Recent Breakthroughs in HIV Prevention for Men who Have Sex with Men and Transgender Populations

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Continuing Medical Education Disclosure

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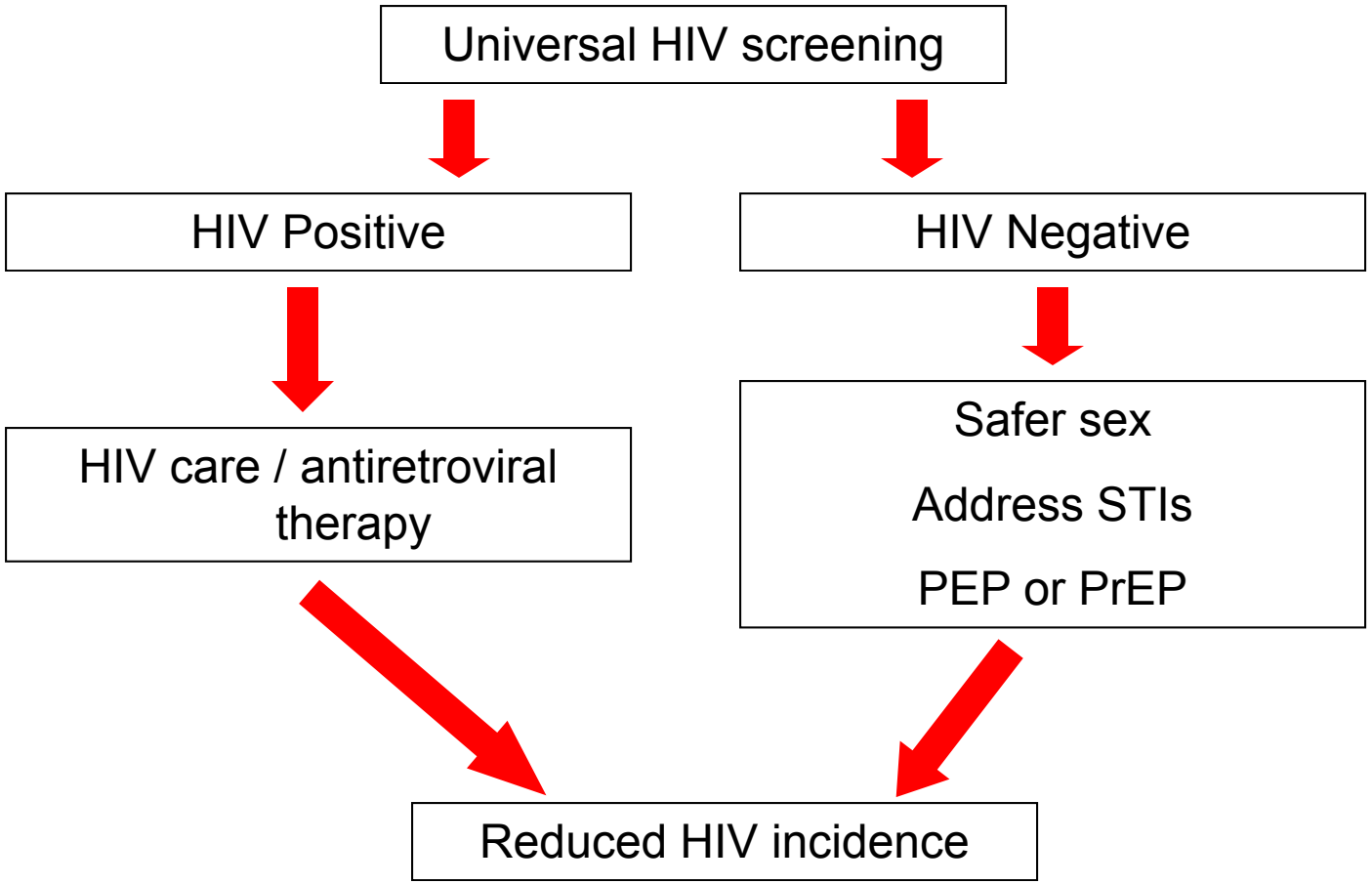
Learning Objectives

- Review the epidemiology of HIV transmission in the United States.
- Describe new HIV prevention tools.
- Discuss how to implement HIV prevention programs in patient-centered medical homes (PCMHs).

HIV Prevention Pathway



HIV in the United States

HIV in the United States

- Approximately 1.2 million people are living with HIV.
- There are ~50,000 new cases of HIV diagnosed every year.

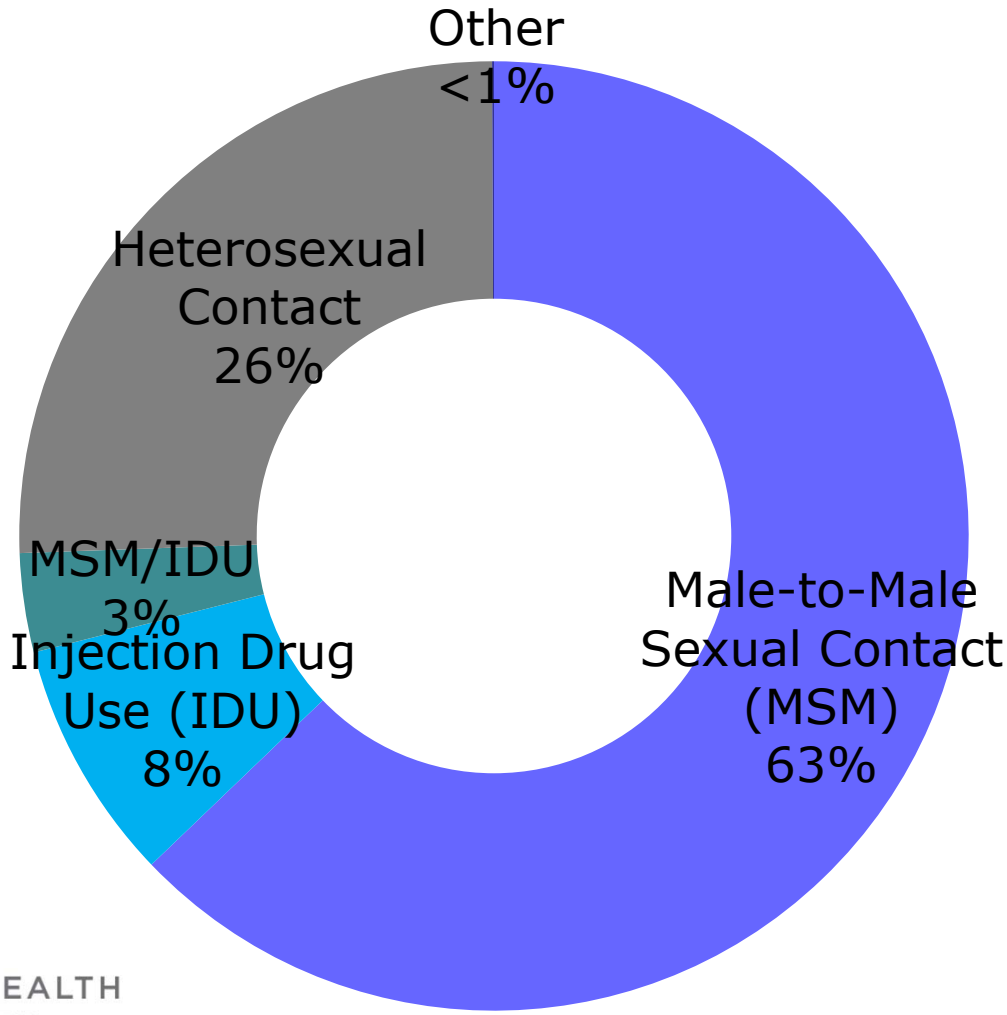
CDC, 2012

Audience Polling Question

In which of the following demographic groups is HIV incidence increasing?

