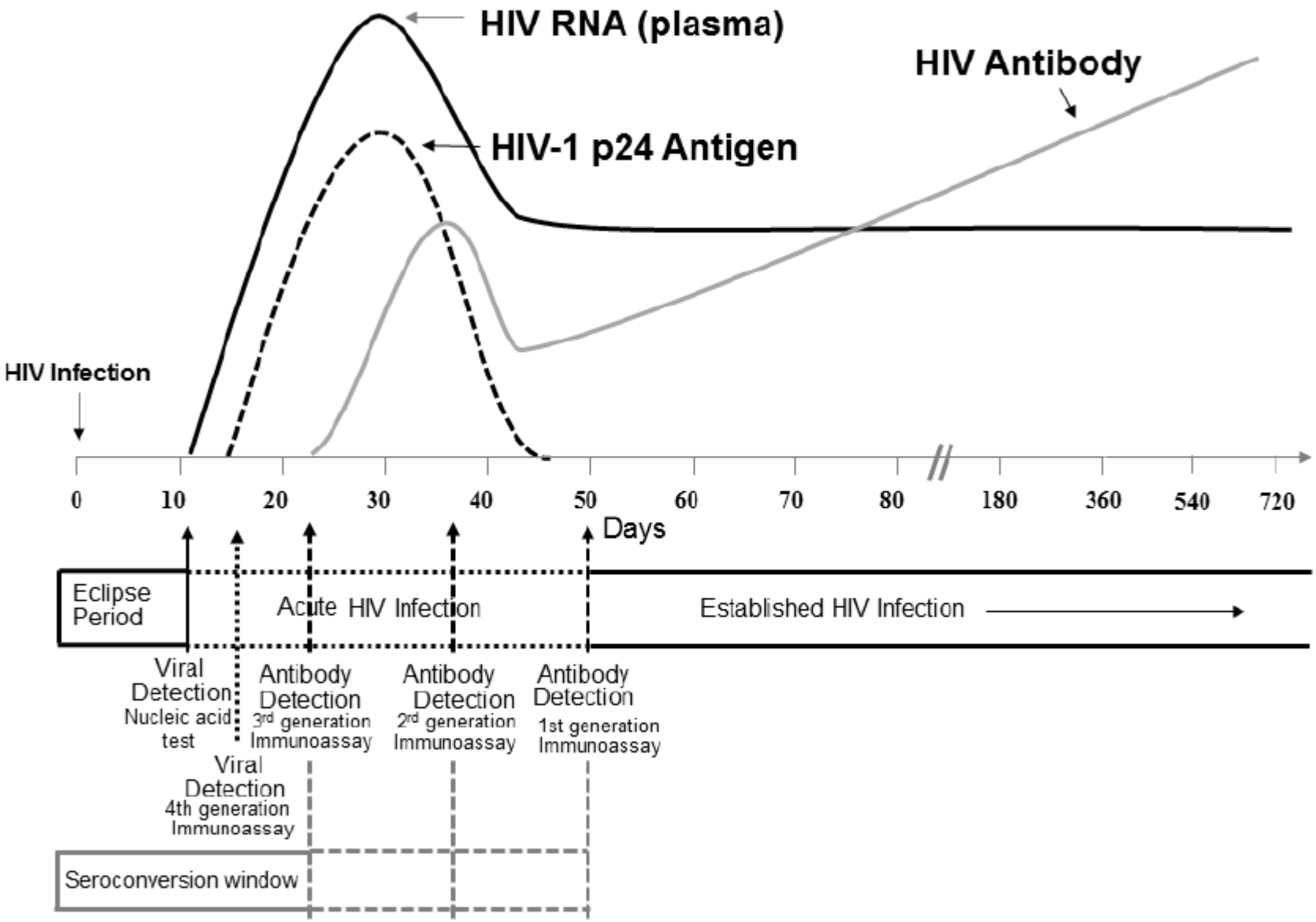
This HIV outbreak was first recognized by a local disease intervention specialist. In late 2014, interviews conducted with three persons newly diagnosed with HIV infections in three separate venues (i.e., an outpatient clinic, a drug rehabilitation program, during a hospitalization) indicated that two of these persons had recently injected drugs and had numerous syringe-sharing and sexual partners. Contact tracing identified eight additional HIV infections leading to the current outbreak investigation, which has demonstrated that HIV had spread recently and rapidly through the local network of PWID. Without an attentive health department, active case finding, and additional testing provided as part of this investigation, this cluster may not have been identified.

Urgent action is needed to prevent further HIV and HCV transmission in this area and to investigate and control any similar outbreaks in other communities.

Injection drug use accounts for an estimated 8%[2] of the approximate 50,000 annual new HIV infections in the United States.[3] HCV infection is the most common blood-borne infection in the United States and percutaneous exposure via drug-injecting equipment contaminated with HCV-infected blood is the most frequent mode of transmission. Nationally, acute HCV infections have increased 150% from 2010 to 2013,[4] and over 70% of long-term PWID may be infected with HCV.[5] Abuse of prescription-type opioids is increasing nationally[6] and opioid-analgesic poisoning deaths have nearly quadrupled from 1999 through 2011.[7] Rates of acute HCV infection are increasing, especially among young nonurban PWID, often in association with abuse of injected prescription-type opioids. These increases have been most substantial in nonurban counties east of the Mississippi River.[8]

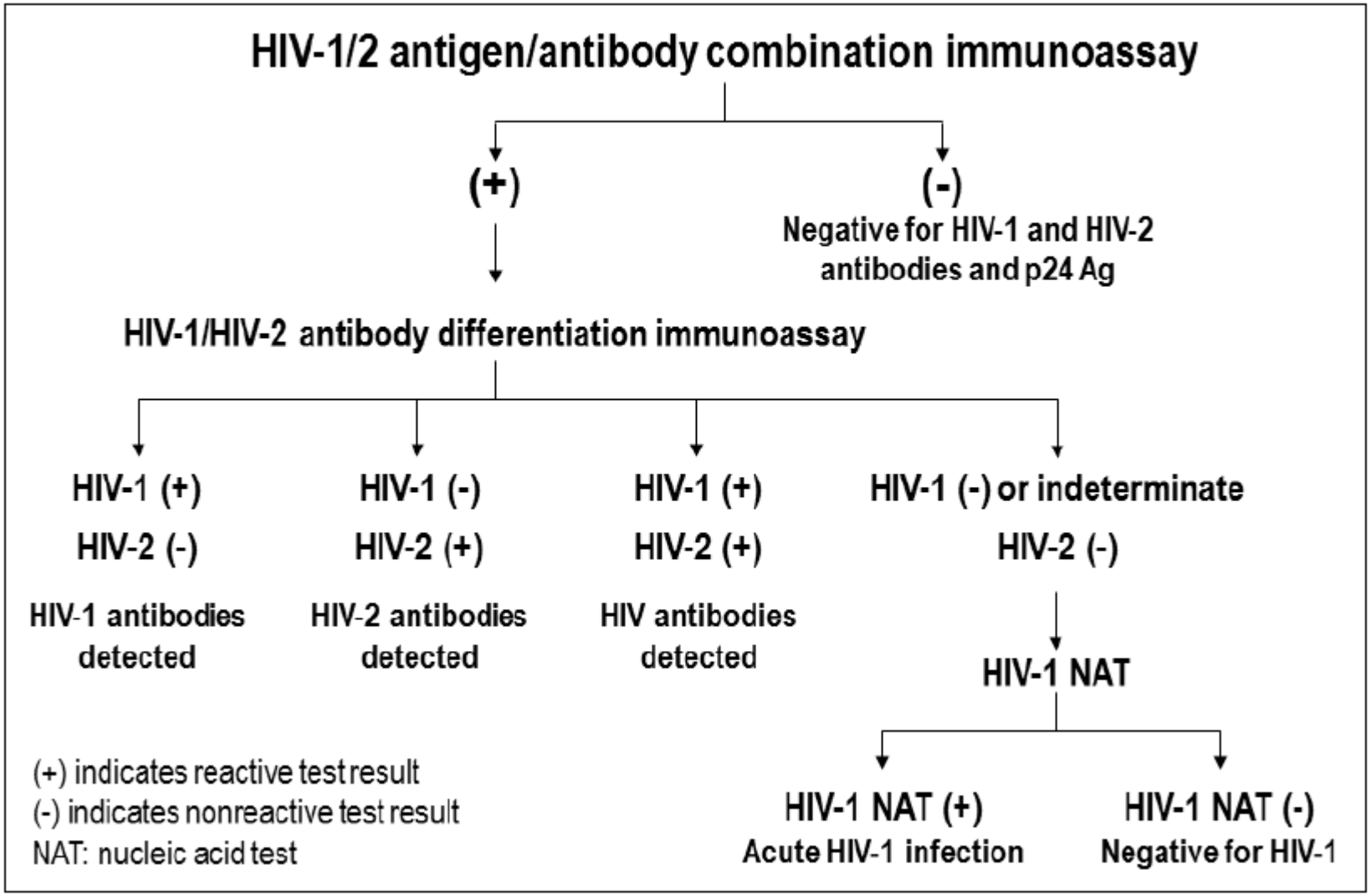
Recommendations for Health Departments

- *For patients in all health-care settings*
  - *HIV screening is recommended for patients in all health-care settings after the patient is notified that testing will be performed unless the patient declines (opt-out screening). Persons at high risk for HIV infection should be screened for HIV at least annually. Separate written consent for HIV testing should not be required; general consent for medical care should be considered sufficient to encompass consent for HIV testing. Prevention counseling should not be required with HIV diagnostic testing or as part of HIV screening programs in health-care settings.*
- *For pregnant women*
  - *HIV screening should be included in the routine panel of prenatal screening tests for all pregnant women. HIV screening is recommended after the patient is notified that testing will be performed unless the patient declines (opt-out screening).*
  - *Separate written consent for HIV testing should not be required; general consent for medical care should be considered sufficient to encompass consent for HIV testing.*
  - *Repeat screening in the third trimester is recommended in certain jurisdictions with elevated rates of HIV infection among pregnant women.*



CDC: Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations. Published June 27, 2014

Box 1. Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens



CDC: Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations. Published June 27, 2014

HIV testing

- Using newer 3rd or 4th generation testing can become positive days or weeks before the Western blot (2 weeks vs 4 weeks)– risk for false negative if Western blot used for confirmation – next stop Multispot HIV1/HIV2 ab test; followed by RNA VL
- Risk for false positive higher in low prevalence population
- But risk for transmission higher in early stages of infection – CONSULT if short interval to delivery anticipated

HIV testing – false positive

- A Multispot follow-up test could be used to differentiate HIV type 1 vs. type 2 antibodies, as the Multispot is the only test that provides this specificity. Also, if using 4th generation testing, the Multispot test is the next stage in the algorithm. If there is significant concern regarding HIV-2 infection, it may be helpful to identify the Western Blot bands, as some patterns can be more suspicious for HIV-2. Infection is unlikely if any of the bands that usually reveal HIV (p24, gp41, and gp120/160) are negative. False reactivity on the EIA or Western Blot assays can be due to HLA antibody, autoimmune diseases (such as lupus), cross reactivity to yeast, or to other contaminating antigens used to prepare the HIV antigens. HIV infection is unlikely in this scenario and this is likely a false positive 4th generation HIV test.

