Advancing PrEP Delivery

An Update on Pre-Exposure Prophylaxis

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UNC
INSTITUTE FOR GLOBAL HEALTH & INFECTIOUS DISEASES

NC AIDS ATEC
University of North Carolina at Chapel Hill
AIDS Training and Education Center

Disclosures

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The views expressed are not necessarily those of NIMH or the NIH.

Overview

- A brief look at the NCATEC network
- Clinical case addressing questions we've gotten
- News since last year's webinar
  - HIV epidemiology
  - Adolescents and PrEP
  - Resistance
  - Impact, uptake, and access
  - TAF, the "pipeline," and local clinical trials

PrEP network numbers

NC ATEC
University of North Carolina at Chapel Hill
AIDS Training and Education Center

55*
sites statewide

25
responded to census

536
patients on PrEP across 24 sites

76%
take uninsured patients

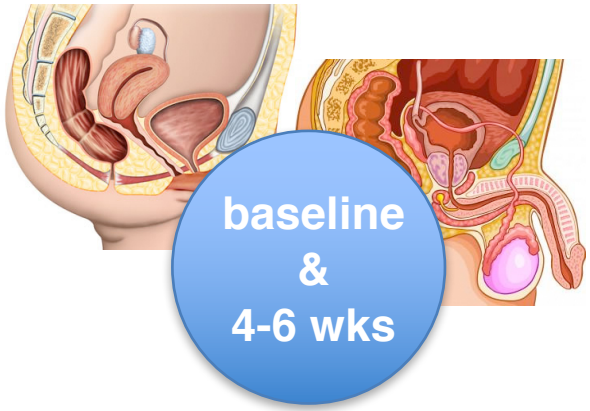
88%
accept Medicaid

100%
wanted to remain listed ☺

You're seeing Brandon in clinic

- Healthy 18 year-old Black man
- Sexual exposure about 60 hours ago
  - New male partner of unknown status
  - Partner (top) wasn't wearing condom
- Oral rapid test negative at home yesterday
- Still concerned – "I just want to get checked"

What tests do we need to obtain?

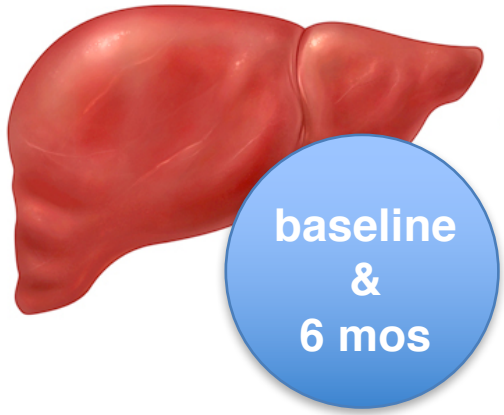


Sexual health

Syphilis
Gonorrhea NAAT*
Chlamydia NAAT*

Pregnancy

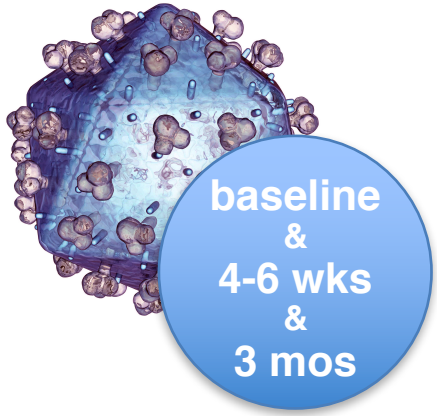
*from **all** exposed sites



Viral hepatitis

HBV surface Ab
HBV surface Ag
HBV core Ab

Hepatitis C Ab



HIV testing

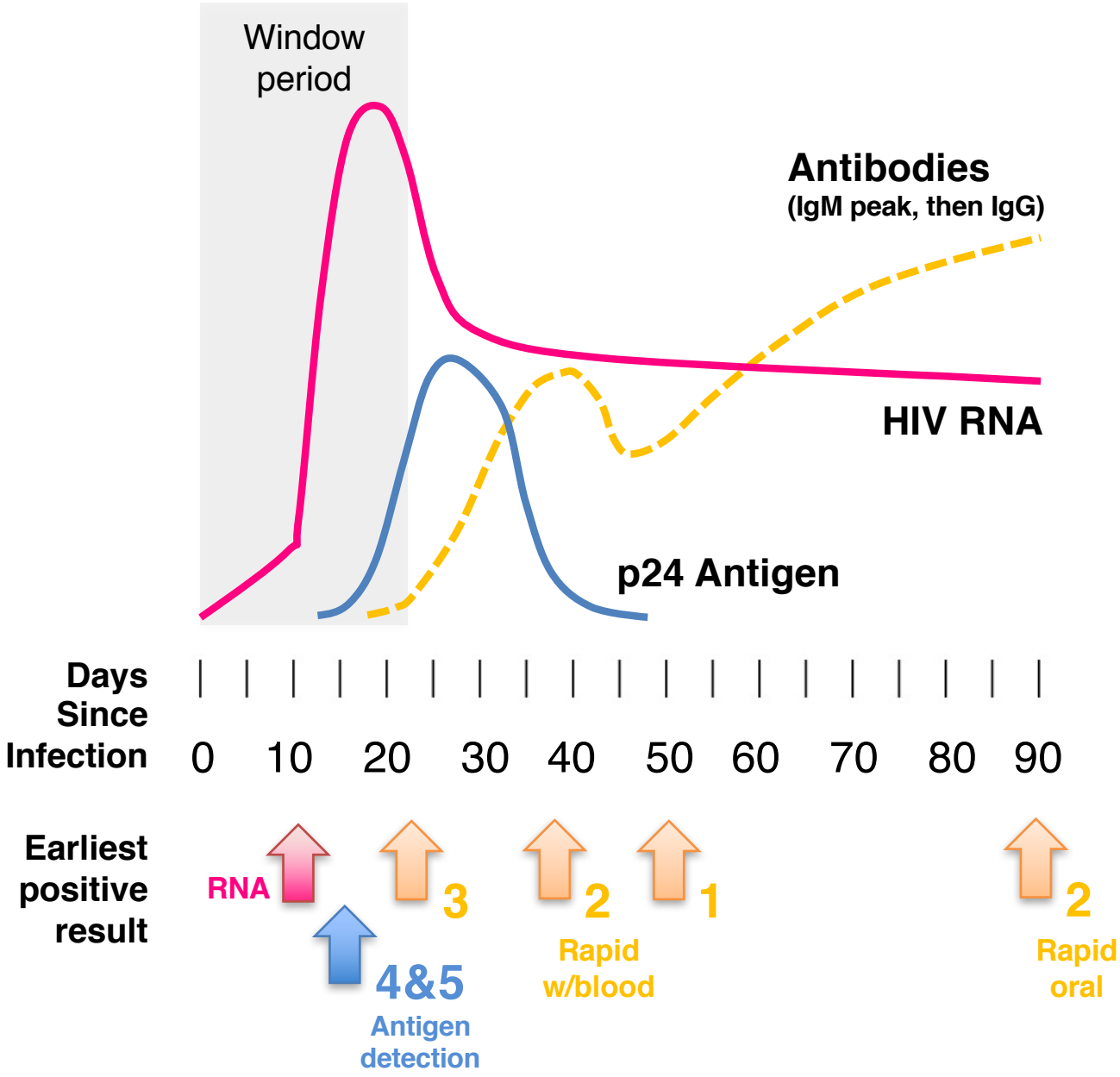
Ag/Ab combo§
- rapid test, if possible

Too early for RNA

§ Ab-only is acceptable if Ag testing unavailable

Dominguez KL, et al. CDC nPEP Guidelines 2016. https://stacks.cdc.gov/view/cdc/38856 **Table 2**

Timeline following infection

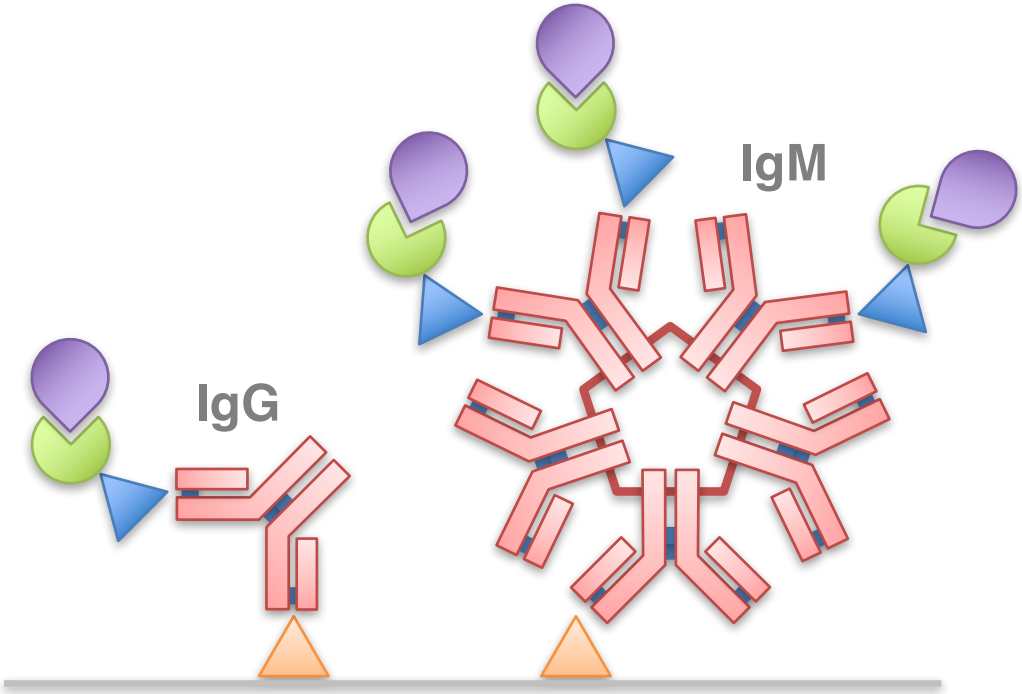


- RNA precedes p24 Ag by 5-7d
- Earliest Ab detection around 20-25d (IgM in 3rd – 5th gen)
- Earliest 2nd gen Ab detection at 35-40d (as IgG begins rising)
- Rapid tests with oral transudate may take **up to 90d** to convert (self-test implications)

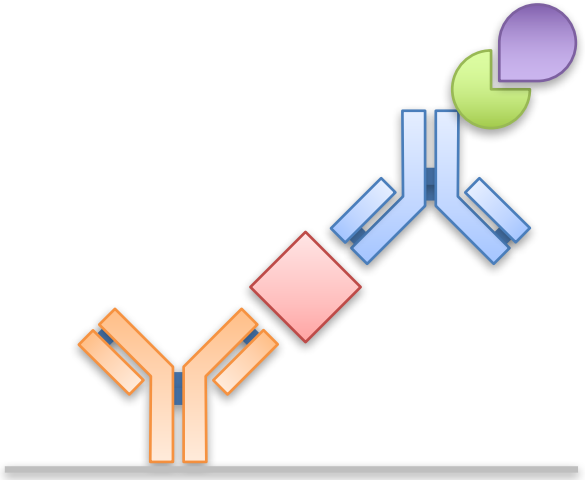
Adapted from Branson BM, et al. Laboratory testing for the diagnosis of HIV infection: updated recommendations. (2014)

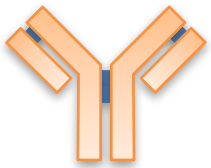
Ag/Ab combo allows very early detection

Fourth & fifth generation



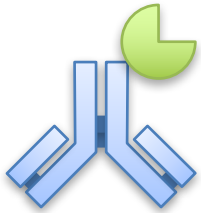
3rd gen with **simultaneous** p24 Ag detection **added**





Monoclonal anti-p24 Ab

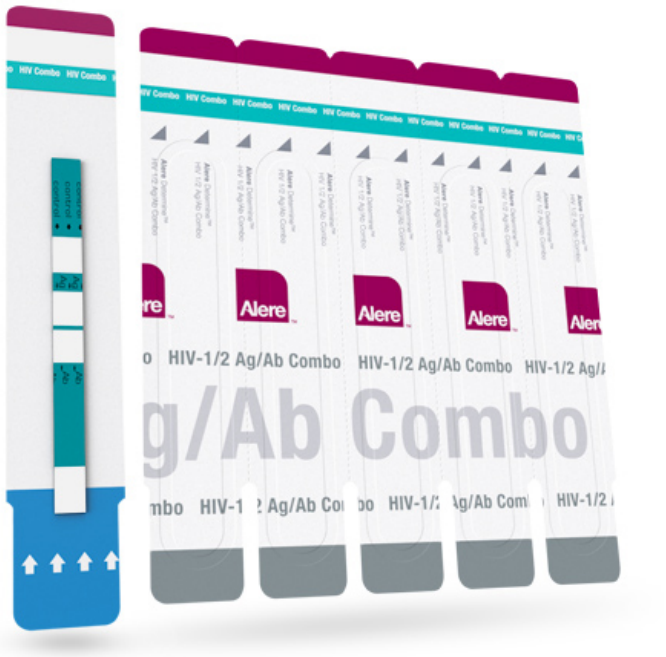
p24 antigen (from patient)



Enzyme-linked anti-p24 antibody

Detection reagent

Alere Determine HIV-1/2 Ag/Ab Combo



Fourth generation
Lateral flow "sandwich"

First FDA-approved 4th gen **rapid**[1]

Marketed for detection of early infections[2]

Advantages

- Ab sensitivity is **excellent** (99.4%)[3,4]
- Portable; 1 year shelf-life
- Results in 20 minutes

Disadvantages

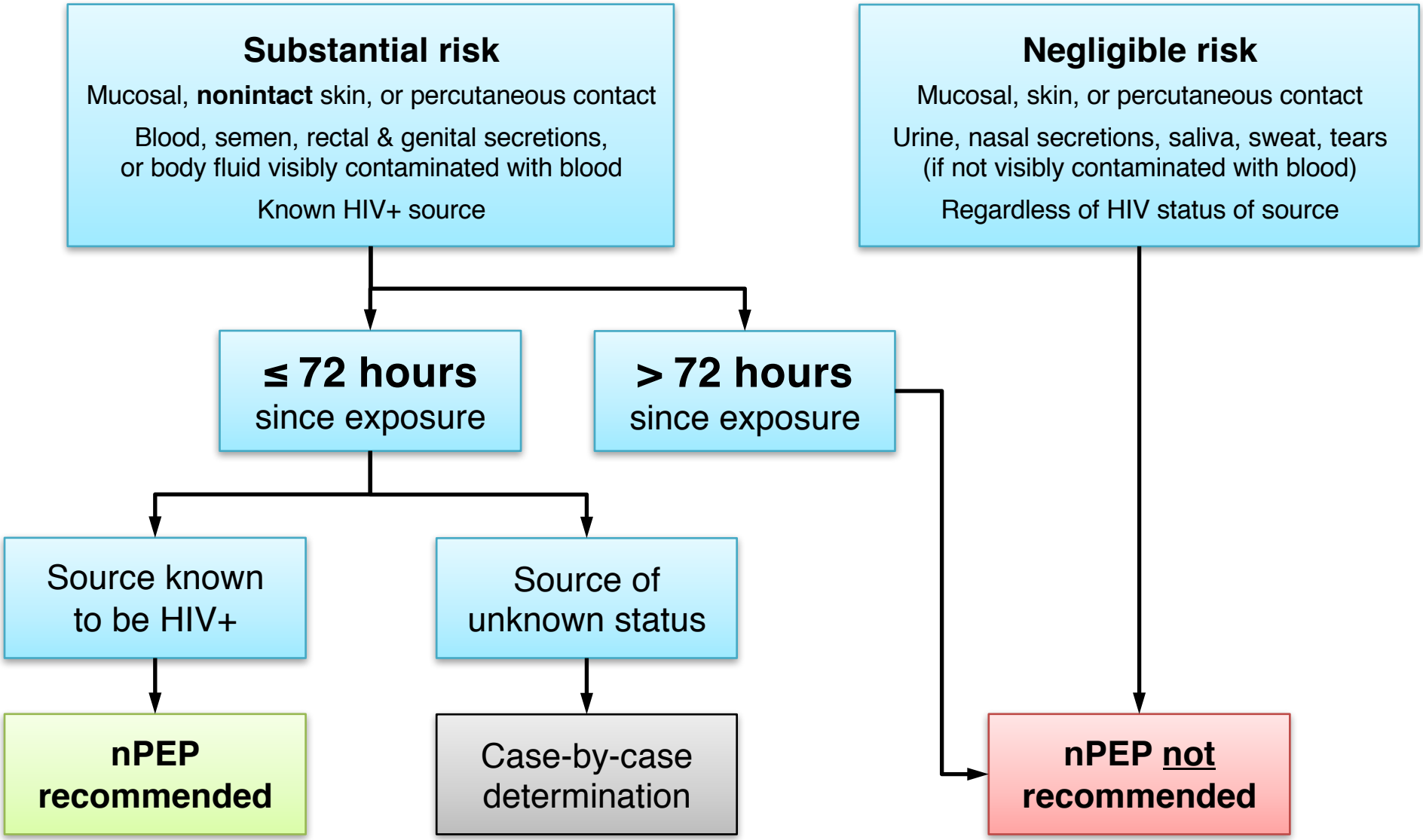
- **Multiple field studies replicated poor sensitivity in p24 detection (ranging 0-50%)[3, 5-7] [7 = meta-analysis]**
- **False (+) p24 in 1.7% of HIV(–) [3]**

1 FDA website, 7 Mar 2016. **2** Alere website, 7 Mar 2016 **3** Rosenberg NE. JID 2012;205(4):528 **4** Delaney KP. CID 2011;52(2):257.
5 Fox J. STI 2011;87(2):178 **6** Conway DP. PLOS ONE 2014;9(4):e94062 **7** Lewis JM. AIDS 2015;29(18):2465

Brandon, cont'd

- Rapid 2nd gen Ab test negative
  - Fingerstick specimen used, not oral swab
- Four months ago, prescribed 28 days of:
  - emtricitabine/tenofovir disoproxil fumarate
  - lopinavir/ritonavir
- Didn't finish prior regimen due to adverse effects
- "Is there an alternative to what I took before?"

