HIV: Update on Epidemiology and PrEP

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New Cases of HIV, USA, AI/AN

(CDC surveillance, 2010-2014)

- Approximately 44,000 new cases/year in the USA
- HIV incidence among AI/AN patients has increased from 174 cases (7.9/100,000) in 2010 to 222 in 2014 (9.5/100,000)
- In 2014, an estimated 84% of new HIV cases were transmitted via sexual contact among Men Who Have Sex with Men (MSM)

Centers for Disease Control and Prevention. *HIV Surveillance Report, 2014*; vol. 26. http://www.cdc.gov/hiv/library/reports/surveillance/. Published November 2015. Accessed March 28, 2016

Death rates

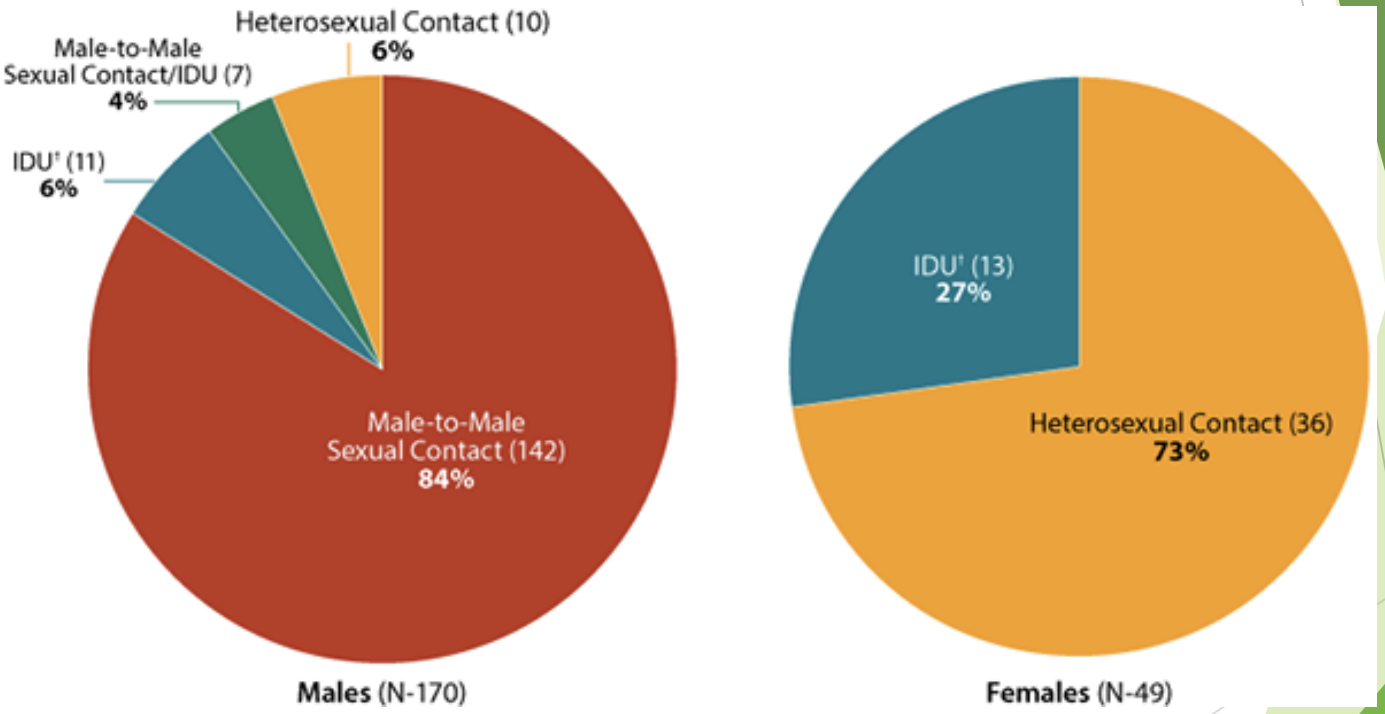
- AI/AN persons living with HIV/AIDS (PLWHA) have the lowest proportion of survival after 12, 24, and 36 months when compared to other age-matched groups
- Death rates from HIV among AI/AN about double Whites 1999-2008
- Late Diagnosis, poor linkage to care possible factors for change

Death Rates From Human Immunodeficiency Virus and Tuberculosis Among American Indians/Alaska Natives in the United States, 1990–2009

Reilley, B., Bloss, E., Byrd, K. K., Iralu, J., Neel, L., & Cheek, J. (2014). Death rates from human immunodeficiency virus and tuberculosis among American Indians/Alaska Natives in the United States, 1990–2009. *American journal of public health*, *104*(S3), S453-S459.

Main Transmission routes, Indian Country

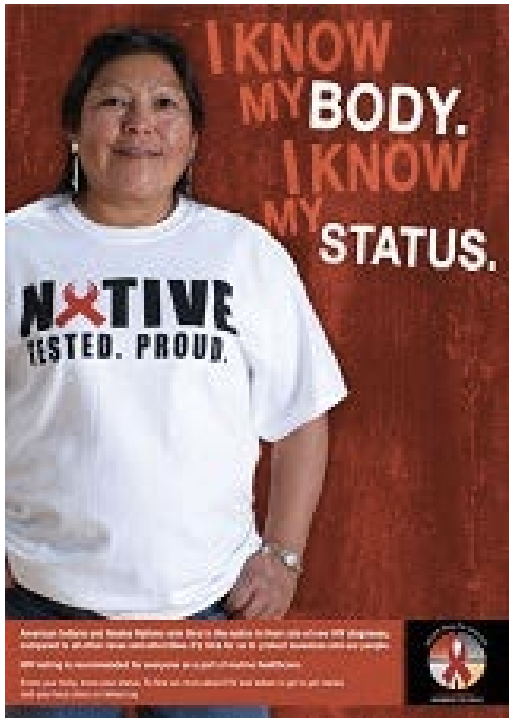
(CDC AI/AN Fact sheet)