a) Black, heterosexual women
b) Black, heterosexual men
c) Black MSM
d) White MSM
e) Injection drug users

HIV Incidence by Transmission Category, United States, 2010



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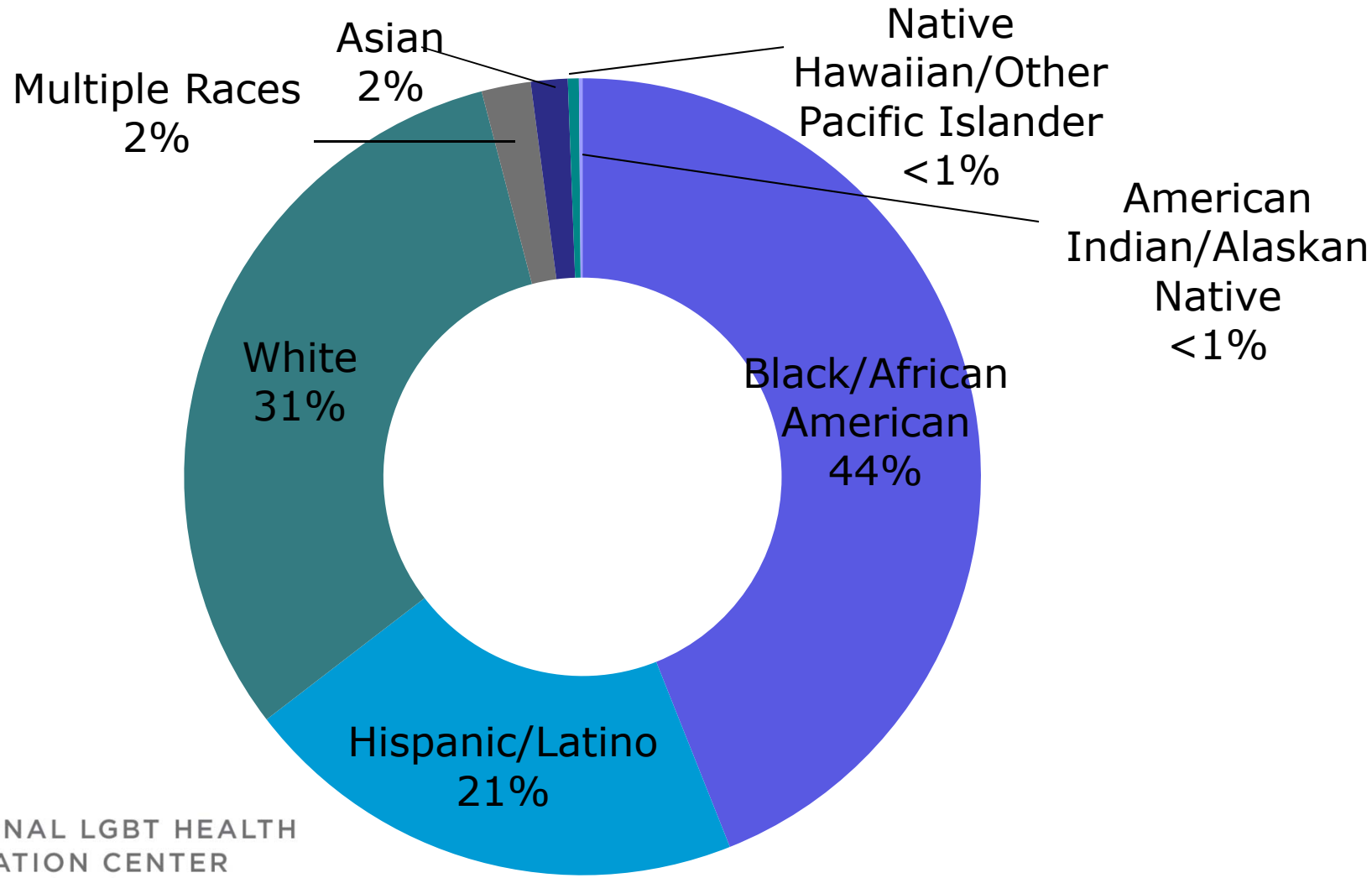
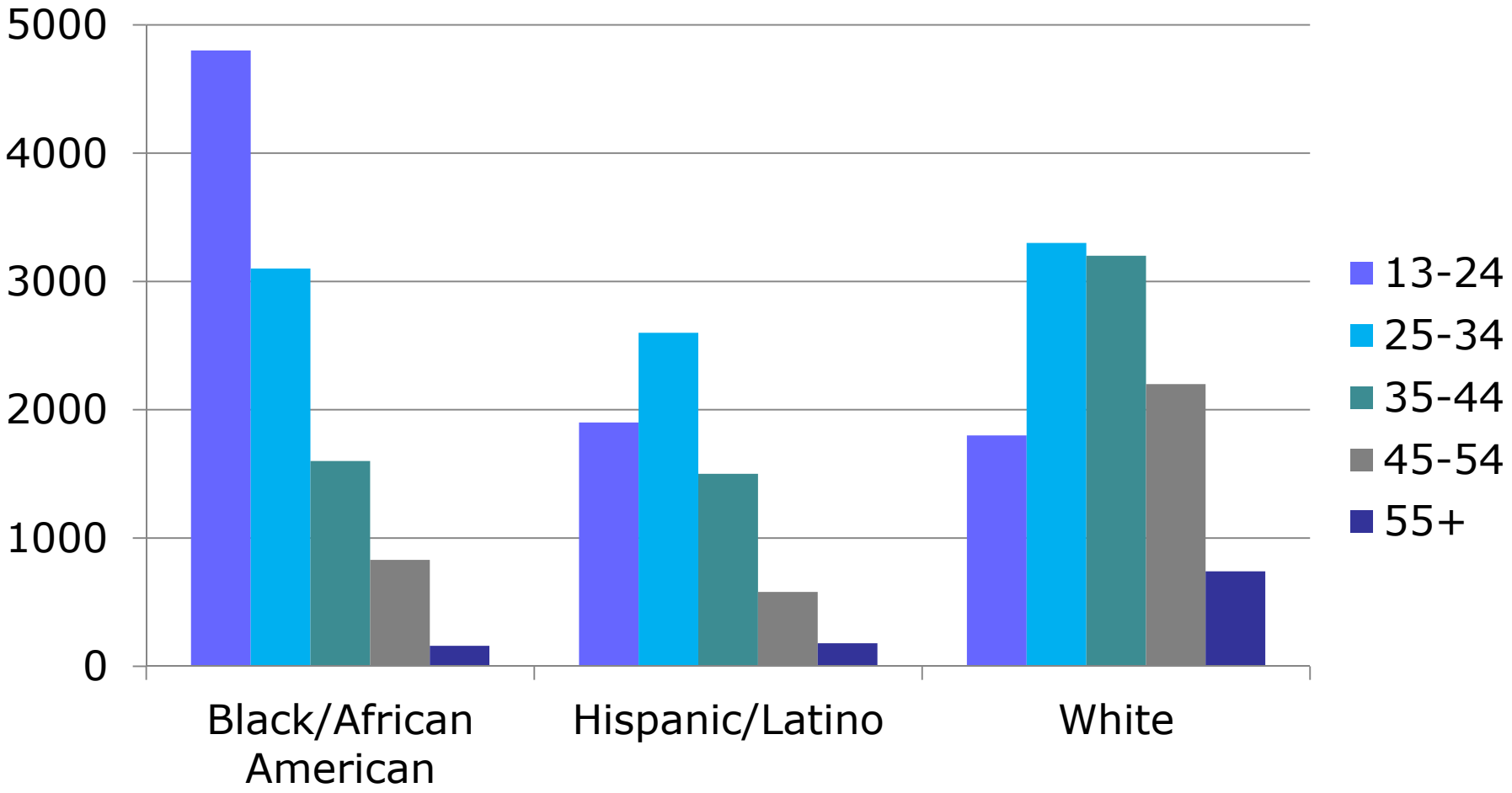
CDC, 2011