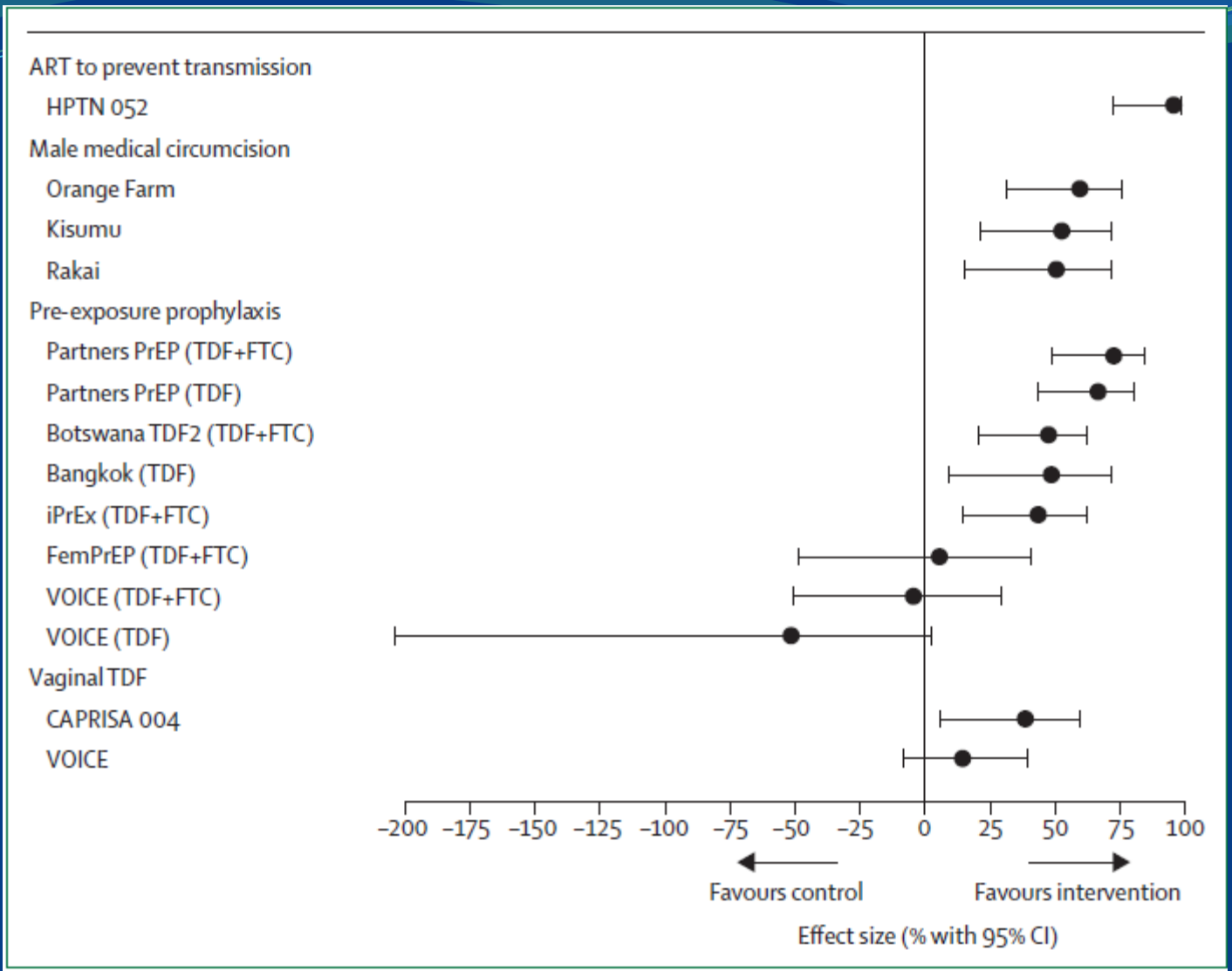


Figure 5: **Clinical trials of interventions to prevent sexual transmission of HIV-1**
TDF=tenofovir. FTC=emtricitabine. References for studies: HPTN052;[135] Orange Farm;[141] Kisumu;[142] Rakai;[143] Partners PrEP;[144] Botswana TDF2;[145] Bangkok;[146] iPrEX;[147] FemPrEP;[148] VOICE;[149] CAPRISA 004.[150]

PrEP

	Efficacy of tenofovir-emtricitabine compared with placebo	Adherence*
Partners PrEP[144]	75%	82%
Botswana TDF2[145]	62%	79%
Bangkok Tenofovir Study[146]	49%	67%
iPrEx[147]	44%	51%
Fem-PrEP[148]	6%	26%
VOICE[149]	−4·2%	29%

*Assessed by plasma tenofovir concentrations.

Table 2: Association between adherence and efficacy of oral tenofovir-emtricitabine for the prevention of HIV-1 acquisition in trials of pre-exposure prophylaxis

www.thelancet.com Vol 384 July 19, 2014

PrEP

Table 1: Summary of Guidance for PrEP Use

	Men Who Have Sex with Men	Heterosexual Women and Men	Injection Drug Users
Detecting 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)
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 3 months to provide the following: HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, STI symptom assessment At 3 months and every 6 months thereafter, assess renal function Every 6 months, test for bacterial STIs		
	Do oral/rectal STI testing	Assess pregnancy intent Pregnancy test every 3 months	Access to clean needles/syringes and drug treatment services

STI: sexually transmitted infection

Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2014 Clinical Practice Guideline

ACOG May 2014
Committee Opinion # 595

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Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health *and* Interventions to Reduce Perinatal HIV Transmission in the United States

Developed by the HHS Panel on Treatment of HIV-Infected Pregnant Women and Prevention of Perinatal Transmission—A Working Group of the Office of AIDS Research Advisory Council (OARAC)

http://aidsinfo.nih.gov/contentfiles/lvguidelines/PerinatalGL.pdf.

What's New in the Guidelines (Last updated August 6, 2015; last reviewed August 6, 2015)

Key changes to the Recommendations for the Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women and Interventions to Reduce Perinatal HIV Transmission in the United States are summarized below. Text, appendices, and references have been updated to include new data and publications where relevant. Throughout the guidelines, content has been revised to refer to expedited HIV testing, preferably using fourth-generation antigen/antibody expedited HIV tests, in accordance with current Centers for Disease Control and Prevention (CDC) recommendations. All changes are highlighted throughout the guidelines.

Pregnant Women with Perinatal HIV Infection

- The Panel has added a new section about pregnant women with perinatal HIV infection. Although the components of prenatal care and general principles of combination antiretroviral therapy (cART) and HIV management do not differ between pregnant women who were perinatally infected and those who acquired HIV infection in other ways, this section discusses some of the unique challenges in meeting these young women's reproductive health care needs and optimizing prevention of perinatal HIV transmission.

Preconception Counseling and Care for HIV-Infected Women of Childbearing Age

- HIV infection does not preclude use of any contraceptive method **(AII)**. However, the Panel on Treatment of HIV-Infected Pregnant Women and Prevention of Perinatal Transmission (the Panel) recommends that drug-drug interactions between hormonal contraceptives and cART should be taken into account (see Table 3: Drug Interactions between Antiretroviral Agents and Hormonal Contraceptives).

http://aidsinfo.nih.gov/contentfiles/lvguidelines/PerinatalGL.pdf.

Panel's Recommendations

For Couples Who Want to Conceive

For Concordant (Both Partners are HIV-Infected) and Discordant Couples:

- Expert consultation is recommended so that approaches can be tailored to couples' specific needs **(AIII)**.
- Partners should be screened and treated for genital tract infections before attempting to conceive **(AII)**.
- The HIV-infected partner(s) should attain maximum viral suppression before attempting conception **(AIII)**.

For Discordant Couples:

- The HIV-infected partner should be receiving combination antiretroviral therapy and demonstrate sustained suppression of plasma viral load below the limits of detection **(AI)**.
- Periconception administration of antiretroviral pre-exposure prophylaxis for HIV-uninfected partners may offer an additional tool to reduce the risk of sexual transmission **(CIII)**. The utility of pre-exposure prophylaxis for the uninfected partner when the infected partner is receiving combination antiretroviral therapy with maximal viral suppression has not been studied.

Discordant Couples with HIV-Infected Women:

- The safest conception option is artificial insemination, including the option of self-insemination with a partner's sperm during the peri-ovulatory period **(AIII)**.

Discordant Couples with HIV-Infected Men:

- The use of donor sperm from an HIV-uninfected man with artificial insemination is the safest option **(AIII)**.
- When the use of donor sperm is unacceptable, the use of sperm preparation techniques coupled with either intrauterine insemination or *in vitro* fertilization should be considered **(AII)**.
- Semen analysis is recommended for HIV-infected men before conception is attempted to prevent unnecessary exposure to infectious genital fluid when the likelihood of conception is low because of semen abnormalities **(AIII)**.

Rating of Recommendations: *A = Strong; B = Moderate; C = Optional*

Rating of Evidence: *I = One or more randomized trials with clinical outcomes and/or validated laboratory endpoints; II = One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion*

http://aidsinfo.nih.gov/contentfiles/lvguidelines/PerinatalGL.pdf.