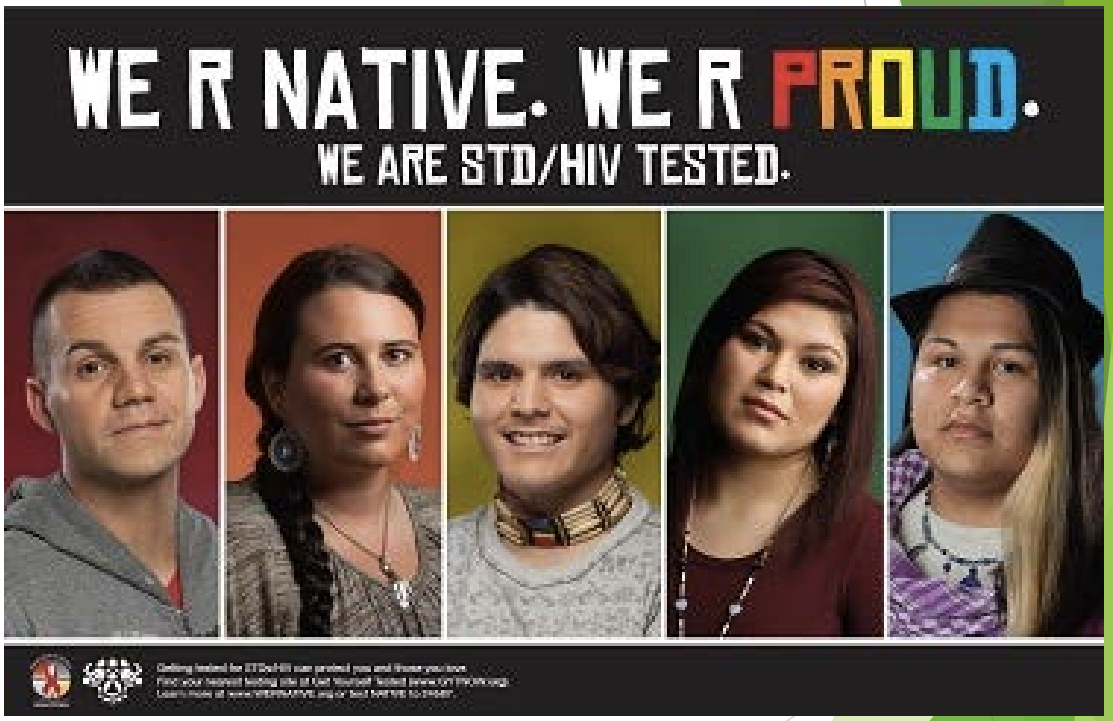


HIV Incidence, I/T/U, By sex

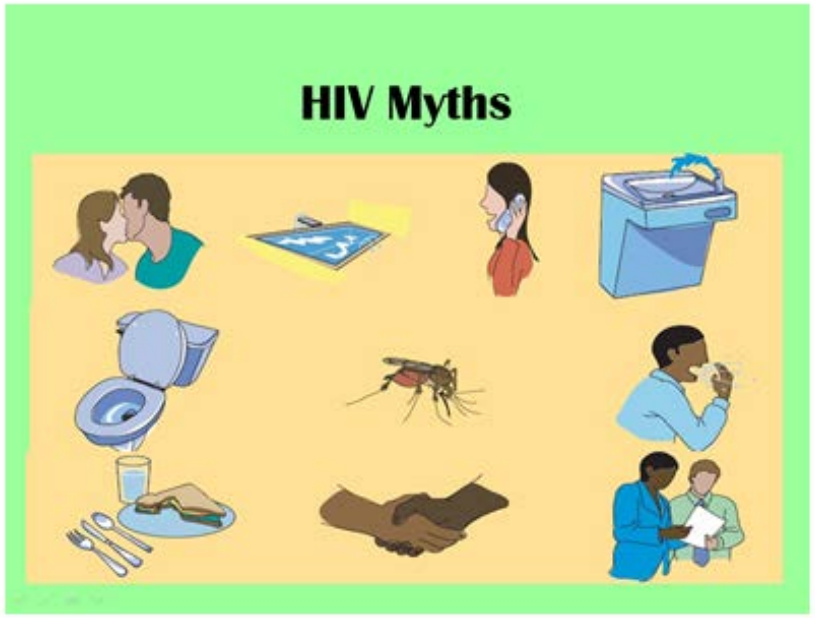
- Men about twice as likely as women to be diagnosed (Risk Ratio 2.2, 2.1-2.4)
- Men ages 20-49 about 3x more likely than age matched women to be diagnosed (RR 3.0, 2.3-3.7)
- Overall rate of new diagnoses increased 20% among males from 2010-2014

Prevention – Social Media





Prevention - HIV 101 Flip Chart



Screening-
When is it the best course of action?

- Disease is often asymptomatic
- Early detection bestows benefits on patient (and community in infectious disease)
- Test is reliable, non-invasive, inexpensive
- *Screening does not replace risk-based testing/clinical judgment*

HIV Screening Recommendation

- HIV 13-64 GPRA measure as of 2016
- Prenatal HIV at over 90%, will be continue to be monitored

Milestones in HIV screening

- 1996 blood donors
- 2001 prenatal patients
- 2006 adolescents and adults

GPRA measure has also evolved

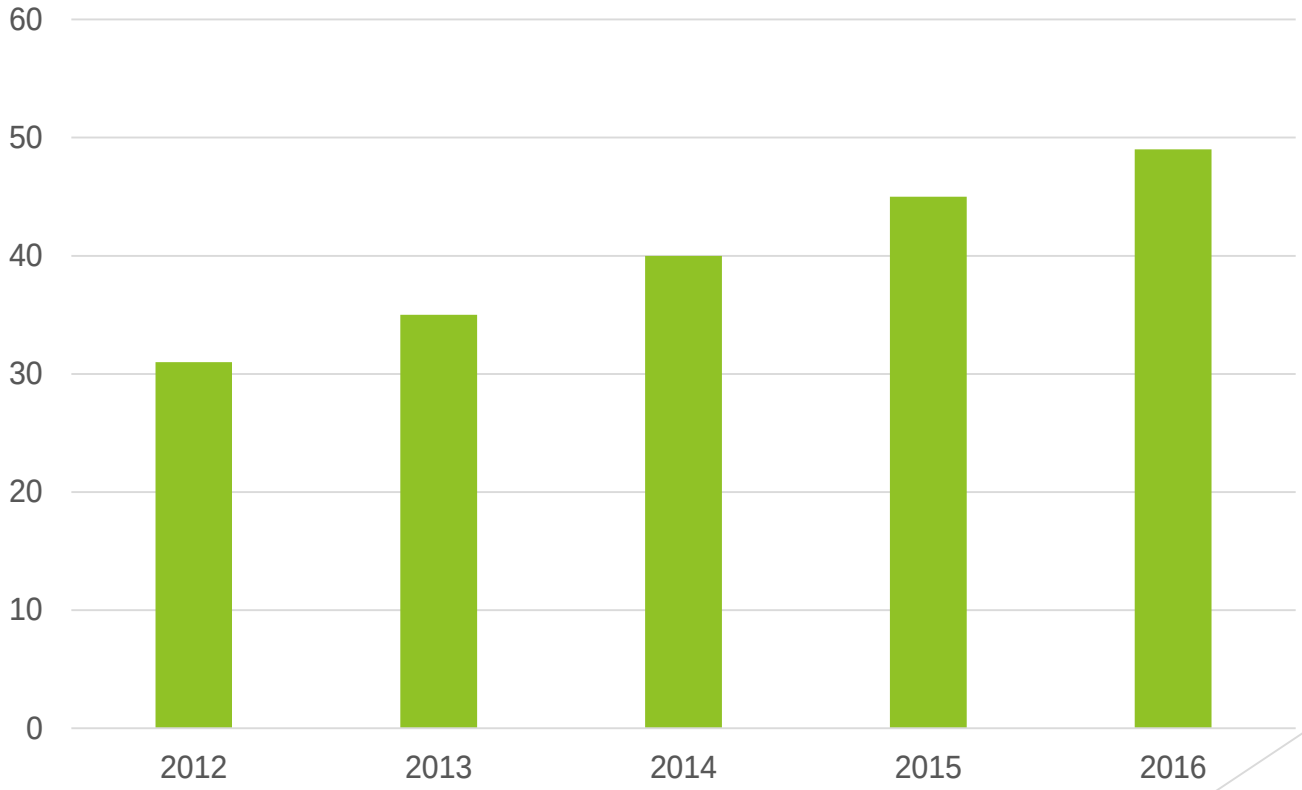
Screening is voluntary

- Inform patients orally or in writing (general medical consent) that HIV testing will be performed unless they decline.
- Arrange access to care, prevention, and support services for patients with positive HIV test results

HIV Screening, best practices

- Facility level policy for HIV/STI testing and screening
- Clinical reminder in EHR
- Standing protocols
- Delegated away from provider
- Age-based targeting removes any stigma/judgment