Is he a candidate for PEP?



Dominguez KL, et al. CDC nPEP Guidelines 2016. https://stacks.cdc.gov/view/cdc/38856 **Fig 1 & Table 1**

Which ARVs are recommended for PEP?

Adults with normal renal function (CrCl ≥ 60 mL/min)

emtricitabine/tenofovir DF [2 NRTIs] QD
Truvada (Gilead)

plus ONE from either column

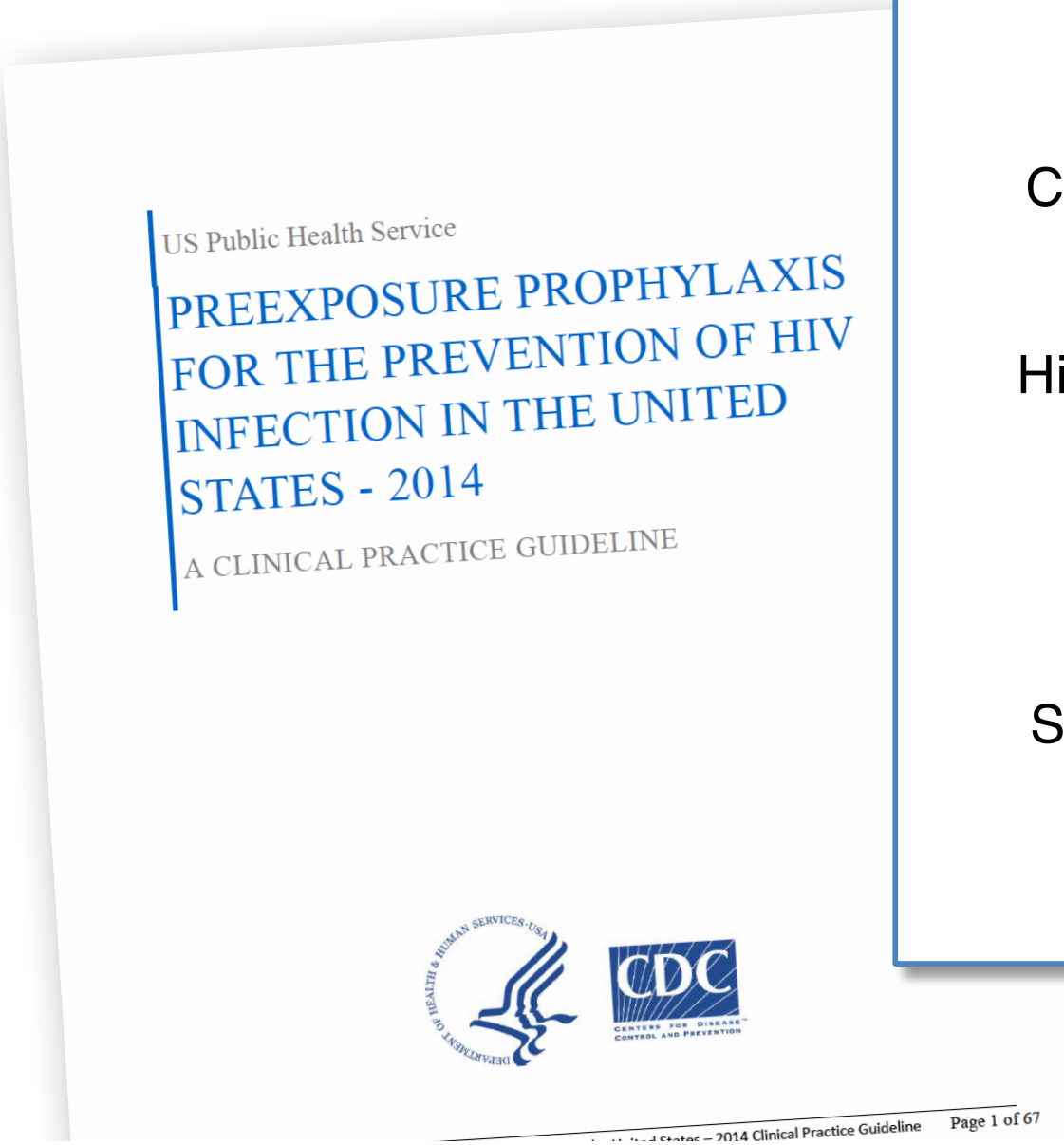
Preferred	Alternative
 **raltegravir** [INI] BID Isentress (Merck)	 **darunavir** [PI] QD Prezista (Janssen) **BOOSTED WITH**
 **dolutegravir** [INI] QD Tivicay (ViiV)	 **ritonavir** [PKE] QD Norvir (AbbVie)

Dominguez KL, et al. CDC nPEP Guidelines 2016. https://stacks.cdc.gov/view/cdc/38856

Brandon, cont'd

- Returns 6 months after starting PEP regimen
  - Was HIV uninfected at 3 months
  - HBV immune, HCV uninfected
  - All STI testing was negative
- No sex partners since episode prompting PEP
- "I've read some about PrEP online. Do you think it would it be good for someone like me?"

Does he meet criteria for PrEP?


US Public Health Service

PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES - 2014

A CLINICAL PRACTICE GUIDELINE

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

CDC

CENTERS FOR DISEASE CONTROL AND PREVENTION

United States – 2014 Clinical Practice Guideline Page 1 of 67

HIV uninfected, plus:

Any HIV+ partner(s)

Condomless sex in past 6m

Any STI in past 6m

High number of sex partners

In high-prevalence area or sexual network

Commercial sex work

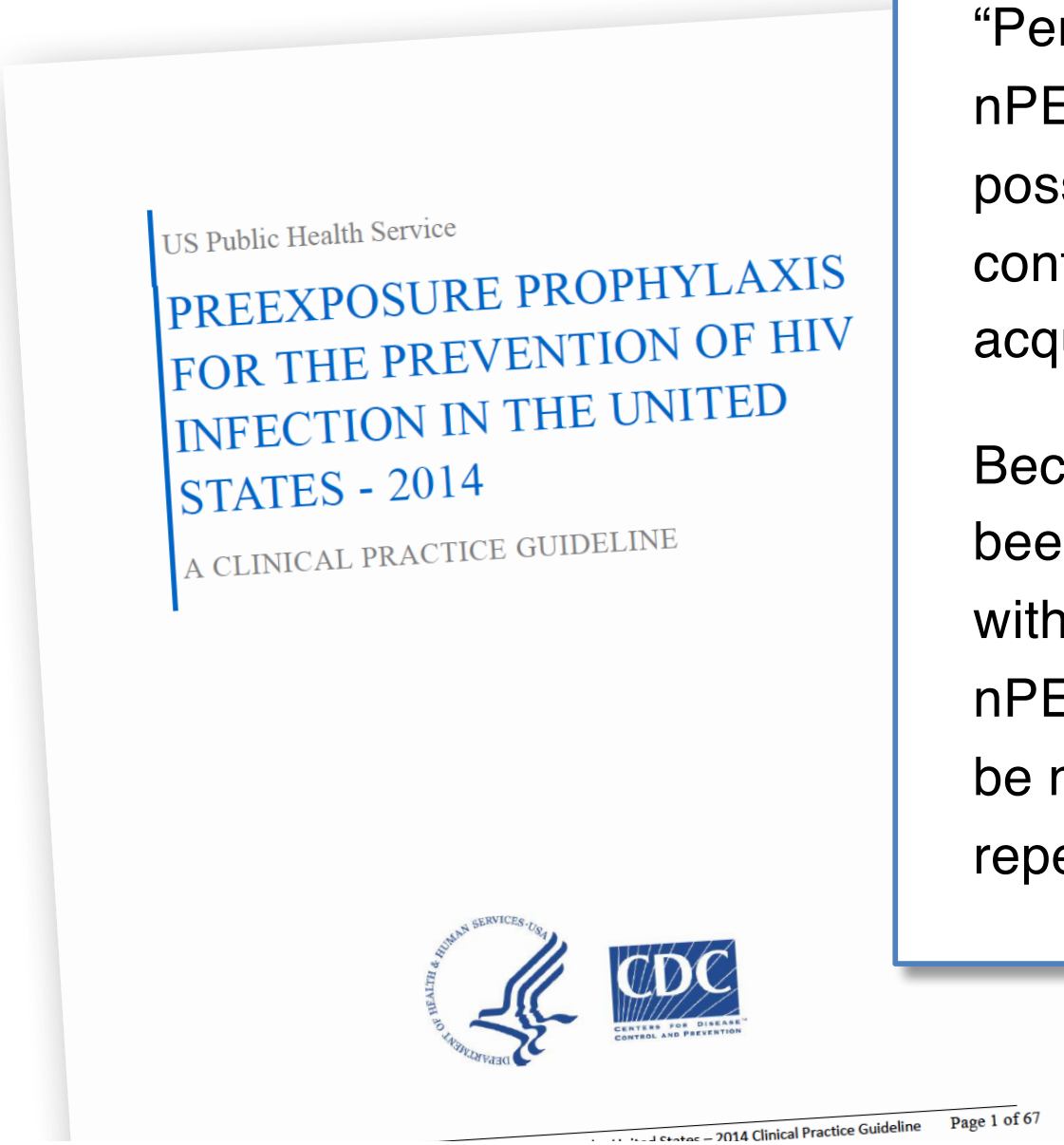
Shared injection equipment

Recent drug treatment & current relapse

p.28-30

USPHS PrEP Guidelines 2014
https://stacks.cdc.gov/view/cdc/23109

Does he meet criteria for PrEP?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United States – 2014 Clinical Practice Guideline Page 1 of 67

"Persons who repeatedly seek nPEP should be evaluated for possible PrEP use after confirming they have not acquired HIV infection.

Because HIV infection has been reported in association with exposures soon after an nPEP course, daily PrEP may be more protective than repeated episodes of nPEP."

p.43

USPHS PrEP Guidelines 2014
https://stacks.cdc.gov/view/cdc/23109

Does he meet criteria for PrEP?

Clinical Infectious Diseases

MAJOR ARTICLE

HIV/AIDS

Willingness to Take, Use of, and Indications for Pre-exposure Prophylaxis Among Men Who Have Sex With Men—20 US Cities, 2014

Brooke E. Hoots,[1] Teresa Finlayson,[1] Lina Nerlander,[1,2] and Gabriela Paz-Bailey[1]; for the National HIV Behavioral Surveillance Study Group

[1]Division of HIV/AIDS Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention, Atlanta, Georgia; and [2]Department of
Sciences, Karolinksa Institute, Stockholm, Sweden

Background. Pre-exposure prophylaxis (PrEP) is an effective prevention tool for people at substantial risk of acquirin
immunodeficiency virus (HIV). To monitor the current state of PrEP use among men who have sex with men (MSM), we
willingness to use PrEP and PrEP utilization. To assess whether the MSM subpopulations at highest risk for infection hav
tions for PrEP according to the 2014 clinical guidelines, we estimated indications for PrEP for MSM by demographics.

Methods. We analyzed data from the 2014 cycle of the National HIV Behavioral Surveillance (NHBS) system among
tested HIV negative in NHBS and were currently sexually active. Adjusted prevalence ratios and 95% confidence interval
timated from log-linked Poisson regression with generalized estimating equations to explore differences in willingness to
PrEP use, and indications for PrEP.

Results. Whereas over half of MSM said they were willing to take PrEP, only about 4% reported using PrEP. There
ference in willingness to take PrEP between black and white MSM. PrEP use was higher among white compared with black
among those with greater education and income levels. Young, black MSM were less likely to have indications for PrEP
with young MSM of other races/ethnicities.

Conclusions. Young, black MSM, despite being at high risk of HIV acquisition, may not have indications for PrE
current guidelines. Clinicians may need to consider other factors besides risk behaviors such as HIV incidence and pr
subgroups of their communities when considering prescribing PrEP.

Keywords. HIV; pre-exposure prophylaxis; PrEP; MSM; United States.

Men who have sex with men (MSM) are at increased risk of human immunodeficiency virus (HIV) infection. Despite representing only 2% of the US population, MSM accounted for 65% of estimated HIV diagnoses in the United States in 2013 [1]. Among MSM, blacks are disproportionately affected by HIV. In 2010, black MSM accounted for 42% of estimated incident HIV infections attributed to male-to-male sexual contact, whereas blacks accounted for only about 12% of the US population [2, 3]. The largest number of new infections among black MSM (45%) occurred in those aged 13–24 years, and new infections increased 20% in this age group from 2008 to 2010 [2]. These data indicate a need for increased HIV prevention efforts to further reduce new HIV infections, especially among young,

taken consistently, PrEP has been shown to reduce
fections by up to 92% among MSM in randomized
US Food and Drug Administration approved a fixe
containing tenofovir disoproxil fumarate and emt
use as daily oral PrEP in 2012, and PrEP is no
many health insurance plans [6]. In 2014, the Cente
Control and Prevention (CDC) published clinical
lines for PrEP use in populations at high risk of i
on sexual or injection drug use behaviors [7]. For MSM, PrEP use
is recommended for HIV-uninfected adults with a male sex part-
ner in the past 6 months, for those who are not in a monogamous
partnership with an HIV-uninfected man, and for those who
meet one of the following criteria: condomless anal sex in the
past 6 months, a sexually transmitted infection in the past 6
ongoing sexual relationship with an HIV-infected

Young, Black MSM were less likely to have an indication for PrEP

≥ 2 sex partners plus either bacterial STI or UAI in past 12 m

1 main HIV+ partner in past 12 m

Sexual behavior alone is insufficient to explain higher incidence among Black MSM

In high prevalence networks, fewer missteps needed to acquire HIV

See various papers by Greg Millett

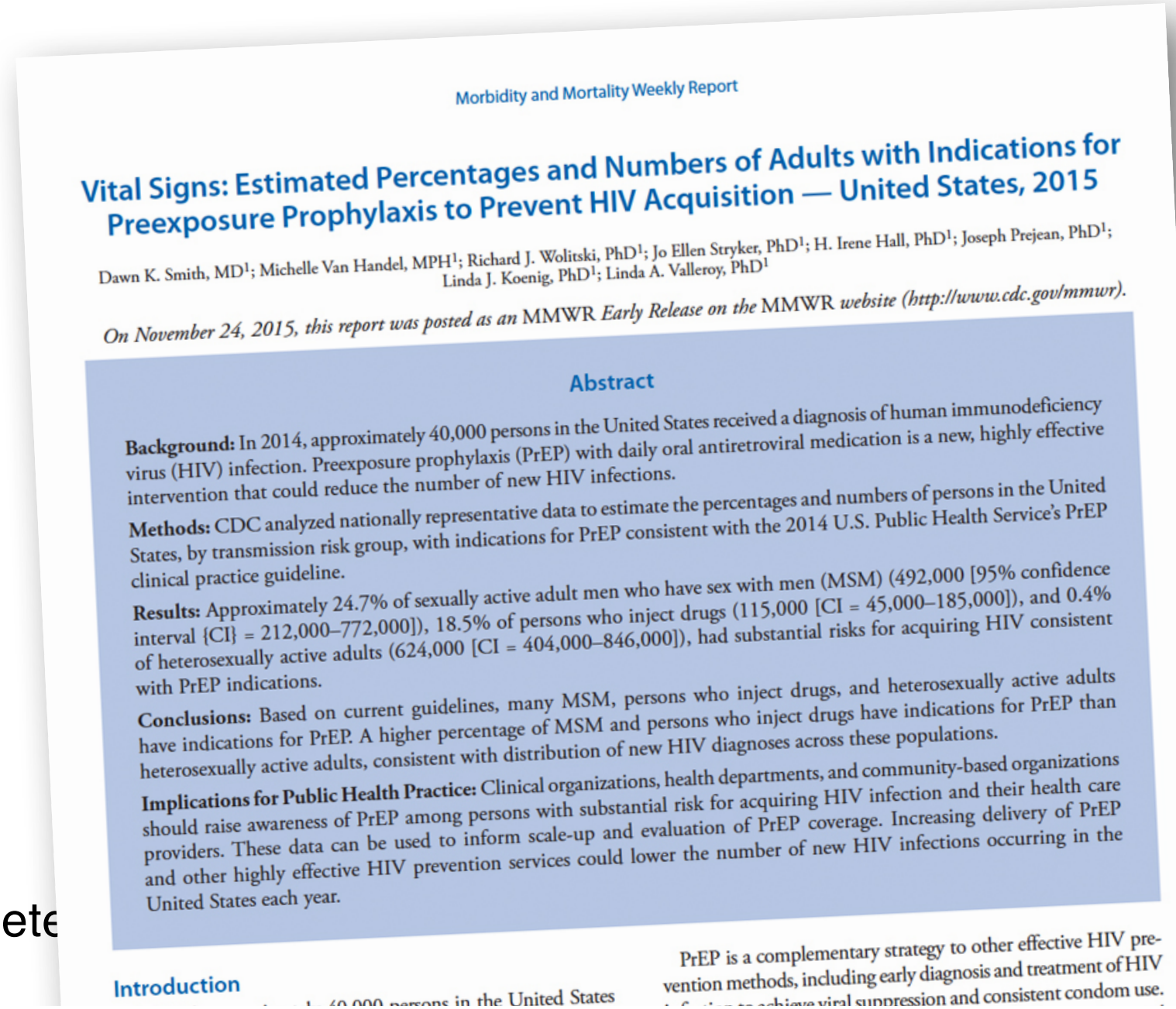
Hoots et al. CID. 2016:63(5):672-7
Maulsby et al. AIDS Behav 2014:18(1):10-25

Brandon, cont'd

- Seeing him 6 months after he starts PrEP
  - Adherence good, feeling well
  - Interim rectal chlamydia, treated
  - Now in "monogamish" relationship
- Follow-up labs show stable SCr
- Transaminases were checked with today's visit:
  - AST 70
  - ALT 92

What's new since our last webinar?

