

WOMEN AS THE FACE OF AIDS

Iris House Summit

Pre-Exposure Prophylaxis (PrEP) for HIV

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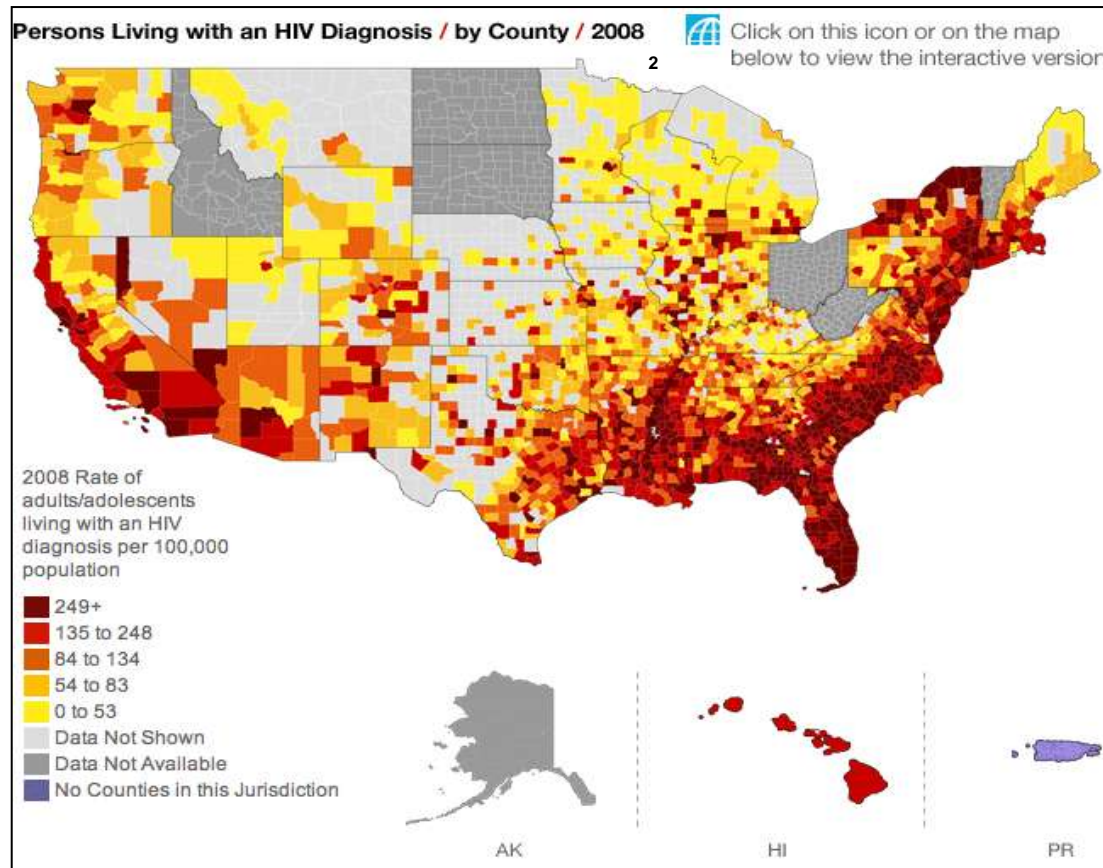
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New York, NY

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- **The Need for HIV Prevention**
 - Prevention Strategies
 - Where are we now?

Persons Living with HIV in the U.S.