Preconception counseling HIV positive women

- Folic acid
- Cessation of tobacco use or illicits
- Optimizing weight, health overall
- Screening for genital tract infections
- Optimizing cART (e.g. removal of efavirenz)
- Consistent condom use (self-insemination)
- PrEP for partner

Preconception counseling HIV negative women (partner +)

- Folic acid and optimizing health
- Optimal viral suppression for HIV + partner
- PrEP
- Use of donor sperm safest option
  - Donor sperm preferred
  - Semen analysis to limit unnecessary exposure
  - Sperm prep techniques and IUI of IVF
- Screening for genital tract infections

For an HIV-negative woman planning pregnancy with an HIV-positive male partner

Options

Reducing the risk of HIV acquisition by an HIV-negative woman during conception can be achieved by use of the following, singly or ideally in combination[3,4]:

- Antiretroviral treatment of the HIV-positive male partner to achieve an undetectable viral load[5]
- STI diagnosis and any indicated treatment for both partners before conception attempts
- Daily, oral doses of TDF/FTC beginning 1 month before a conception attempt and continuing for 1 month after a conception attempt
- Intravaginal[6] or intrauterine insemination, or intracytoplasmic sperm injection with a semen sample processed by "sperm washing" and confirmed to have a negative test result for the presence of remnant HIV[9]

OR

- Limit sex without a condom (natural conception) to peak fertility times identified by home or laboratory tests for ovulation in the female partner[10].

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Division of HIV/AIDS Prevention

CS246841-A

Potential Benefits of PrEP use

In clinical trials with heterosexually active adults, daily oral PrEP with TDF/FTC was safe and reduced the risk of HIV acquisition by an average of 63%–75%. Higher levels of protection (≥90%) were found among persons whose drug levels in their blood indicated that they had consistently taken the medication[7,8].

The risk of HIV acquisition increases during pregnancy[11], as does the risk of HIV transmission to an infant born to a mother who becomes infected during pregnancy or breastfeeding[12] Therefore, an HIV-negative woman whose sexual partner/spouse has HIV infection may benefit from continuing PrEP use throughout her pregnancy and breastfeeding to protect herself and her infant.

Potential Risks of PrEP use

In PrEP trials, follow-up with persons taking medication has been conducted for an average of 1–4 years. Although no serious health risks were associated with PrEP use by HIV-uninfected adults, the long-term safety of PrEP has not yet been determined.

In PrEP trials women were taken off medication as soon as pregnancy was detected. During these trials, no health problems have been associated with PrEP use by women in early pregnancy or for their offspring. However, the long-term safety of PrEP taken HIV-uninfected women after fetal (during pregnancy) or infant (during breastfeeding) exposure is not yet determined.

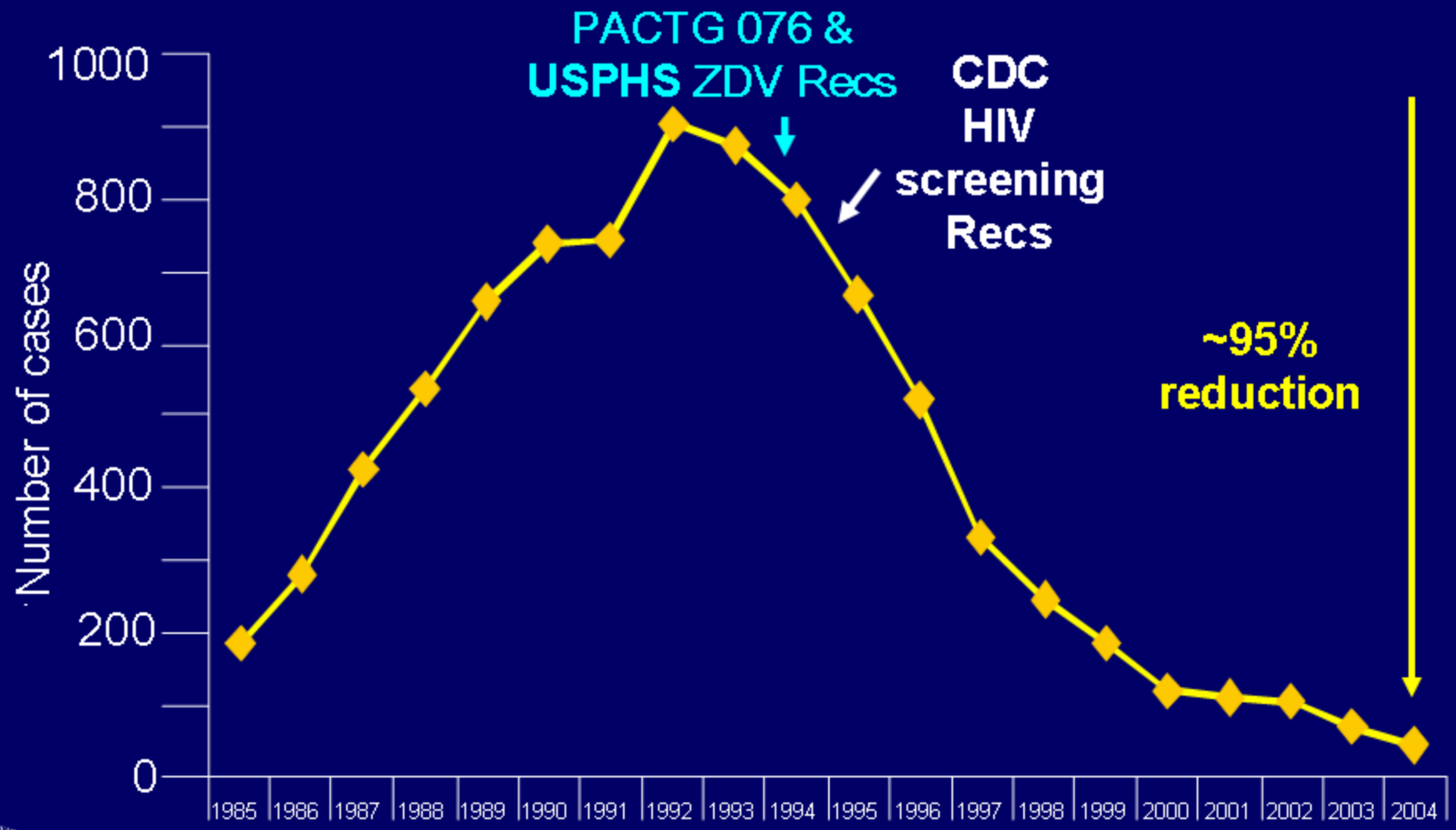
No adverse effects have been found among infants exposed to TDF/FTC when the medications were taken as part of a treatment regimen for HIV-infected women during pregnancy[13-15] or during breastfeeding (for which data suggest limited drug exposure[16,17]).

If you prescribe PrEP to a woman while pregnant, you are encouraged to prospectively and anonymously submit information about the pregnancy to the Antiretroviral Use in Pregnancy Registry (http://www.apregistry.com/).

National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Division of HIV/AIDS Prevention

CS246841-A

Estimated Number of Perinatally Acquired AIDS Cases, by Year of Diagnosis, 1985-2004 – United States



SCREENING RECOMMENDATIONS

- All pregnant women should be screened for HIV infection as early as possible during each pregnancy using the opt-out approach where allowed.
- Repeat HIV testing in the third trimester is recommended for women in areas with high HIV incidence or prevalence and women known to be at risk of acquiring HIV infection.
- Women who were not tested earlier in pregnancy or whose HIV status is otherwise undocumented should be offered rapid screening on labor and delivery using the opt-out approach where allowed.
- If a rapid HIV test result in labor is reactive, antiretroviral prophylaxis should be immediately initiated while waiting for supplemental test results.
- If the diagnosis of HIV infection is established, the woman should be linked into ongoing care with a specialist in HIV care for comanagement.

antepartum → intrapartum → neonatal

99.5% OF CHILDREN BORN FROM HIV POSITIVE WOMEN DON'T HAVE HIV.

This World AIDS Day, the National AIDS Trust is changing the way the world sees HIV.
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THINK P&SITIVE
#RETHINK HIV

Vanderbilt Comprehensive Care Clinic at One Hundred Oaks

www.compclinic.org

719 Thompson Lane, Suite 37189,
Nashville, TN 37204

615-875-5111

History of (OCCC) OC3 Clinic

- Started March 1999 at VUMC TVC
- Moved to CCC December 2000
- Moved to 100 Oaks in October 2010
- ~ 350 infants born (1999-2015)
- All but 1 infant born to HIV+ women followed in OC3 have been HIV negative

OC3 Staffing

HIV Family Nurse Practitioner
VUMC MFM Faculty
Peds ID Clinical Nurse Specialist
Medical Care Manager
RN Case Manager
Nutritionist
Mental Health Clinician (PMHNP and Psychiatrist available)
HIV Educator
ACTC Study Nurse
Adherence counseling – pharmacy team

Prenatal Care

- OB care + HIV care
- HIV education/medication adherence
- Pediatric education – ZDV for neonate
- Nutrition education and counseling
- Mental health and substance abuse screening and referral
- Viral load, CD_4, renal and hepatic profiles, CBC, hepatitis panel, Hep A, C and TB screening
- Immunizations – hepatitis A and B, pneumovax, influenza, Tdap

Antepartum care

- All HIV+ women should receive cART during pregnancy regardless of VL or CD_4 count
- Duration of cART for 24 weeks has been associated with reduced risk for transmission compared to shorter intervals
- Regimen should include nucleoside/nucleotideRTI with high placental transfer

ART Treatment During Pregnancy

- Combination antiretroviral therapy consists of three or four drugs from two different classes.
- Drug choices are individualized - based on resistance testing and patient history.
- Medication regimens determined in clinical conference at CCC.
- Adherence to regimen is primary to treatment success.