HIV Incidence by Race/Ethnicity, United States, 2010



HIV Incidence among MSM, United States 2010



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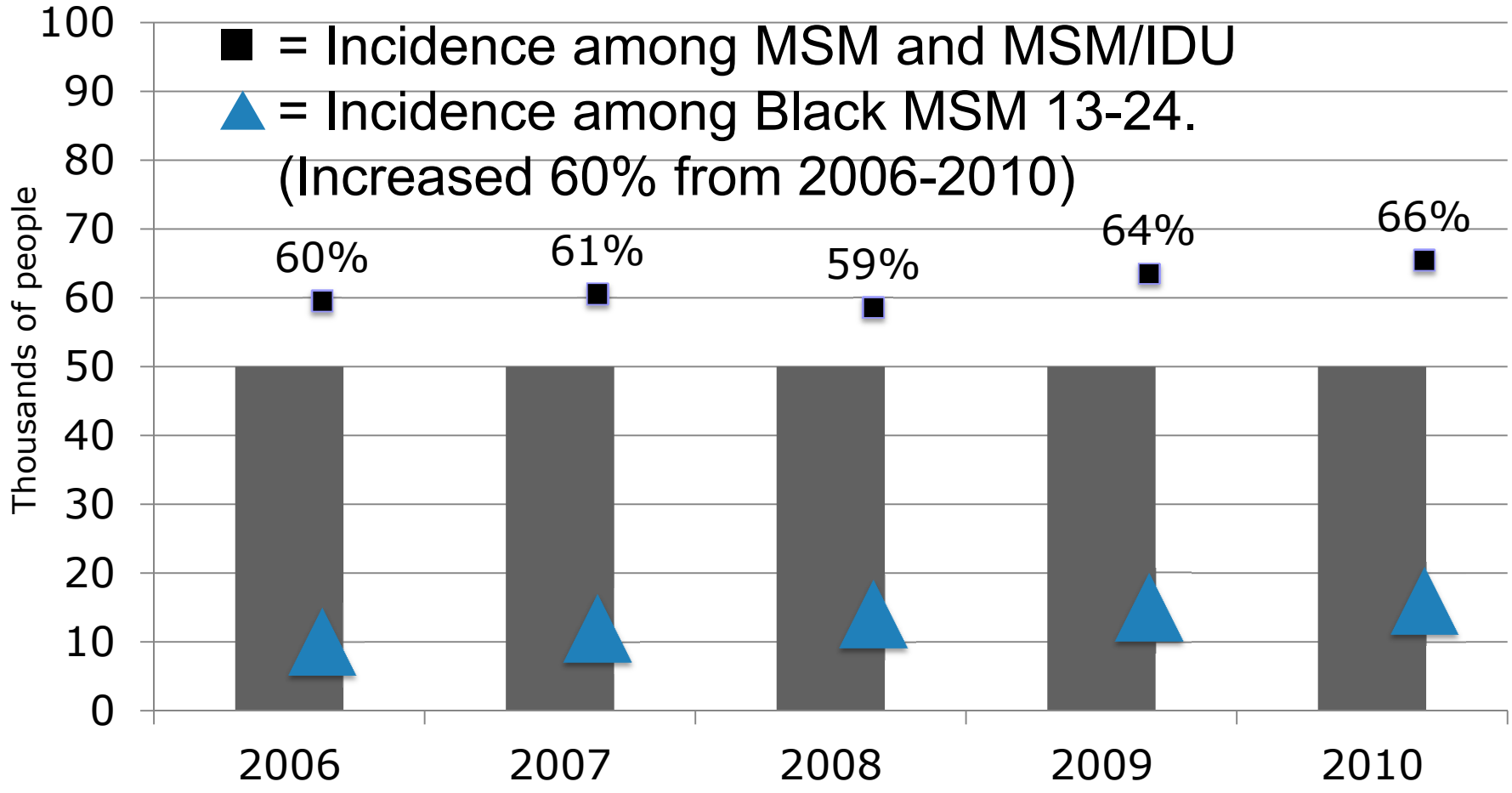
Audience Polling Question

In which of the following demographic groups is HIV incidence increasing?

a) Black, heterosexual women
b) Black, heterosexual men
c) Black MSM
d) White MSM
e) Injection drug users

HIV Incidence in the United States, 2006-2010



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Why is HIV incidence highest among black MSM?

- Barriers to health care access
- Lower rates of HIV testing
- Higher HIV prevalence in black MSM networks
- Higher STI prevalence

CDC, 2011

Transgender women are also at high risk

- Overall HIV prevalence: **~22%**
- Prevalence among black transgender women: **~50%**

Baral, 2013; Herbst, 2008; Schulden, 2008

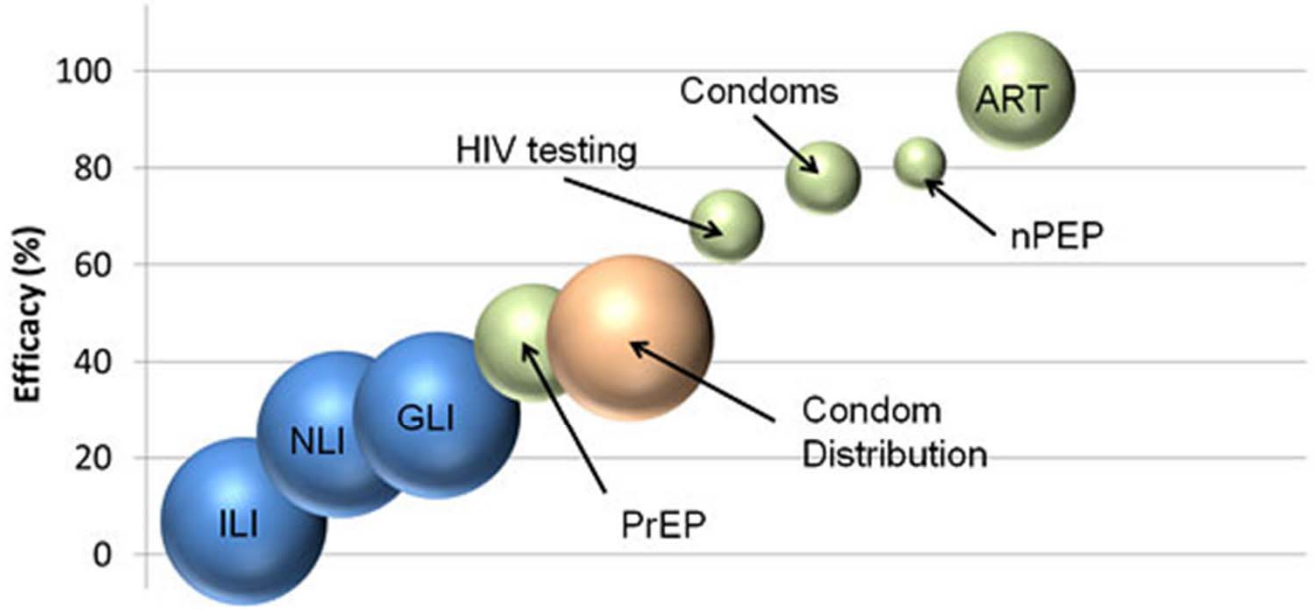
Case

- 28-year-old male who reports unprotected, receptive anal sex yesterday
- Learned afterwards that his partner is HIV-infected and taking ART
- Has no chronic medical problems
- Has been treated for syphilis, gonorrhea, LGV, and genital HSV in the past
- Has had 3 similar exposures to HIV in the past year

Questions

- Is he HIV-infected at baseline?
- How should his recent, high risk exposure be managed?
- How should his long-term risk of HIV infection be managed?