Over 1 million people living with HIV in the United States¹



**Estimated U.S. number of new HIV infections annually (2009):
48,100 (95% CI 42,200 – 54,000)³**

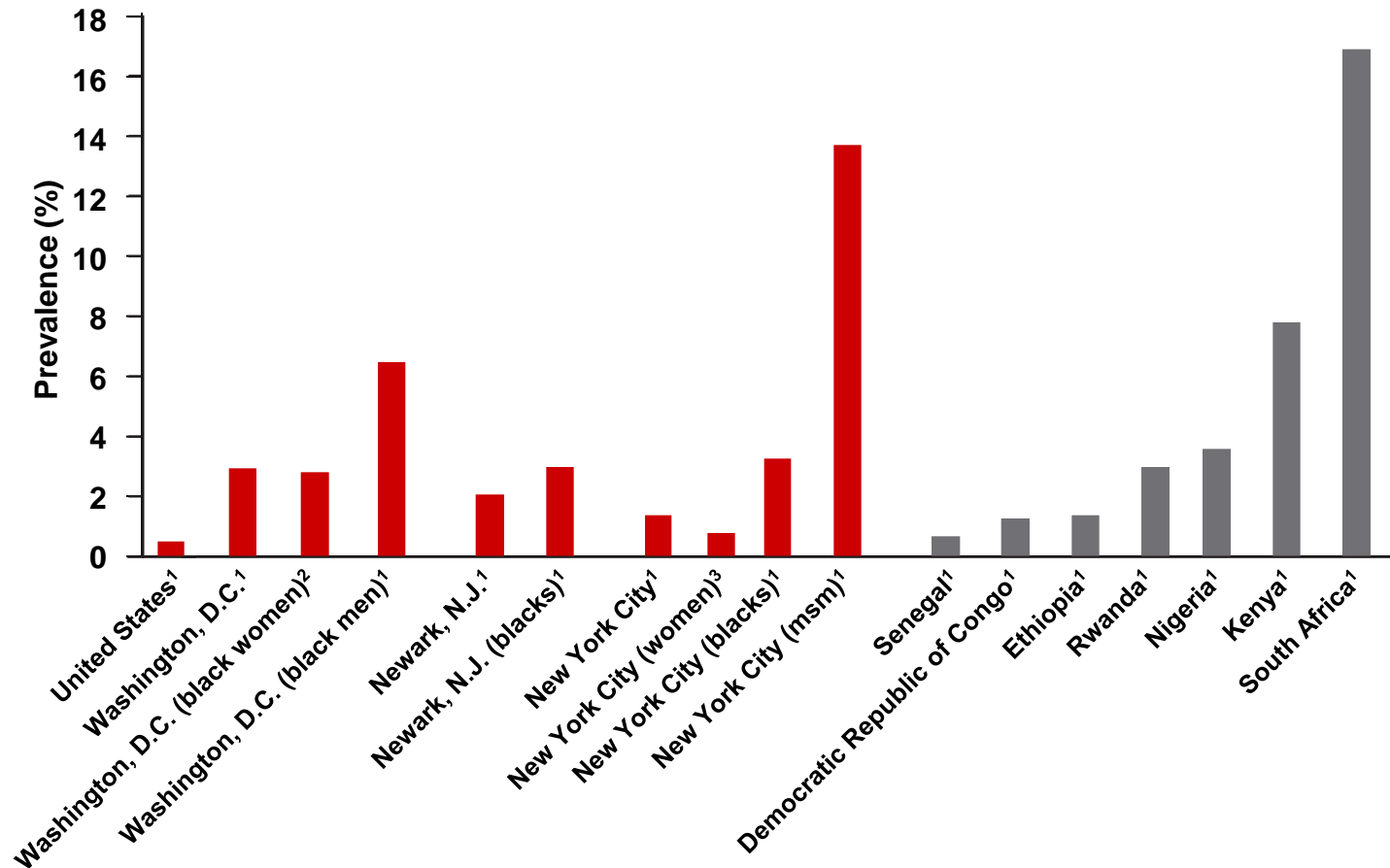
1. CDC. HIV in the United States Fact Sheet. Available at: <http://www.cdc.gov/hiv/resources/factsheets/PDF/us.pdf>. Accessed Sept 2011

2. AIDSvu. Available at: <http://www.aidsvu.org>. Accessed Sept 2011. Support for AIDSvu is provided by Gilead Sciences, Inc.

3. Prejean J, et al. PLoS ONE 2011;6:e17502



HIV Prevalence in the U.S. and Africa



In subpopulations in the U.S., HIV prevalence rates mirror those in Africa

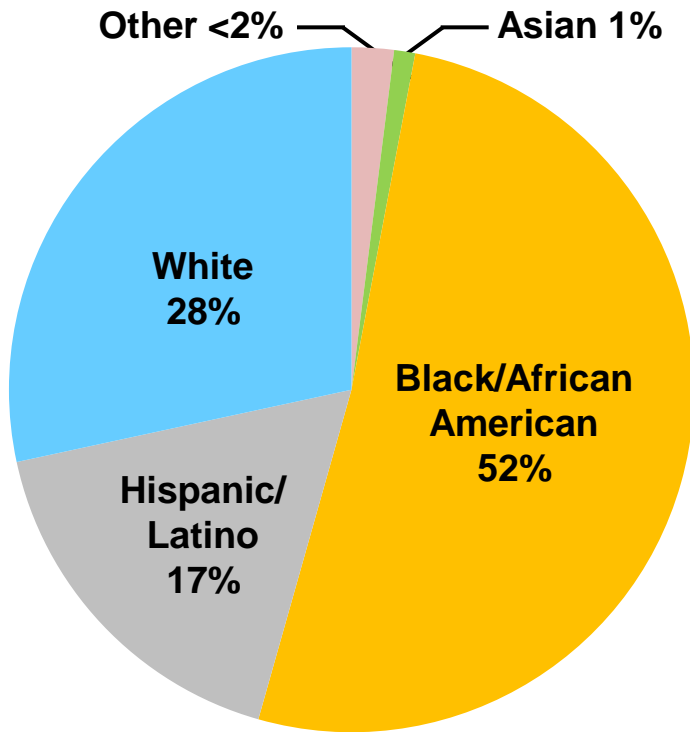
1. El-Sadr WM, et al. N Engl J Med 2010;362:967-970

