



INCLUSIVE HIV PREVENTION & SEXUAL HEALTH: ADDRESSING THE NEEDS OF OLDER ADULTS IN CLINICAL TRIALS AND PRACTICE

DECEMBER 13, 2024

9:00-10:15AM PST/12-1:15PM EST

speakers



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NETWORK COORDINATION ON BEHALF OF THE DIVISION OF
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INCLUSIVE HIV PREVENTION & SEXUAL HEALTH: ADDRESSING THE NEEDS OF OLDER ADULTS IN CLINICAL TRIALS AND PRACTICE

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Aging, HIV Prevention, Sexual Health

Jeffrey Kwong, DNP, MPH, AGPCNP-BC, FAANP, FAAN

Professor, Rutgers University – Newark, NJ

Nurse Practitioner, NYU Langone Medical Associates – New York, NY

In the U.S., the number of adults 65 yrs and older is projected to increase **47% by 2050**

- 58 million in → 82 million



Older Adults Are Vulnerable to HIV

- **Between 2013-2023, among adults 65 yrs +:**
 - Primary and secondary syphilis increased **> 6x**
 - Gonorrhea increased **~4 x**
 - Chlamydia increased **~3x**
- More than 11% of respondents of the 2021 National Survey on Drug Use and Mental Health age 50 yrs + reported substance use including heroin, methamphetamine, cocaine

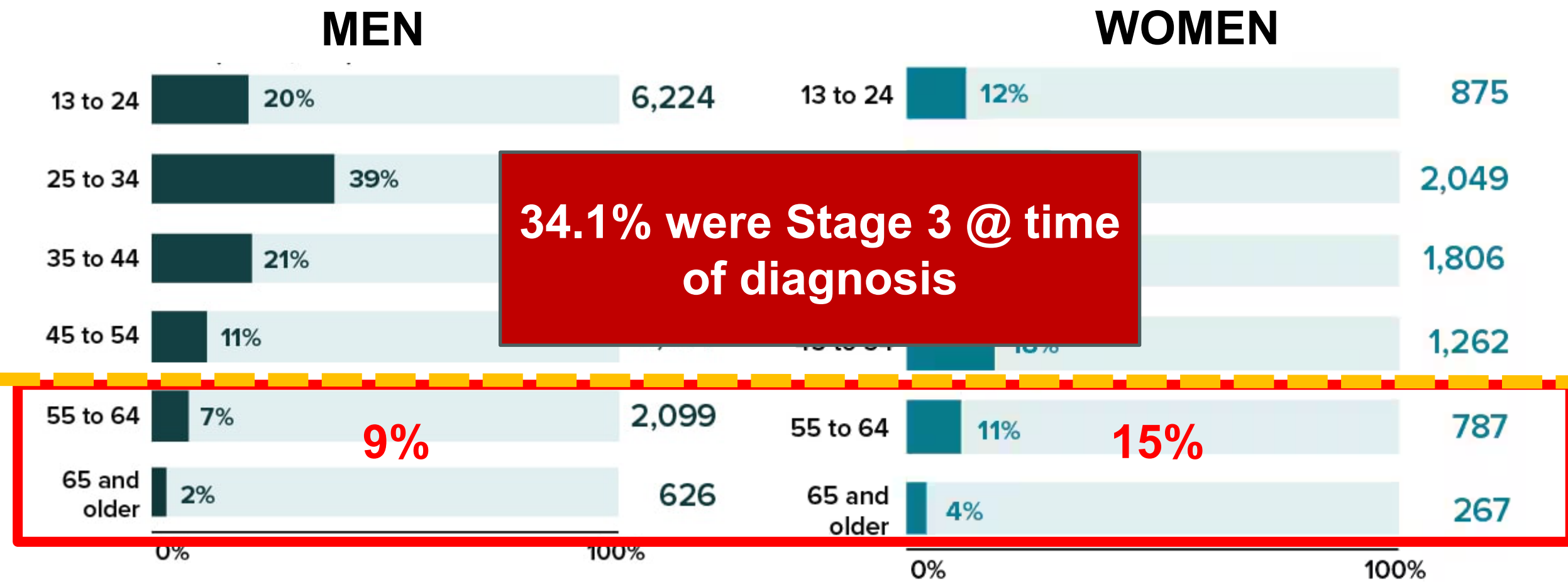
3 to 4 People Acquire HIV Every Hour in the US