Who should get PrEP?



Morbidity and Mortality Weekly Report

Vital Signs: Estimated Percentages and Numbers of Adults with Indications for Preexposure Prophylaxis to Prevent HIV Acquisition — United States, 2015

Dawn K. Smith, MD[1]; Michelle Van Handel, MPH[1]; Richard J. Wolitski, PhD[1]; Jo Ellen Stryker, PhD[1]; H. Irene Hall, PhD[1]; Joseph Prejean, PhD[1]; Linda J. Koenig, PhD[1]; Linda A. Valleroy, PhD[1]

On November 24, 2015, this report was posted as an MMWR *Early Release on the* MMWR *website (http://www.cdc.gov/mmwr).*

Abstract

Background: In 2014, approximately 40,000 persons in the United States received a diagnosis of human immunodeficiency virus (HIV) infection. Preexposure prophylaxis (PrEP) with daily oral antiretroviral medication is a new, highly effective intervention that could reduce the number of new HIV infections.

Methods: CDC analyzed nationally representative data to estimate the percentages and numbers of persons in the United States, by transmission risk group, with indications for PrEP consistent with the 2014 U.S. Public Health Service's PrEP clinical practice guideline.

Results: Approximately 24.7% of sexually active adult men who have sex with men (MSM) (492,000 [95% confidence interval {CI} = 212,000–772,000]), 18.5% of persons who inject drugs (115,000 [CI = 45,000–185,000]), and 0.4% of heterosexually active adults (624,000 [CI = 404,000–846,000]), had substantial risks for acquiring HIV consistent with PrEP indications.

Conclusions: Based on current guidelines, many MSM, persons who inject drugs, and heterosexually active adults have indications for PrEP. A higher percentage of MSM and persons who inject drugs have indications for PrEP than heterosexually active adults, consistent with distribution of new HIV diagnoses across these populations.

Implications for Public Health Practice: Clinical organizations, health departments, and community-based organizations should raise awareness of PrEP among persons with substantial risk for acquiring HIV infection and their health care providers. These data can be used to inform scale-up and evaluation of PrEP coverage. Increasing delivery of PrEP and other highly effective HIV prevention services could lower the number of new HIV infections occurring in the United States each year.

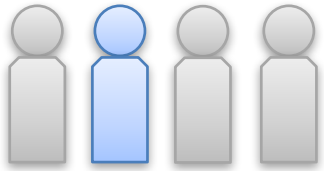
Introduction

PrEP is a complementary strategy to other effective HIV prevention methods, including early diagnosis and treatment of HIV

hete

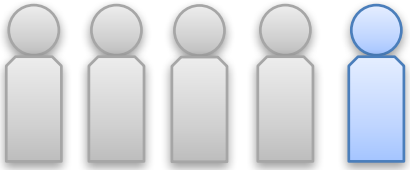
6):1291-1295

Who should get PrEP?



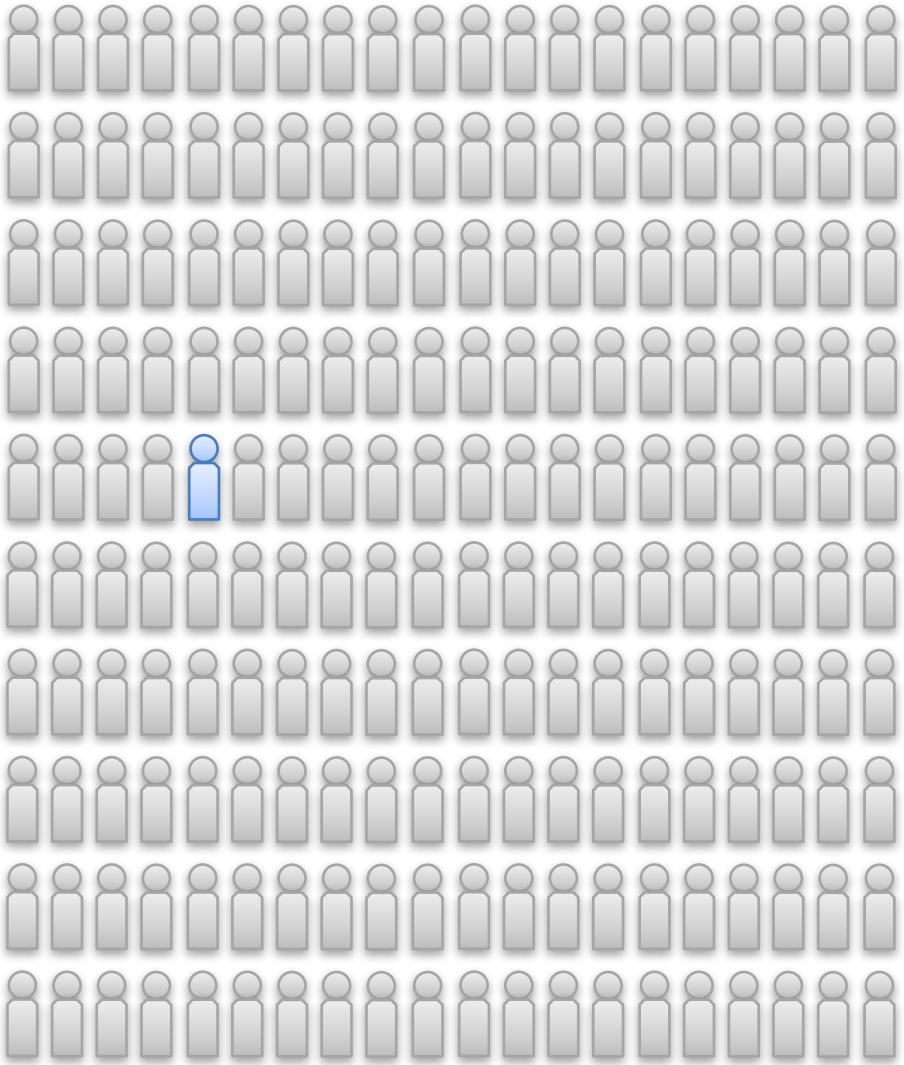
1 in 4

sexually active MSM



1 in 5

persons who inject

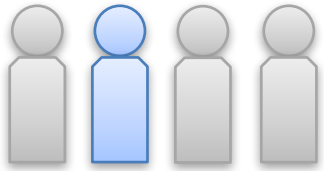


1 in 200

heterosexually active adults

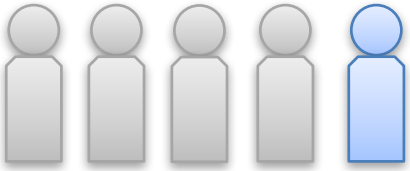
Smith DK et al. MMWR 2015 64(46):1291-1295

Who should get PrEP?



492,000

sexually active MSM

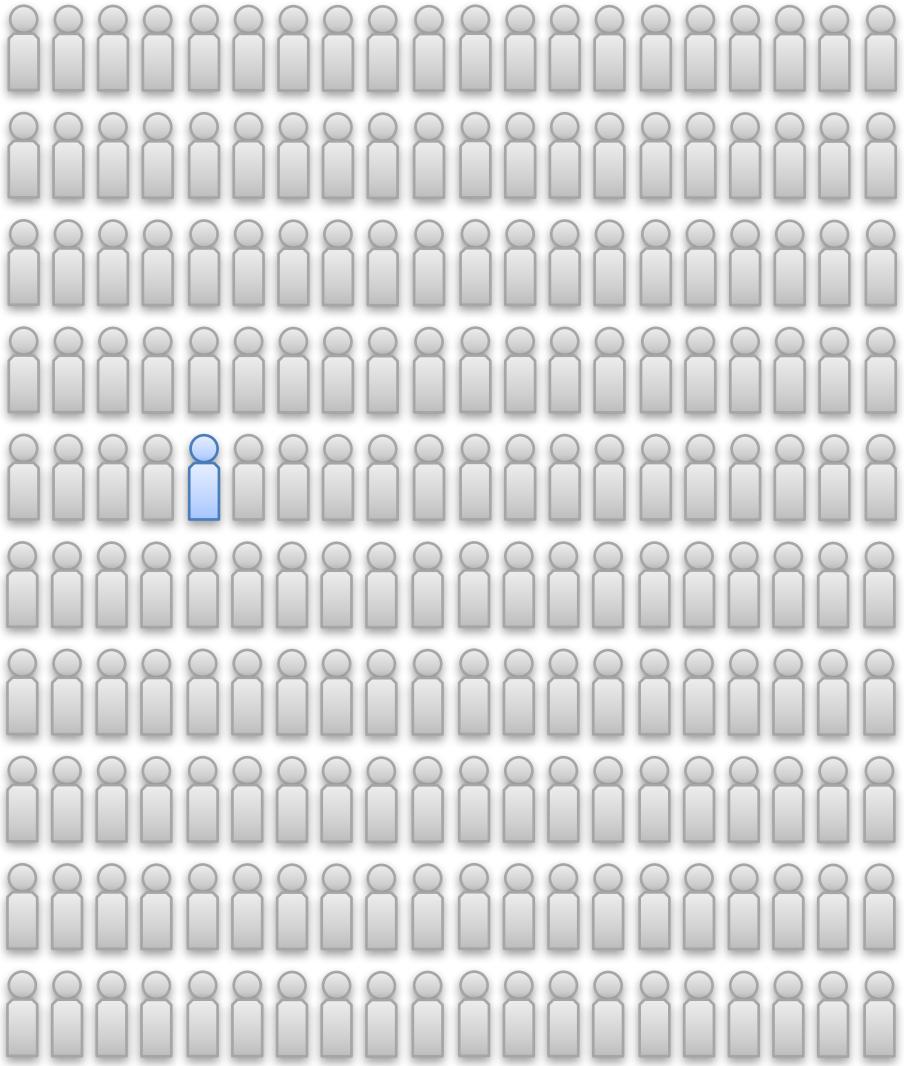


115,000

persons who inject

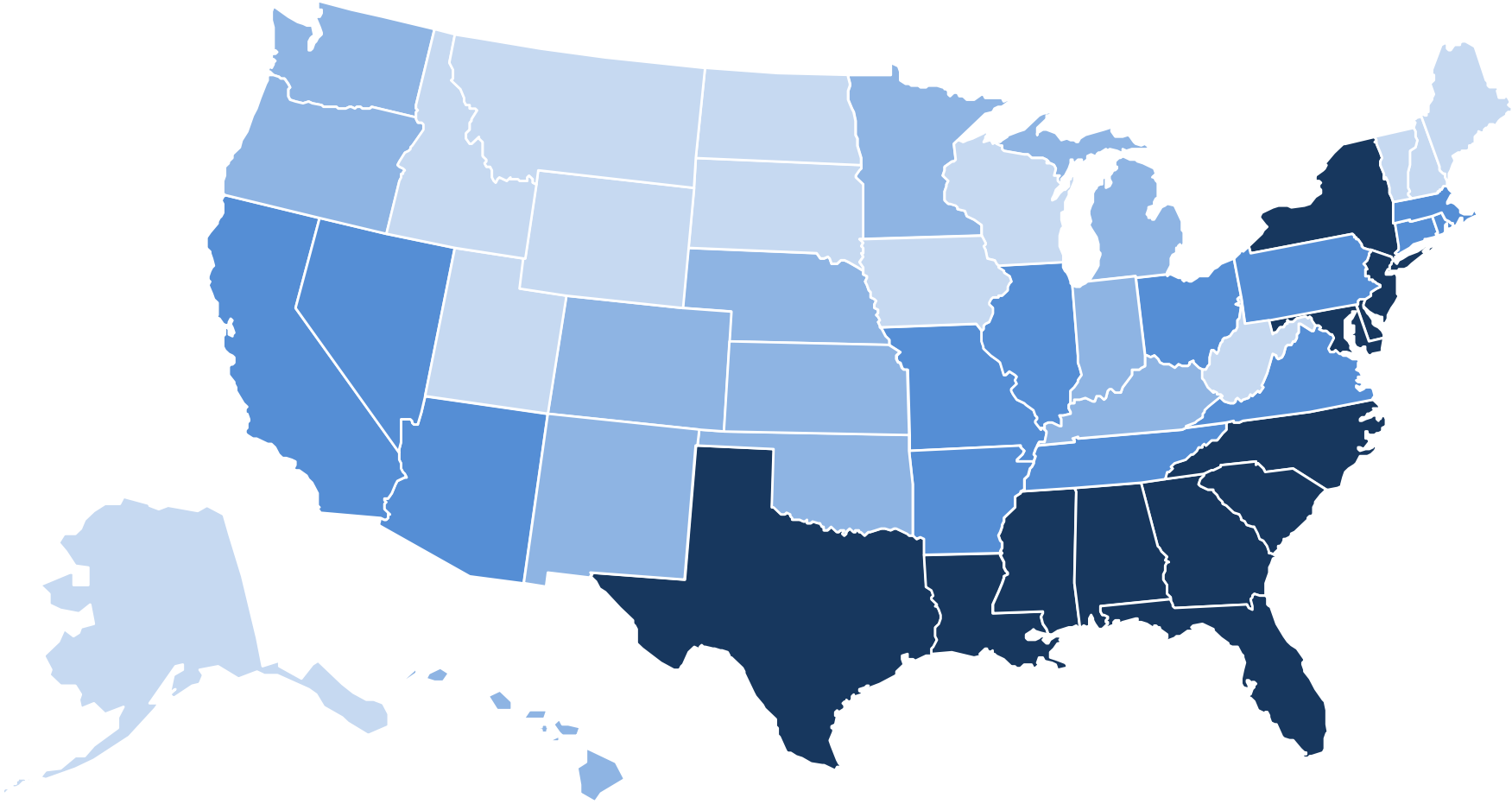
624,000

heterosexually active adults



Smith DK et al. MMWR 2015 64(46):1291-1295

Lifetime risk of acquiring HIV

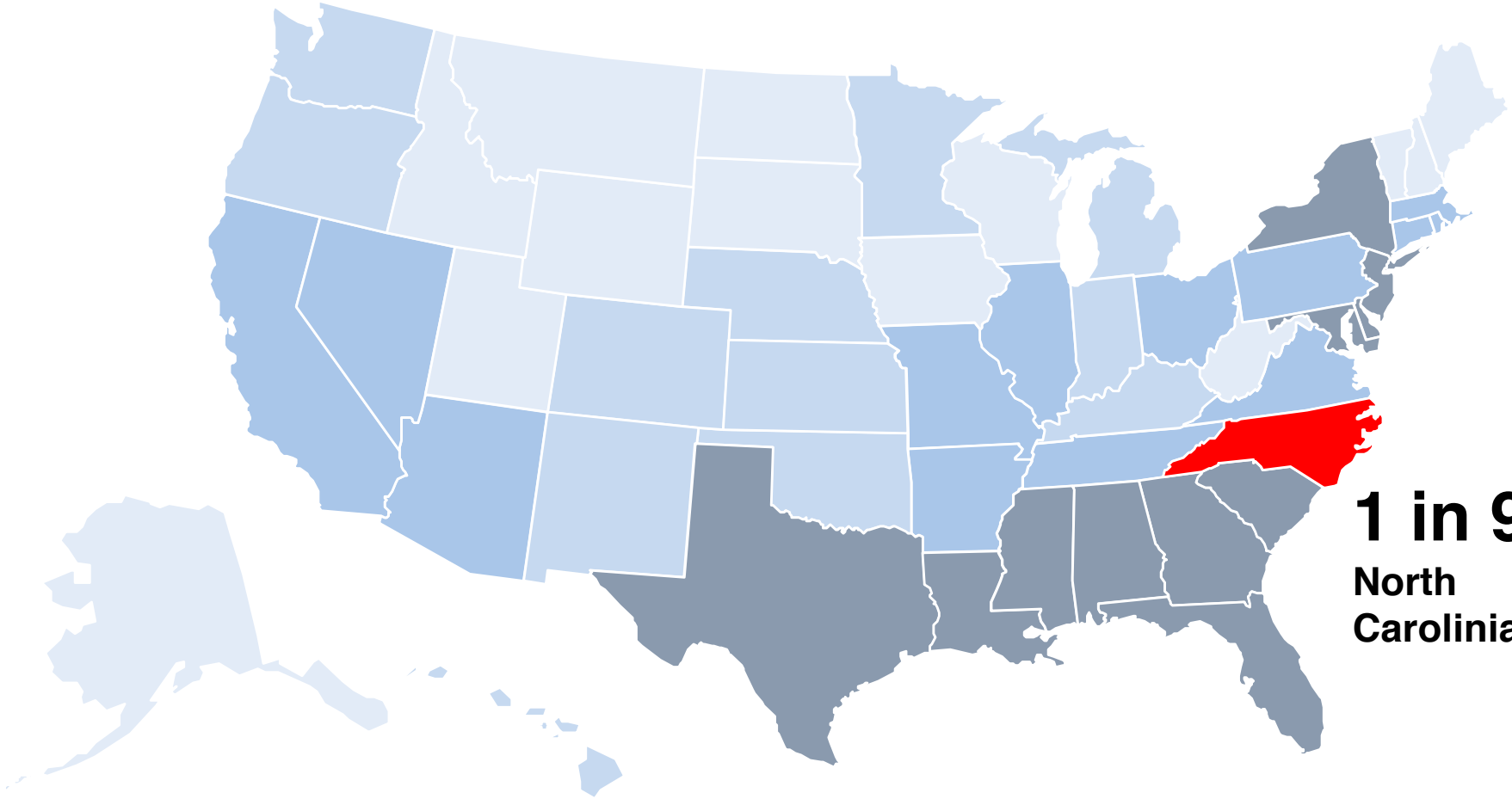


Highest – Lowest

Hess K et al. CROI 2016, abstract #52

Map from CDC website: http://www.cdc.gov/hiv/statistics/overview/geographicdistribution.html