Perinatal Transmission

- In Utero – 25-40% cases
- During birth process – 60-75% cases
- Breastfeeding

  14% increase risk with established infection

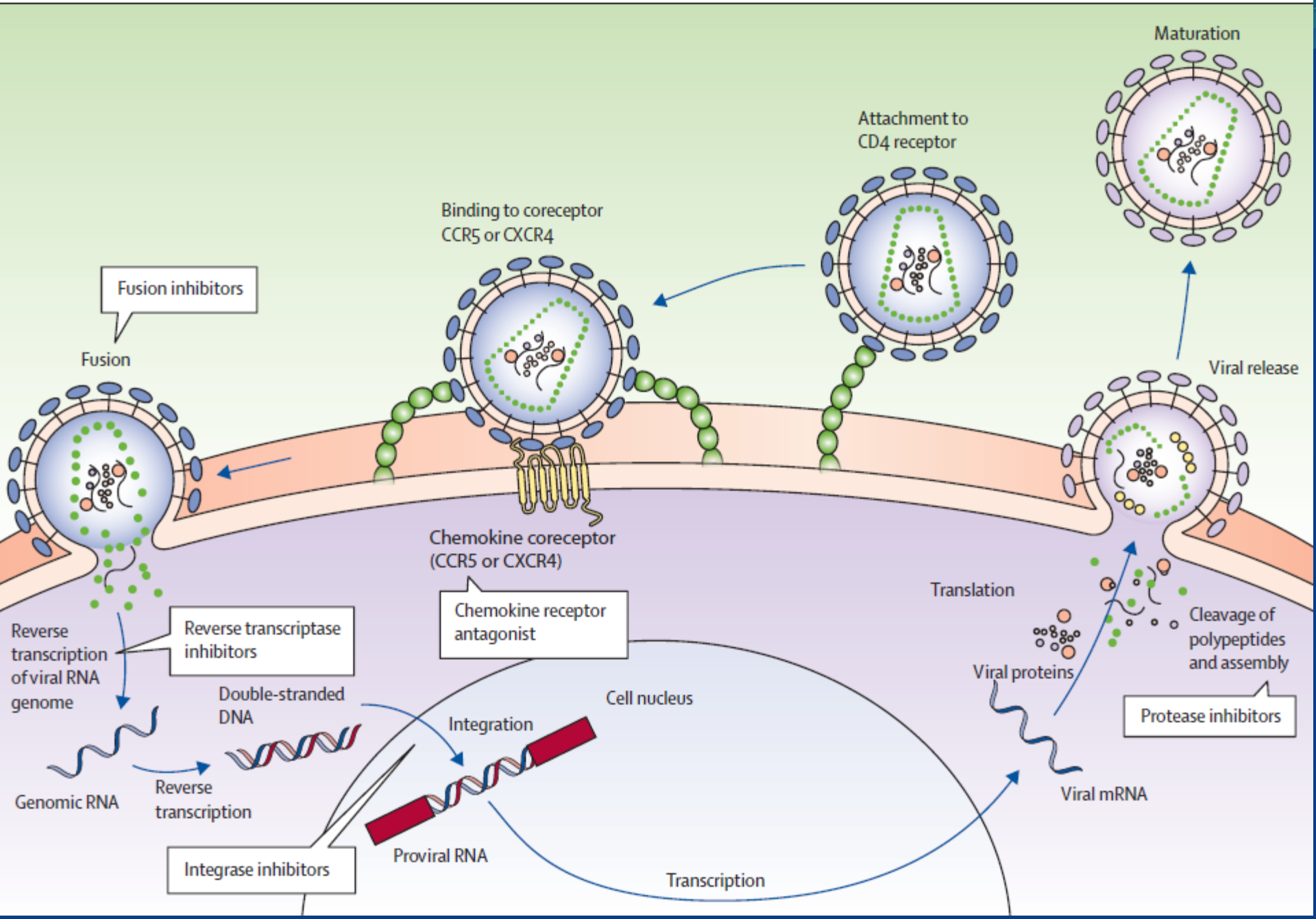
  20% increase risk with primary infection

MTCT

- 25% risk for HIV tansmission without treatment
- 2% risk for treatment
- < 1% for women reaching and maintaining undetectable VL early in pregnancy
- Avoid amniocentesis or other invasive procedures
- Breastfeeding transmission rate of 8.9/100 child years after 4th week; higher rates during first four weeks

HIV Viral Load the Predictor of Perinatal Transmission

- Considerations regarding use of ART in pregnancy (Guidelines for the Use of ART Agents in HIV infected Adults and Adolescents)
- Nucleoside Analogue Drugs
- Non-Nucleoside Reverse Transcriptase Inhibitors
- Protease Inhibitors
- Entry Inhibitors
- Fusion Inhibitors
- Integrase Inhibitors


Maturation
Attachment to
CD4 receptor
Binding to coreceptor
CCR5 or CXCR4
Fusion inhibitors
Fusion
Viral release
Chemokine coreceptor
(CCR5 or CXCR4)
Chemokine receptor
antagonist
Translation
Cleavage of
polypeptides
and assembly
Reverse
transcription
of viral RNA
genome
Reverse transcriptase
inhibitors
Viral proteins
Protease inhibitors
Double-stranded
DNA
Cell nucleus
Integration
Genomic RNA
Reverse
transcription
Viral mRNA
Integrase inhibitors
Proviral RNA
Transcription

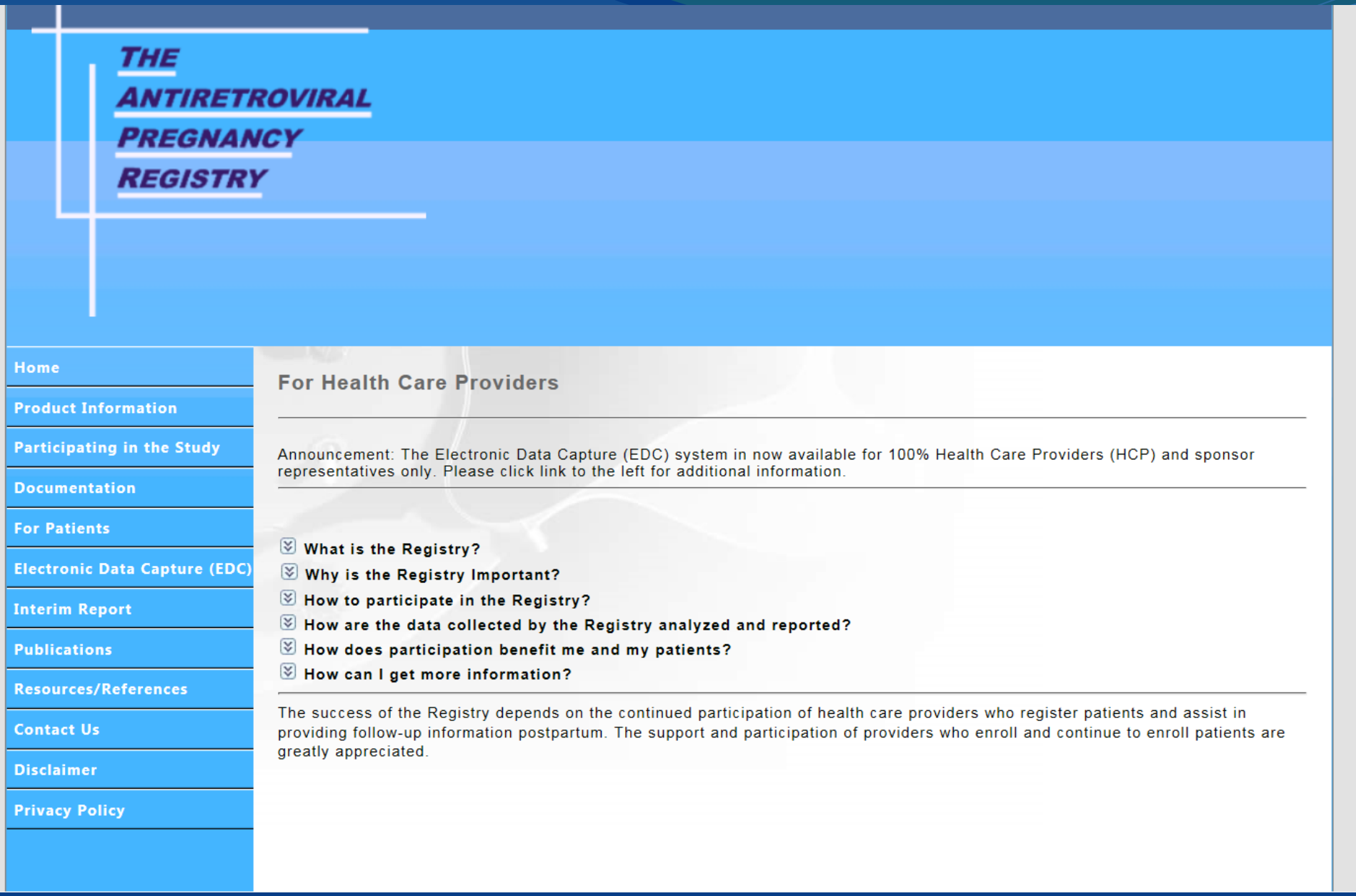
Testing for viral resistance

- May be limited with VL < 1000
- Recommended prior to initiation of meds unless later in pregnancy then begin treatment while awaiting results
- Example:
  - 11/10/15 16:32Virology **ABA**: No Evidence of Resistance **AMP**: No Evidence of Resistance **DEL**: No Evidence of Resistance **DID**: No Evidence of Resistance **EFAV**: No Evidence of Resistance **INDV**: No Evidence of Resistance **LAMV**: No Evidence of Resistance **LOPRIT**: No Evidence of Resistance **ATAZNV**: No Evidence of Resistance **NEL**: No Evidence of Resistance **NEV**: No Evidence of Resistance **SAQ**: No Evidence of Resistance **STAV**: No Evidence of Resistance **TENV**: No Evidence of Resistance **ZID**: No Evidence of Resistance **Emtric**: No Evidence of Resistance **ETR**: No Evidence of Resistance **FOSAM**: No Evidence of Resistance **TIPRA**: No Evidence of Resistance **DARUN**: No Evidence of Resistance
  - 11/10/15 16:32MIDL **B5701G**: Negative

- HLA-B 5701 GENOTYPING; (Reported on 11/16/15 11:13)
  Comment:
  Indication for testing: Considering or recently prescribed abacavir.
  Interpretation: The HLA-B*57:01 allele was not detected; therefore, this patient is not predicted to be at increased risk for abacavir hypersensitivity.
  Recommendations: This negative result does not replace the need
  for therapeutic drug or other clinical monitoring. Abacavir therapy should be discontinued in all individuals with clinically-suspected abacavir hypersensitivity reaction regardless of HLA-B*57:01 status.