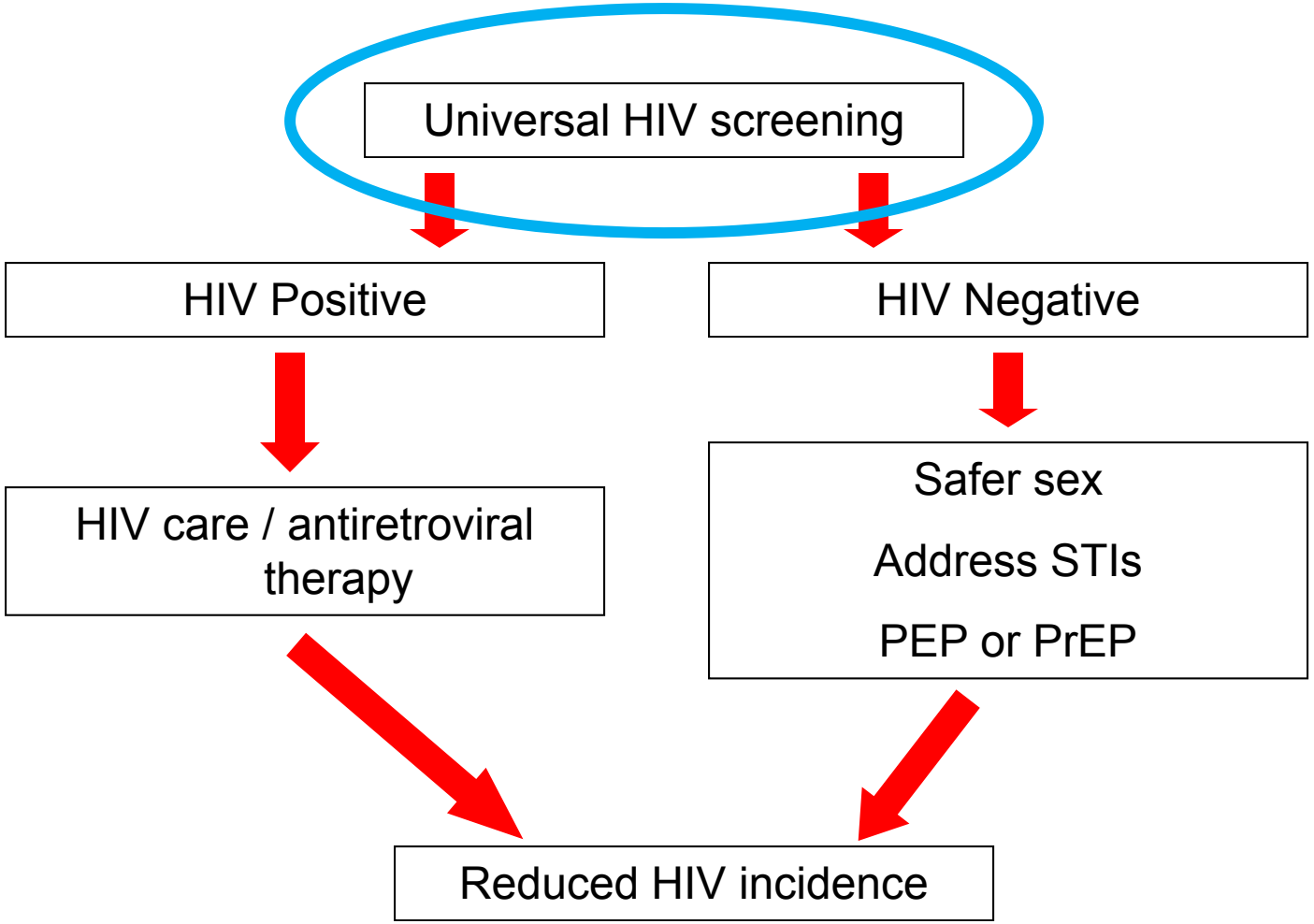
Evidence-Based Interventions



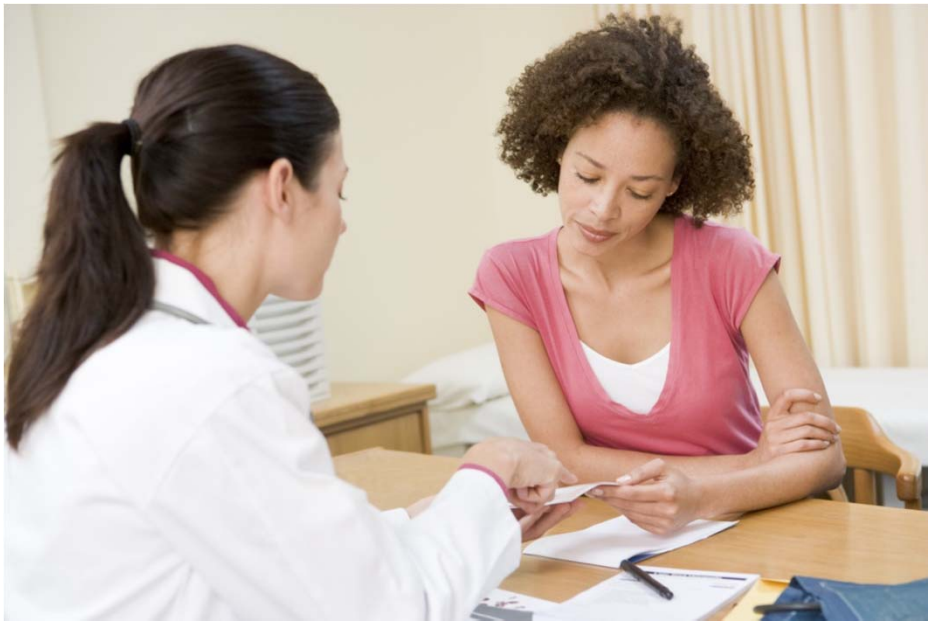
ILI: Individual-level behavior change intervention; NLI: Network-level behavior change Intervention; GLI: Group level Behavior change intervention. Size of bubble is proportional to strength of evidence. Blue: Behavior change; Green: Biomedical; Orange: Structural

Patrick Sullivan, www.nyas.org

Is he HIV-infected at baseline?



Testing is a prevention intervention



- Testing positive leads to decreased risk behavior.
- Testing is a pre-requisite for:
  - Treatment as prevention
  - Pre-exposure prophylaxis
- USPSTF grade A recommendation

Weinhardt, 1999

What's new in HIV testing?

- Newer testing algorithms which use successive immunoassays to **eliminate the Western blot** have been proposed.