Lifetime risk of acquiring HIV



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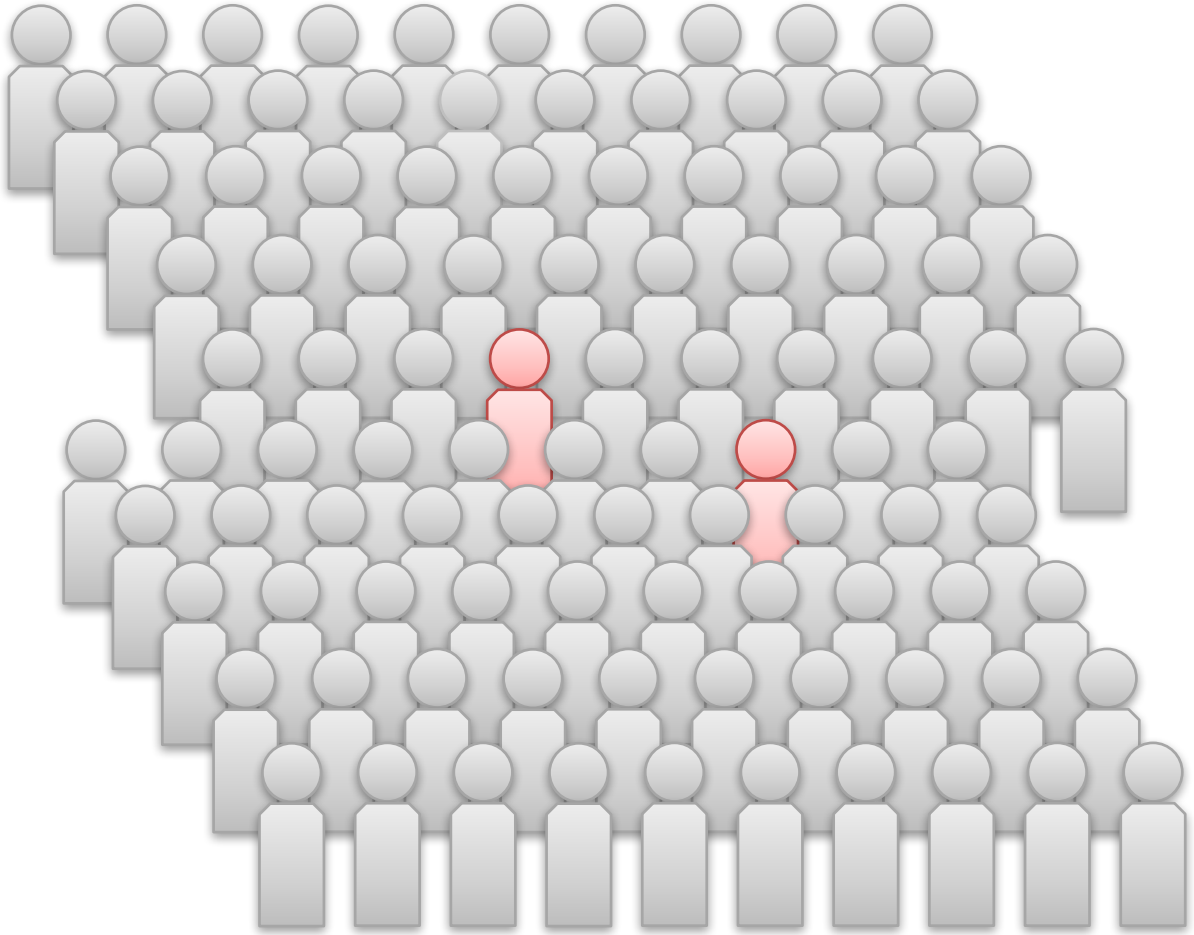
Map from CDC website: http://www.cdc.gov/hiv/statistics/overview/geographicdistribution.html

Lifetime risk of acquiring HIV



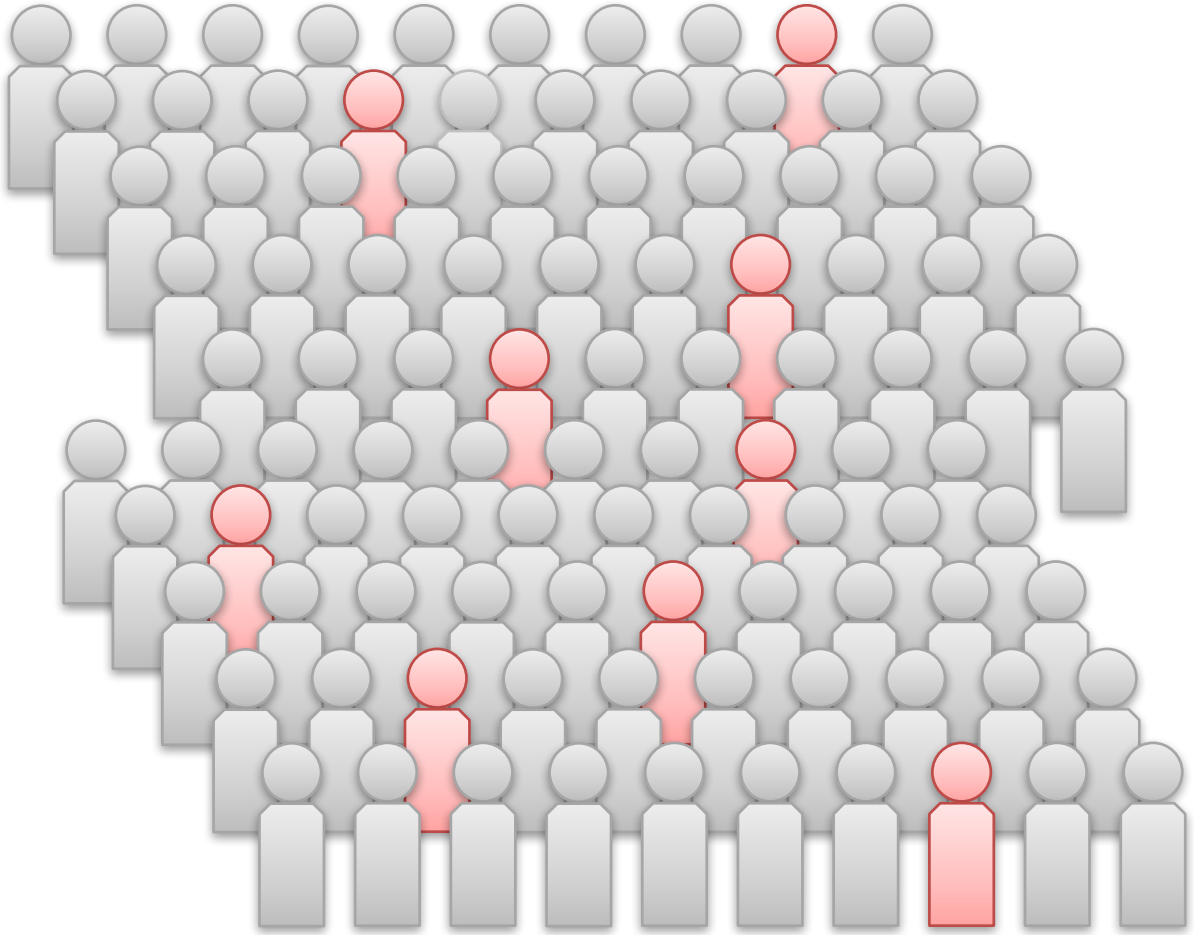
If current diagnosis rates persist...

2

out of 100
Black women
will become HIV+

Hess K et al. CROI 2016, abstract #52

Lifetime risk of acquiring HIV



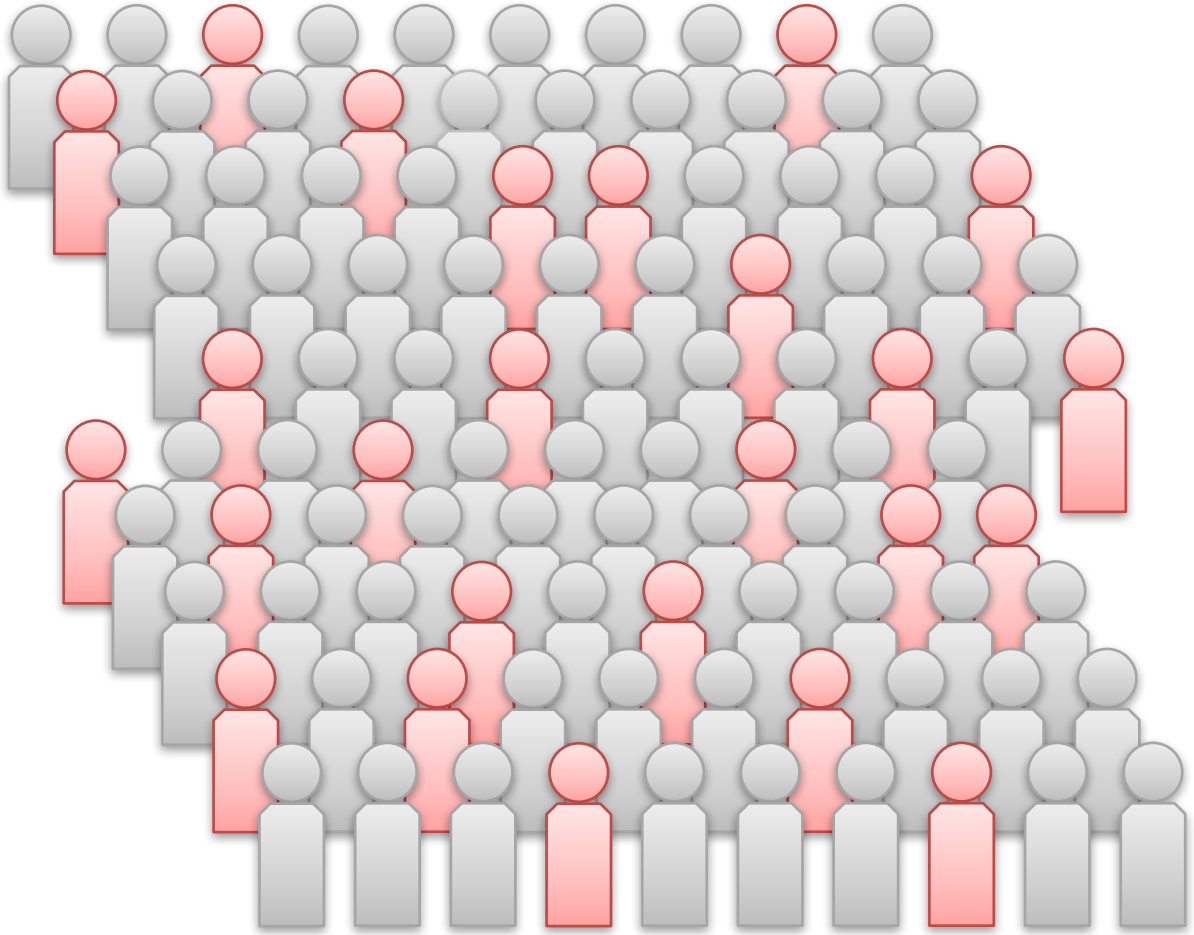
If current diagnosis rates persist...

9

out of 100
White MSM
will become HIV+

Hess K et al. CROI 2016, abstract #52

Lifetime risk of acquiring HIV



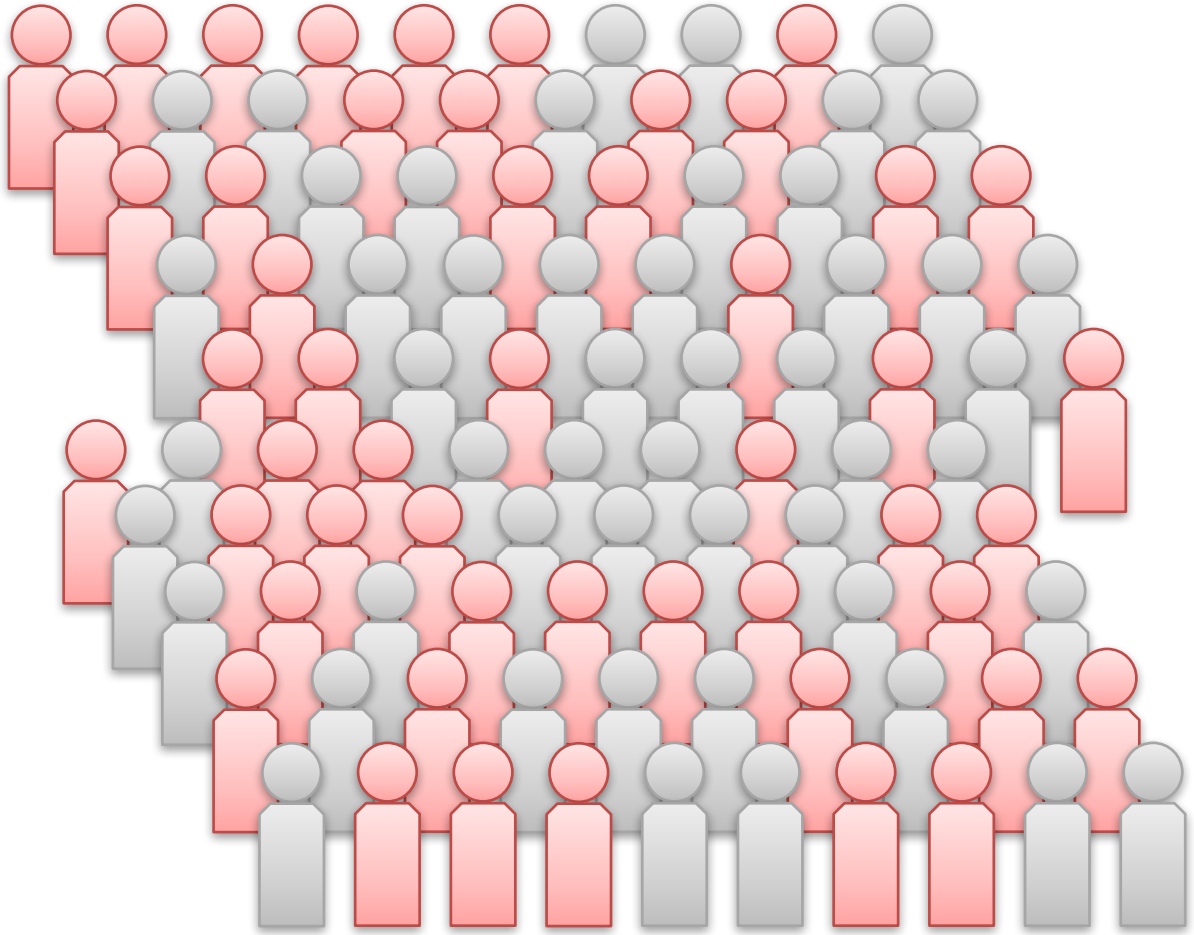
If current diagnosis rates persist...