In 2022, there were an estimated **31,800** new HIV cases

Estimated 1.2 million people living with HIV in the US

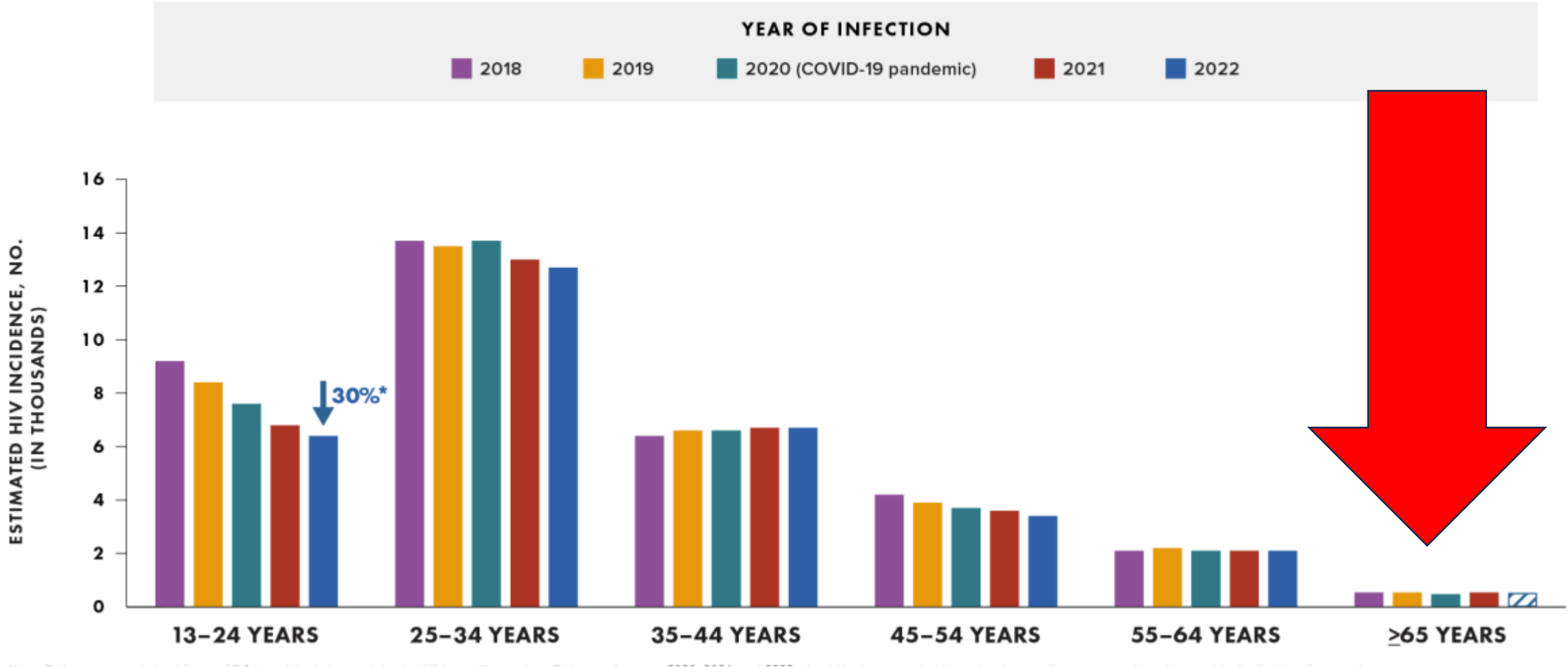


HIV Diagnosis (2022)



CDC. [Diagnoses of HIV infection in the United States and dependent areas, 2022](#). HIV Surveillance Report 2024; 29(1)

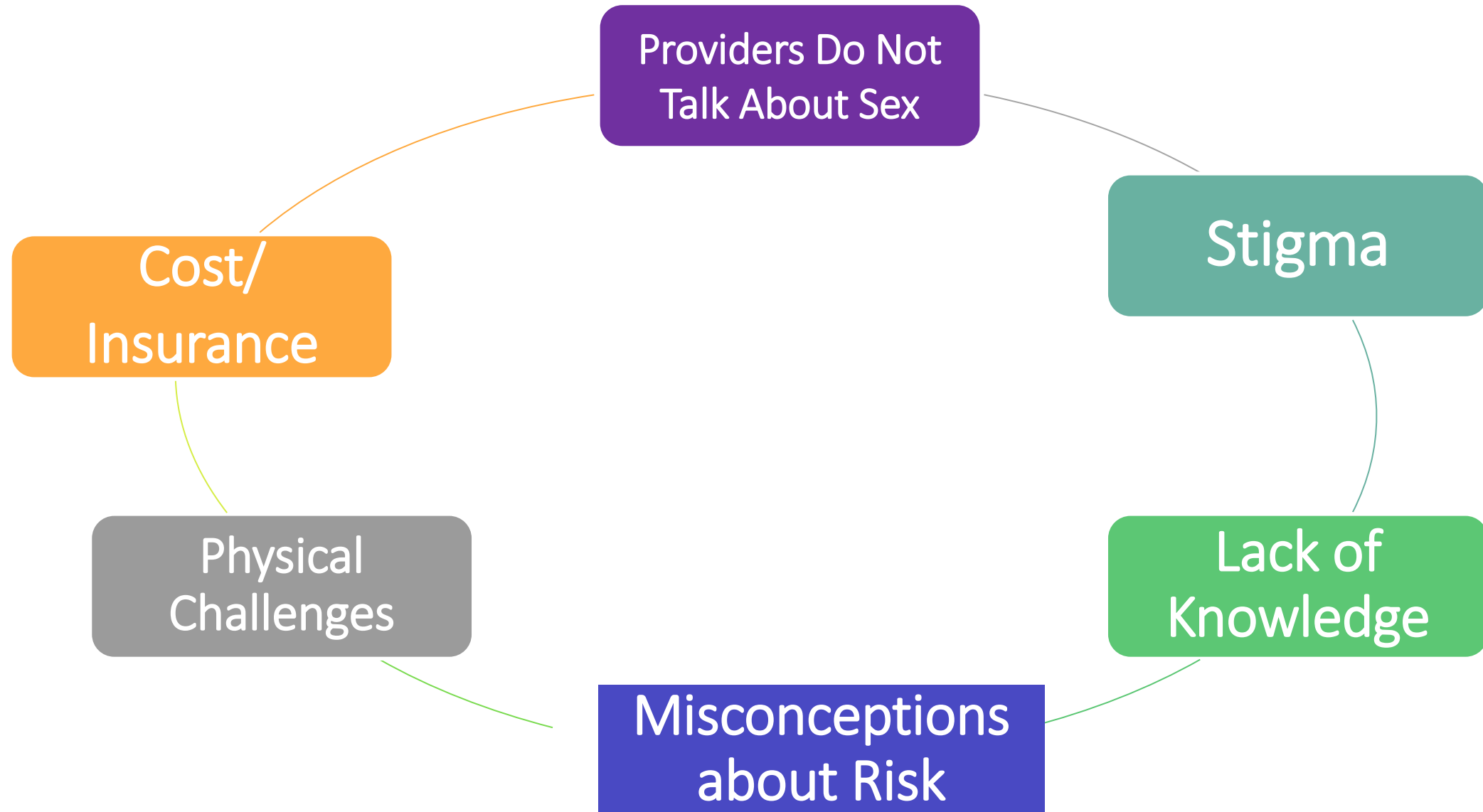
Figure 3. Estimated HIV incidence among persons aged ≥13 years, by age at infection, 2018–2022—United States