- **"Fourth generation" antibody/antigen tests** shorten the window period by ~7 days.

- **Home HIV tests** may increase testing but raise concerns about cost, appropriate use, and follow-up.

Branson, 2010

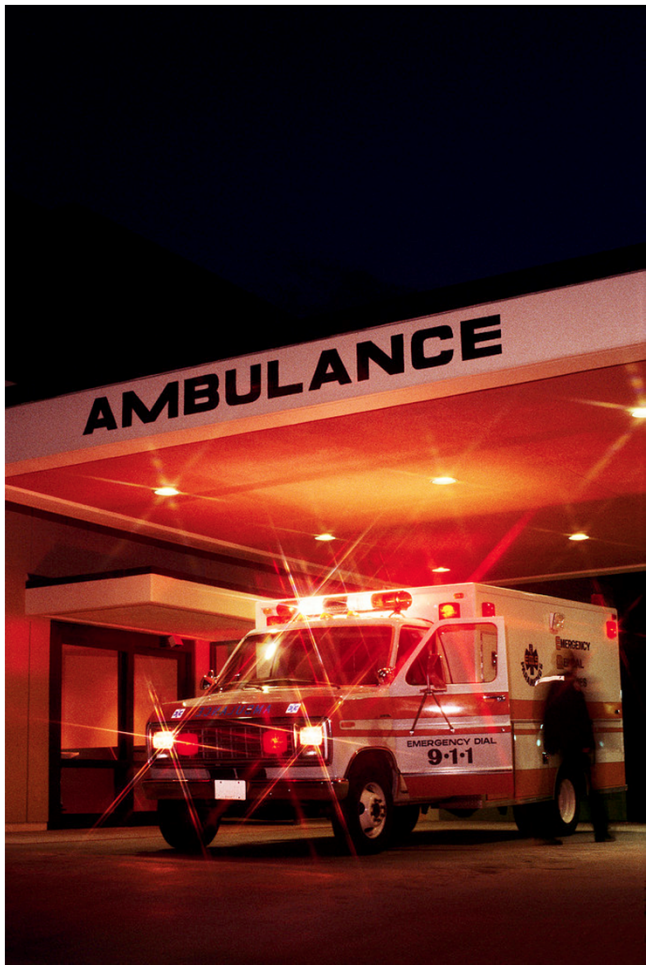
More testing is needed

- **20%** of those with HIV **do not know they are infected**.
- **32%** receive an AIDS diagnosis **within one year** of HIV diagnosis.

MMWR, 2010

Barriers to HIV Testing

- Only **61%** of general internists offer HIV testing regardless of risk.
- **50%** of EDs are aware of CDC's guidelines, and only **56%** offer HIV testing.



Haukoos, 2011; Korthuis, 2011

HIV testing is cost-effective

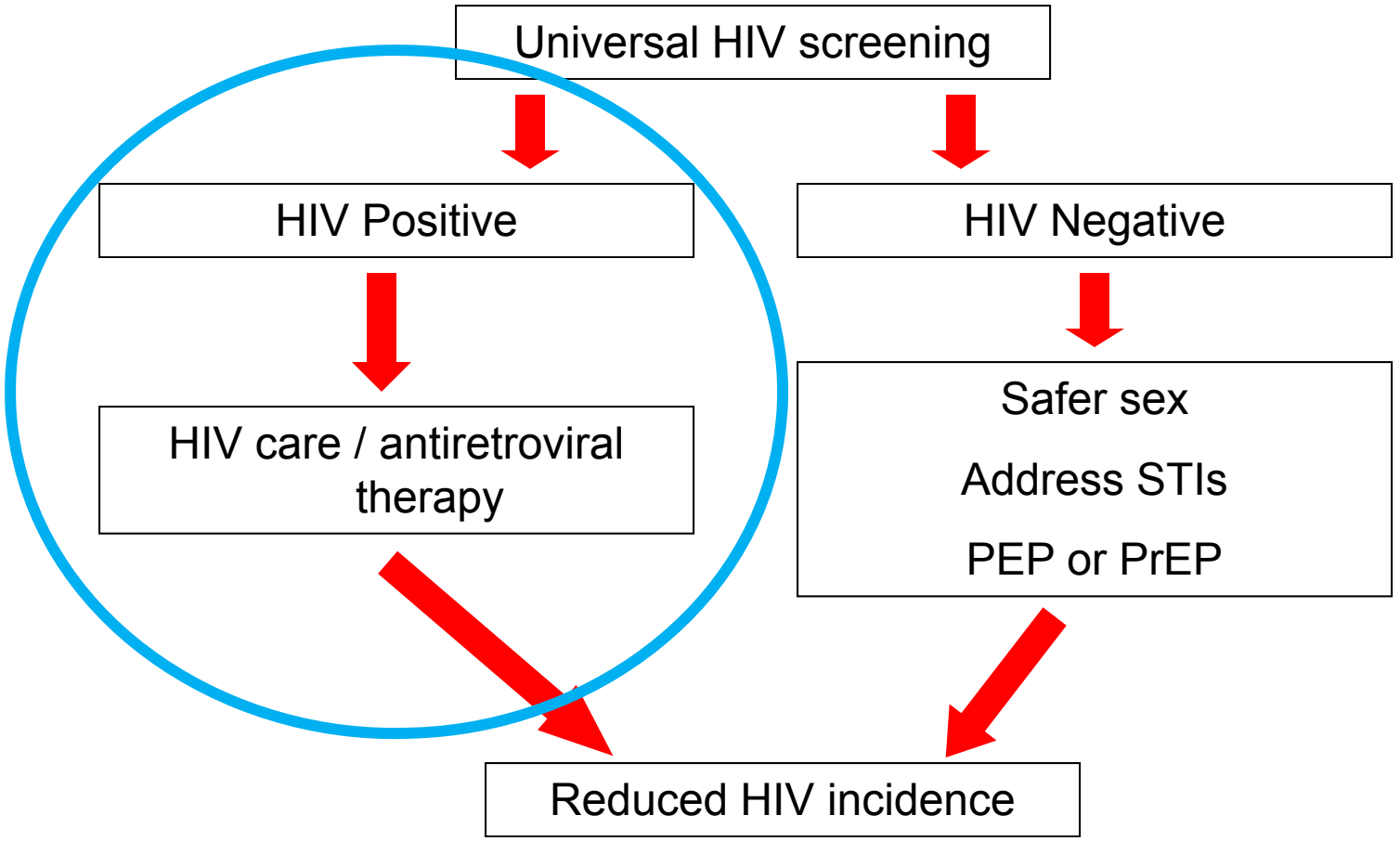
- Routine HIV testing is as cost-effective as mammography for women ages 50-69.

- Cost-effectiveness improves with better linkage of HIV-infected individuals to care.

Questions

- Is he HIV-infected at baseline?
  → **No**
- How should his recent, high risk exposure be managed?
- How should his long-term risk of HIV infection be managed?