2. District of Columbia Department of Health. HIV/AIDS, Hepatitis, STD and TB Annual Report 2010. Published June 2011

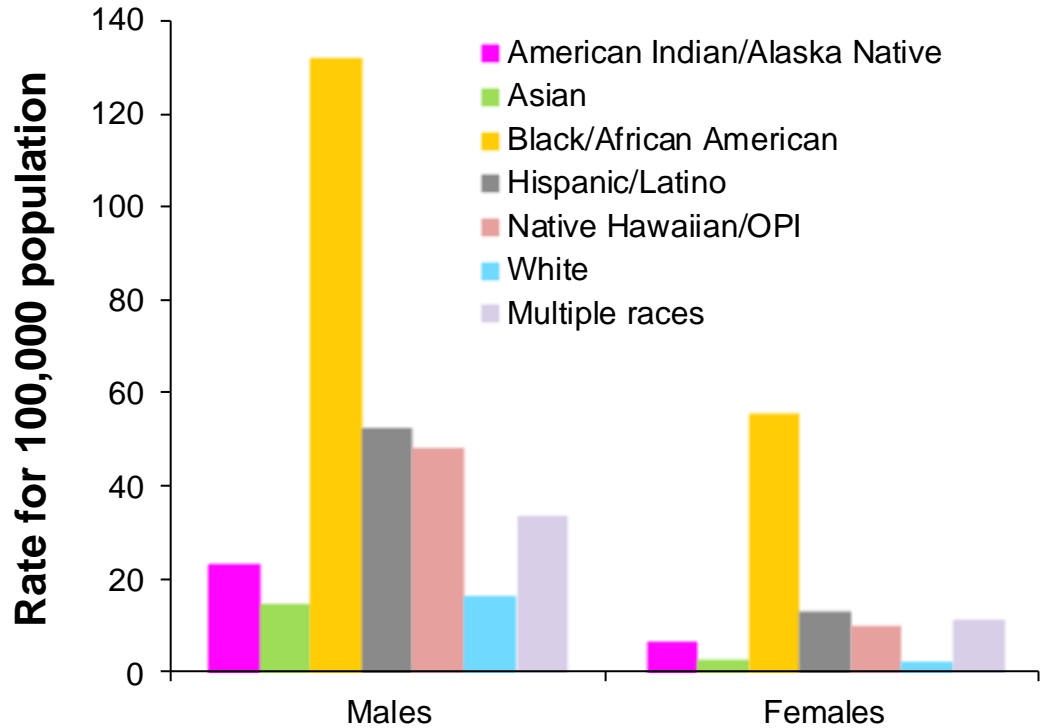
3. New York City Department of Health and Mental Hygiene. HIV/AIDS Among Females in New York City in 2010. Published February 2012

Incidence and Rates of Diagnoses of HIV Infection in Adults and Adolescents by Race/Ethnicity and Sex (US, 2008)^a

Distribution of Diagnoses of HIV Infection by Race/Ethnicity (2008)¹



Estimated Rates of Diagnoses of HIV Infection in Adults and Adolescents by Sex and Race/Ethnicity (2008)²



^a37 states with confidential name-based HIV infection reporting.

Estimated rates resulted from statistical adjustment that accounted for reporting delays, but not for incomplete reporting.

Hispanics/Latinos can be of any race.

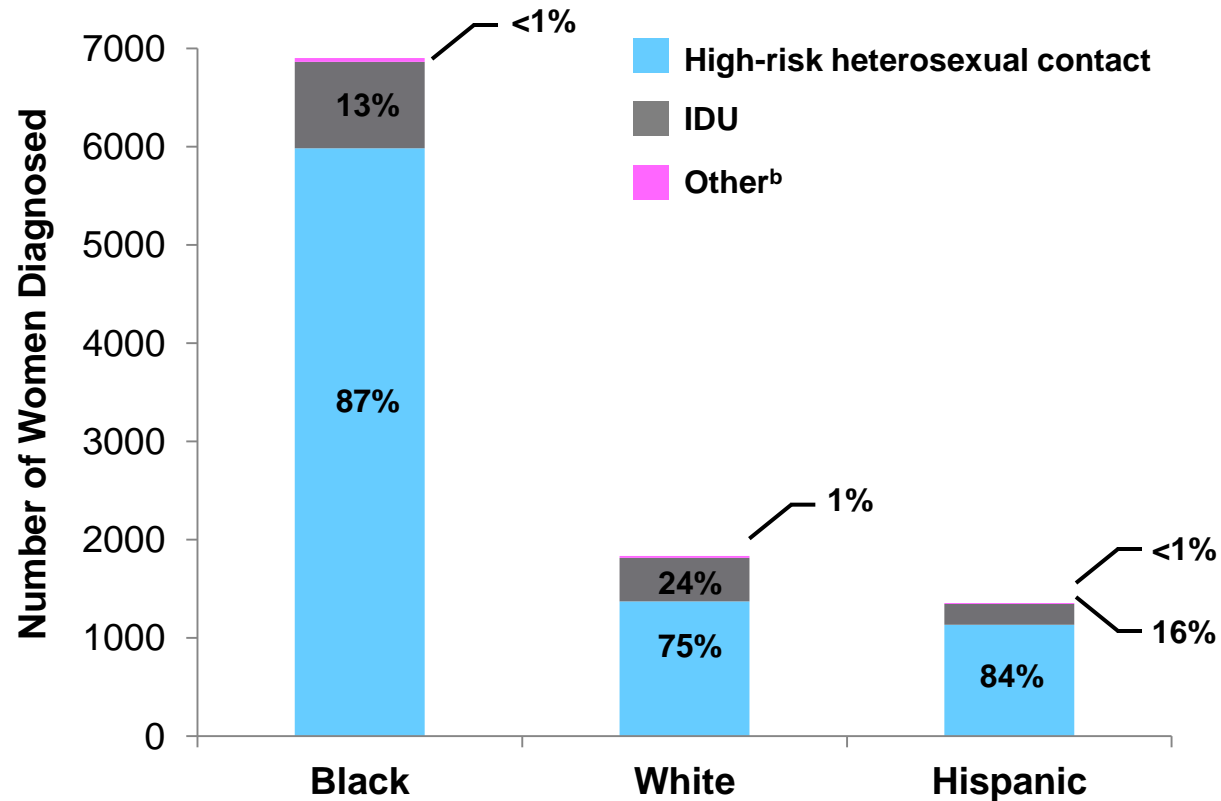
OPI, Other Pacific Islander.

¹Adapted from CDC. *HIV Surveillance Report, 2008*. Vol. 20. Table 1a.

²CDC. *HIV Surveillance Report, 2008*. 20:1.