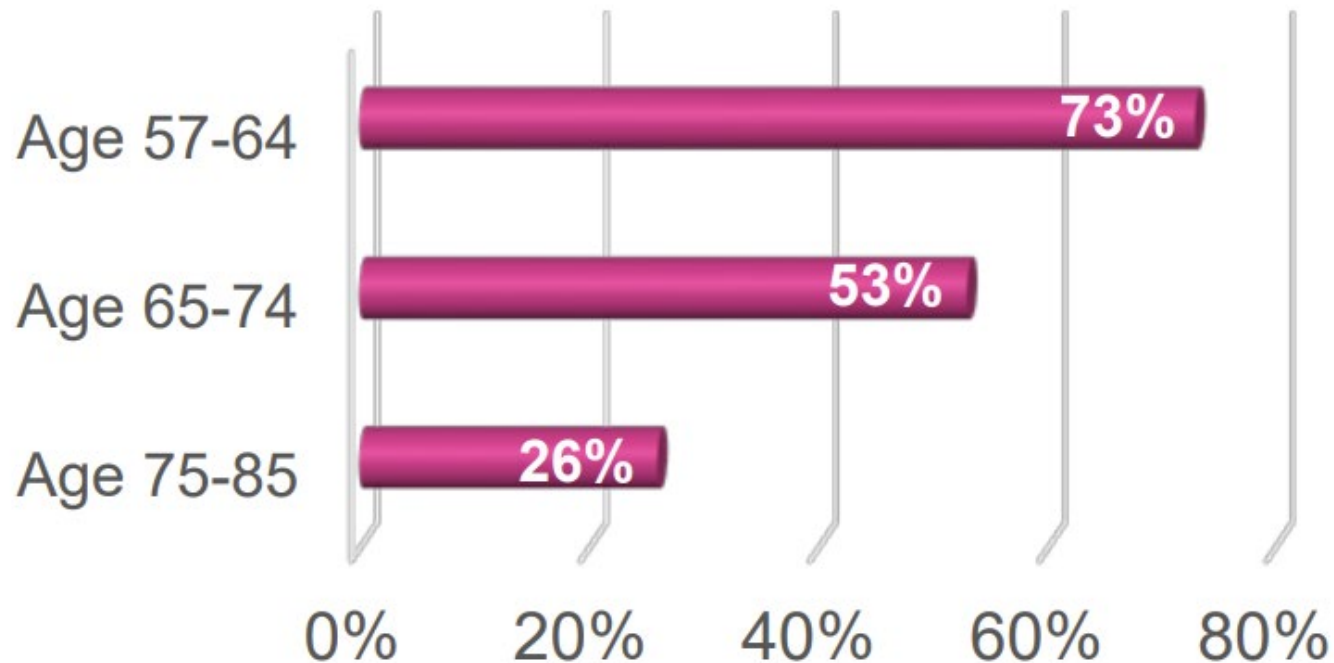
Centers for Disease Control and Prevention. Estimated HIV incidence and prevalence in the United States, 2018–2022. HIV Surveillance Supplemental Report 2024;29(No. 1). <https://www.cdc.gov/hiv-data/nhss/estimated-hiv-incidence-and-prevalence.html>. Published May 2024. Accessed December 10, 2024



Barriers to HIV Prevention in Older Adults



Sexually Active Adults by Age



In a US study of people **aged 75–85 yrs** who were sexually active, **54%** reported having sex **2-3 x/month** and **23%** reported having sex **1+ x/week**

www.norc.org/Research/Projects/Pages/national-social-life-health-and-aging-project.aspx.