HIV Prevention Pathway



Early antiretroviral therapy decreases HIV transmission

1763 stable, healthy, serodiscordant couples, sexually active
CD4 count: 350 to 550 cells/mm^3

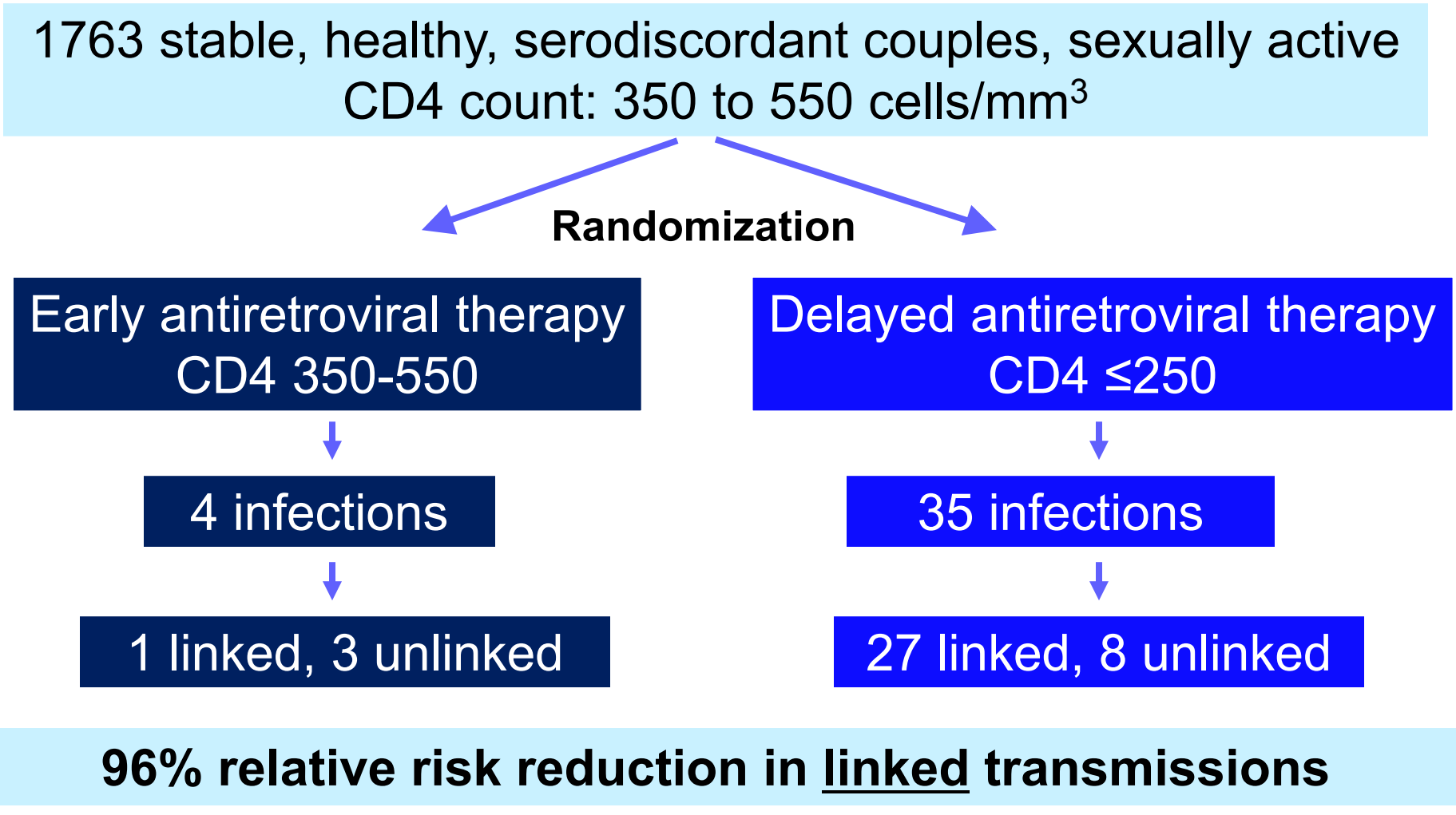
Randomization

Early antiretroviral therapy CD4 350-550	Delayed antiretroviral therapy CD4 ≤250

Cohen, 2011

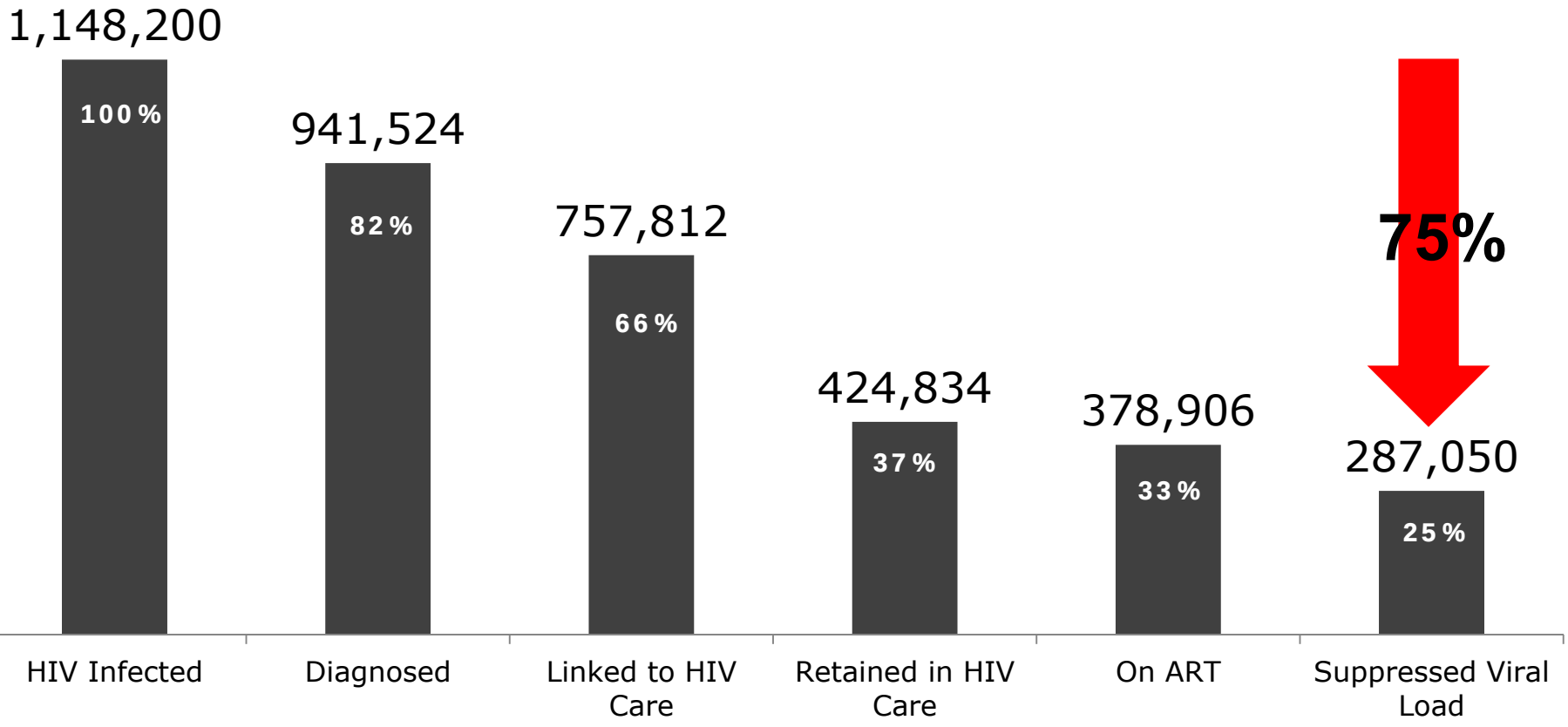
Courtesy of Doug Krakower, Ken Mayer

Early antiretroviral therapy decreases HIV transmission



96% relative risk reduction in linked transmissions

Lapses in care limit the impact of "treatment as prevention"