25

out of 100
Hispanic MSM
will become HIV+

Hess K et al. CROI 2016, abstract #52

Lifetime risk of acquiring HIV



If current diagnosis rates persist...

50

out of 100
Black MSM
will become HIV+

Hess K et al. CROI 2016, abstract #52

Can addressing barriers improve adherence?

HIV Prevention Trials Network Study 073, 2013-15

Los Angeles, Washington DC, Raleigh-Durham-Chapel Hill

Client-centered care coordination plus offer of PrEP through study

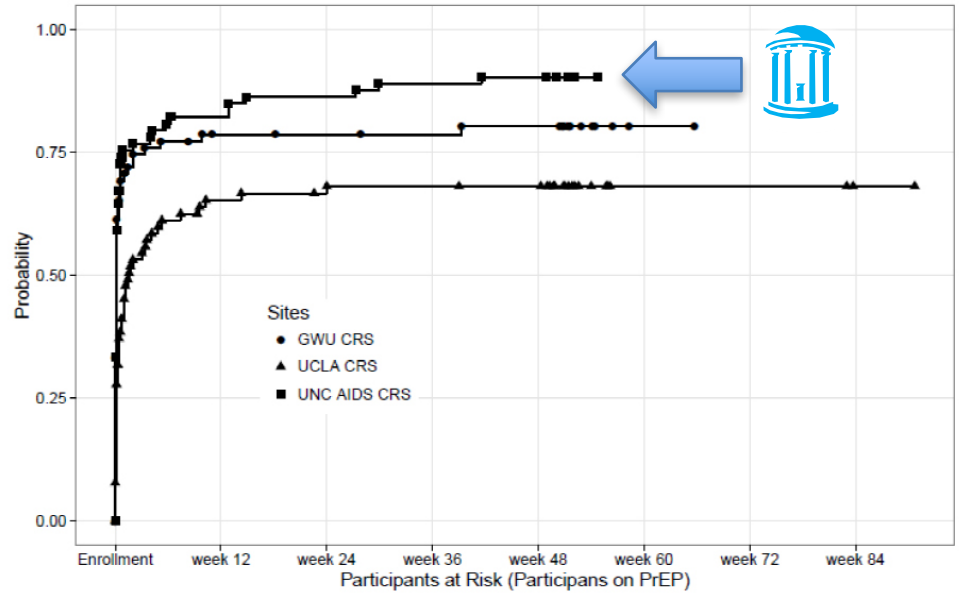
225
Black MSM

40%
under 25 y.o.

79%
accepted PrEP

68%
on PrEP at week 26

Probability of being on PrEP, by week



Wheeler DP, et al. CROI 2016. Abstract 883LB.

Can adolescents be prescribed PrEP?

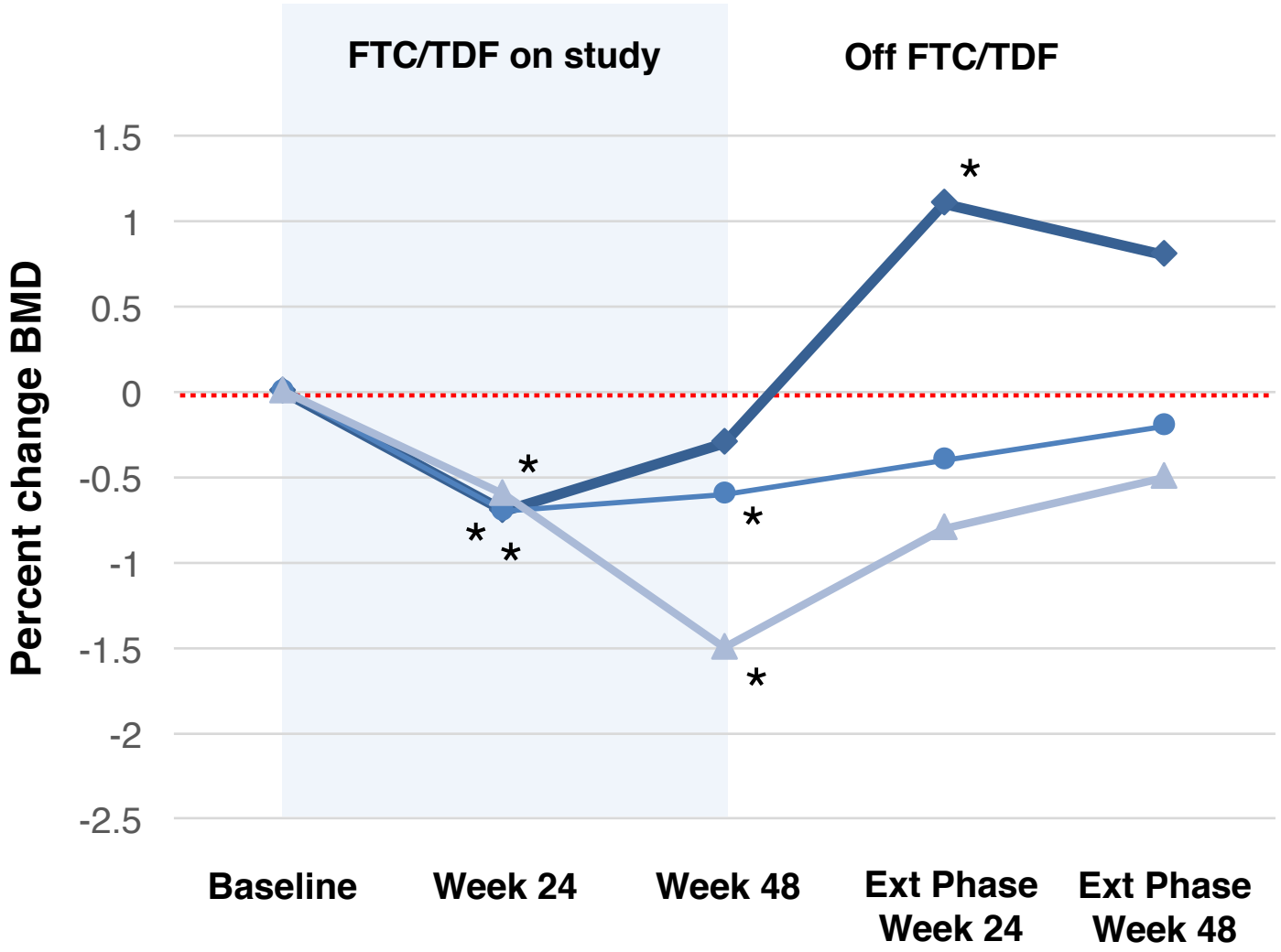
- Truvada is FDA approved:
  - "with safer sex practices … to reduce the risk of sexually acquired HIV-1 in **adults at high risk**"
  - for "treatment of HIV-1 infection in adults and pediatric patients weighing at least 17 kg"

- USPHS/CDC PrEP guidelines:
  - **safety, efficacy data insufficient for adolescents**
  - weigh risks & benefits in context of local laws on autonomy in health care decision-making

US Public Health Service. PrEP Guideline – 2014.
Truvada package insert, http://gilead.com/~/media/files/pdfs/medicines/hiv/truvada/truvada_pi.pdf

What about bone health in young adults?

Project PrEPare 2 (ATN 110), 72 who stopped FTC/TDF



18-22
years old

Spine
P=0.03 vs W48
P=0.04 vs BL

Whole Body
P=0.01 vs W48
P=0.7 vs BL

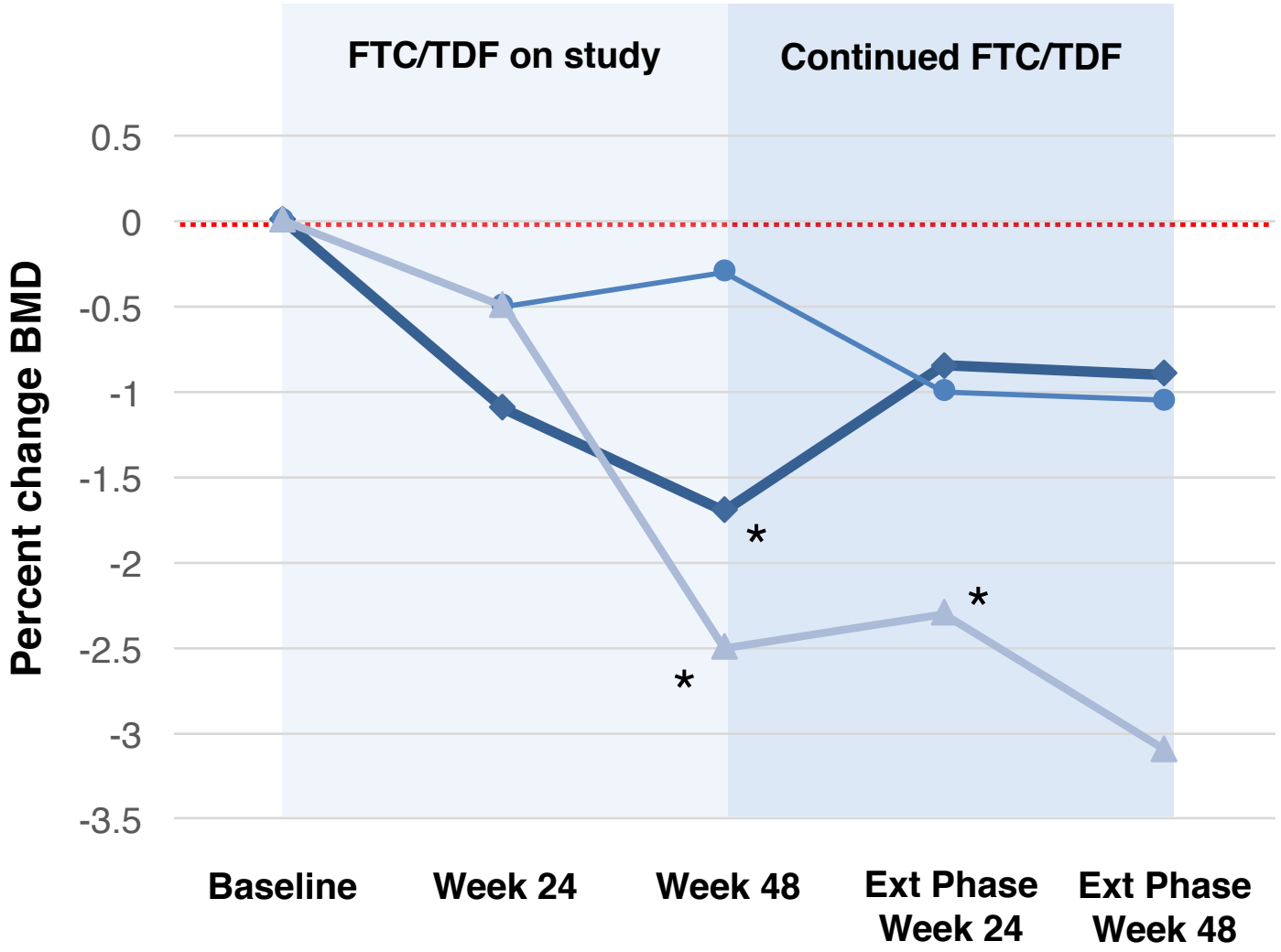
Hip
P=0.04 vs W48
P=0.5 vs BL

* $P < 0.05$ vs BL

Mulligan K, et al. 18th Int'l Workshop on Comorbidities and Adverse Drug Reactions in HIV. 12-13 Sept 2016. New York City, NY. Abstract 001.

What about bone health in young adults?

Project PrEPare 2 (ATN 110), 15 who continued FTC/TDF



18-22
years old

Spine
P=0.15 vs W48
P=0.44 vs BL

Whole Body
P=0.25 vs W48
P=0.17 vs BL

Hip
P=0.57 vs W48
P=0.001 vs BL

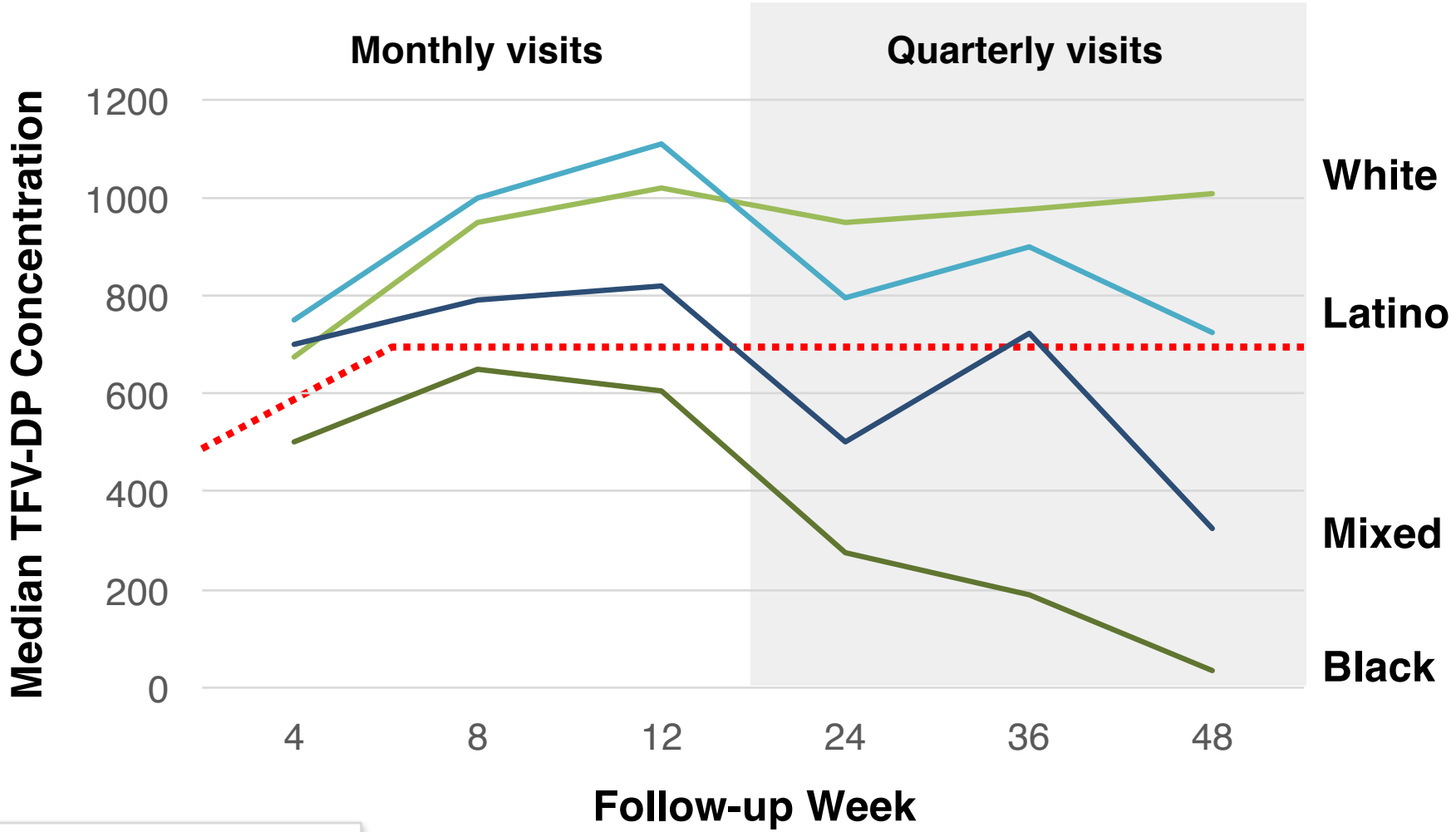
* $P < 0.05$ vs BL

Mulligan K, et al. 18th Int'l Workshop on Comorbidities and Adverse Drug Reactions in HIV. 12-13 Sept 2016. New York City, NY. Abstract 001.

What about adherence in young adults?