Lindau ST, et al. A study of sexuality and health among older adults in the United States. *N Engl J Med*. 2007;357(8):762-774.
doi:10.1056/NEJMoa067423



Image: creative commons

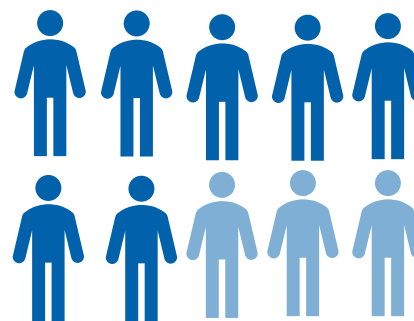
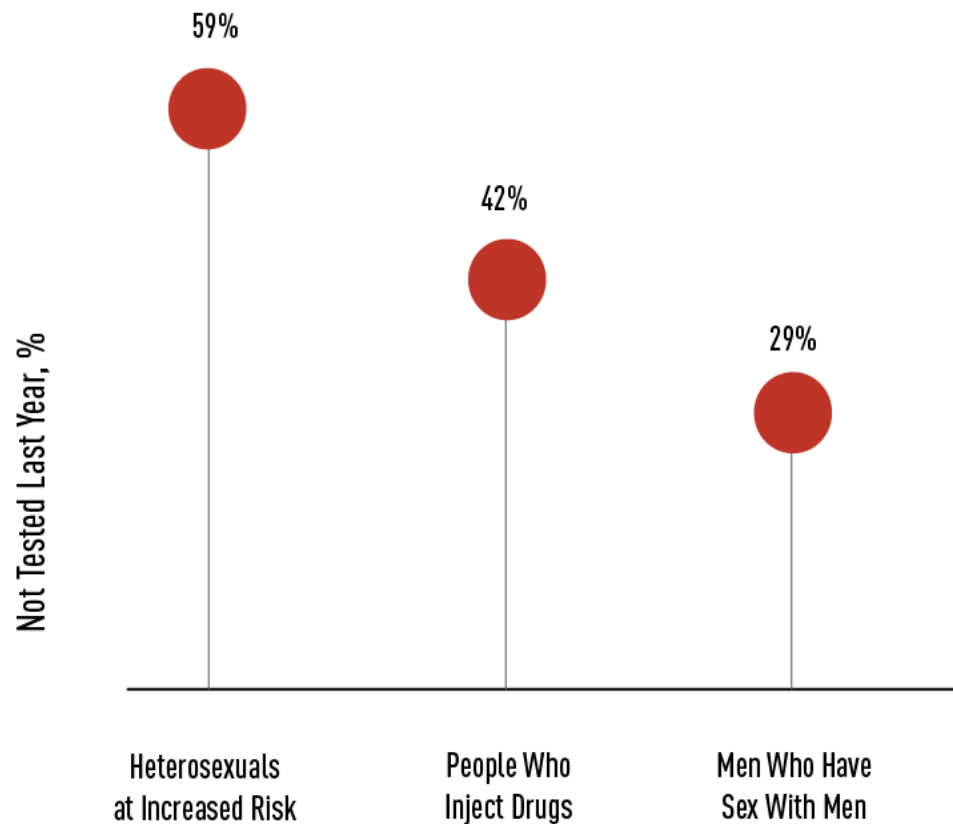
17% of older adults (65-80)
talked about sex with a
health care provider

However, 60% of older
adults said **they had to**
initiate the conversation

CDC Recommendations For Routine Screening

Infection	Recommendation	Last Update
HIV	<ul style="list-style-type: none">• 13-64 yrs• Vulnerability factors	2006 **
Hepatitis B	<ul style="list-style-type: none">• Universal screening 18 yrs and older• Vulnerability factors• Anyone who asks for test	2023
Hepatitis C	<ul style="list-style-type: none">• Universal screening \geq 18 yrs• Recognized Exposure• Ongoing vulnerability• Anyone who asks for test	2020