HIV Screening, Cumulative, IHS Service Units, 2012-2016



HIV Screening Ever, Q2 2017, IHS facilities

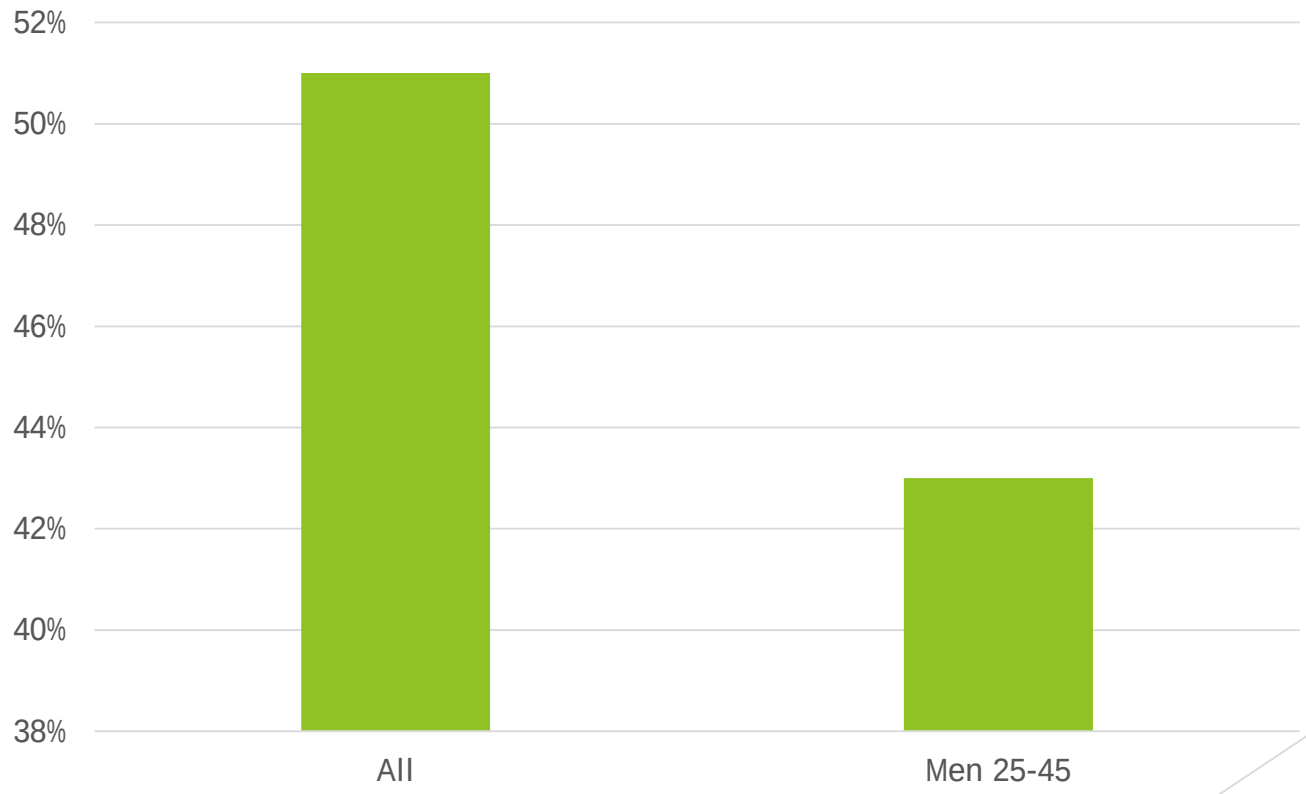
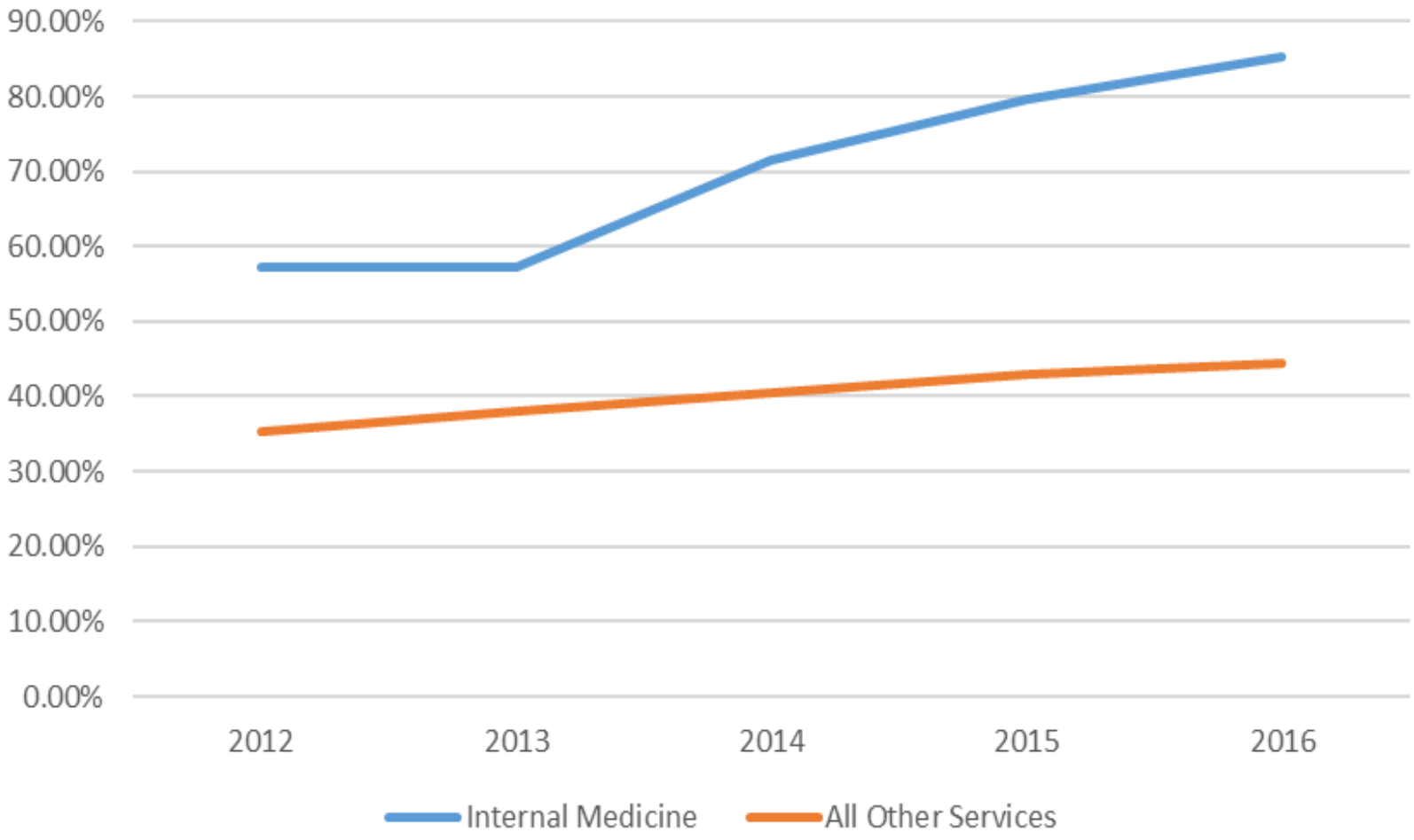


Figure 1. Proportion of Active Clinical Patients Tested for HIV, Cumulative, Southwest IHS Hospital, 2012-2016



ER, UC testing

- Positive result followed up by non ER clinician
- Can be paired with other high prevalence disease
  - STIs/urine (“cups by cuffs), HCV
- Can be tailored for feasibility
  - Only men ages 20-49
  - Only if blood being drawn for other reasons

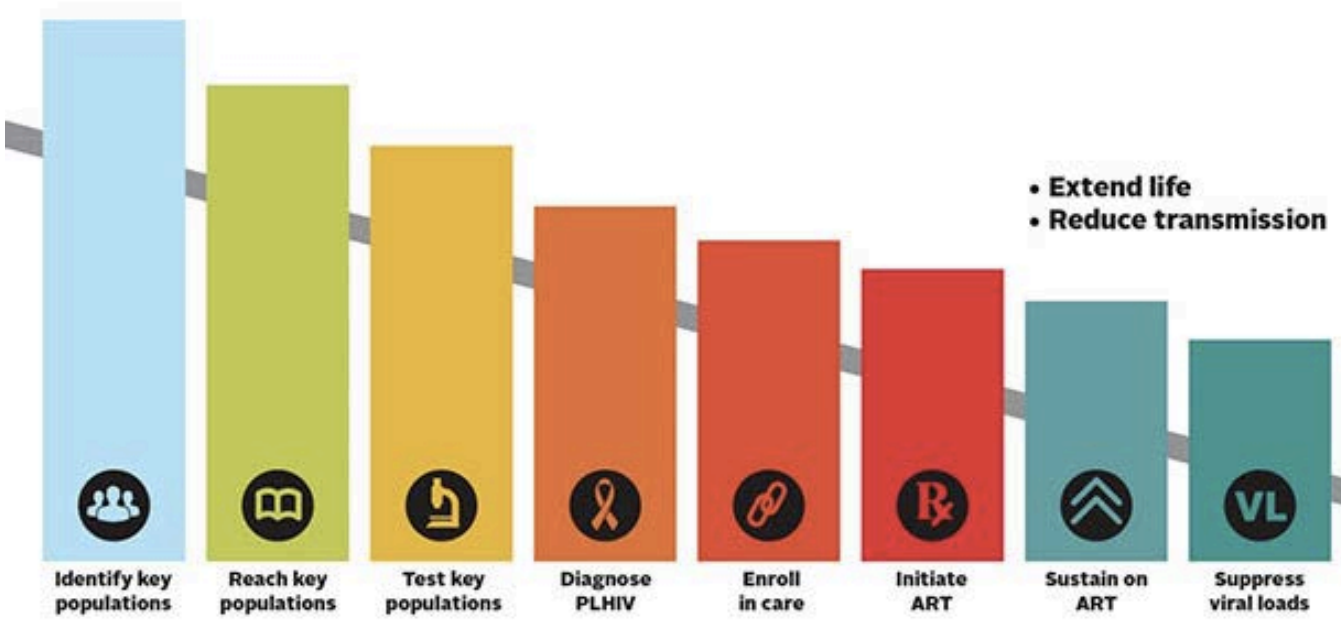
HIV Screening - Recap

- Goal of new CDC recommendations to increase number who know HIV+ status
- People do not perceive risk
- Clinicians do not offer test
- Stigma more with “identified” risk and infection less so with testing itself
- Knowing HIV+ status can reduce transmission by:
  - Behavior change
  - Addressing Co-morbidity
  - Reducing viral load