Project PrEPare 2 (ATN 110), Oct 2012 - Feb 2015

18-22
years old

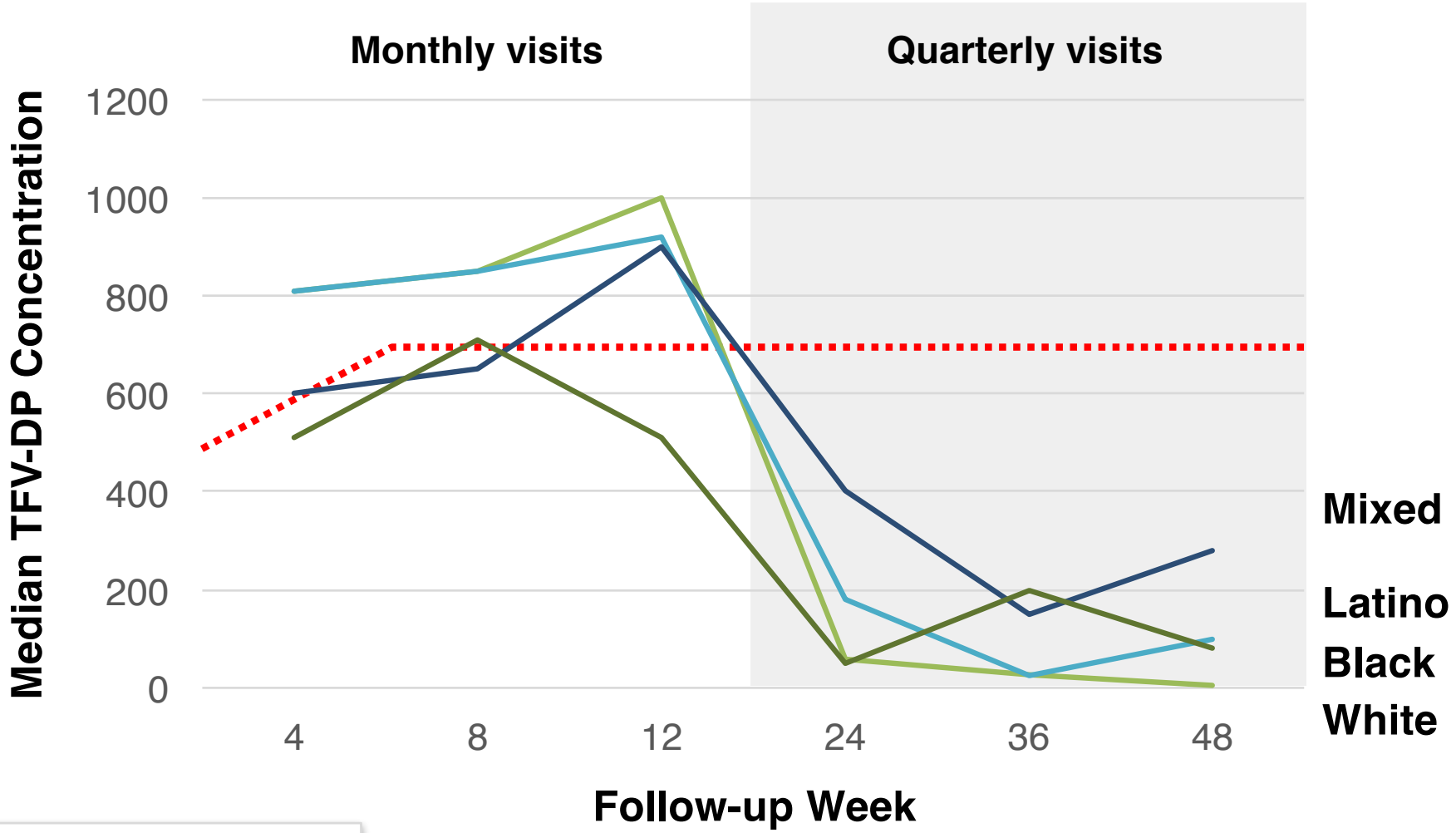


Hosek S, et al. IAS Vancouver 2015.

What about adherence in young adults?

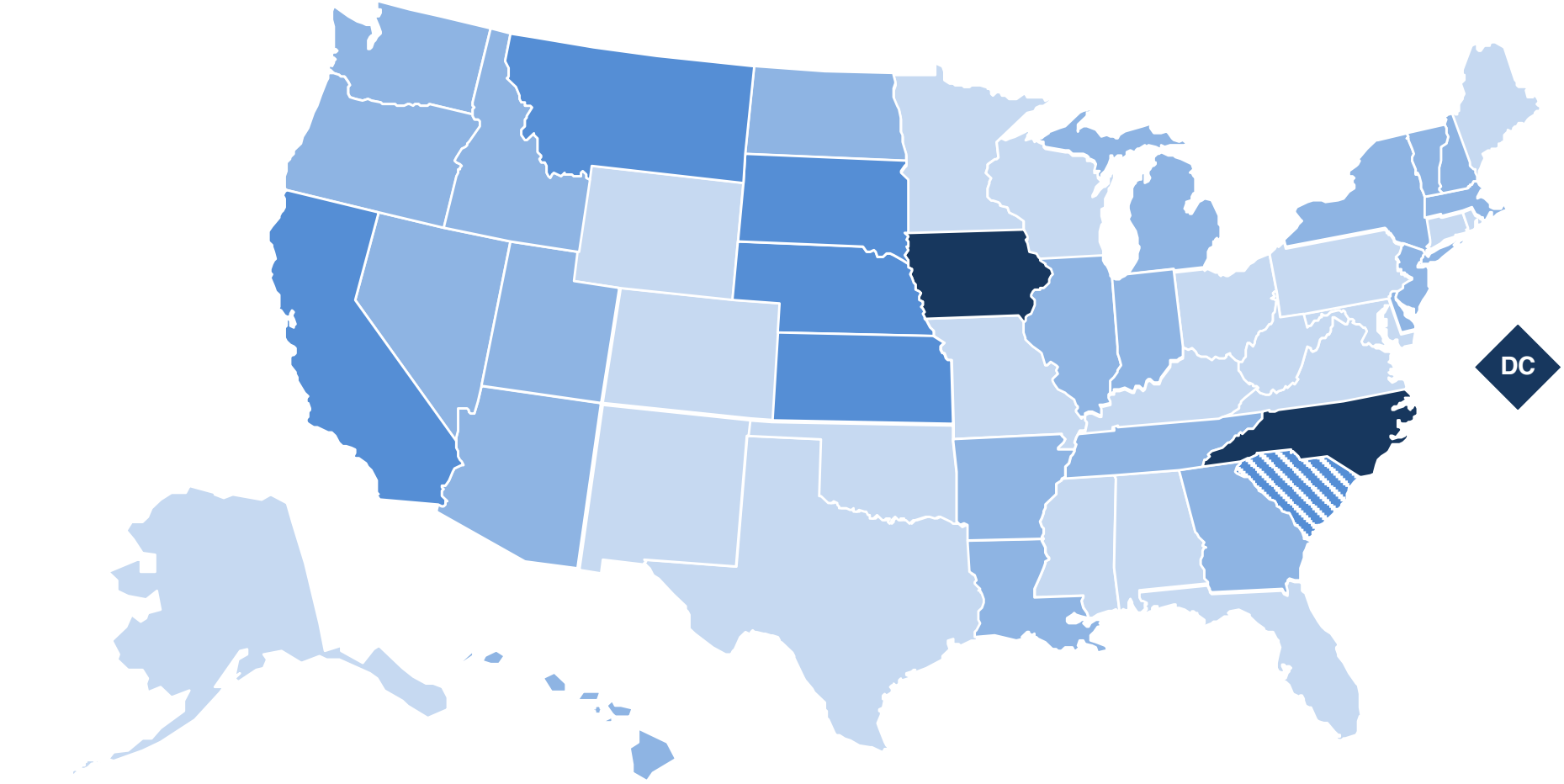
Project PrEPare 3 (ATN 113), Aug 2013 – Mar 2016

15-17
years old



Hosek S, et al. IAS Vancouver 2015.

Minor's capacity to consent for STI services



Diagnosis and treatment only, all minors

Preventive services, all minors

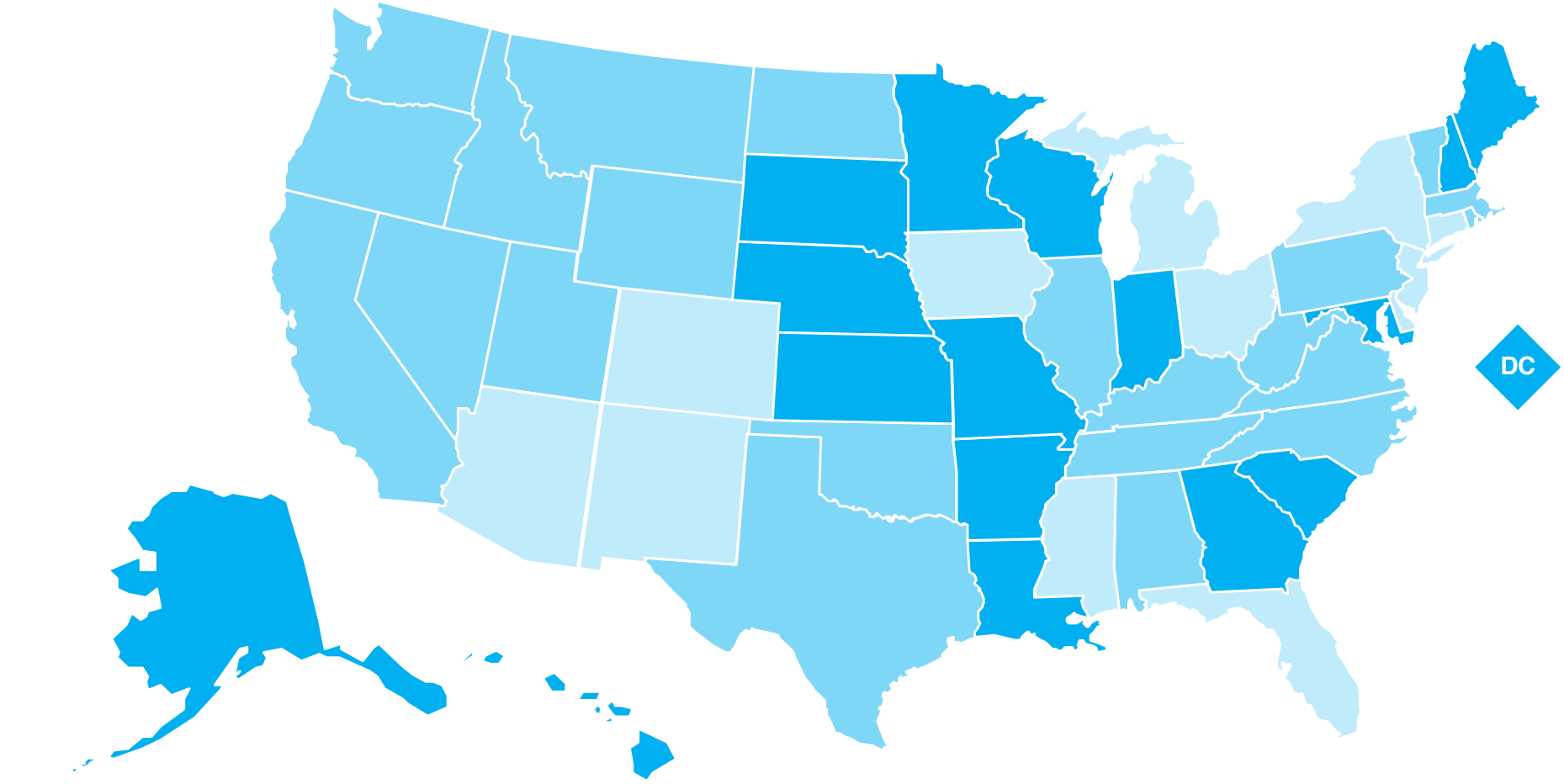
Any care, status conditional

Diagnosis and treatment only, status conditional

Preventive services, status conditional

Culp L & Caucci L. Am J Prev Med. 2013;44(1S2):S119-24

Minor's capacity to consent for HIV services



Express provision

Express provision for STI or communicable disease (HIV included)

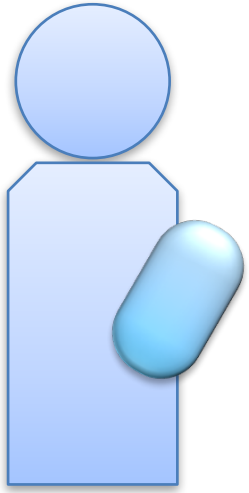
Express provision for STI or communicable disease (silent on HIV)

Culp L & Caucci L. Am J Prev Med. 2013;44(1S2):S119-24

Can HIV break through PrEP?

Patient

- On PrEP for 24 months
- Likely fully adherent (based on DBS drug levels and Rx refill data)

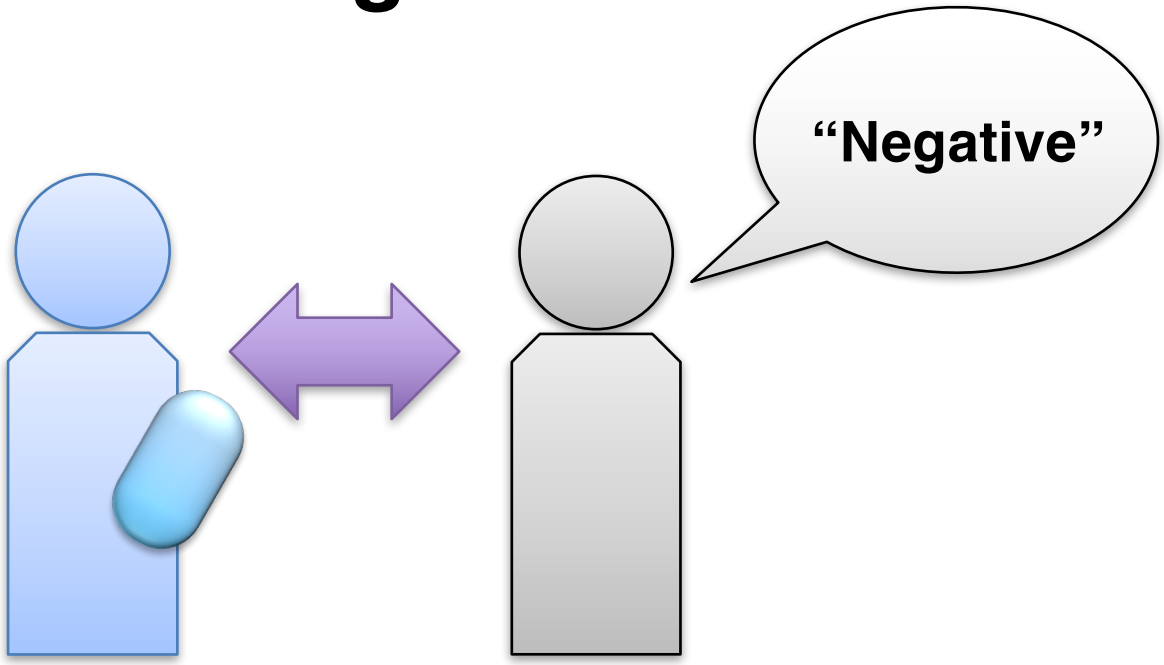


Knox DC, et al. CROI 2016. Abstract 169aLB
https://www.poz.com/article/meet-man-got-hiv-daily-prep

Can HIV break through PrEP?

Patient

- Meets partner on barebacking hook-up site
- Tried following up afterward, but partner became unreachable

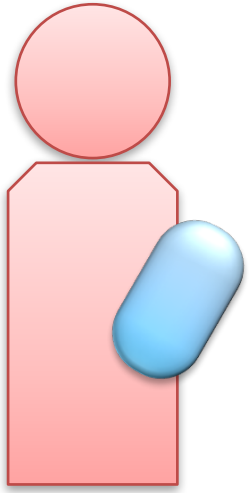


Knox DC, et al. CROI 2016. Abstract 169aLB
https://www.poz.com/article/meet-man-got-hiv-daily-prep

Can HIV break through PrEP?