Missed Opportunities for HIV Testing

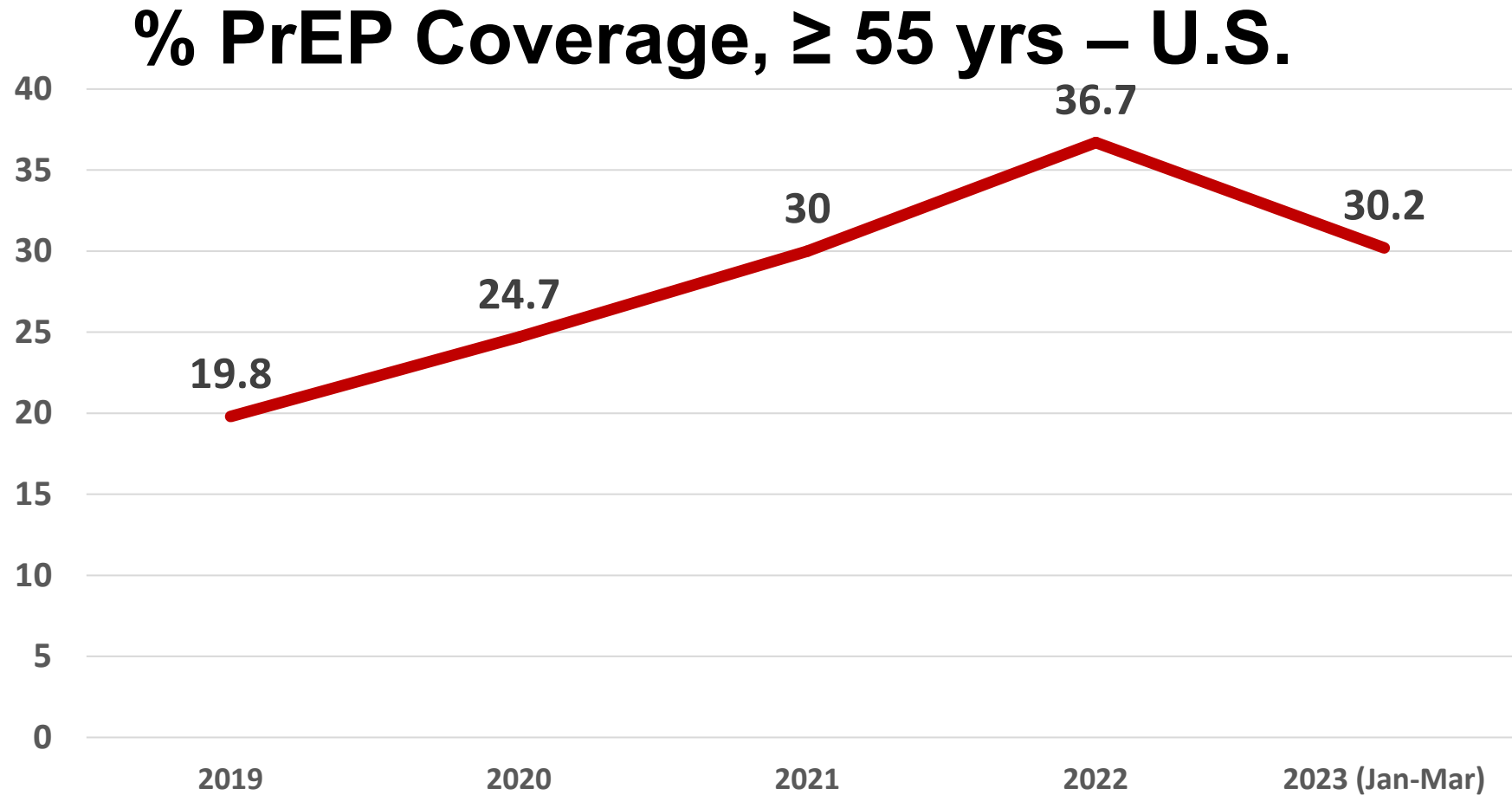


7 out of 10 people who were vulnerable to HIV who were **not tested** for HIV in the past year **saw a primary care provider** during that period

75%

of the people who saw their primary care provider were **not offered a test**

More older adults are being prescribed PrEP in the U.S.

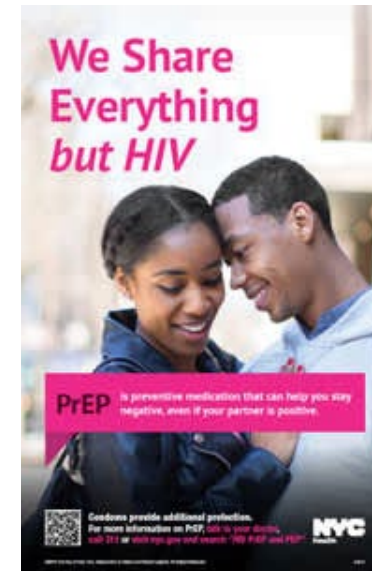
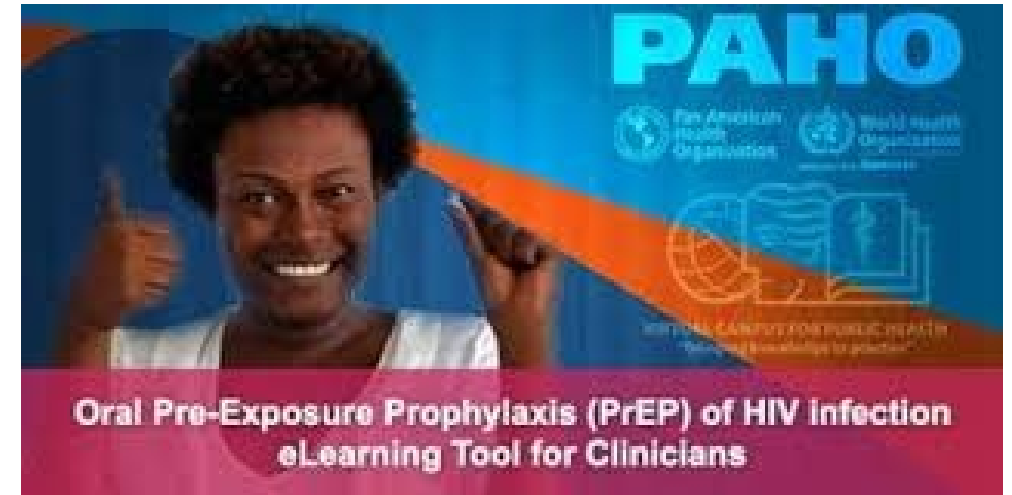




Is there enough data?