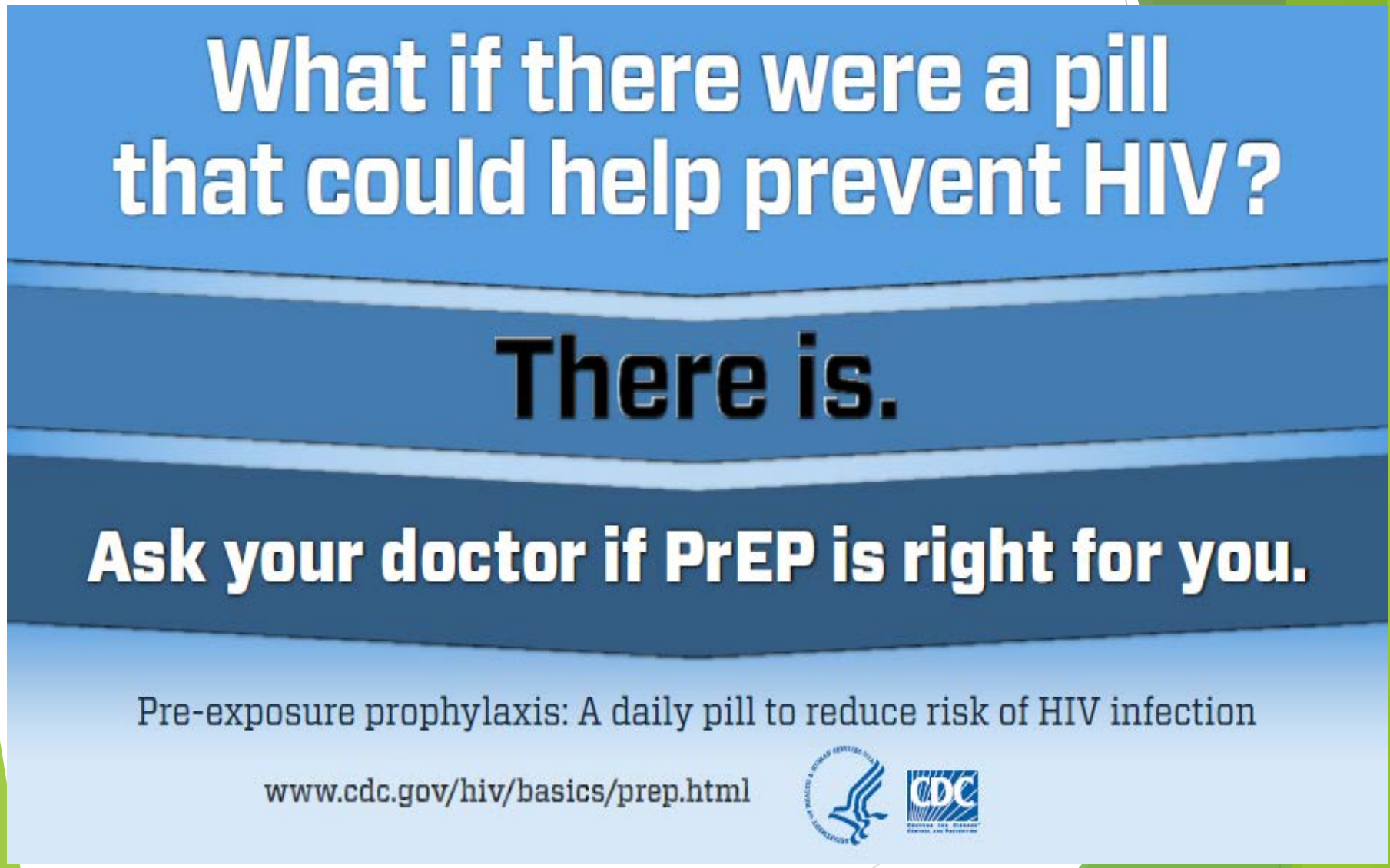
MMWR 55:1-7, 2006

Inungu J. AIDS Patient Care STDs 16:293, 2002

The **LINKAGES** Prevention, Care and Treatment Cascade



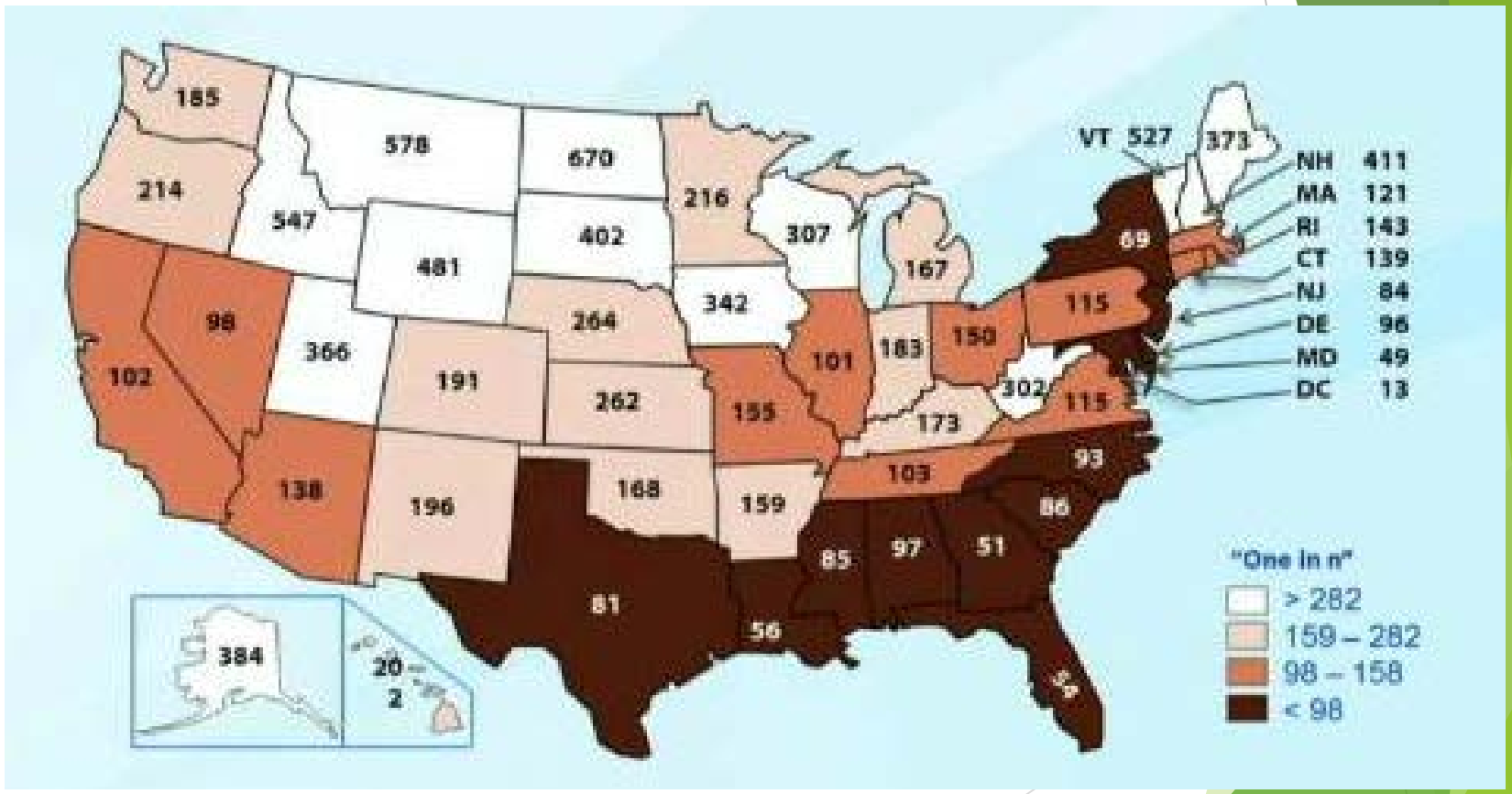

Project
ECHO
ECHO Whale
PCA Espanola
Baton Rouge
Pecos Valley MC
DOH Las Cruces
SBRT-First Choice South Va
Memorial HDX7000
LAS VEGAS ECFH


What if there were a pill that could help prevent HIV?
There is.
Ask your doctor if PrEP is right for you.
Pre-exposure prophylaxis: A daily pill to reduce risk of HIV infection
www.cdc.gov/hiv/basics/prep.html
CDC

Epidemiology of New HIV Diagnoses (Why is PrEP needed)

Lifetime Risk of an HIV Diagnosis by State

Overall: 1 in 99 (1.01%)



Source: Hess K, et al . CROI 2016, http://www.croiwebcasts.org/console/player/29467?mediaType=slideVideo&

Lifetime Risk* of an HIV Diagnosis

	"One in n"				
	MSM	Heterosexuals		PWID	
		Female	Male	Female	Male
All race/ethnicities	6	241	473	23	36
Black/African American	2	49	86	6	9
Hispanic/Latino	4	242	390	21	21
Native Hawaiian/Pacific Islander	7	395	2,706	45	62
American Indian/Alaska Native	12	493	1,116	19	43
Asian	14	910	1,760	223	178
White	11	1,083	2,514	47	103

*From age 13 years Source: Hess K, et al . CROI 2016, http://www.croiwebcasts.org/console/player/29467?mediaType=slideVide

What is PrEP? How well does it work?

What Is PrEP?