Teratogenesis

- Ongoing surveillance – importance of submitting outcomes data to APR (prospective registry)
- Interpretation of small studies with caution given multitude of confounders
  - Use of folic acid
  - Use of illicits
- other



http://www.apregistry.com/HCP.aspx

THE ANTIRETROVIRAL PREGNANCY REGISTRY

Interim Report

1 JANUARY 1989 THROUGH 31 JULY 2015

(Issued: December 2015)
(Expiration: 6 months after issue)

Measured against 16699 live births with exposure at any time during pregnancy, there were 473 outcomes with birth defects identified, a prevalence of 2.8 birth defects per 100 live births (95% CI: 2.6 - 3.1). This proportion is not significantly higher than those reported in the Registry's two population based comparators, the CDC's birth defects surveillance system (MACDP) (3, 4, 5, 6) (2.72 per 100 live births) and the Texas Birth Defects Registry (TBDR) (7) (4.17 per 100 live births). No increases in risk of specific defects have been detected to date when compared with observed MACDP or TBDR rates or with rates among those with earliest exposure in the second or third trimester. In analyzing individual drugs with sufficient data to warrant a separate analysis with the exception of didanosine and nelfinavir, no increases

SUMMARY OF CHANGES: JANUARY 2015 to JULY 2015

Primary Prospective Analysis	*January 2015*	*July 2015*
Pregnancies Reported	19,607	19,957
Pending	308	337
Lost to follow-up	1967	2002
With follow-up data	17,332	17,618
Earliest Exposure		
1st trimester exposures	8459	8669
2nd trimester	6631	6686
3rd trimester	2240	2261
Unknown (defects only)	2	2
Outcomes	17,630	17,920
Defects/Live births		
1st trimester	219/7544 2.9% (95% CI: 2.5% - 3.3%)	221/7738 2.9% (95% CI: 2.5% - 3.3%)
2nd/3rd trimester	249/8882 2.8% (95% CI: 2.5% - 3.2%)	250/8959 2.8% (95% CI: 2.4% - 3.2%)
Any trimester	470/16428 2.9% (95% CI: 2.6% - 3.1%)	473/16699 2.8% (95% CI: 2.6% - 3.1%)
1st to 2nd/3rd trimester prevalence ratio	1.04 (95% CI: 0.87, 1.24)	1.02 (95% CI: 0.86, 1.22)

ANTIRETROVIRAL PREGNANCY REGISTRY

REGISTRATION FORM

Fax to: +1-800-800-1052 (US, Canada)
+1-910-256-0637 (International) or +32-2-714-5024 (Europe)
0800-5812-1658 (UK, Germany, France)
0800-892-1472 (Brazil)
Email to: SM_APR@INCResearch.com

FOR OFFICE USE ONLY (1)

Registry Patient ID _____ HCP ID _____

Prospective ☐ Retrospective ☐ 100% Provider ☐

Country _____ State _____

Registry date of notification ____ ____ ____ ☐ Phone
DD MMM YYYY

Patient (Log) ID: _____ ***Registry assigned ID number or Sponsor MCN***

Note: To help assure patient anonymity the Registry uses a Registry assigned patient ID to refer to your patient to obtain follow-up and outcome information.

Date patient first seen during this pregnancy

Date: ____ ____ ____
DD MMM YYYY

1. MATERNAL INFORMATION

1.1 Is the patient enrolled in a clinical study? *(treatment or observational study)* ☐ Yes ☐ No ☐ Unknown

If yes, provide the protocol number _____

Was the clinical study conducted in pregnant women? ☐ Yes ☐ No ☐ Unknown

1.2 Last Menstrual Period ____ ____ ____
DD MMM YYYY

1.3 Corrected EDD ____ ____ ____ *(e.g., by ultrasound)*
DD MMM YYYY

1.4 Patient Age: _____ *(at conception)*

1.5 Race: ☐ White ☐ Black ☐ Hispanic ☐ Asian ☐ Other (specify) _____

2. PRENATAL TESTS

2.1 Was a prenatal test done?

☐ No *(go to section 3)*

☐ Yes *(complete below and question 2.2)*

Date OR Gestational Age when test(s) done:

(✓) test(s)

☐ Ultrasound _____ date

☐ Ultrasound _____ date

☐ Ultrasound _____ date

☐ Amniocentesis _____ date

☐ MSAFP/serum markers _____ date

☐ Other: _____ date

☐ Unknown *(go to section 3)*

2.2 Is there evidence of a structural defect from one or more of these prenatal tests?

☐Yes ☐No ☐Unknown. If yes, Specify defect _____

☐Yes ☐No ☐Unknown. If yes, Specify defect _____

☐Yes ☐No ☐Unknown. If yes, Specify defect _____

☐Yes ☐No ☐Unknown. If yes, Specify defect _____

☐Yes ☐No ☐Unknown. If yes, Specify defect _____

☐Yes ☐No ☐Unknown. If yes, Specify defect _____

ARV other issues

- Potential small increased risk for preterm birth with PI
- Conflicting study outcomes likely limited to ability to account for all potential confounders (e.g. CD_4 count, other risk factors for PTL)
- Mitochondrial toxicity
- Glucose intolerance with PI

Recent Studies (2005–Current)

Results of studies published since 2005 are conflicting with regard to an association between preterm birth and cART use. Multiple observational studies with similar limitations published through 2008 have detected small but significant increases in preterm birth with PI- and non-PI-based cART (odds ratio [OR] 1.2–1.8 in the largest studies).[5-8] A meta-analysis of 14 European and American clinical studies demonstrated that use of cART during pregnancy did not increase the overall risk of preterm birth. A subgroup analysis demonstrated a modest increased risk of preterm birth with PI-based cART use compared to non-PI based cART (OR 1.35; 95% confidence interval [CI], 1.08–1.7).[9]

http://aidsinfo.nih.gov/contentfiles/lvguidelines/PerinatalGL.pdf.

Other risks associated with cART

- Possible increased risk for early delivery, SGA
- ? Preecl
- ? GDM
- Decrease in bone mineralization in children with tenofovir exposure
- Mitochondrial toxicity

Summary of Hepatitis B Virus Mono-infected Pregnancies

In 1998, the antiviral activity of lamivudine against the Hepatitis B virus was recognized by the FDA as a supplemental indication for that drug followed by tenofovir in 2008. With the FDA approval of adefovir with the sole indication of treatment for infection with hepatitis B virus (HBV), the APR agreed to provide a repository for reports of pregnancy exposures for these drugs and to include the results as part of the APR's semi-annual interim report. Based on this, and the likely future rise in the use of ARVs to treat HIV/HBV co-infected individuals as well as mono-infected HBV patients, the APR began to systematically collect hepatitis B infection status in 2003. Since the addition of adefovir (2002), two additional HBV drugs, entecavir (2005) and telbivudine (2006), have been added to the Registry.

Since the addition of the hepatitis B indication, the APR has received 442 prospective reports of diagnosed hepatitis B patients with or without concurrent HIV infection, all of which are included in the overall registry data. This sub-analysis is limited to the hepatitis B mono-infected population. Through 31 July 2015, a total of 262 prospective reports of hepatitis B mono-infected pregnancies with outcome have been reported (Table 2). Three birth defect cases have been reported among 231 live births, including 146 live births with initial exposure during the first trimester of pregnancy. All 3 birth defect cases were initially exposed during the first trimester of pregnancy. There is no pattern among the types of births defects reported.

These numbers do not permit definitive conclusions regarding the possible teratogenicity of these agents for this indication. For lamivudine and tenofovir they should be viewed through the perspective of wide use in HIV-infected pregnant women without emerging signals. Further reports from the hepatitis treating community are urged.

Treatment

Panel's Recommendations
• In general, the same regimens as recommended for treatment of non-pregnant adults should be used in pregnant women unless there are known adverse effects for women, fetuses, or infants that outweigh benefits **(AII)**.
• Multiple factors must be considered when choosing a regimen for a pregnant woman including comorbidities, convenience, adverse effects, drug interactions, resistance testing results, pharmacokinetics, and experience with use in pregnancy **(AIII)**.
• Pharmacokinetic changes in pregnancy may lead to lower plasma levels of drugs and necessitate increased dosages, more frequent dosing, or boosting, especially of protease inhibitors **(AII)**.

- If there is no evidence of resistance, cART regimens that are preferred for the treatment of antiretroviral-naive HIV-infected pregnant women include: a dual nucleoside reverse transcriptase inhibitor combination (abacavir/lamivudine, tenofovir disoproxil fumarate/emtricitabine or lamivudine, or zidovudine/lamivudine) and either a ritonavir-boosted protease inhibitor (atazanavir/ritonavir or darunavir/ritonavir), a non-nucleoside reverse transcriptase inhibitor (efavirenz initiated after 8 weeks of pregnancy), or an integrase inhibitor (raltegravir) (see Table 6) **(AIII)**.

http://aidsinfo.nih.gov/contentfiles/lvguidelines/PerinatalGL.pdf.

Preferred Regimens

Regimens with clinical trial data in adults demonstrating optimal efficacy and durability with acceptable toxicity and ease of use, PK data available in pregnancy, and no evidence to date of teratogenic effects or established adverse outcomes for mother/fetus/newborn. To minimize the risk of resistance, a PI regimen is preferred for women who may stop ART during the postpartum period.

Preferred Two-NRTI Backbone	
ABC/3TC	Available as FDC. Can be administered once daily. ABC **should not be used** in patients who test positive for HLA-B*5701 because of risk of hypersensitivity reaction. ABC/3TC with ATV/r or with EFV is not recommended if pretreatment HIV RNA >100,000 copies/mL.
TDF/FTC or 3TC	TDF/FTC available as FDC. Either TDF/FTC or TDF and 3TC can be administered once daily. TDF has potential renal toxicity, thus TDF-based dual NRTI combinations should be used with caution in patients with renal insufficiency.
ZDV/3TC	Available as FDC. NRTI combination with most experience for use in pregnancy but has disadvantages of requirement for twice-daily administration and increased potential for hematologic toxicities.
Preferred PI Regimens	
ATV/r plus a Preferred Two-NRTI Backbone	Once-daily administration. Extensive experience in pregnancy. Maternal hyperbilirubinemia
DRV/r plus a Preferred Two-NRTI Backbone	Better tolerated than LPV/r. PK data available. Increasing experience with use in pregnancy. Must be used twice daily in pregnancy.