Trial Name	Age Information
iPREX (TDF/FTC v Placebo) - MSM/TGW	11% ≥ 40 yrs old = TDF/FTC
iPreXOLE (TDF/FTC)- MSM/TGW	17% ≥ 40 yrs old = TDF/FTC
DISCOVER (TAF/FTC vs TDF/FTC) - MSM/TGW	Max Age: TAF/FTC = 43 y TDF/FTC = 44 yrs
Partners PrEP (TDF vs TDF/FTC vs Placebo) - heterosexual men and women	14% ≥ 45 yrs old = TDF/FTC 13% ≥ 45 yrs old = TDF
IPERGAY (TDF/FTC vs placebo) - MSM	10% ≥ 50 yrs = TDF/FTC
HPTN 083 (CAB vs TDF/FTC) - MSM/TGW	> 60 yrs CAB (0.3%) CAB /TDF/FTC (0.3%) 50-59 yrs CAB (2.6%) and TDF/FTC (2.2%)
HPTN 084 (CAB vs TDF/FTC) - cisgender women	upper age 45 yrs

Is PrEP right for me?



Key Points

- Healthcare teams caring for older adults must take into account **physiologic, psychosocial, and cultural** aspects of aging when providing care.
- **Normalizing conversations** about sexual health and substance use should be a part of **routine care** for older adults.
- **HIV Treatment and Prevention Services** are **not** bound by age.
- **Interventions, research efforts, and policies** must be inclusive and take into consideration needs of older adults