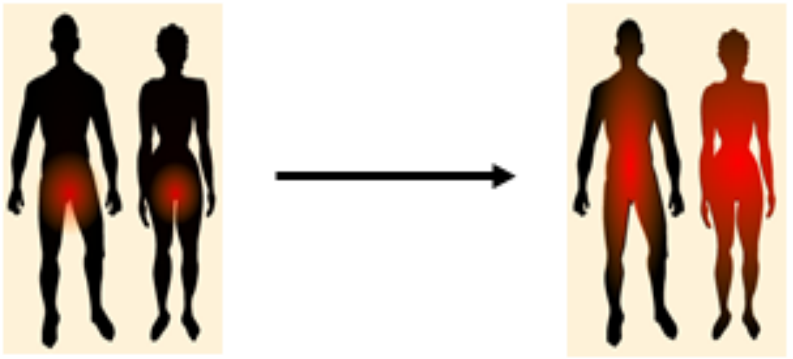
- Daily use of an antiretroviral pill for Pre-exposure prophylaxis (PrEP) is a highly effective method to reduce the risk of HIV infection

- FDA approved a once-daily pill containing a fixed-dose combination of two antiretrovirals:
  - Tenofovir disoproxil fumarate (TDF) 300 mg
  - Emtricitabine (FTC) 200 mg

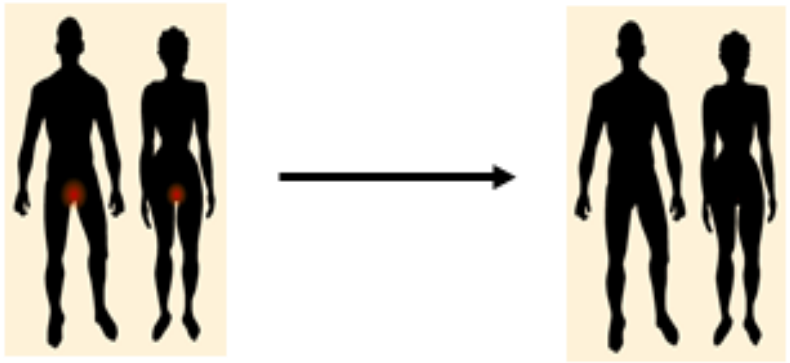
- Brand name is Truvada

How PrEP Works

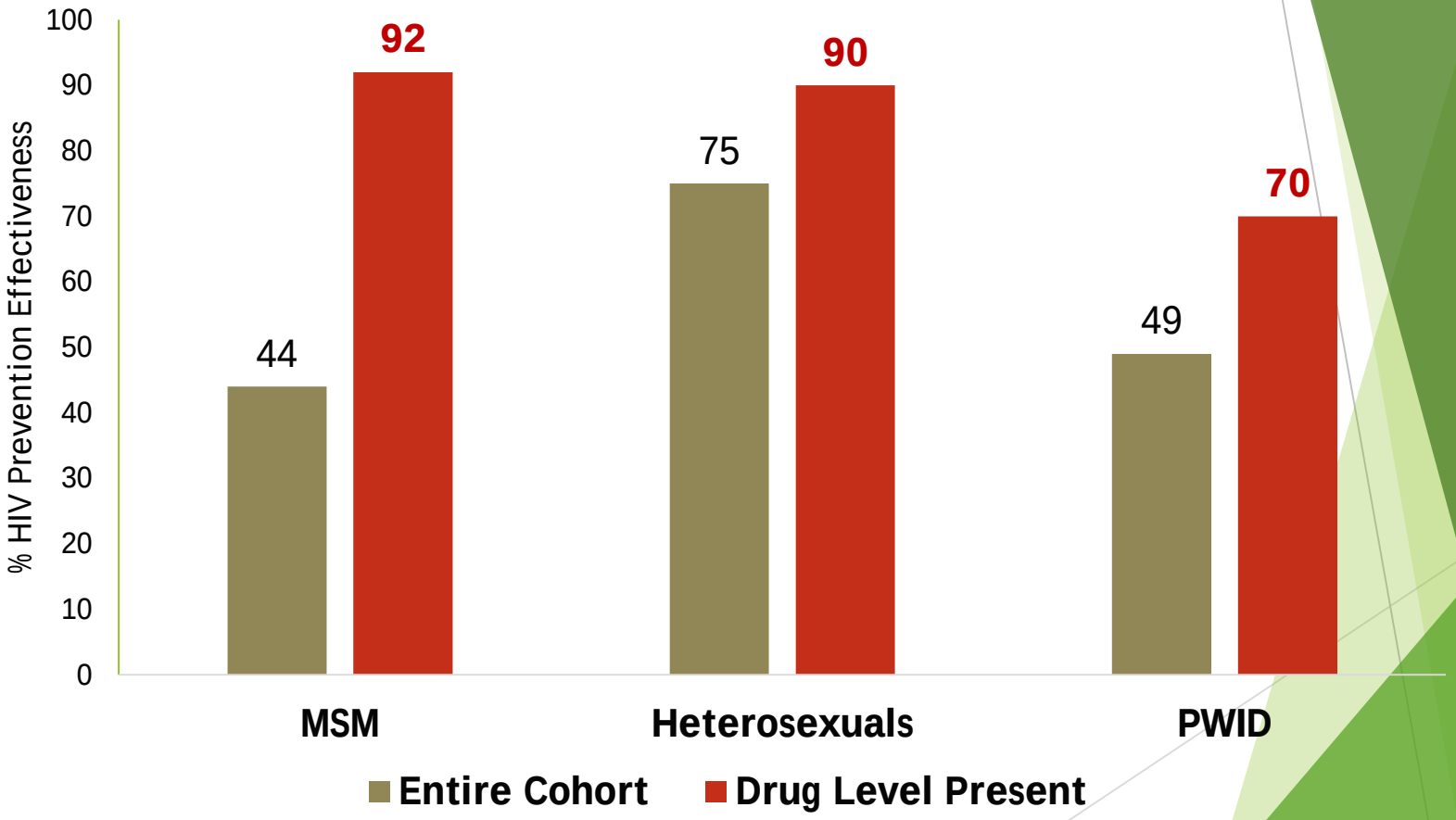
Without PrEP, if a person is exposed to HIV, the virus will grow new copies of itself in the genital area and over 3-4 days will spread throughout the body.



With PrEP inside a persons cells, if they are exposed to HIV, the virus cannot grow. So HIV does not spread in the body and become an established HIV infection.



Daily Oral PrEP Effectiveness by Adherence in Initial Randomized Trials



Sources: Grant RM, et al. *N Engl J Med*. 2010;363:2587-99; Baeten JM, et al. *N Engl J Med*. 2012;367:399-410; Choopanya K, et al. *Lancet*. 2013;381: 2083-90

PrEP Effectiveness and Adherence in Open-label and Observational Studies

- MSM
  - No HIV infections among men with protective drug levels
- HIV discordant couples
  - No infections among consistent PrEP users whose partners were not on ARVs for treatment

Adherence by Drug Concentration	HIV Incidence per 100 PY
0 pills/week	4.7
<2 pills/week	2.3
2-3 pills/week	0.6
≥4 pills/week	**0.0**

Common Provider Concerns about PrEP (How safe is it?)

PrEP Side Effects and Safety

- **Start-up syndrome**
  - <10% with nausea, vomiting, cramps
  - Lasts a couple of weeks in most patients
  - Can be managed with over the counter medication
- **Renal safety**
  - Small decrease in creatinine clearance
  - Not clinically important
  - Returns to normal after PrEP use discontinued
- **Bone safety**
  - Small decrease in bone mineral density
  - Not associated with increased fractures
  - Returns to normal after PrEP use discontinued

Drug resistance in PrEP users who acquire HIV infection

- Most PrEP patients remain HIV-uninfected
  - No virus to develop resistance
- PrEP patients who stop taking their drug or take it infrequently have a risk of developing resistance or acquiring a drug-resistant virus from a partner
  - 2 cases of acquiring a multiple-drug resistant virus out of ~100,000 persons currently on PrEP
- PrEP patients who are fully adherent to daily dosing can (very rarely) acquire HIV infection
  - 1 case reported out of ~100,000 persons currently on PrEP
  - Virus had no drug resistance mutations

Primary Care Provider Issues

PrEP Compares Favorably with Other High-Impact Preventive Measures

Outcome to Prevent	Intervention	Number needed to treat to prevent one case
Death from colorectal cancer	Annual fecal occult blood testing colorectal screen[a]	4551
Stroke in women with no previous CV disease	Aspirin 81 mg daily[b]	411
Myocardial infarction in individuals with hypertension and average cholesterol	Atorvastatin 10 mg daily[c]	100
HIV infection in MSM	TDF/FTC 1 pill daily[d]	13

Sources: a. Mandel JS, et al. *N Engl J Med*. 1993;328:1365-71; b. Berger JS, et al. *JAMA*. 2006;295:306-13; c. Sever PS, et al. *Lancet.* 2003;361:1149-58; d. McCormack S, et al. CROI 2015. Abstract 22LB.

Primary Care PrEP Provision (How do I do this?)