Heterosexual Contact Is the Main Source of HIV Infection in Women

Transmission Categories and Race/Ethnicity of Women Diagnosed with HIV Infection in 2008^a



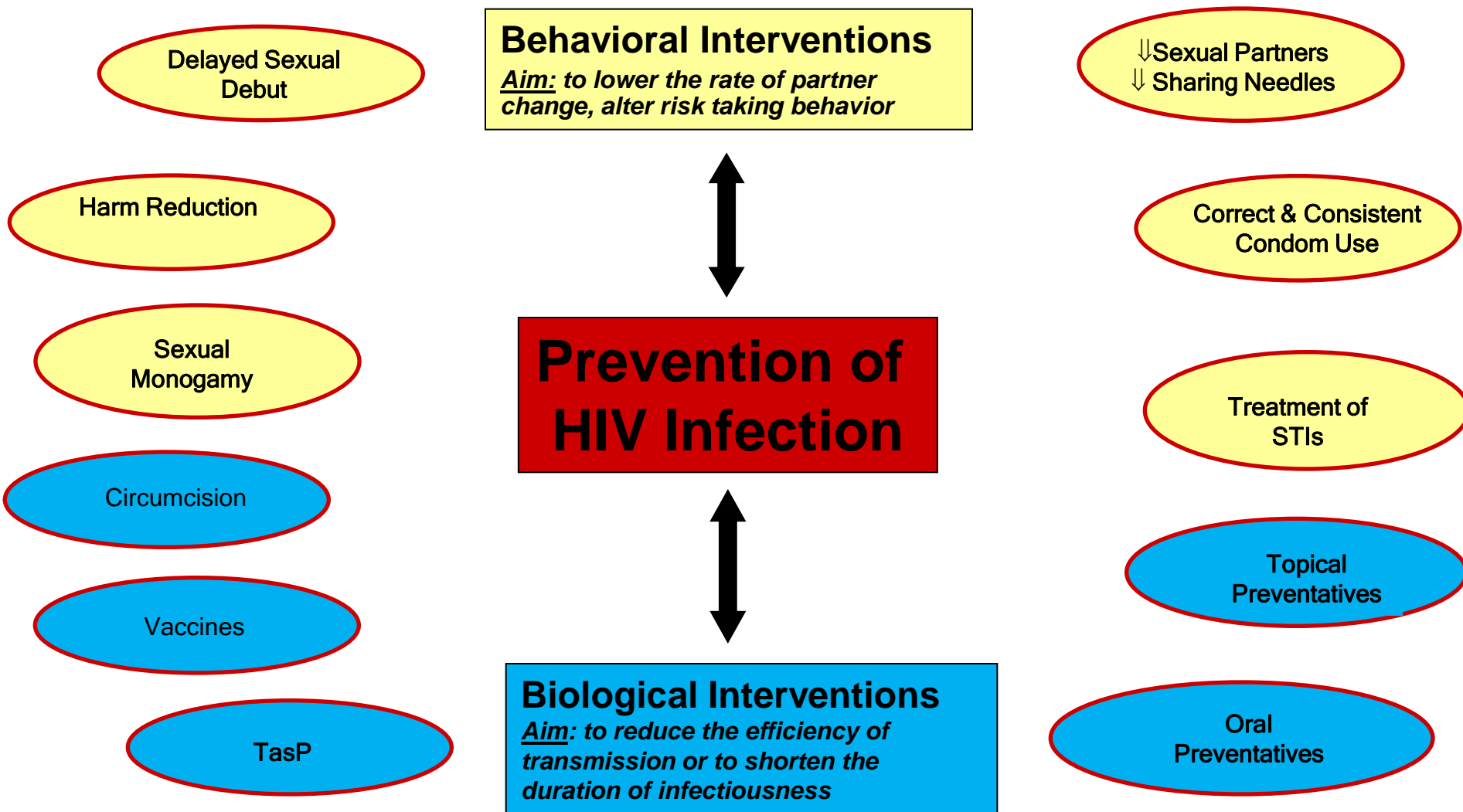
^a37 states with confidential name-based HIV infection reporting.

^bIncludes hemophilia, blood transfusion, perinatal exposure, and risk factor not reported or not identified.

Adapted from CDC. *HIV Surveillance Report, 2008*. Vol. 20. Table 3a.