Patient

- p24 antigen positive on routine quarterly testing
- No reported symptoms suggestive of acute HIV infection



Knox DC, et al. CROI 2016. Abstract 169aLB
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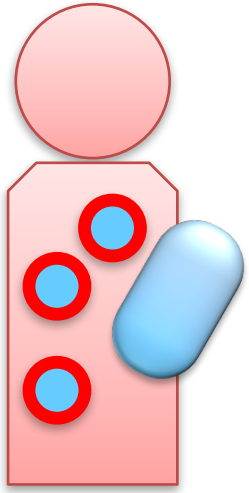

Resistance testing

Class	Mutation(s)
NRTI	M41L, D67G, 69ins, K70R, **M184V**, T215E
NNRTI	Y181C
InSTI	H51Y, E92Q

Knox DC, et al. CROI 2016. Abstract 169aLB
https://www.poz.com/article/meet-man-got-hiv-daily-prep

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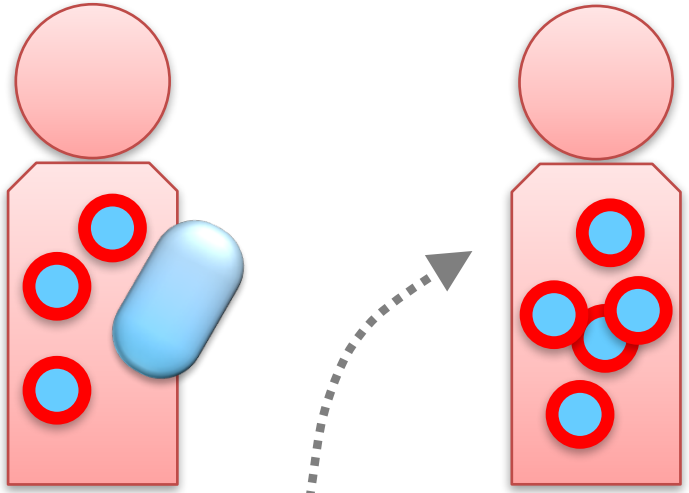


Donor (inferred)

- Acquired (and/or transmitted) resistance
- Viremic with resistant HIV (off ARVs or failing)

Resistance testing

Class	Mutation(s)
NRTI	M41L, D67G, 69ins, K70R, **M184V**, T215E
NNRTI	Y181C
InSTI	H51Y, E92Q

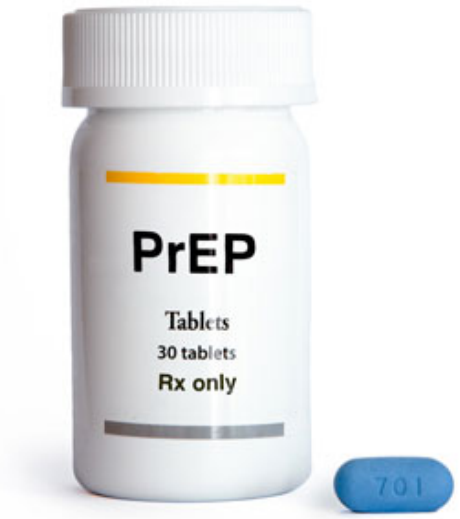
Implications

- Special, unusual circumstances but could certainly happen again
- **Any condomless sex poses a risk**; lower with PrEP, but never truly zero

Knox DC, et al. CROI 2016. Abstract 169aLB
https://www.poz.com/article/meet-man-got-hiv-daily-prep

Acquired resistance is much more likely…

Hypothetical scenario



- Period of nonadherence
- Exposure event(s)
- Symptoms develop but aren't reported
- Concern prompts resumption of PrEP
- Perfect adherence
- Resistance develops to emtricitabine ± tenofovir DF*

* Assuming still taking PrEP at time of HIV diagnosis and resistance testing

Hurt CB, et al. *Clin Inf Dis.* Dec 2011;53(12):1265-70

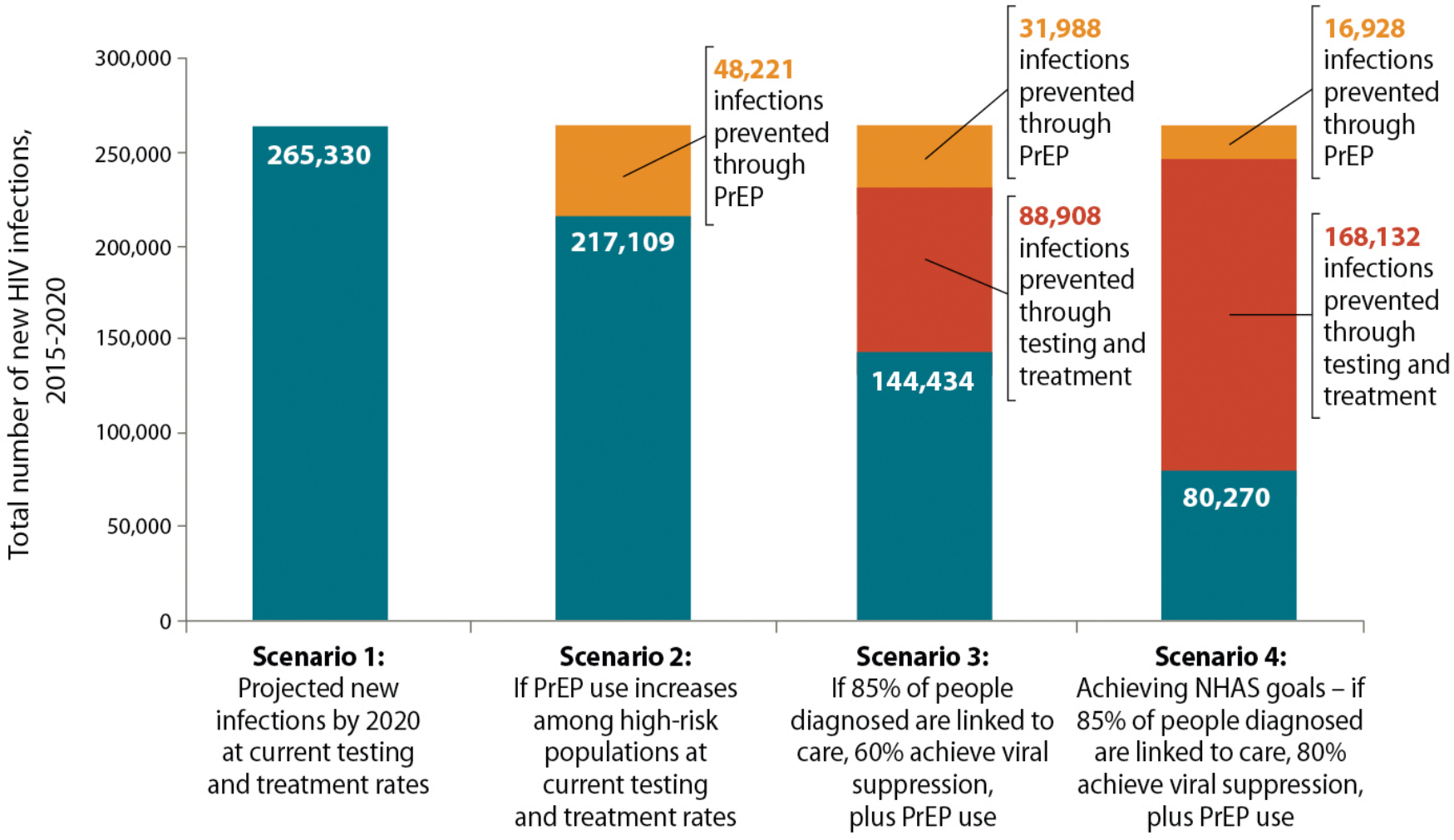
Can we use FTC/TAF for PrEP?

The jury is still out…

- CDC: TAF was protective against repeated low-dose rectal $SHIV_{162p3}$ challenges in 6 macaques
- UNC: after 1 dose TAF, human genital & rectal levels of active tenofovir were unexpectedly low
- **FTC/TAF (Descovy) should NOT be used for PrEP until more comprehensively evaluated**

Massud I et al. CROI 2016. Abstract 107.
Garrett K et al. CROI 2016. Abstract 102LB.

Potential impact of interventions, 2015-2020



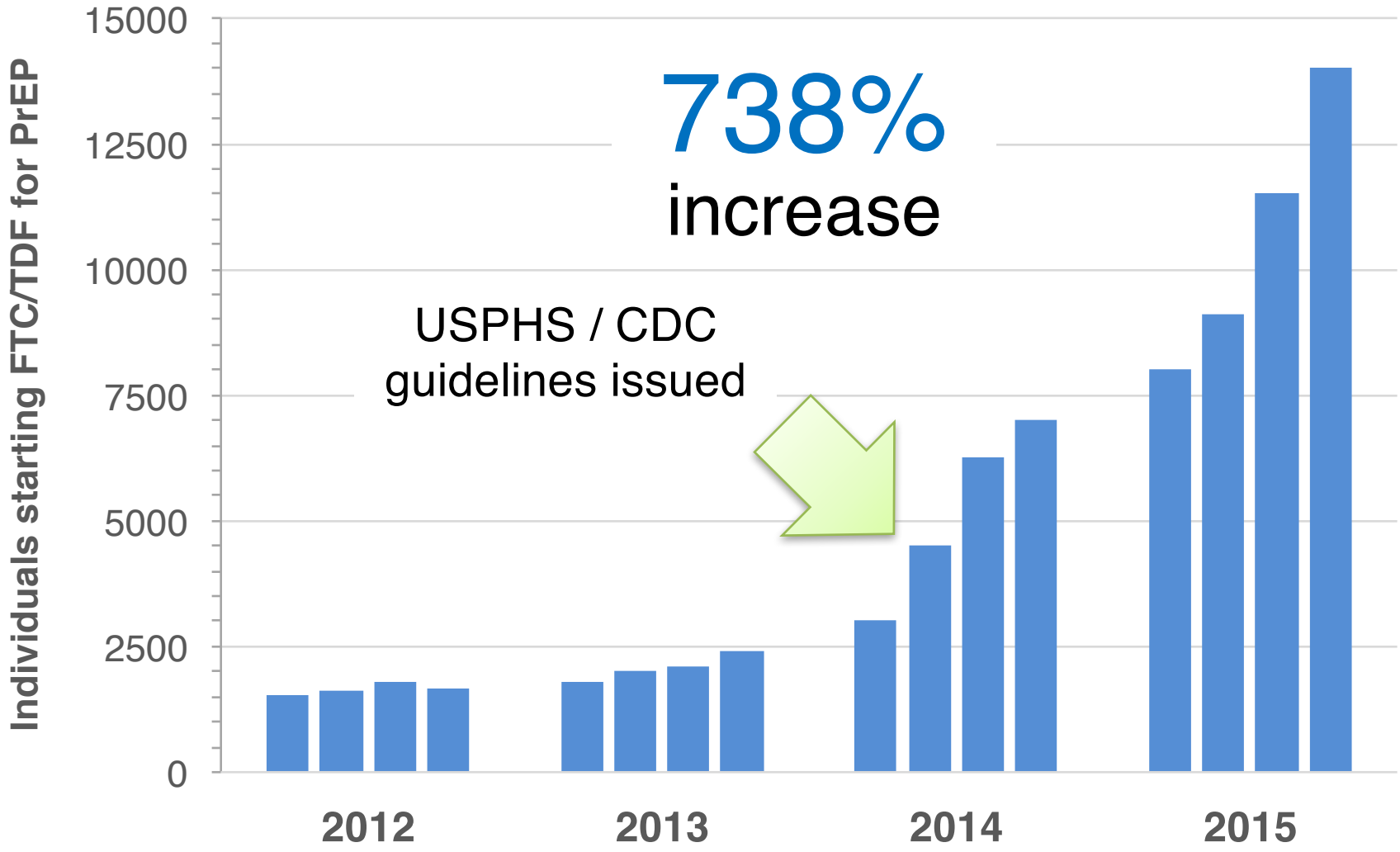
New infections

HIV infections prevented due to expanded testing and treatment

HIV infections prevented due to PrEP (assumes PrEP use among high-risk populations = 40% MSM; 10% PWID; 10% HET)

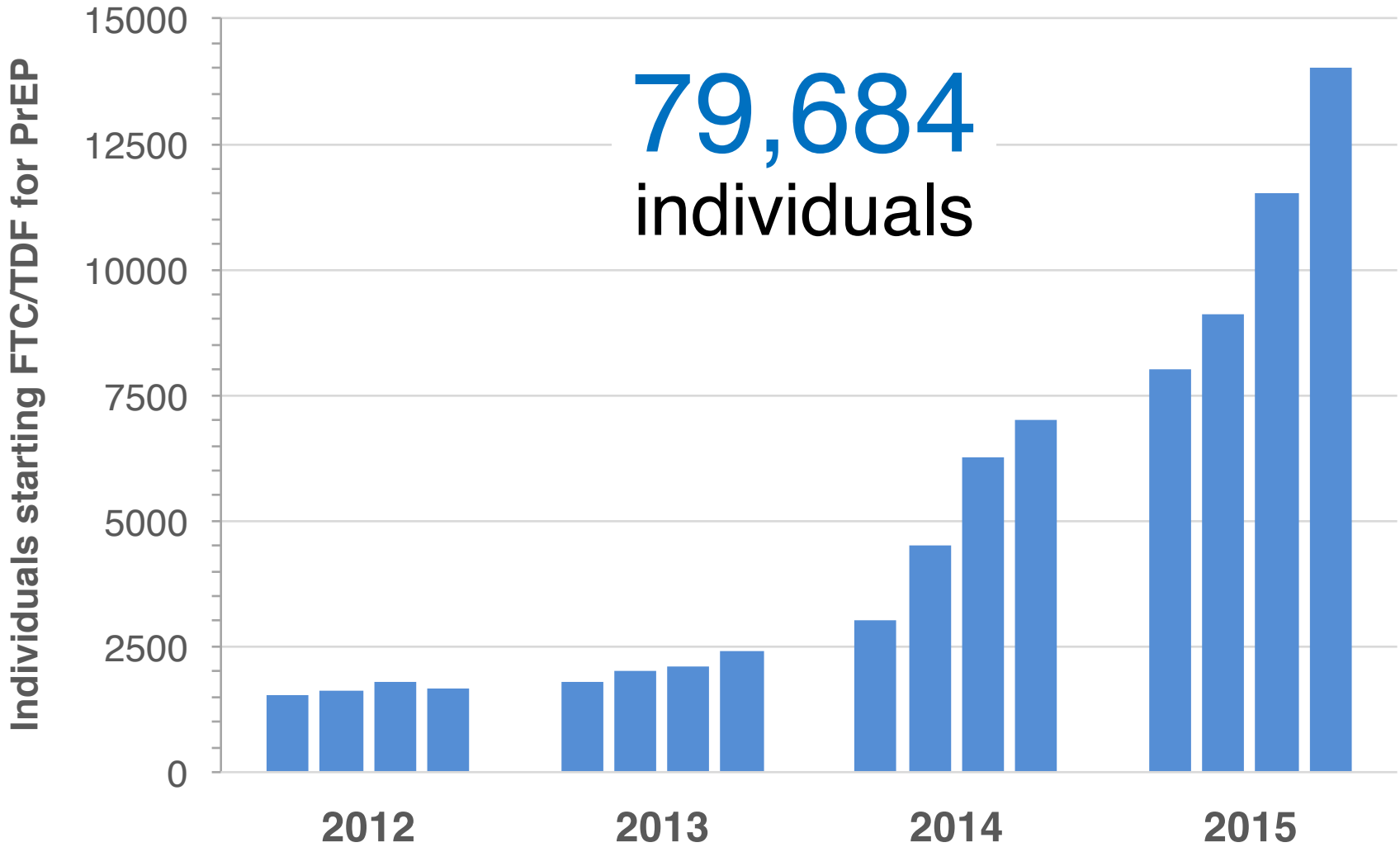
Yaylali E et al. CROI 2016, abstract #1051
Graphic from CDC

PrEP is taking off in the US…



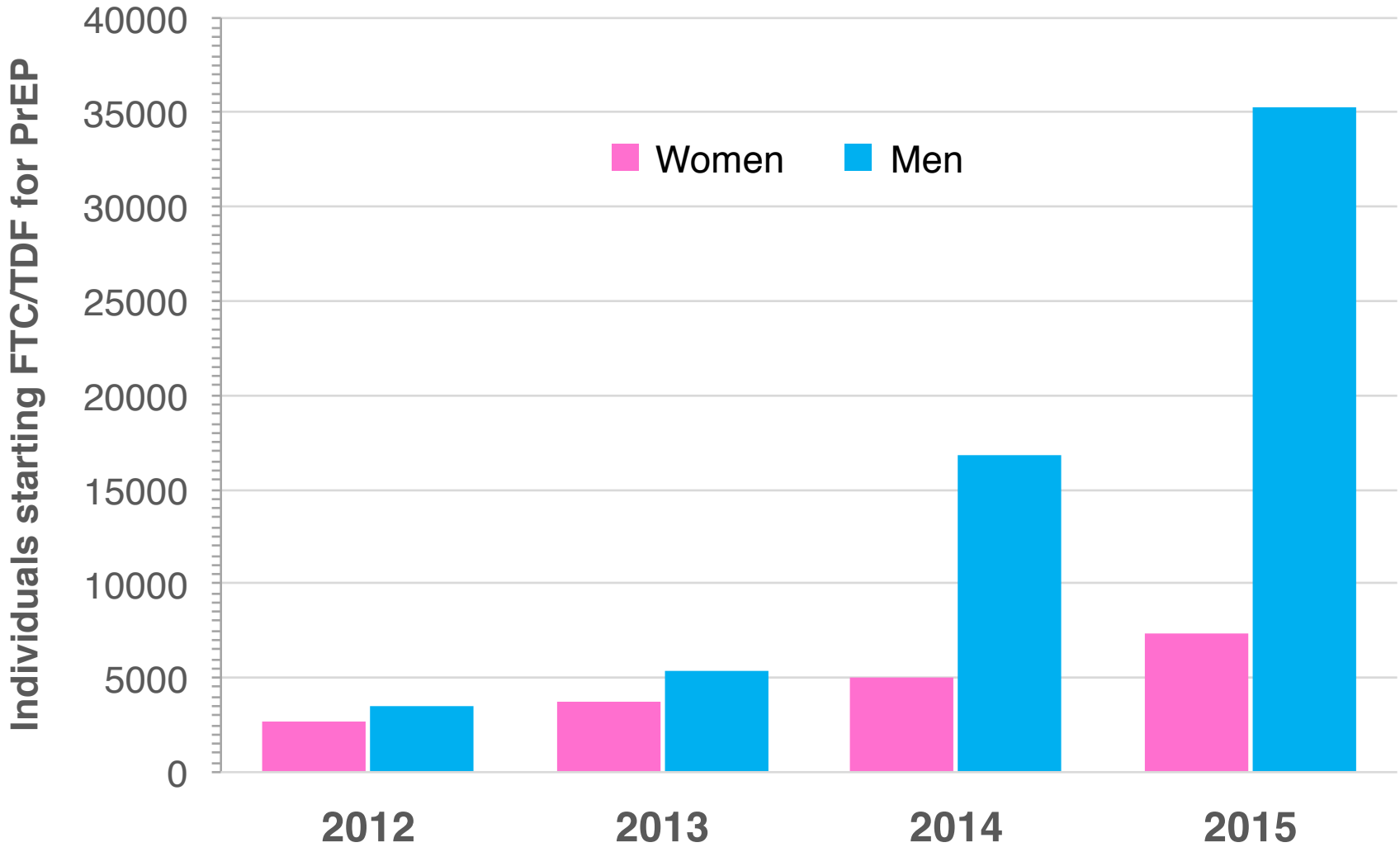
Rawlings K et al (McAllister presenting). IAC Durban 2016, abstract #TUAX0105LB
http://www.natap.org/2016/IAC/IAC_17.htm