CDC PrEP Guidelines Summary

Component	Recommendation
Risk assessment	• PrEP is indicated for adult MSM, heterosexually-active women and men, and PWID who are at substantial risk for HIV infection through ongoing exposures
Lab screen before prescribing	• HIV test, test for acute HIV infection if symptomatic • Adequate renal function (eCrCl ≥ 60 mL/min)
Prescribing	• 1 daily TDF/FTC tablet (Truvada) • Prescribe no more than 90 day supply
Follow-up	• Test for HIV and pregnancy every 3 months • Test for sexually transmitted infections (STIs) every 6 months, even if asymptomatic • Counsel on risk reduction and medication adherence • Test creatinine clearance at 3 months and then every 6 months
Discontinuation	• At least every 12 months, assess risk behavior, medication adherence, and need for continuing PrEP use

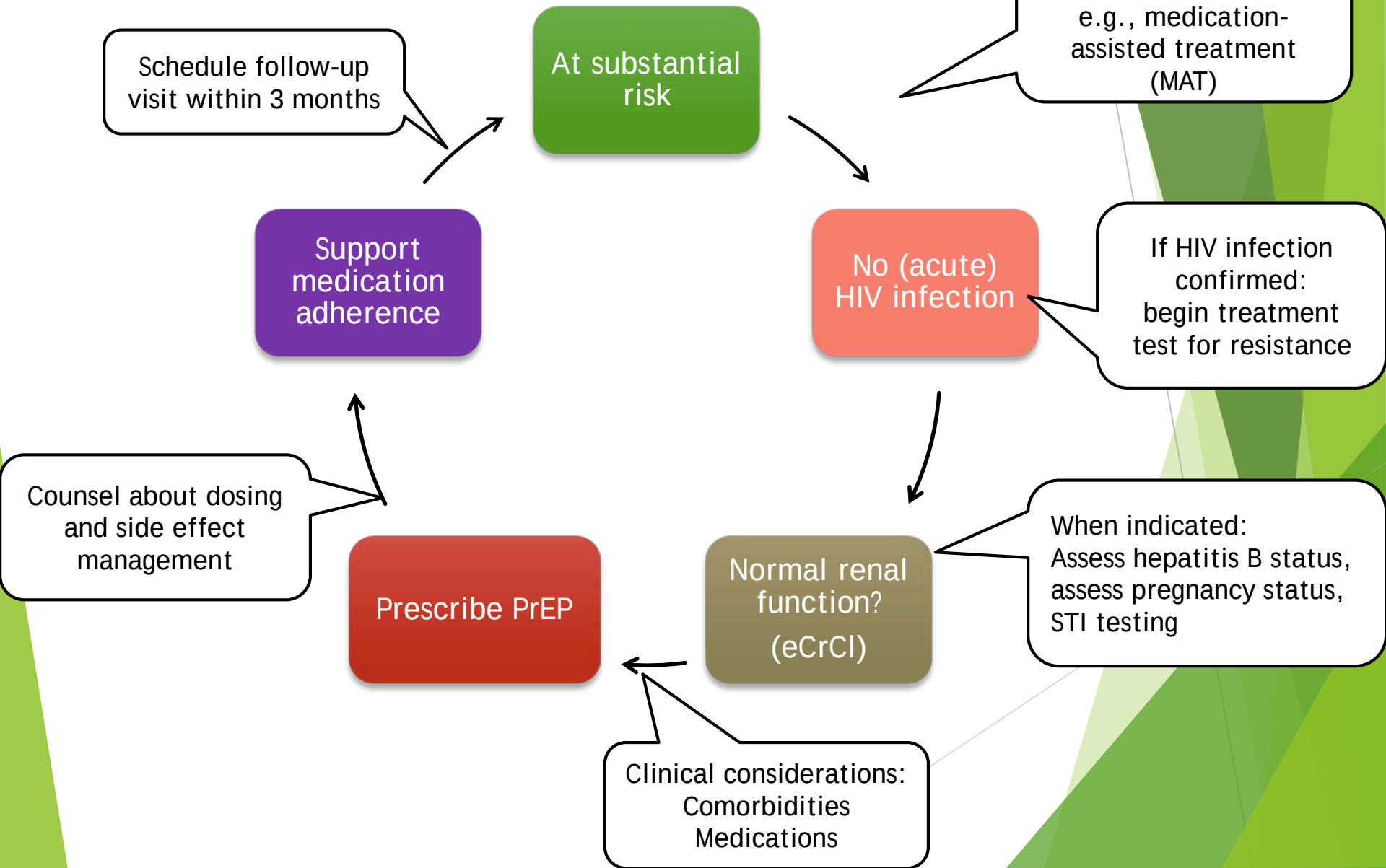
People at Substantial Risk of HIV Infection (Meet Indications for PrEP)

MSM	Heterosexual Men and Women	PWID
In the past 6 months: • HIV-positive sexual partner • Bacterial STI (esp. GC or syphilis) • More than one sex partner not known to have HIV infection • Inconsistent or no condom use • Commercial sex work		In the past six months • HIV-positive injecting partner • Sharing injection equipment
	In high-prevalence area	

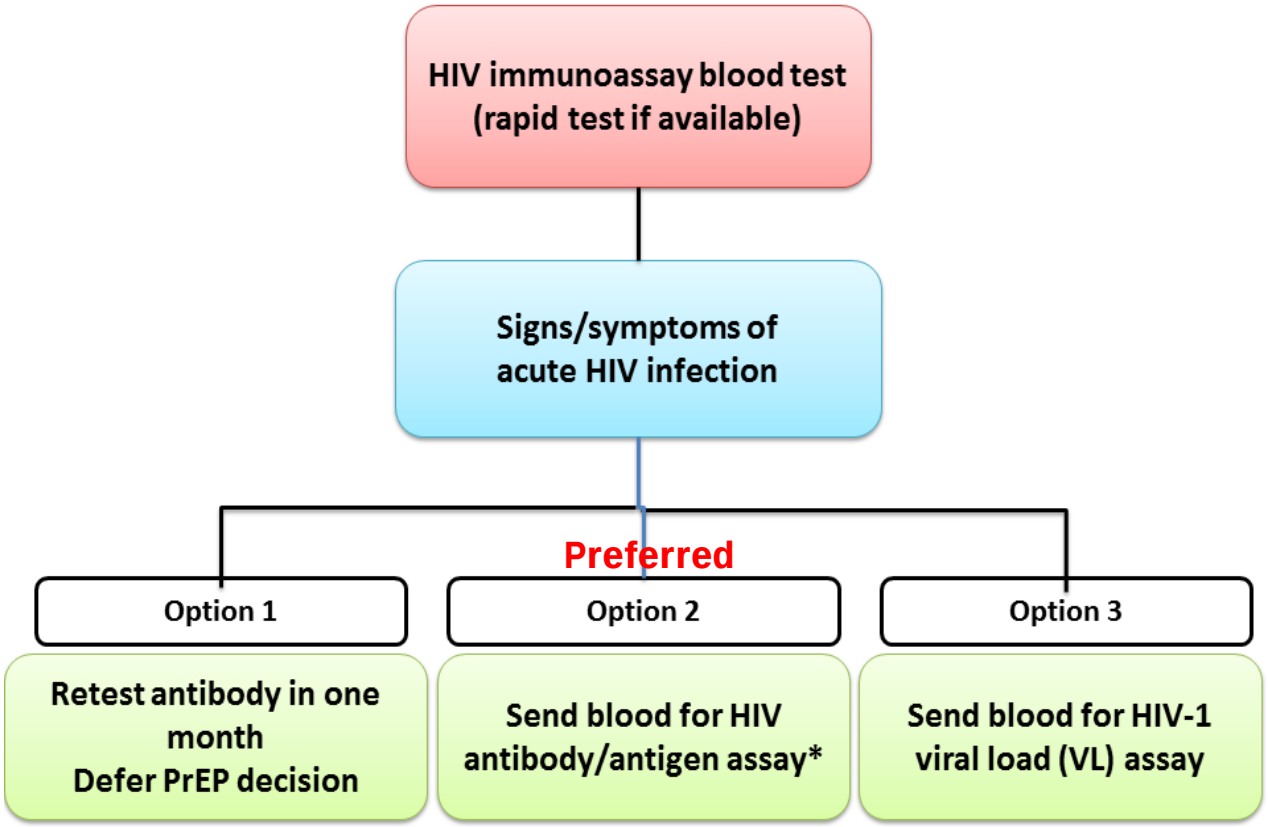
Examples of Brief Risk Assessment Questions

- Sexual risk
  - In the last year, how may sex partners have you had?
  - Did you have sex with men, women, or both?
  - Do you use condoms consistently?
  - Did any of your partners have HIV infection?
- Injection risk
  - Have you ever injected drugs that were not prescribed for you?
  - If yes…
  - When did you last inject drugs?
  - Do you ever inject using works that have been used by others before you?