Key Resources and References

Let's Stop HIV Together

<https://www.cdc.gov/stophivtogether/index.html>

HIV Nexus

<https://www.cdc.gov/hiv/clinicians/index.html>

HealthinAging.org

<https://www.healthinaging.org/a-z-topic/sexual-health>

National Coalition for Sexual Health

<https://nationalcoalitionforsexualhealth.org/>

Substance Abuse and Mental Health Administration – Resources for Older Adults

<https://www.samhsa.gov/resources-serving-older-adults>

HPTN 083: Lessons Learned for Older Adults

Raphael J. Landovitz, MD MSc

Professor of Medicine

Interim Chief, Division of Infectious Diseases

Director, UCLA Center for Clinical AIDS Research & Education

David Geffen School of Medicine at UCLA

Importance of HIV Prevention for Adults 50+ Webinar

13 December 2024

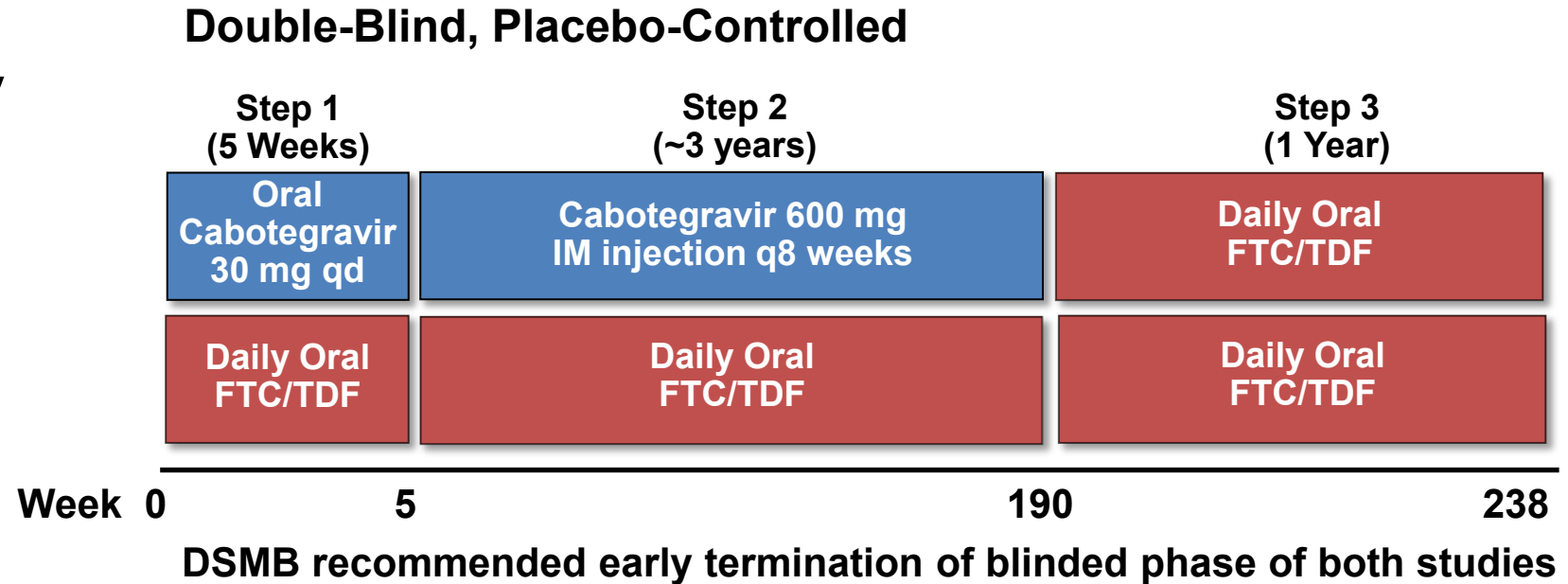
Disclosures

Raphael J. Landovitz reports consulting agreements and/or Scientific Advisory roles for Gilead Sciences, Merck Inc, RedQueen Therapeutics, and ViiV Healthcare (Financial Interest)

HPTN 083

Long-acting injectable cabotegravir for PrEP

- Phase 3 study
- Double-blind, safety and efficacy study for persons at high-risk for HIV infection in general good health
- No IDU, HCV, HBV, seizure disorder, CVD, abnormal liver function
- MSM/transgender women
- Median age: 26 (22 – 32)
 - 123 (2.7%) participants were age 50+



Matching oral and IM placebos included in the oral and injection phase double-blind arms.
Conducted in US, Brazil, Peru, Argentina, South Africa, Vietnam, and Thailand.

HPTN 083: Bone Mineral Density

CAB-LA versus TDF-FTC PrEP

BACKGROUND

- **HIV PrEP:** Highly effective for HIV prevention
 - TDF-FTC Oral PrEP: Effective but limited by adherence; may impact bone mineral density (BMD) with long-term use
 - CAB-LA (HPTN 083): Found superior to TDF-FTC for HIV prevention, but relative bone safety remains unclear

METHODS

- **Bone Substudy:** Conducted at 19 sites to assess BMD at lumbar spine, femoral neck, and total hip using DXA scans.
- **Analysis:** Percentage BMD changes compared between arms; models adjusted for age and race differences.

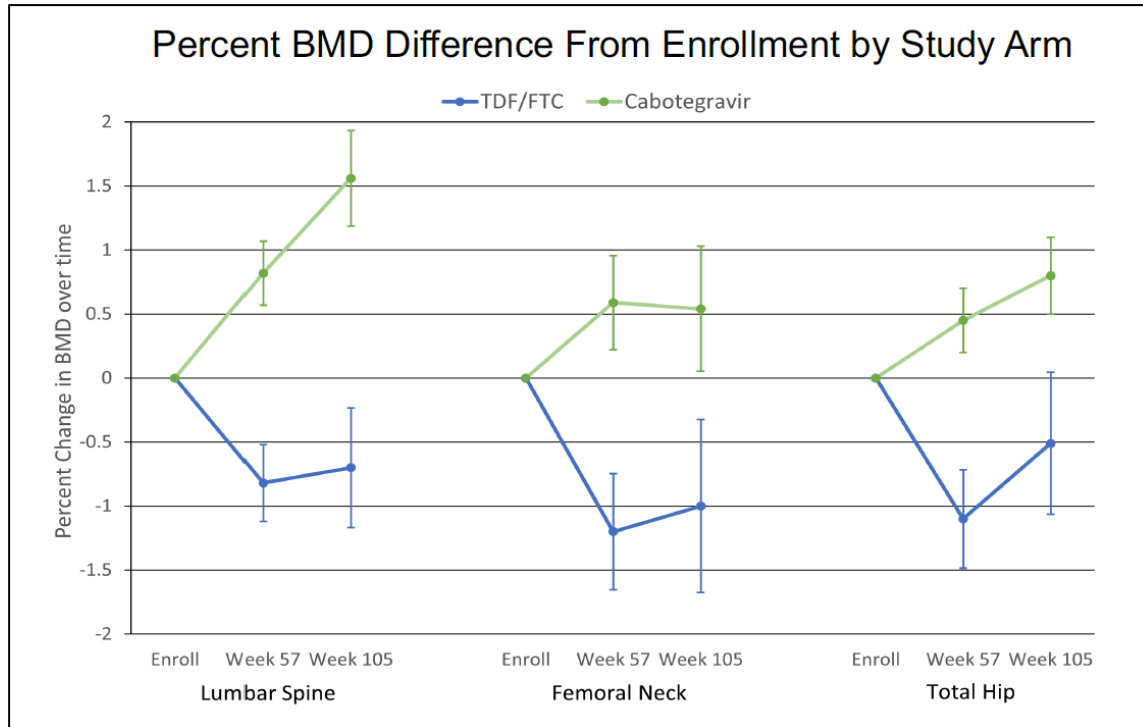
Table 1. Baseline Characteristics

	TDF/FTC	CAB-LA
Median (Q1, Q3) or %	(N=122)	(N=132)
Age (years)	29.0 (23.0, 41.0)	26.0 (22.0, 31.0)
Race		
ASIAN	15%	9%
BLACK	25%	36%
OTHER	13%	7%
WHITE	47%	48%
Transgender Women	8%	11%