PrEP is taking off in the US…



Rawlings K et al (McAllister presenting). IAC Durban 2016, abstract #TUAX0105LB
http://www.natap.org/2016/IAC/IAC_17.htm

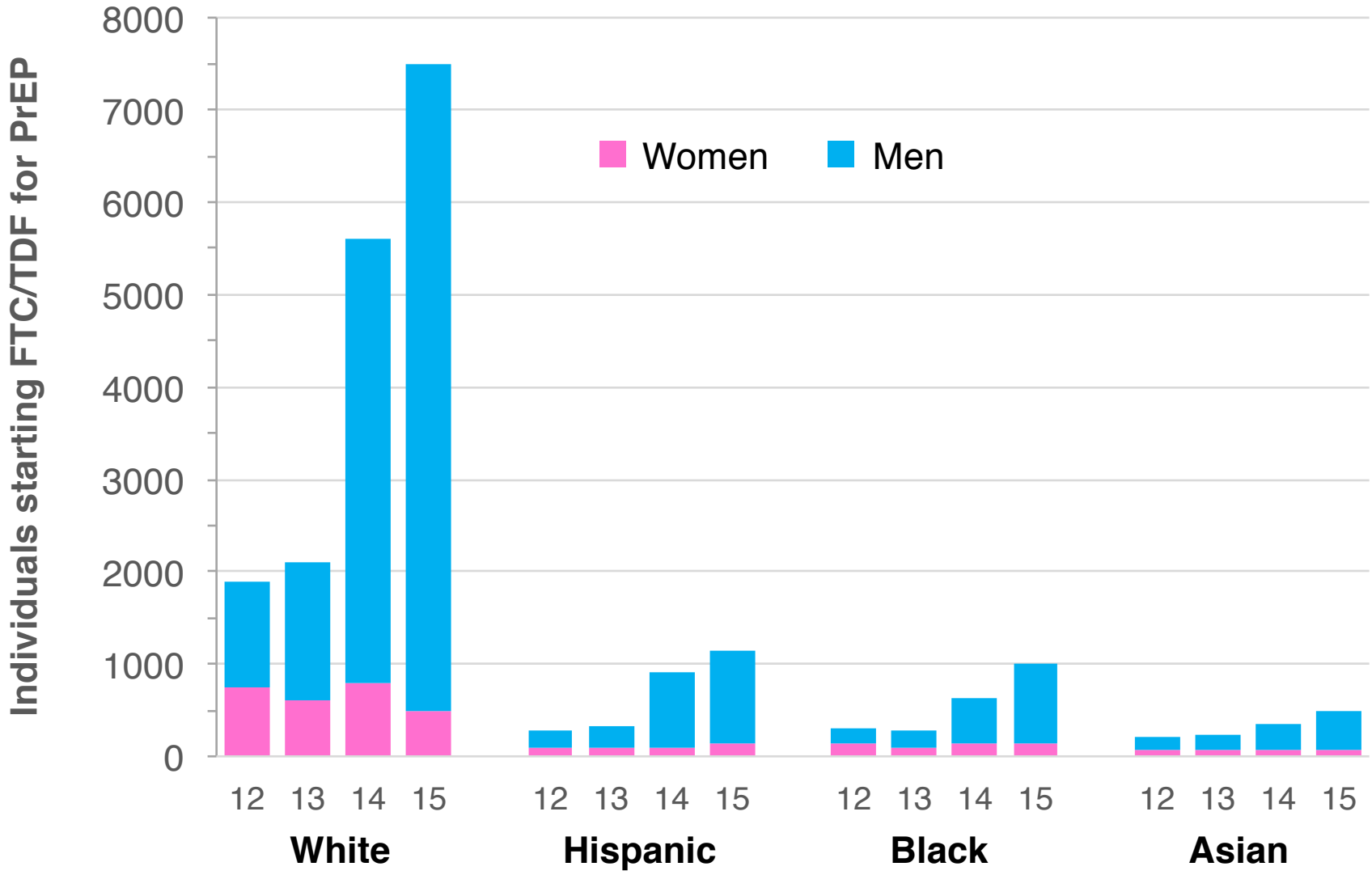
…but its distribution is uneven…



Rawlings K et al (McAllister presenting). IAC Durban 2016, abstract #TUAX0105LB
http://www.natap.org/2016/IAC/IAC_17.htm

…but its distribution is uneven…

n=21,463
(44% of all started)

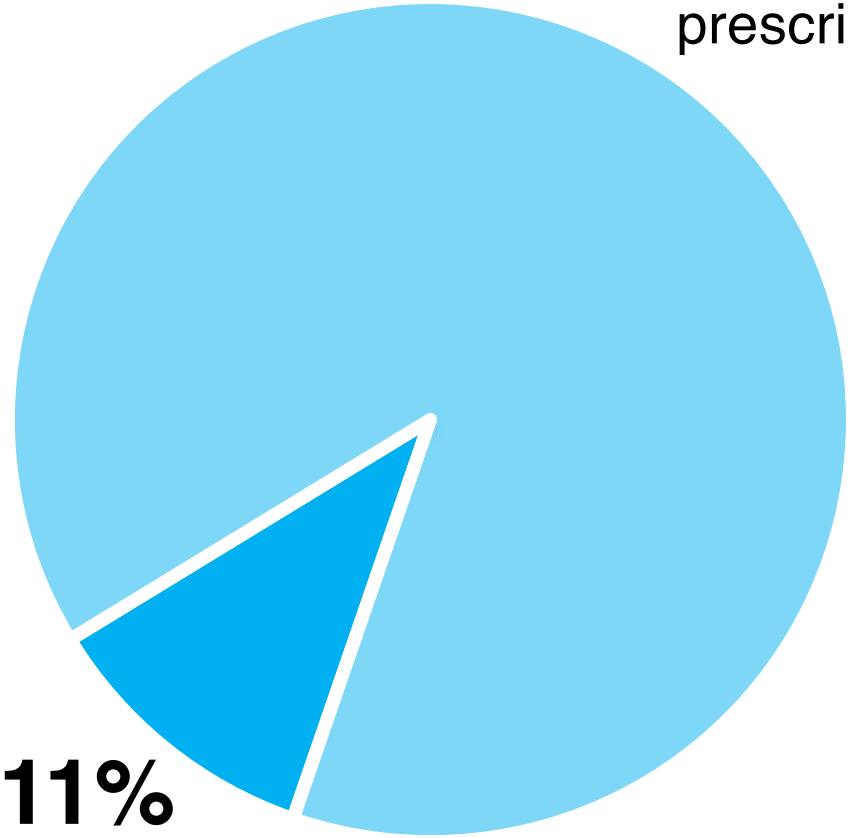


Bush S et al. ASM / ICAAC 2016, abstract #2651
http://www.aidshealth.org/wp-content/uploads/2016/07/GILD_Bush-PrEP-Race-Utilization.ext-June-2016.pdf

…and it's not reaching those most at-risk

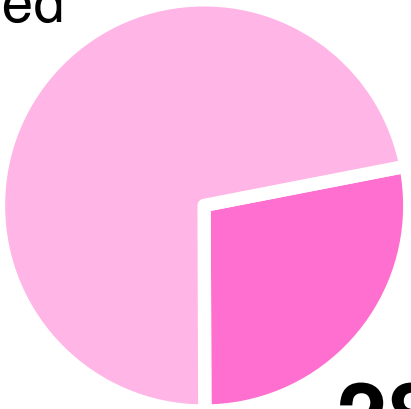
22%
of all new infections in 2014 among 13-24 yo

60,872
men
prescribed



11%
< 25 yo

18,812
women
prescribed

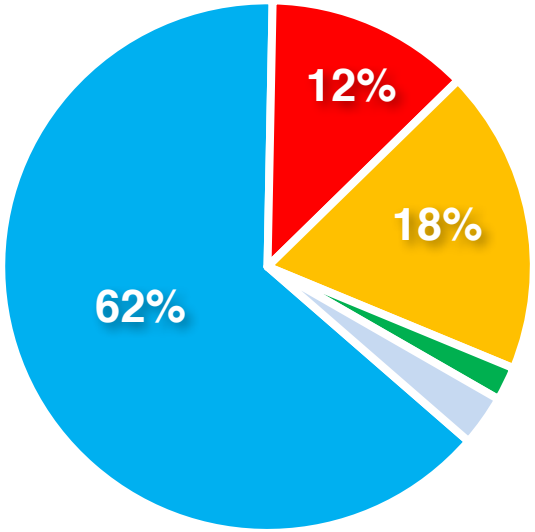


28%
< 25 yo

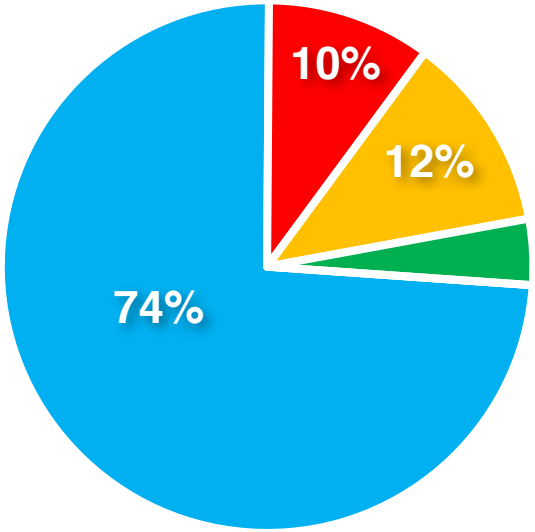
Rawlings K et al (McAllister presenting). IAC Durban 2016, abstract #TUAX0105LB
http://www.natap.org/2016/IAC/IAC_17.htm

…and it's not reaching those most at-risk

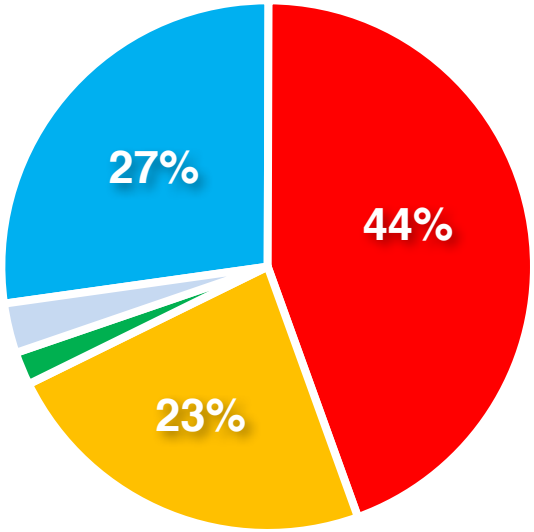
US Population
2014



PrEP Utilization
Sept 2015



New Infections
2014 (estimated)



Black Hispanic Asian Multi/Other White

Bush S et al. ASM / ICAAC 2016, abstract #2651
http://www.aidshealth.org/wp-content/uploads/2016/07/GILD_Bush-PrEP-Race-Utilization.ext-June-2016.pdf

PrEP is now a matter of social justice






PrEP 2.0 is coming…

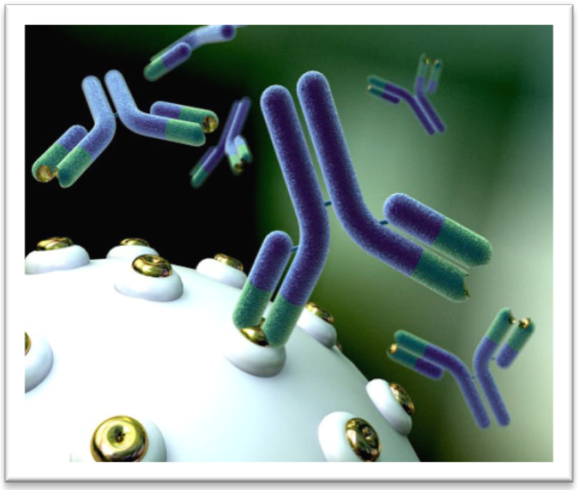
FTC / TAF

DISCOVER
(Gilead)

dapivirine NNRTI

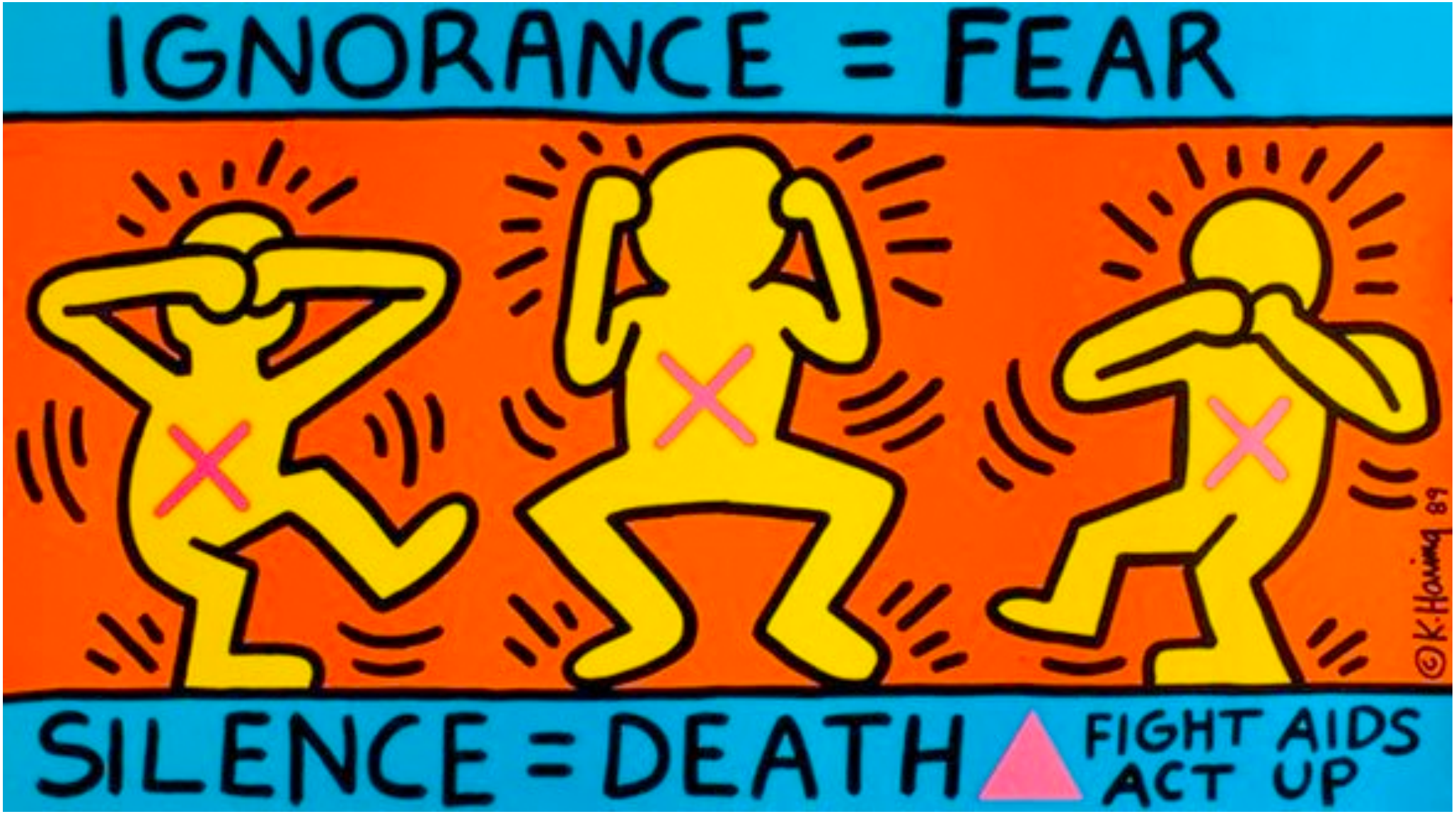
cabotegravir-LA INI

TRIUMPH
(HPTN 083)



broadly neutralizing monoclonal antibodies (bnAbs)

AMP Study
(HPTN 085)



Questions?

Feel free to email me

churt@med.unc.edu

NCATEC online PrEP resources

- Visit us at www.med.unc.edu/ncatec for information & resources for:
  - Consumers
  - PrEP prescribers (protocols, etc.)
  - “PrEP curious” providers

- Need more training assistance related to HIV, STIs, hepatitis C, cultural competency?
  - Email Michele Bailey, NCATEC Program Manager at: michele.bailey@med.unc.edu

NCATEC
University of North Carolina at Chapel Hill
AIDS Training and Education Center