Prescribing PrEP



Excluding Acute or Established HIV Infection

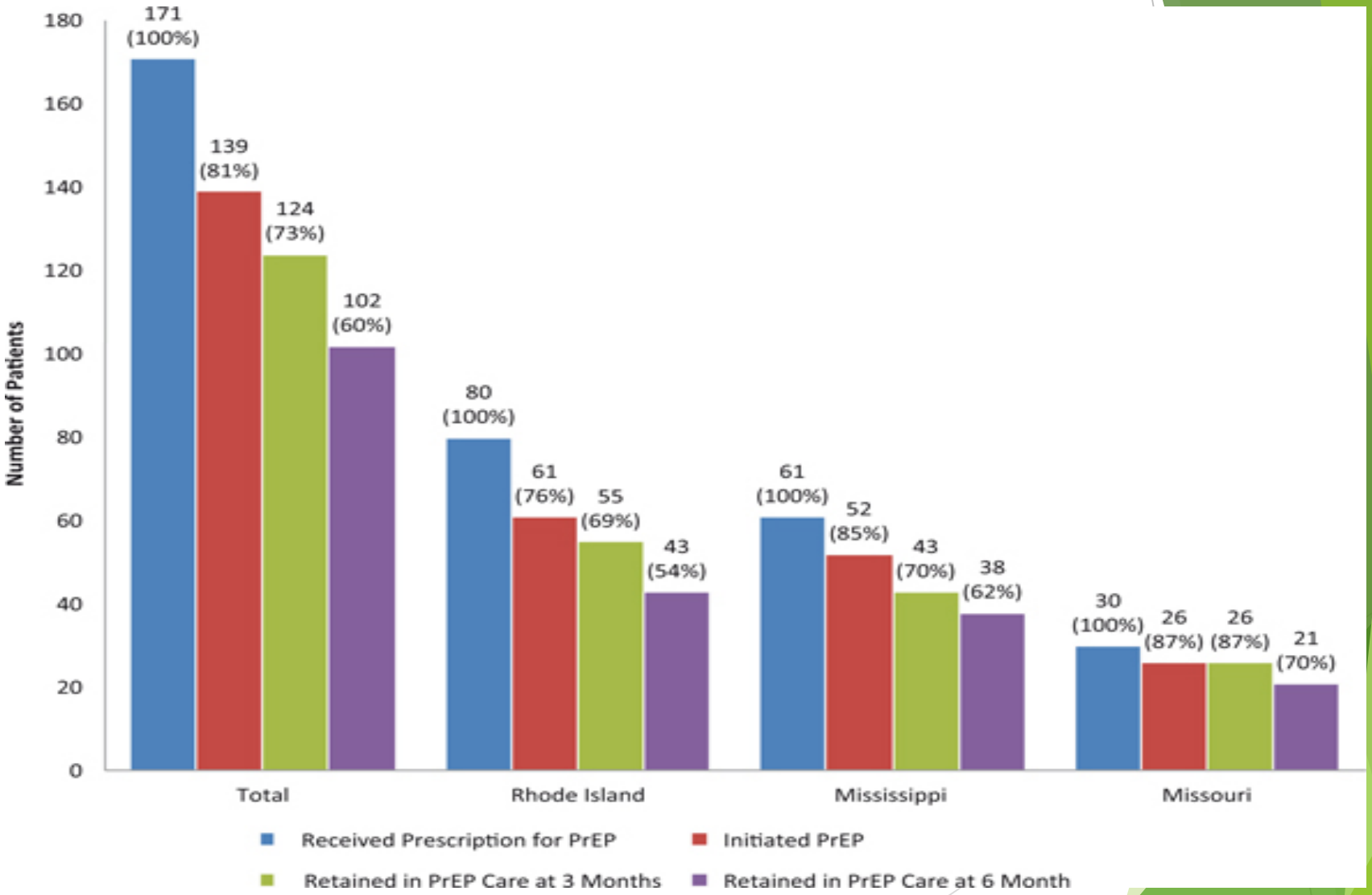


www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf

Supporting Medication Adherence

- Inform about any expected side effects and their management
  - Nausea, cramps, mild diarrhea in <10%
  - Resolves over 2-3 weeks
- Assess past issues with pill adherence
- Suggest adherence methods tailored to patient lifestyle and adherence history
  - Forget? Pill boxes, link to daily activity
  - Side effects? Take in before going to sleep
  - Away from home? Keep a pill or two with them

Retention in PrEP Care



Chan et al. Journal of the International AIDS Society. 2016;19(1).

Discontinuing PrEP

- For HIV seroconversion
  - Offer immediate transition to treatment regimen
  - Document HIV resistance test results
- For HIV negative persons
  - Document HIV and creatinine test results
  - Assure that HIV prevention plan is in place
  - If chronic hepatitis B infection, monitor liver function and if a flare occurs, treat in consultation with expert

Resources for Clinicians (How can I get answers to my questions?)

PrEPline
(855) 448-7737 or (855) HIV-PrEP

- Clinical advice available Monday-Friday 11:00 am to 6:00 pm EST
- Voice mail available 24 hours a day. Typical response within 2 hours

- Clinical consultation staff
  - ID specialists
  - family physicians
  - clinical pharmacists
  - obstetricians
  - general internists
  - nurses

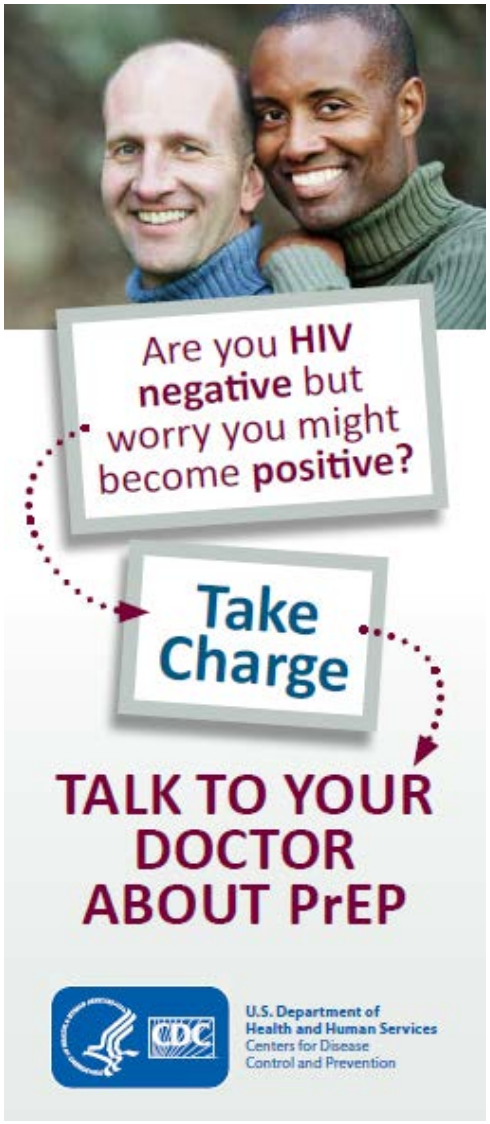
- Advice on
  - Initial and follow-up laboratory evaluation
  - Administering medications
  - Addressing adherence issues
  - Transitioning from PEP to PrEP
  - Managing PrEP for conception and pregnancy

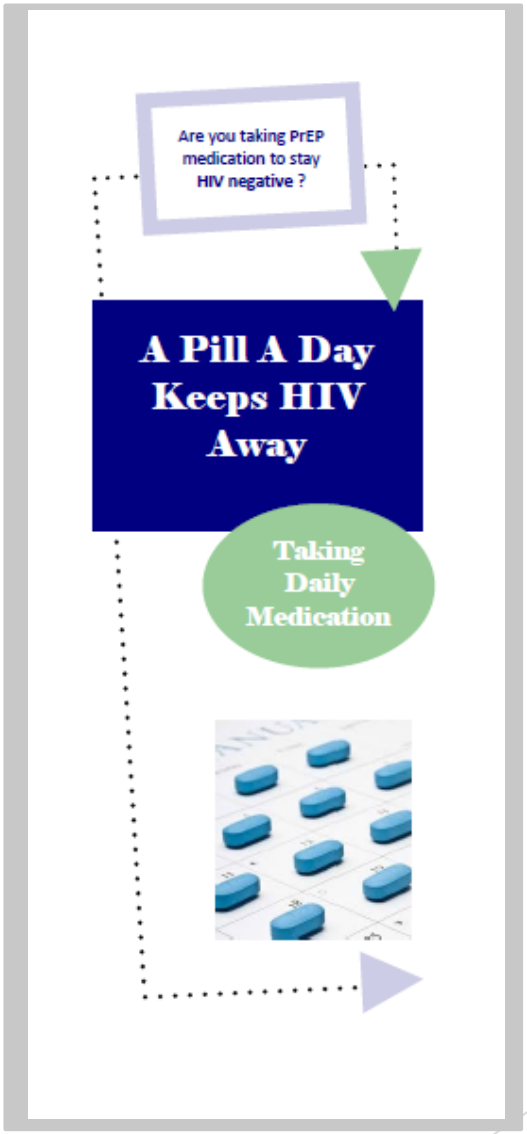
Additional Information

PrEPline (clinician telephone consultation)	**855-448-7737 (855-HIV-PREP)** http://nccc.ucsf.edu/clinical-resources/pep-resources/prep/
PHS PrEP Clinical Practice Guidelines	http://www.cdc.gov/hiv/pdf/PrEPguidelines 2014.pdf
PHS PrEP Providers Supplement	http://www.cdc.gov/hiv/pdf/ prepprovidersupplement2014.pdf
CDC Patient PrEP materials (English and Spanish)	http://www.cdc.gov/hiv/guidelines/ preventing.html
Truvada for PrEP Medication Assistance Program	https://start.truvada.com/content/pdf/ medication_assistance_program.pdf
Gilead PrEP information for healthcare providers	https://start.truvada.com/hcp#

Resources for Patients (What can I give my patients to aid them?)

Patient Brochures





Source: http://www.cdc.gov/hiv/risk/prep/

Covering the Cost of PrEP

- Insurance
- Medicare
- Patient Assistance Programs
  - Consider highlighting AI/AN status in application

PrEP Uptake and Impact (Does this really make a difference?)