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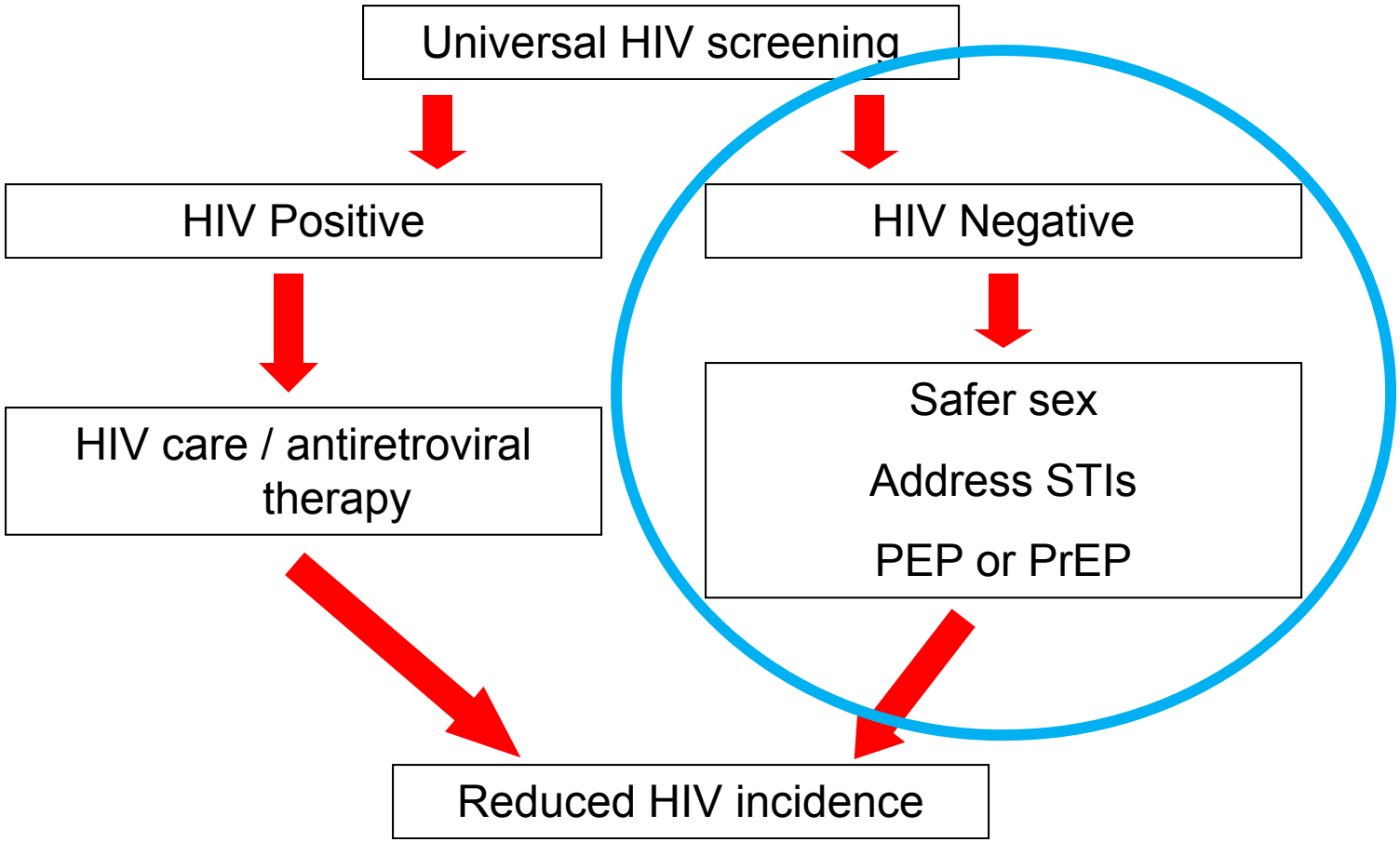
Adapted from CDC, "HIV in the US-The Stages of Care" July 2012

HIV Prevention Pathway



Post-Exposure Prophylaxis (PEP)

- Indicated for high-risk exposures to HIV-infected individuals
- Consists of 28 days of antiretrovirals (usually tenofovir-emtricitabine +/- others, often raltegravir)
- Earlier initiation = better efficacy (likely not useful after 72 hours)
- HIV testing at baseline, 1, and 3 months

Questions

- Is he HIV-infected at baseline?
  → **No**
- How should his recent, high risk exposure be managed?
  → **PEP (and partner's ART may help)**
- How should his long-term risk of HIV infection be managed?

Pre-Exposure Prophylaxis (PrEP)

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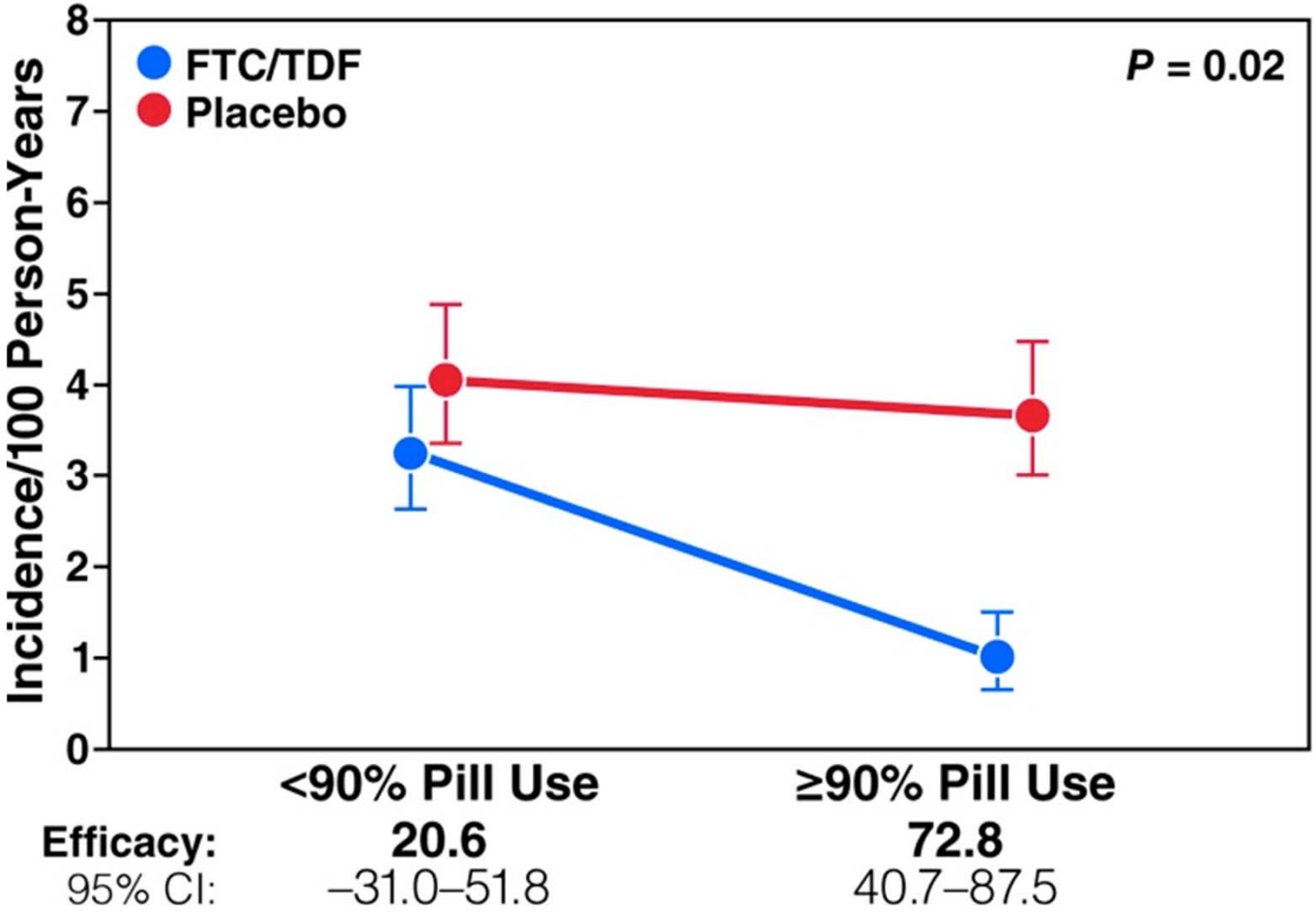
PrEP works (but adherence is vital)