Preferred NNRTI Regimen	
EFV plus a Preferred Two-NRTI Backbone **Note:** May be initiated after the first 8 weeks of pregnancy	Concern because of birth defects seen in primate study; risk in humans is unclear (see Teratogenicity and Table 7). Postpartum contraception must be ensured. Preferred regimen in women who require co-administration of drugs with significant interactions with PIs or the convenience of co-formulated, single-tablet, once-daily regimen.
Preferred Integrase Inhibitor Regimen	
RAL plus a Preferred Two-NRTI Backbone	PK data available and increasing experience in pregnancy. Rapid viral load reduction. Useful when drug interactions with PI regimens are a concern. Twice-daily dosing required.
Alternative Regimens Regimens with clinical trial data demonstrating efficacy in adults but one or more of the following apply: experience in pregnancy is limited, data are lacking or incomplete on teratogenicity, or regimen is associated with dosing, formulation, toxicity, or interaction issues	
PI Regimens	
LPV/r plus a Preferred Two-NRTI Backbone	Abundant experience and established PK in pregnancy. More nausea than preferred agents. Twice-daily administration. Once-daily LPV/r is not recommended for use in pregnant women.
NNRTI Regimen	
RPV/TDF/FTC (or RPV plus a Preferred Two-NRTI Backbone)	RPV not recommended with pretreatment HIV RNA >100,000 copies/mL or CD4 cell count <200 cells/mm^3. Do not use with PPIs. PK data available in pregnancy but relatively little experience with use in pregnancy. Available in co-formulated single-pill once daily regimen.

http://aidsinfo.nih.gov/contentfiles/lvguidelines/PerinatalGL.pdf.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EPZICOM®
(abacavir sulfate and lamivudine)
600 mg 300 mg
TABLETS
Each tablet contains 600 mg of abacavir as abacavir sulfate and 300 mg of lamivudine.
Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) (see USP Controlled Room Temperature).
See prescribing information for dosage information.
Lamivudine is manufactured under agreement from Shire Pharmaceuticals Group plc, Basingstoke, UK
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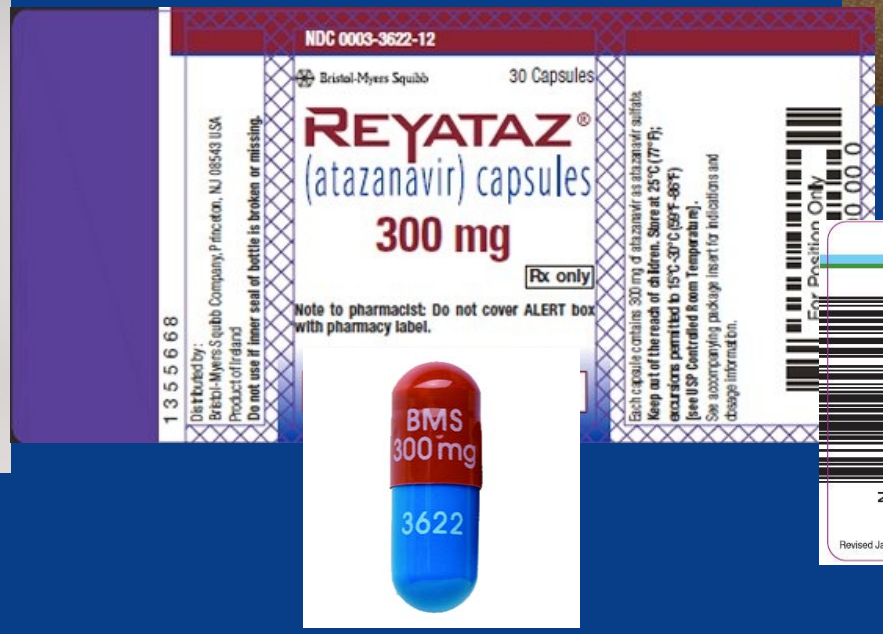
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30 Capsules
REYATAZ®
(atazanavir) capsules
300 mg
Rx only
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BMS 300 mg
3622
Distributed by:
Bristol-Myers Squibb Company, Princeton, NJ 08543 USA
Product of Ireland
Do not use if inner seal of bottle is broken or missing.
Each capsule contains 300 mg of atazanavir as atazanavir sulfate.
Keep out of the reach of children. Store at 25°C (77°F); excursions permitted to 15°-30°C (59°F-86°F) [see USP Controlled Room Temperature].
See accompanying package insert for indications and dosage information.
For Physician Only


240 Tablets NDC 59676-564-01
PREZISTA®
(darunavir) tablets
150 mg
Each tablet contains darunavir ethanolate equivalent to 150 mg of darunavir.
Store at 25°C (77°F); with excursions permitted to 15°-30°C (59°-86°F).
USUAL DOSAGE:
See package insert for full Prescribing Information.
Keep out of reach of children.
ALERT
Find out about medicines that should NOT be taken with PREZISTA.
Manufactured by:
Janssen Ortho LLC
Gurabo, PR 00778
Manufactured for:
Janssen Therapeutics,
Division of Janssen Products, LP
Titusville, NJ 08560
© Janssen 2009
10181903
janssen
59676-564-01
Revised January 2012
Rx only
LOT:
EXP:
800

cART

- Addition of raltegravir if inadequate suppression or short duration to allow for suppression
  - 2 log decrease reported within 2 weeks (100x decrease)
- Frequent monitoring of levels

Table 18. Drugs That Should Not Be Used With Antiretroviral Agents (Last updated April 8, 2015; last reviewed April 8, 2015) (page 1 of 2)

This table only lists drugs that should not be coadministered at any dose, regardless of RTV or COBI enhancing. See Tables 19 and 20 for more detailed PK interaction data.

ARV Agents[a,b]	Cardiac Agents	Lipid-Lowering Agents	Antimyco-bacterial Agents	Antiepileptic Agents	Neurologic Agents	Herbs	HCV Agents[c]	Other Agents
ATV +/– RTV or COBI	Dronedarone Ranolazine	Lovastatin Simvastatin	Rifampin Rifapentine[d]	None	Lurasidone Midazolam[e] Pimozide Triazolam	St. John's wort	Boceprevir Simeprevir	Alfuzosin Cisapride[f] Ergot derivatives Irinotecan Salmeterol Sildenafil for PAH
DRV/c or DRV/r	Dronedarone Ranolazine	Lovastatin Simvastatin	Rifampin Rifapentine[d]	None	Lurasidone Midazolam[e] Pimozide Triazolam	St. John's wort	Boceprevir Dasabuvir Ombitasvir Paritaprevir Simeprevir	Alfuzosin Cisapride[f] Ergot derivatives Salmeterol Sildenafil for PAH
FPV +/– RTV	Dronedarone Flecainide Propafenone Ranolazine	Lovastatin Simvastatin	Rifampin Rifapentine[d]	None	Lurasidone Midazolam[e] Pimozide Triazolam	St. John's wort	Boceprevir Dasabuvir Ombitasvir Paritaprevir Simeprevir	Alfuzosin Cisapride[f] Ergot derivatives Salmeterol Sildenafil for PAH
LPV/r	Dronedarone Ranolazine	Lovastatin Simvastatin	Rifampin[g] Rifapentine[d]	None	Lurasidone Midazolam[e] Pimozide Triazolam	St. John's wort	Boceprevir Dasabuvir Ombitasvir Paritaprevir Simeprevir	Alfuzosin Cisapride[f] Ergot derivatives Salmeterol Sildenafil for PAH
SQV/r	Amiodarone Dofetilide Dronedarone Flecainide	Lovastatin Simvastatin	Rifampin[g] Rifapentine[d]	None	Lurasidone Midazolam[e] Pimozide Trazodone	Garlic supple-ments St. John's	Boceprevir Dasabuvir Ombitasvir Paritaprevir	Alfuzosin Cisapride[f] Ergot derivatives Salmeterol

Table 19a. Drug Interactions between Protease Inhibitors and Other Drugs (Last updated April 8, 2015; last reviewed April 8, 2015) (page 8 of 14)

Concomitant Drug	PI	Effect on PI and/or Concomitant Drug Concentrations	Dosing Recommendations and Clinical Comments
Corticosteroids, continued			
Budesonide, Fluticasone, Mometasone Inhaled or Intranasal	All RTV- or COBI-boosted PIs	↑ glucocorticoids possible RTV 100 mg BID ↑ fluticasone AUC 350-fold and ↑ C_{max} 25-fold	Coadministration can result in adrenal insufficiency and Cushing's syndrome. **Do not coadminister unless potential benefits of inhaled or intranasal corticosteroid outweigh the risks of systemic corticosteroid adverse effects.** Consider alternative corticosteroid (e.g., beclomethasone).
Dexamethasone Systemic	All PIs	↓ PI levels possible	Use systemic dexamethasone with caution. Consider alternative corticosteroid for long-term use.
Prednisone	LPV/r	↑ prednisolone AUC 31%	Use with caution. Coadministration can result in adrenal insufficiency and Cushing's syndrome. **Do not coadminister unless potential benefits of prednisone outweigh the risks of systemic corticosteroid adverse effects.**
	All PIs	↑ prednisolone possible	
Methyl-prednisolone, Prednisolone, Triamcinolone (local injections, including intra-articular, epidural, intra-orbital)	All RTV- or COBI-boosted PIs	↑ glucocorticoids expected	**Do not coadminister.** Coadministration can result in adrenal insufficiency and Cushing's syndrome.
Salmeterol	All PIs	↑ salmeterol possible	**Do not coadminister** because of potential increased risk of salmeterol-associated cardiovascular events.

HIV 2

- Uncommon in the US
- Primarily found in West African countries
- Longer asymptomatic phase and longer progression to AIDS
- Sexual transmission 5x lower compared to HIV1
- Vertical transmission lower (0-4%) compared to HIV1
- 2 NRTI + PI combo (e.g Combivir/Kaletra)
- ZDV 6 weeks for infant

http://nccc.ucsf.edu/clinician-consultation/perinatal-hiv-aids/

CLINICIAN CONSULTATION CENTER

Perinatal HIV/AIDS

Rapid perinatal HIV consultation from practicing providers

- HIV testing in pregnancy
- Treating HIV-infected pregnant women
- Preventing transmission during labor and delivery and the post-partum period
- HIV-exposed infant care

Call for a Phone Consultation

(888) 448-8765

24 hours,
Seven days a week

CALL

Advice from national experts in perinatal HIV care

Our clinical consultation staff includes OB/GYNs, Infectious Disease specialists, internists, family practitioners, and clinical pharmacists at the University of California, San Francisco. We provide consultation on all levels of perinatal HIV management, including on complex and unique treatment dilemmas, to provide you the best possible information on up-to-date, high-quality care.

Consultation on complex perinatal HIV treatment issues

- Addressing adherence issues
- Managing HIV-positive pregnancies with late presentation to care
- Safer conception options for HIV-affected couples

Related Information

Find Education and Training

Our consultants can help you on the phone, online, and can connect you with training and education to help improve patient outcomes. Explore our clinical training and education resources.

Table 4. Perinatal Human Immunodeficiency Virus Type 1 Transmission Rate According to Timing of Antiretroviral Therapy Initiation and Maternal Viral Load Near Delivery (Enquête Périnatale Française, Metropolitan France, 2000–2011): Multivariate Logistic Regression[a]

Maternal VL and ART Timing	PT, % (95% CI)	No. With PT/Total No.	Adjusted OR (95% CI)	*P* Value
Overall PT (all infants with determined HIV status)	0.7 (.5–.9)	56/8075	. . .	. . .
Maternal VL nearest delivery, copies/mL				
≥400	2.8 (1.8–4.2)	23/818	6.2 (2.6–15.2)	<.001
50–399	1.5 (.9–2.4)	18/1174	4.3 (1.8–9.8)	
Undetectable, threshold >50	0.2 (<.01 to 1.2)	1/474	1.1 (.1–8.6)	
<50	0.3 (.1–.4)	14/5345	1	
Missing VL		0/264		
Timing of ART initiation				
3rd trimester (≥28 wks gestation)	2.2 (1.4–3.3)	23/1051	7.8 (2.1–28.8)	<.001
2nd trimester (14–27 wks gestation)	0.9 (.5–1.3)	24/2810	6.0 (1.7–20.7)	
1st trimester (<14 wks gestation)	0.4 (.09–1.2)	3/709	2.9 (.6–17.7)	
Before conception	0.2 (.06–.4)	6/3505	1	

Abbreviations: ART, antiretroviral therapy; CI, confidence interval; HIV, human immunodeficiency virus; OR, odds ratio; PT, perinatal transmission; VL, viral load.