Estimated percentages and numbers of adults with indications for preexposure prophylaxis (PrEP), by transmission risk group — United States, 2015

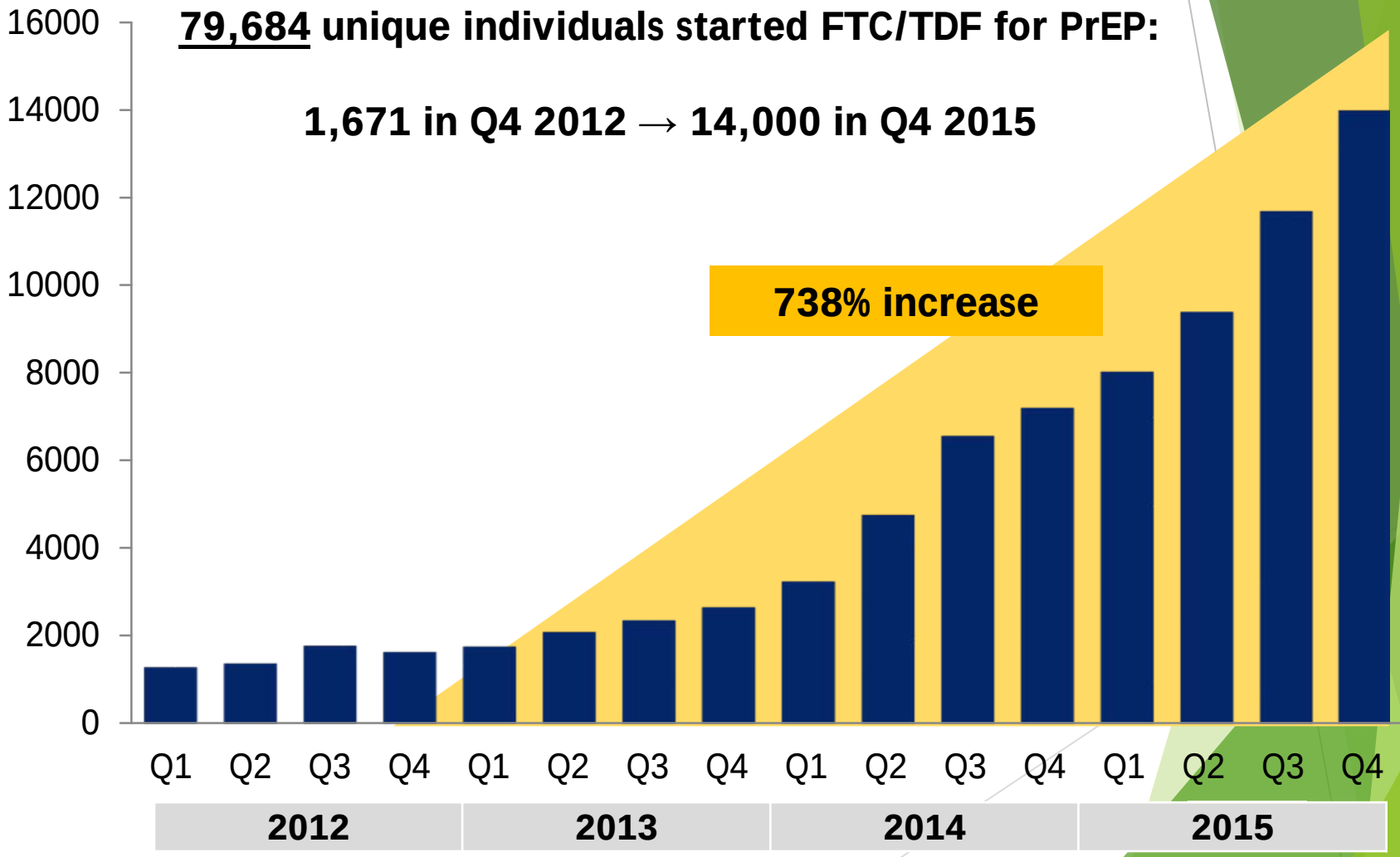
Transmission Risk Group	% with PrEP indications*	Estimated no.	(95% CI)
Men who have sex with men, aged 18–59 yrs	**24.7**	492,000	(212,000–772,000)
Adults who inject drugs, aged ≥18 yrs	**18.5**	115,000	(45,000–185,000)
Heterosexually active adults, aged 18–59 yrs	**0.4**	624,000	(404,000–846,000)
Men	0.2	157,000	(62,000–252,000)
Women	0.6	468,000	(274,000–662,000)
Total	—	**1,232,000**	(661,000–1,803,000)

Abbreviation: CI = confidence interval.

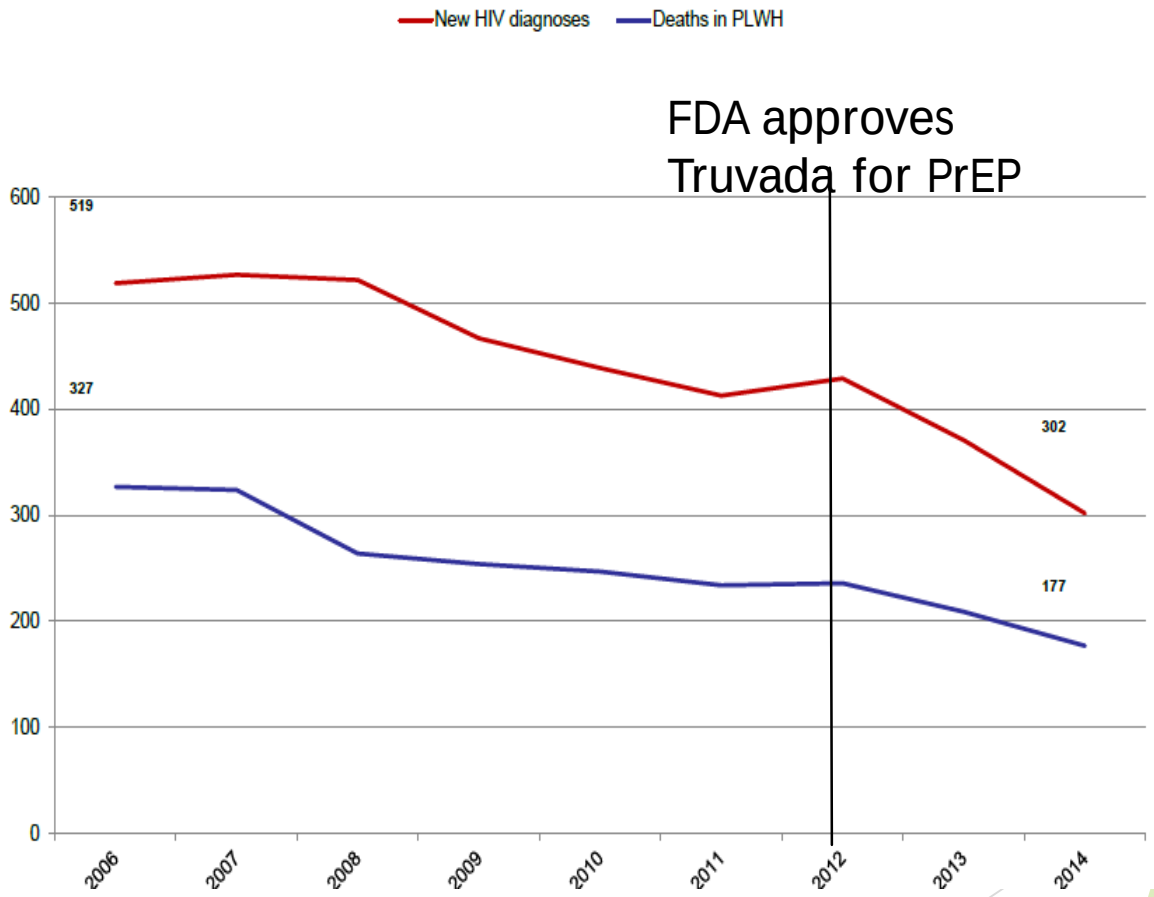
* Percentage of all estimated persons in each transmission risk group and demographic subset with PrEP indications.

Source: Smith DK, et al. Morbidity and Mortality Weekly Report. 2015;64(46):1291-5.

Unique Individuals Starting FTC/TDF for PrEP in US, 2012 to 2015 (by quarter)



New HIV diagnoses and deaths in people living with HIV, San Francisco, 2006-2014



Billing Code Examples

- CPT codes
  - 99385 New preventive visit (20 minutes), 18-39 yo
  - 99395 Established preventive visit (15 minutes)
  - 99401 Risk factor counseling visit (15 minutes)
  - HIV and other tests ordered, venipuncture (36415)
- ICD 9-CM codes
  - V01.79Contact with other viral diseases (HIV)
  - V69.2 High risk sexual behavior
  - V07.9 Unspecified prophylactic measure
  - Codes for specific STIs, IDU, or pregnancy

In Sum

- Prevention options available for your facility
- Risk based testing and screening, especially men 25-49 important for early detection
- Linkage to care available
- PrEP is an effective new tool
- Support for PrEP available
- More information also available on related topics that were not covered in this presentation (substitution therapy, etc.)