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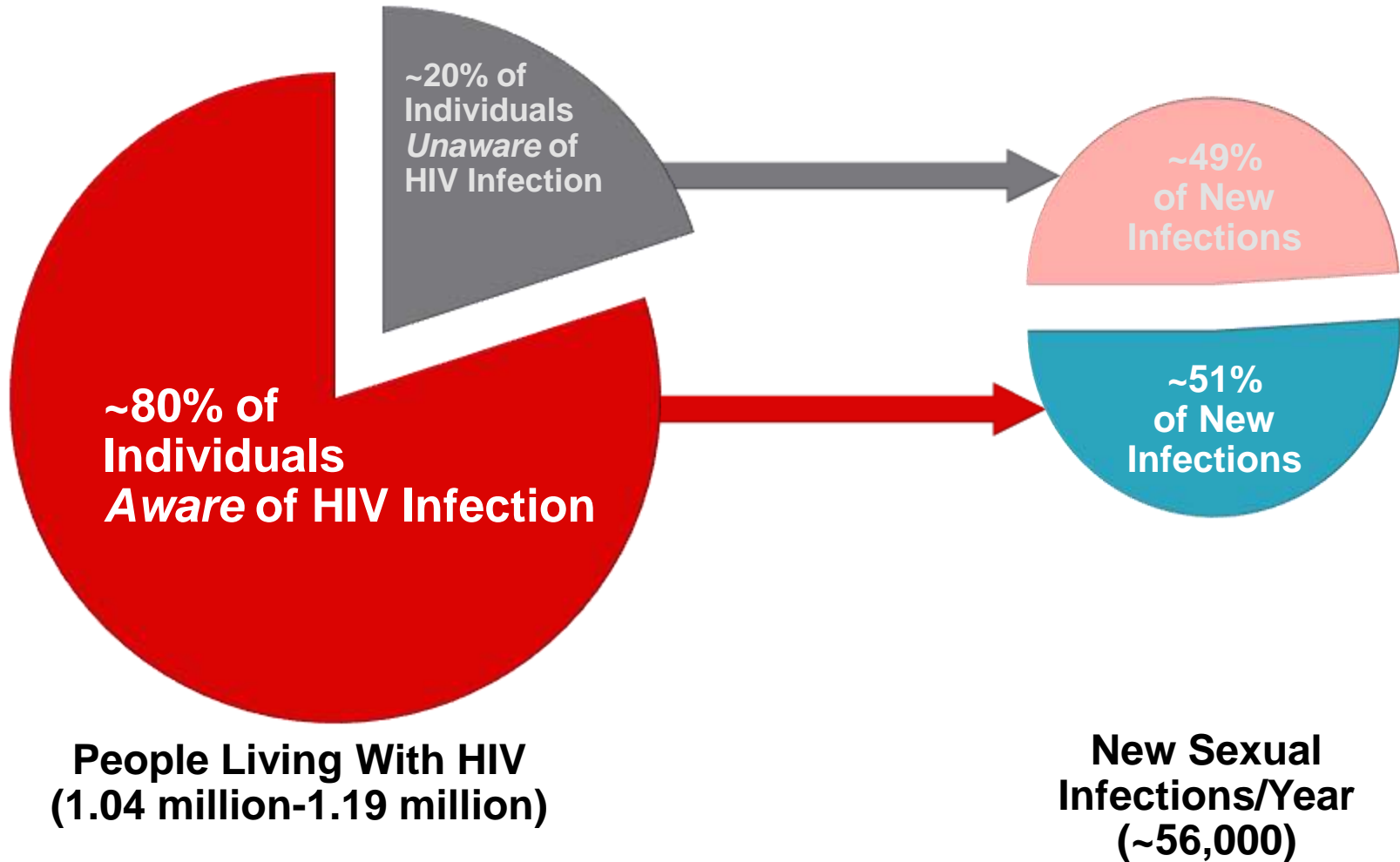
HIV Prevention Opportunities



Relative Risk of HIV Infection According to Exposure Type

Exposure	Risk per 10,000 Exposures
Needle sharing	67
Receptive anal intercourse	50
Percutaneous (occupational exposure)	30
Receptive vaginal intercourse	10
Insertive anal sex	6.5
Insertive vaginal sex	5
Receptive oral intercourse	1
Insertive oral intercourse	0.5

HIV Is More Likely to Be Transmitted by Individuals Unaware of Their Infection †



Biological Prevention Strategies

Use of anti-HIV medications

- By HIV **positive** people:
 - To prevent transmission to others
 - Treatment as prevention (TasP)
 - Mother to child transmission
- By HIV **negative** people:
 - Before exposure to HIV – Pre-exposure Prophylaxis (PrEP)
 - Topical preventatives
 - Oral preventatives
 - After possible exposure to HIV – Post-exposure Prophylaxis (PEP)



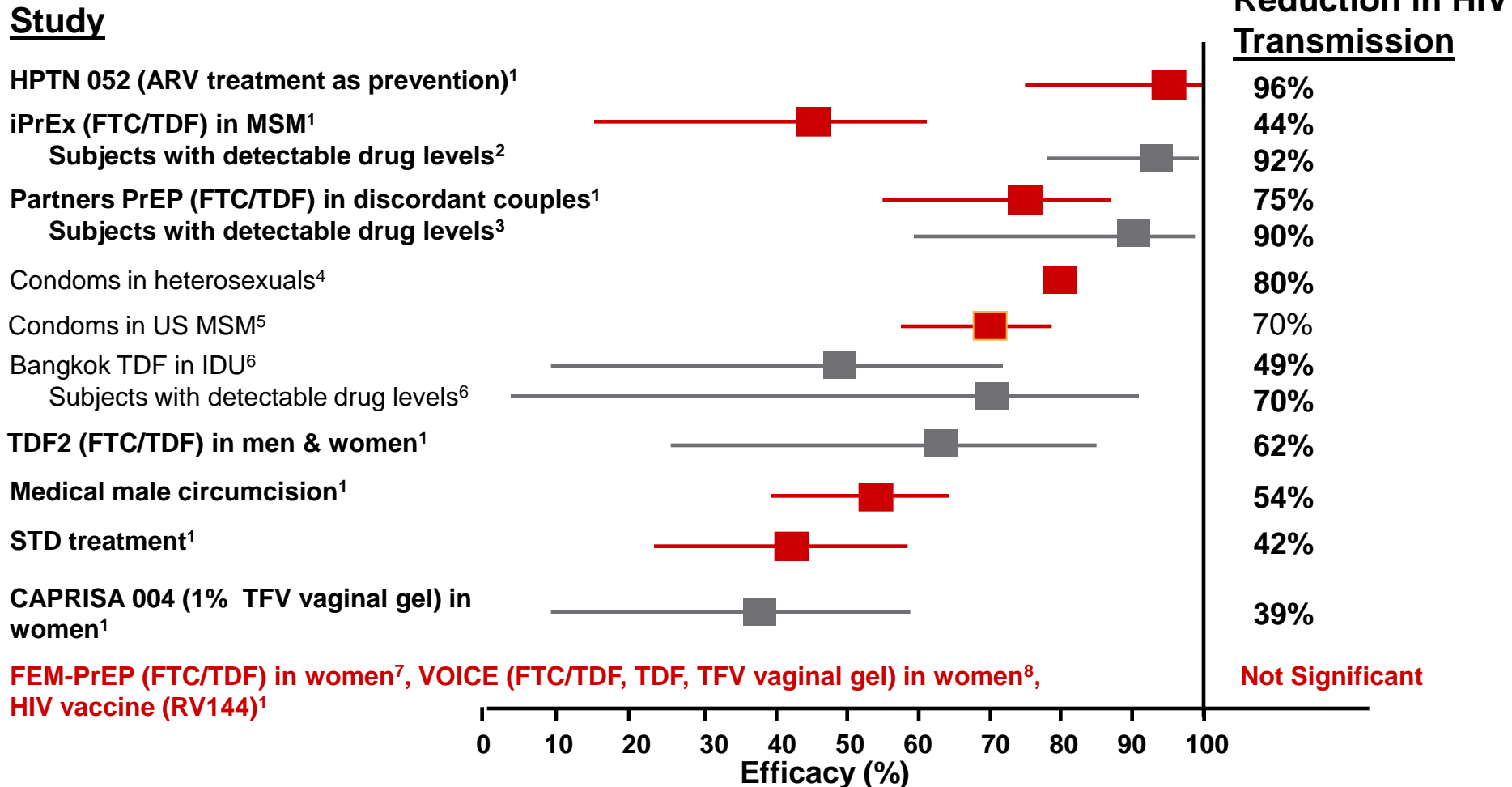
Effective ART Reduces the Risk of Mother-to-Child HIV Transmission