[a] Adjusted for maternal age, geographic origin, mode of delivery, gestational age, protease inhibitor–based versus nonnucleoside reverse-transcriptase inhibitor–based first combination ART regimen, zidovudine intrapartum prophylaxis, postnatal prophylaxis, postnatal nevirapine, and child's sex. The HIV status was unknown in 603 children.

Intrapartum

- IV ZDV - known to cross the placenta with high cord blood to maternal serum ratio (infant PrEP)
- Continuation of antiretroviral regimen
- No contraindication to regional anesthesia
- Avoidance of scalp electrodes, scalp sampling or prolonged rupture of membranes (~ 2% increase per hr risk in old pre cART era)
- Cesarean delivery at 38 weeks for VL > 1000
  - IV ZDV should begin 3 hours before scheduled delivery
- **PRIVACY**

Postpartum

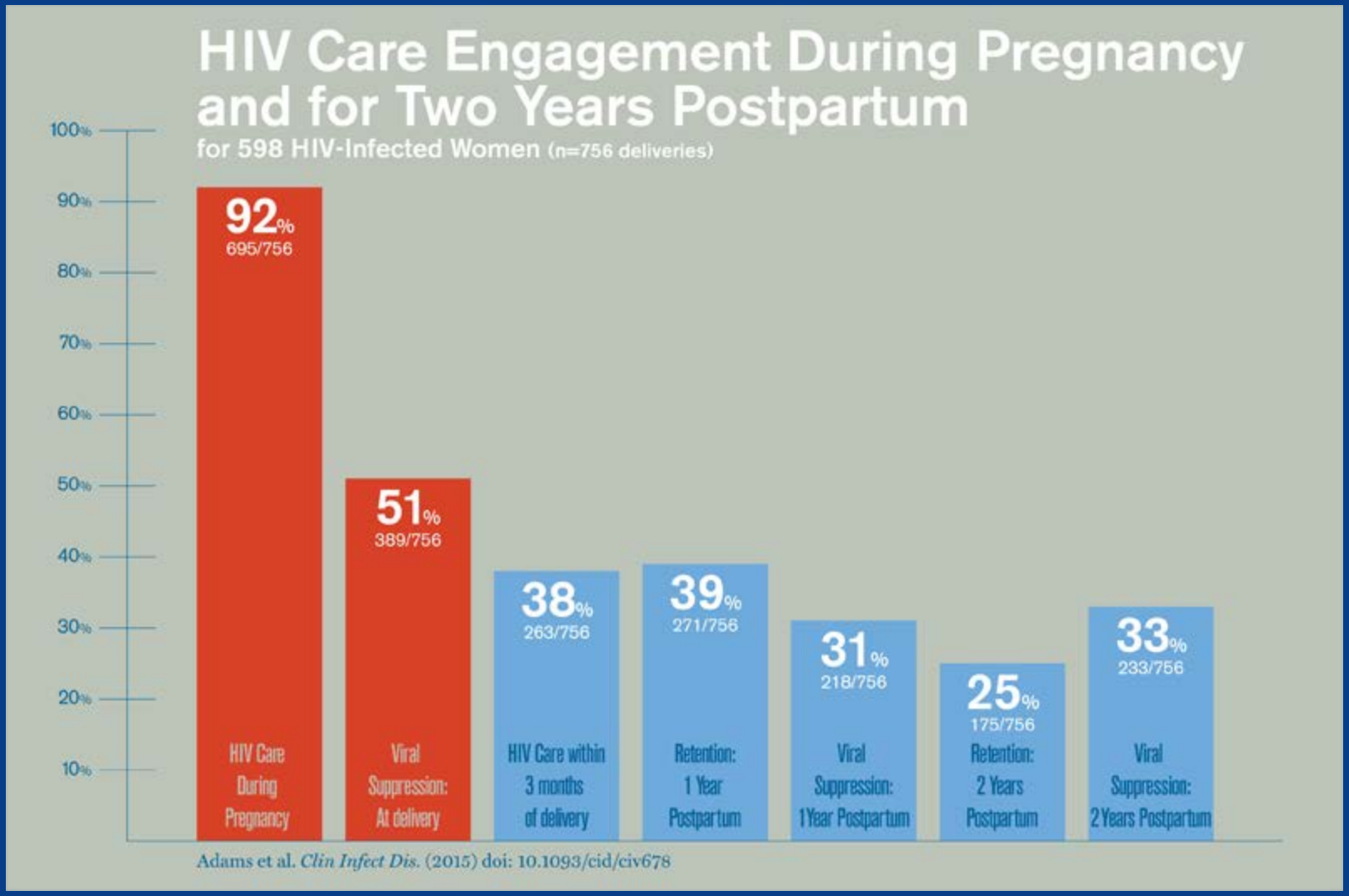
- Avoidance of methergine (interaction with PIs)
- Continuation of antepartum cART
- No breast feeding
- No pre-mastication of food for infant
- **PRIVACY**

Infant

- Initiate ZDV preferably within 6-12 hours of delivery
- 6 weeks therapy (can consider 4 weeks if mothers with consistent viral suppression and no concerns adherence; lower rate of anemia)
- ZDV + nevirapine (birth , 48 and 96 hrs later)
- Three drug regimen with lamivudine -neutropenia more common without greater efficacy compared to two drug

Infant

- In NY state study, delay in prophylaxis > 48 hrs, loss of benefit
- Oral fluid testing not recommended in infants
- Virologic rebound unfortunately reported in at least 2 cases of suspected functional cures after discontinuation of meds (Mississippi case)
- National perinatal hotline 1-888-448-8765


HIV Care Engagement During Pregnancy and for Two Years Postpartum
for 598 HIV-Infected Women (n=756 deliveries)
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
92%
695/756
HIV Care During Pregnancy
51%
389/756
Viral Suppression: At delivery
38%
263/756
HIV Care within 3 months of delivery
39%
271/756
Retention: 1 Year Postpartum
31%
218/756
Viral Suppression: 1 Year Postpartum
25%
175/756
Retention: 2 Years Postpartum
33%
233/756
Viral Suppression: 2 Years Postpartum
Adams et al. Clin Infect Dis. (2015) doi: 10.1093/cid/civ678

OC3 retention in care

- 72.8% retained in care (one year postpartum)
- 72% VS at delivery
- 36.4% VS at one year (but improved since routine continuation of cART after 2008)

Contraception

- **LARC**
  - **IUD, progesterone IUDs, Implant**
- **CONDOMS**
- **Others**
  - **HIV does not preclude use of any contraception BUT drug-drug interactions may lower effectiveness**

BOX. Categories for Classifying Hormonal Contraceptives and Intrauterine Devices

1 = A condition for which there is no restriction for the use of the contraceptive method.
2 = A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.
3 = A condition for which the theoretical or proven risks usually outweigh the advantages of using the method.
4 = A condition that represents an unacceptable health risk if the contraceptive method is used.

TABLE 1. Percentage of women experiencing an unintended pregnancy during the first year of typical use and the first year of perfect use of contraception and the percentage continuing use at the end of the first year — United States

Method	Women experiencing an unintended pregnancy within the first year of use		Women continuing use at 1 year[§]
	Typical use*	Perfect use[†]	
No method[¶]	85%	85%	
Spermicides[**]	29%	18%	42%
Withdrawal	27%	4%	43%
Fertility awareness–based methods	25%		51%
Standard Days method[††]		5%	
TwoDay method™[††]		4%	
Ovulation method[††]		3%	
Sponge			
Parous women	32%	20%	46%
Nulliparous women	16%	9%	57%
Diaphragm[§§]	16%	6%	57%
Condom[¶¶]			
Female (Reality®)	21%	5%	49%
Male	15%	2%	53%
Combined pill and progestin-only pill	8%	0.3%	68%
Evra patch®	8%	0.3%	68%
NuvaRing®	8%	0.3%	68%
Depo-Provera®	3%	0.3%	56%
Intrauterine device			
ParaGard® (copper T)	0.8%	0.6%	78%
Mirena® (LNG-IUS)	0.2%	0.2%	80%
Implanon®	0.05%	0.05%	84%
Female sterilization	0.5%	0.5%	100%
Male sterilization	0.15%	0.10%	100%
Emergency contraceptive pills[***]	Not applicable	Not applicable	Not applicable
Lactational amenorrhea methods[†††]	Not applicable	Not applicable	Not applicable

http://womenscommunityclinic.org/birth-control/

HOW WELL DOES BIRTH CONTROL WORK?

What is your chance of getting pregnant?

Really, really well

	The Implant (Nexplanon)	IUD (Skyla)	IUD (Mirena)	IUD (ParaGard)	Sterilization, for men and women
Works, hassle-free, for up to...	3 years	3 years	5 years	12 years	Forever

Less than 1 in 100 women

Okay

	The Pill	The Patch	The Ring	The Shot (Depo-Provera)
For it to work best, use it...	Every. Single. Day.	Every week	Every month	Every 3 months

6-9 in 100 women, depending on method

Not so well

	Withdrawal	Diaphragm	Fertility Awareness	Condoms, for men and women

For each of these methods to work, you or your partner have to use it every single time you have sex.