Trial	Agent	Population	Risk Reduction
iPrEx	TDF-FTC†	MSM, transgender women	44%
TDF2-CDC	TDF-FTC	Heterosexual men and women	62.2%
Partners PrEP	TDF, TDF-FTC	Heterosexual couples	75% TDF-FTC, 67% TDF
FEM-PrEP	TDF-FTC	Women	---
VOICE	TDF-FTC	Women	---

(†TDF-FTC = tenofovir-emtricitabine)

Adapted from van der Straten, 2012

Better adherence = better efficacy



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Courtesy of Doug Krakower

Is PrEP Safe?

- No major safety concerns in PrEP trials
- Nausea more common with TDF-FTC than placebo
- No difference in creatinine elevations or bone fractures (potential TDF toxicities)
- No "risk compensation"

“The PrEP Package”

INTRODUCING THE “PrEP PACKAGE” FOR ENHANCED HIV PREVENTION:

A Practical Guide for Clinicians

October, 2012

THE FENWAY INSTITUTE

PROTECTING YOURSELF FROM HIV THROUGH PRE-EXPOSURE PROPHYLAXIS (PrEP):

What You Need to Know

October, 2012

THE FENWAY INSTITUTE

CDC Interim Guidance on HIV Pre-Exposure Prophylaxis for Men Who Have Sex with Men

- **Determine eligibility:**
  - Document a negative HIV test
  - Confirm high risk of infection
  - Check that the creatinine clearance is ≥ 60 mL/minute

- **Other steps:**
  - Check a pregnancy test
  - Check for chronic hepatitis B infection

CDC, 2012

CDC Interim Guidance on HIV Pre-Exposure Prophylaxis for Men Who Have Sex with Men

- **Prescribe:** TDF-FTC, 1 tablet by mouth daily

- **While on PrEP:**
  - Check an HIV test, pregnancy test, and creatinine every 2-3 months*
  - Assess for STIs at least every 6 months
  - Counsel regarding risk reduction and adherence; provide condoms

*Initially, then creatinine can be checked every 6 months

CDC, 2012

Questions

- Is he HIV-infected at baseline?

  → **No**

- How should his recent, high risk exposure be managed?

  → **PEP (and partner's ART may help)**

- How should his long-term risk of HIV infection be managed?

  → **PrEP + condoms + safer sex + STI treatment**

Audience Polling Question

What concerns do you have about prescribing PrEP to high-risk patients?

a) Medication adherence
b) Increased risk behavior
c) Cost
d) Something else
e) I don't have concerns

Questions and Controversies

- What is the "lower limit" of adherence?
- What level of risk warrants PrEP?
- Who should prescribe it?

Audience Polling Question

What concerns do you have about prescribing PrEP to high-risk patients?

a) Medication adherence
b) Increased risk behavior
c) Cost
d) Something else
e) I don't have concerns

PEP and PrEP

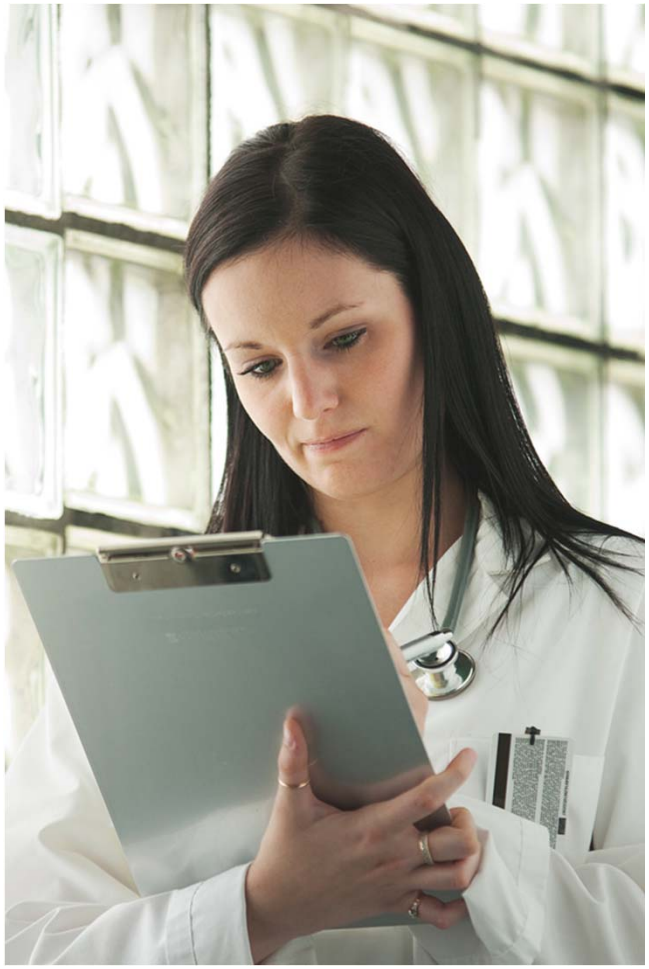
Post-Exposure Prophylaxis (PEP)	Pre-Exposure Prophylaxis (PrEP)
For a past exposure	For future exposures
Episodic	Continuous
Defined, 28-day course	Individualized duration of use
Often 3 drugs	2 drugs (1 pill)
Involves lab monitoring, follow-up	Involves lab monitoring, follow-up
No major safety concerns	No major safety concerns
Small evidence base	Large evidence base
Significant clinical experience	Limited clinical experience

Key Points about Bio-behavioral Interventions

- Adherence is crucial
- Do not replace condoms, safer sex counseling, STI treatment
- Ensuring access for high-risk (often vulnerable) populations is key

Characteristics of Patient-Centered Medical Homes

- Comprehensive Care
- Patient-Centered
- Coordinated Care
- Accessible Services
- Quality and Safety



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Agency for Healthcare Research and Quality

HIV Prevention in Patient-Centered Medical Homes

- ❑ Comprehensive Care
  - Testing, counseling, linkage to care, treatment, and PrEP at the same health center
  - Linking behavioral and biomedical care
- ❑ Patient-Centered
  - Addressing stigma and homophobia in healthcare
  - Understanding the social determinants of health
- ❑ Coordinated Care
  - Case management to ensure linkage to/retention in care for those with HIV
  - Linkage of high-risk individuals to the PrEP package
- ❑ Quality and Safety
  - Collecting information on SO/GI in the EMR
  - Electronic decision support for HIV testing

Summary

- HIV disproportionately affects MSM and transgender individuals.
- HIV testing is the cornerstone of most prevention interventions.
- Treatment-as-prevention, PEP, and PrEP are powerful bio-behavioral tools to decrease HIV incidence.
- PCMHs offer opportunities to create and improve HIV prevention programs.