- ART is necessary for preventing mother-to-child HIV transmission before and after delivery^{1,2}
- Advances in treatment have led to a decrease in the rate of mother-to-child transmission of HIV in high-income countries from 20% in 1994 to less than 1% for women receiving ART in 2009¹
- ART is indicated for all pregnant women living with HIV, because good control of VL at delivery effectively prevents mother-to-child HIV transmission
- Without continued use of ART after delivery, 9% of HIV-negative infants who were born to HIV-positive mothers became infected after 18 months of breastfeeding²

¹ Rachas A, et al. *AIDS*. 2013 Jan 28;27(3):357-367.

² Chasela CS, et al. *N Engl J Med*. 2010;362:2271-2281.

Relative Efficacy of TasP, PrEP and Other Prevention Strategies



1. Adapted from Abdool Karim S and QA. Lancet 2011;S0140-6736:1136-7
 2. Amico R, et al. IAC 2012. Washington DC. #TUPE310
 3. Baeten J, et al. NEJM 2012;367:399-410
 4. Weller S, et al. Cochrane Database Syst Rev 2002:CD003255

5. Smith DK, et al. CROI 2013; Atlanta, GA. Oral #32
 6. Choopanya K, et al. IAS 2013; Kuala Lumpur, Malaysia. Oral #WELBCO5
 7. van Damme L, et al. NEJM 2012;367:411-422
 8. Marrazzo JM, et al. CROI 2013; Atlanta, GA. Oral #26LB



CDC Interim Guidance

Summary of PrEP Efficacy Trials

Study	Population	mITT ^a % Reduction in HIV Incidence (95% CI)			Combined Self-Report and Pill-Count Medication Adherence (95% CI)	Pill-Count Medication Adherence (95% CI)	Efficacy with TFV Blood Detection ^b (95% CI)
iPrEx	MSM	44% (15-63%)			>50%: ^c 50% (18-70%) >90%: ^c 73% (41-88%)	NR	92% (40-99%)
		Overall	Men	Women			
Partners PrEP	Heterosexual discordant couples	75% (55-87%)	84% (54-95%)	66% (28-84%)	NR	100% ^d (87-100%)	90% (58-98%)
TDF2	Heterosexual men and women	62% (22-83%)	80% (25-97%)	49% (-21 to 81%, NS)	NR	NR	84% (-62 to 98%, NS)
FEM-PrEP	Heterosexual women	NS	NS	NS	NR	NR	NS
VOICE	Heterosexual women	NS	NS	NS	NR	NR	NS

a Excluded only those enrolled patients later found to be infected at randomization and those with no follow-up visit or HIV test

b The percentage of reduction in HIV incidence among those with TFV detected in blood, compared with those without detectable TFV

c The percentage of reduction in HIV incidence, compared with placebo, is presented for 2 groups: those with 50% medication adherence & those with 90% medication adherence

d In a substudy of participants who provided counts via home-based unannounced pill counts with supplementary adherence counseling if the counts were <80%