12-24 in 100 women, depending on method

FYI, without birth control, over 90 in 100 young women

BEDSIDER

Bixby Center for Global Reproductive

TABLE. Recommendations for contraceptive use by women who are at high risk for human immunodeficiency virus (HIV) infection, or who have HIV infection, or who have acquired immunodeficiency syndrome (AIDS) — United States, 2012

Condition	Category* COC/P/R	POP	DMPA	Implants	Clarifications/Evidence
High risk for HIV	1	1	1†	1	**Clarification:** Some studies suggest that women using progestin-only injectable contraception might be at increased risk for HIV acquisition; other studies do not show this association. CDC reviewed all available evidence and agreed that the data were not sufficiently conclusive to change current guidance. However, because of the inconclusive nature of the body of evidence on possible increased risk for HIV acquisition, women using progestin-only injectable contraception should be strongly advised to also always use condoms (male or female) and take other HIV preventive measures. Expansion of contraceptive method mix and further research on the relationship between hormonal contraception and HIV infection are essential. These recommendations will be continually reviewed in light of new evidence. **Evidence:** Prospective studies have assessed the risk for HIV acquisition among HIV-negative women using different hormonal contraceptives. Most found no statistically significant association between use of oral contraceptive pills and HIV acquisition, except one study among sex workers in Kenya, which just reached statistical significance. Studies evaluating an association between use of DMPA or nonspecified injectables and HIV acquisition showed inconsistent results and are limited by methodological problems. Because of the inconsistency of the body of evidence, available data do not establish a clear causal association with HIV acquisition, nor is the possibility of an association definitively ruled out.§
HIV infection¶	1†	1†	1†	1†	**Clarification:** Drug interactions might exist between hormonal contraceptives and antiretroviral drugs; refer to the section on drug interactions. **Evidence:** Most studies suggest no association between use of hormonal contraception and progression of HIV, as measured by CD4+ count <200 cells/mm^3, initiation of antiretroviral therapy, or mortality. One randomized controlled trial found an increased risk for a composite outcome of declining CD4+ count or death among hormonal contraceptive users when compared with copper intrauterine device users; however, this study had significant loss to follow-up and method switching among groups, limiting its interpretation. One prospective observational study directly assessed the effect of hormonal contraception on female-to-male HIV transmission by measuring seroconversions in male partners of women with known hormonal contraceptive use status. This study reported a statistically significant association between injectable contraception and female-to-male transmission of HIV. This study had several strengths, including statistical adjustment for multiple potential confounders, low loss to follow-up and frequent follow-up visits, large size of the population studied, genetic linkage of HIV transmissions, and measurement of genital viral shedding. However, the limitations included the potential for residual confounding in observational data, uncertainty regarding whether the genital shedding data bolster the main findings, and the limited statistical power given small numbers of new HIV infections in men. Studies assessing the effect of hormonal contraception on genital viral shedding have been mixed, and studies overall found no association between hormonal contraceptive use and plasma HIV viral load. Thus, direct evidence is extremely limited. Indirect evidence on genital shedding is inconsistent, and indirect evidence on plasma viral load is largely reassuring. Available data do not establish a clear causal association with female-to-male HIV transmission, nor is the possibility of an association definitively ruled out.§
AIDS¶	1†	1†	1†	1†	**Clarification**: Drug interactions might exist between hormonal contraceptives and antiretroviral drugs; refer to the section on drug interactions.

Table 3. Drug Interactions Between Antiretroviral Agents and Hormonal Contraceptives (CIII)
(page 1 of 3)

ARV Drug	Effect on Contraceptive Drug Levels	Dosing Recommendation/ Clinical Comment for Combined Hormonal Methods and Progestin-Only Pills	Dosing Recommendation/ Clinical Comment for DMPA[a]	Dosing Recommendation/ Clinical Comment for Etonogestrel Implants
NNRTIs				
EFV	Oral Ethinyl Estradiol/ Norgestimate: • No effect on ethinyl estradiol concentrations • ↓ active metabolites of norgestimate (levonorgestrel AUC ↓ 83%; norelgestromin AUC ↓ 64%) Implant: • ↓ etonogestrel Levonorgestrel (Emergency contraception) AUC ↓ 58%	Use alternative or additional contraceptive method.	No additional contraceptive protection is needed.	Use alternative or additional contraceptive method.

ARV Drug	Effect on Contraceptive Drug Levels	Dosing Recommendation/ Clinical Comment for Combined Hormonal Methods and Progestin-Only Pills	Dosing Recommendation/ Clinical Comment for DMPA[a]	Dosing Recommendation/ Clinical Comment for Etonogestrel Implants
NNRTIs, continued				
ETR	Ethinyl estradiol AUC ↑ 22% Norethindrone: • No significant effect	No additional contraceptive protection is needed.	No additional contraceptive protection is needed.	No additional contraceptive protection is needed.
NVP	Ethinyl estradiol AUC ↓ 20% Norethindrone AUC ↓ 19% DMPA: • No significant change	Can consider an alternative method or a reliable method of barrier contraception in addition to this method.	No additional contraceptive protection is needed.	Can consider an alternative method or a reliable method of barrier contraception in addition to this method.
RPV	Ethinyl estradiol AUC ↑ 14% Norethindrone: • No significant change	No additional contraceptive protection is needed.	No additional contraceptive protection is needed.	No additional contraceptive protection is needed.
RTV-Boosted PIs				
ATV/r	Ethinyl estradiol AUC ↓ 19% Norgestimate AUC ↑ 85%	Use alternative or additional contraceptive method.	No additional contraceptive protection is needed.	Can consider an alternative method or a reliable method of barrier contraception in addition to this method.
DRV/r	Ethinyl estradiol AUC ↓ 44% Norethindrone AUC ↓ 14%	Use alternative or additional contraceptive method.	No additional contraceptive protection is needed.	Can consider an alternative method or a reliable method of barrier contraception in addition to this method.
FPV/r	Ethinyl estradiol AUC ↓ 37% Norethindrone AUC ↓ 34%	Use alternative or additional contraceptive method.	No additional contraceptive protection is needed.	Can consider an alternative method or a reliable method of barrier contraception in addition to this method.
LPV/r	Ethinyl estradiol AUC ↓ 42% Norethindrone AUC ↓ 17%	Use alternative or additional contraceptive method.	No additional contraceptive protection is needed.	Can consider an alternative method or a reliable method of barrier contraception in

Resources

- www.aidsinfo.nih.gov
  - Perinatal and other HIV related guidelines
- http://www.acog.org/Resources-And-Publications/Endorsed-Documents
  - Many references available to non-members
- http://nccc.ucsf.edu/clinician-consultation/perinatal-hiv-aids/
  - 24 hour /7 day hotline - perinatal
  - PrEP line
- http://www.cdc.gov/hiv/
  - http://www.cdc.gov/hiv/pdf/risk_PrEP_TalkingtoDr_FINALcleared.pdf

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2. Emergency *Contraception*: Resource Overview — November 2015

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THANK YOU!

Medical Services

- Planning Your Visit
- Pregnancy Calculator
- Abortion Services
- Pregnancy Testing
- Pre-natal Care & Deliveries
- Fertility Services
- Birth Control
- LGBTQ Health
- HIV Services
- STI Testing and Treatment
- Teen Health
- Miscarriage Management
- Managing Menopause

HIV Services

HIV Testing

FREE Walk-in HIV (and other STI) Testing (see hours below)

- No appointment necessary
- Results in 10 minutes
- Available to anyone 13 years and older
- Confidential and Private

Want information? Check out Choices' HIV/AIDS Programs and HIV/AIDS Resources.

Walk-in Testing Hours

Monday	9:30am - 11:30am and 1:30pm - 3:30pm
Tuesday	9:30am - 11:30am and 1:30pm - 3:30pm
Wednesday	No walk in testing available on Wednesdays

1981

Pneumocystis Pneumonia --- Los Angeles
In the period October 1980-May 1981, 5 young men, all active homosexuals, were treated for biopsy-confirmed Pneumocystis carinii pneumonia at 3 different hospitals in Los Angeles, California. Two of the patients died. All 5 patients had laboratory-confirmed previous or current cytomegalovirus (CMV) infection and candidal mucosal infection. Case reports of these patients follow.

MMWR *Weekly* **June 5, 1981 / 30(21);1-3**

Epidemiologic Notes and Reports

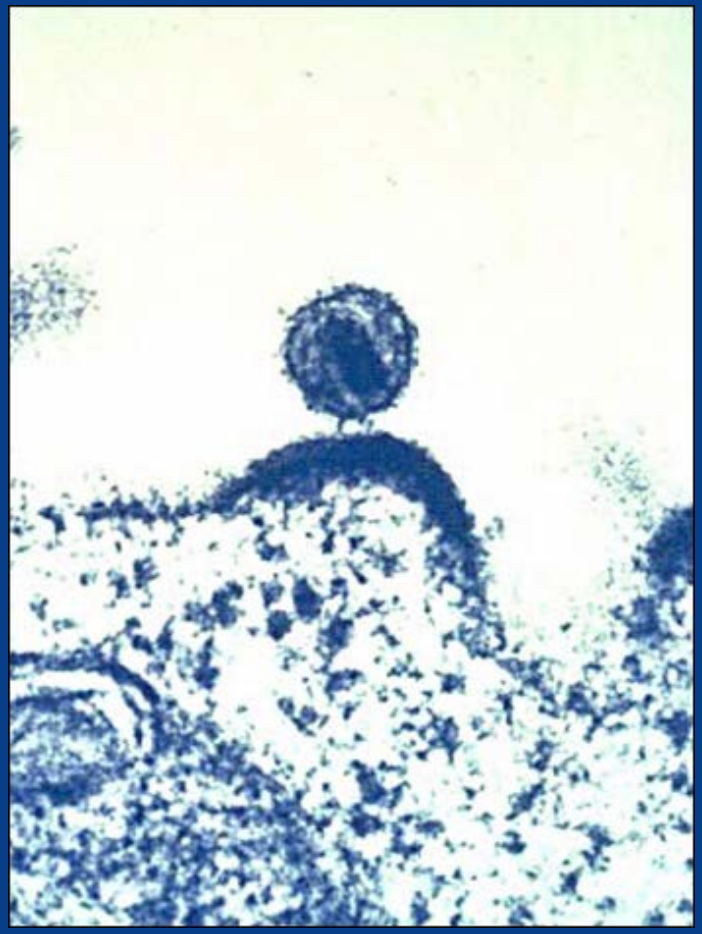
1982

Unexplained Immunodeficiency and Opportunistic Infections in Infants -- New York, New Jersey, California

CDC has received reports of four infants (under 2 years of age) with unexplained cellular immunodeficiency and opportunistic infections.

MMWR **December 17, 1982 / 31(49);665-667**

1984 – Virus identified



Virus emerging from infected T-cell
NIH.gov

1989

- Antiretroviral Pregnancy Registry established

2006-2016

- Improvements in screening – universal screening in pregnancy; opt-out; 1st and 3rd trimester
- Research focused on reduction of MTCT in resource limited countries including regimens for reduction while breast feeding.
- Call for increased enrollment of women in HIV prevention studies
- Continuation of cART after delivery (2009)
- Vaccine studies

1987-1988

- AZT (zidovudine or ZDV) approved by FDA (1987)
- WITS Women and Infants Transmission study initiated 1988