The role of oral PrEP in achieving safe conception in HIV serodiscordant couples

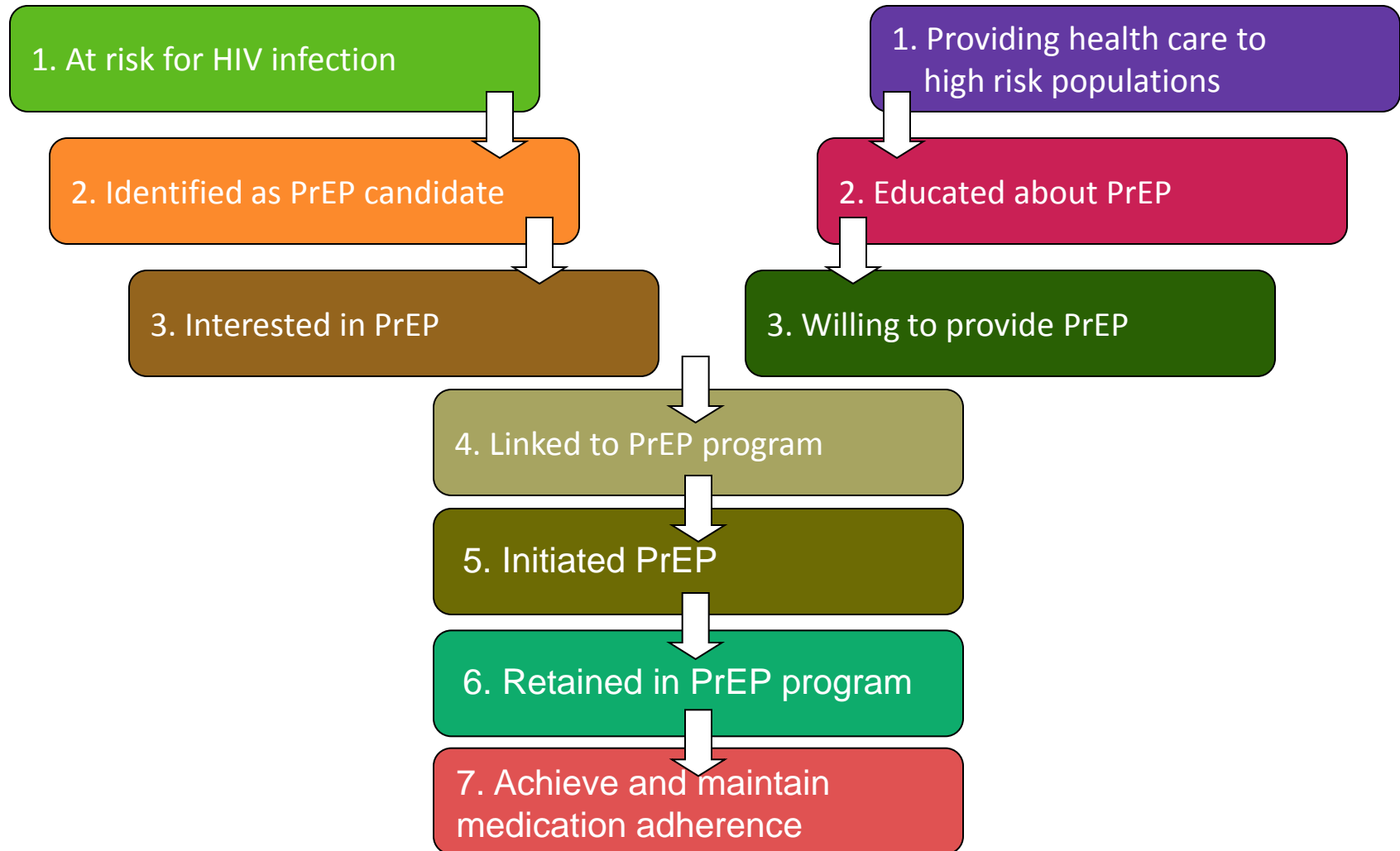
- Of the men and women with a HIV-negative partner, 46% of men and 51% of women intend to have children¹
- Oral PrEP may be an option for discordant couples wanting to conceive²
- Approaches to reduce the risk of HIV transmission during attempted conception for all couples include:²
 - Treatment of the HIV-infected partner to achieve maximal viral suppression
 - Oral or topical PrEP
 - Limiting conception attempts to the periovulation period
 - Screening both partners for STIs and treat for any found
- For HIV+ women with HIV- male partners:²
 - Elective male circumcision, artificial insemination, PrEP for male partner
- For HIV+ men with HIV- female partners:²
 - Semen collection and processing, continuing PrEP during pregnancy

1. Chen JL, et al. Fam Plann Perspect 2001;33:144-52, 165

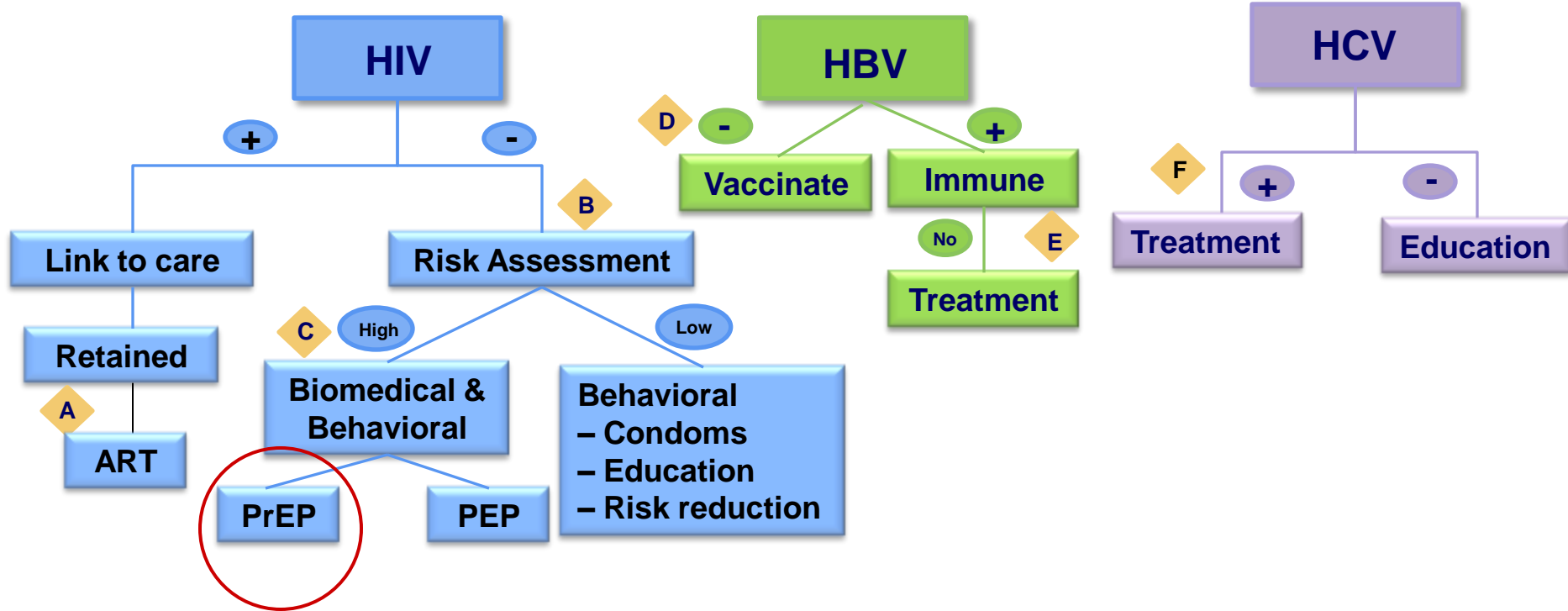
2. Lampe MA, et al. Am J Obstet Gynecol 2011;204:488.e1-8

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PrEP Delivery Cascade



Pan-Viral Testings



CDC Recommendations

Routine Testing for HIV, HBV and HCV

- **HIV¹**
 - **Routine voluntary testing for patients 13-64 years in healthcare settings**
 - **Opt-out testing - not based on patient risk and no separate consent**
 - **Pre-test counseling not required**
 - **Repeat HIV testing based on patient risk, and annually for high risk:**
 - IDUs
 - Sex for money or drugs
 - Sex partners of HIV+ persons
 - >1 sex partner since last HIV test
- **Hepatitis A and B vaccinations are recommended for all MSM and IDUs²**
- **CDC also recommends all baby boomers (born 1945-1965) be tested once for Hepatitis C³**

1. CDC. MMWR 2006;55(RR-14):1-24

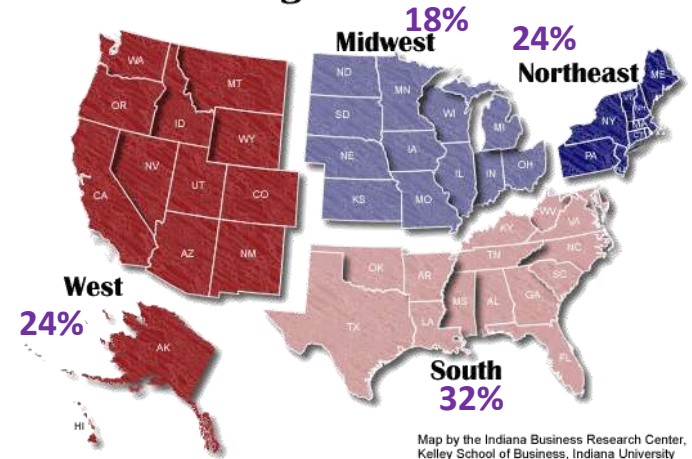
2. CDC. MMWR 2006; 55(R-16):1-56

3. CDC. Press Release: May 18, 2012

Assessment of Truvada for PrEP Utilization in the US

- 1,774 individuals received Truvada for PrEP between 2011 and March 2013
- Geographically **prescribers** of TVD for PrEP are located in 49 states and distributed across approximately 700 cities
- Only 37% also prescribed Truvada for HIV treatment
- Women accounted for 47.7% of PrEP users.
- The highest percentages of female PrEP users (52.6%) were located in the Northeast.

U.S. Census Regions



- When compared to HIV positive patients ^a, **uninfected individuals receiving TVD for PrEP** were:
 - 1.4 times more likely to be from the South (95% CI 1.3 – 1.6)^b
 - 1.8 times more likely to be female (95% CI 1.7 – 2.0)^b
 - 1.4 times more likely to be younger than 25 years old (95% CI 1.2 – 1.6)^b
 - 3.8 times more likely to be treated by a non-ID physician (95% CI 3.3 – 4.2)^b

^a multivariate logistic model ^b $p < 0.01$

Gilead Education and Support Programs

- REMS materials/website
- Laboratory services (HIV/HBV/resistance testing)
- Condom provision
- Patient Assistance Program
- Community Grants

Discussion

- What has worked best? What things have been the greatest challenges?
- How are programs (planning to) make eligible individuals aware of this service in your setting?
- Have your efforts been as successful as you hoped?
- To date, what has been the response to your efforts?
 - At-risk populations
 - medical community?

Discussion

- How are you identifying individuals at high risk?
 - What screenings tools are you using?
- What is the scope of your testing program?
 - Are you doing HBV testing? HCV testing?
- What proportion of your HIV tested population is at high risk?
 - What has been the level of acceptance from those that you define to be at high risk?
- Have you had any seroconversions?
 - At baseline vs. while prescribed PrEP
 - Any resistance?

Discussion

- What type infrastructure obstacles have you encountered?
 - Institution
 - Payer
 - Other
- What do you have in place for linkage to care for PrEP?
 - Internal and external

Thank You