8% of participants were 50 years or older

HPTN 083: Bone Mineral Density

CAB-LA versus TDF-FTC PrEP



- BMD **decreased** in the TDF-FTC arm by 0.5-1.0%
- BMD **increased** in CAB-LA arm 0.5-1.5%

Conclusions

Individuals at higher fracture risk (e.g., older age, lower BMD, osteoporosis) considering PrEP may opt for CAB-LA to support bone health.

HPTN 083: Hypertension

CAB-LA versus TDF-FTC PrEP

BACKGROUND

- Studies (e.g., 2SD, D2EFT, ADVANCE, NAMSAL) suggest INSTIs, particularly DTG, may increase hypertension (HTN) risk compared to NNRTIs, independent of weight/BMI changes; other trials (e.g., NEAT022, RESPOND) show no difference versus PIs.
- HPTN 083 Post-hoc analysis compared HTN incidence rates between CAB and TDF-FTC arms

METHODS

- HTN Definition: Two consecutive BP readings (SBP ≥ 140 mmHg or DBP ≥ 90 mmHg), new HTN diagnosis, or initiation of HTN medications.
- Analysis: Cox regression for HTN risk (CAB vs. TDF-FTC), adjusting for demographics, weight changes, and anti-HTN medication use
- Sensitivity Analyses: Censored at DSMB action and excluded participants on anti-HTN meds for other purposes

Table 1: Baseline Characteristics of Analysis Population

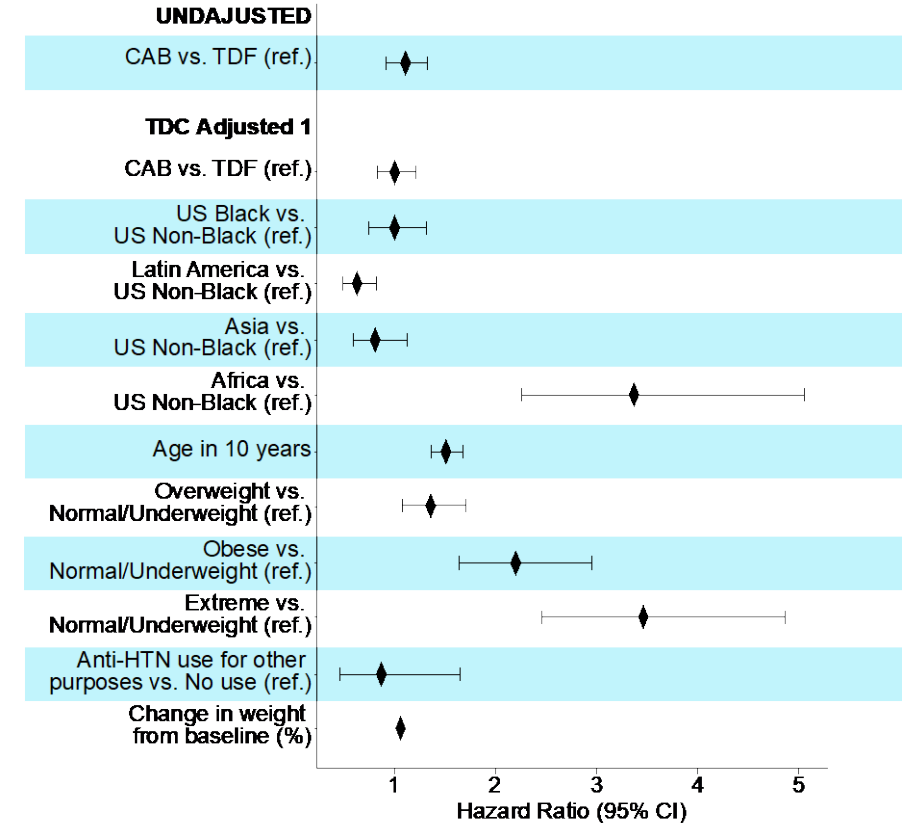
	CAB (n=1993)	TDF/FTC (n=1978)	Total (n=3971)
REGION			
United States	702 (35%)	675 (34%)	1377 (35%)
Latin America (LA)	873 (44%)	884 (45%)	1757 (44%)
Asia (AS)	360 (18%)	354 (18%)	714 (18%)
Africa (AF)	58 (3%)	65 (3%)	123 (3%)
GENDER IDENTITY			
Male	1728 (87%)	1694 (86%)	3422 (86%)
AGE (YEARS)			
Median (Q1, Q3)	26 (22, 30)	26 (22, 31)	26 (22, 31)
WEIGHT (KG)			
Median (Q1, Q3)	71.7 (63.0, 83.0)	71.3 (62.5, 82.5)	71.5 (62.8, 82.7)
BMI (KG/M²)			
Median (Q1, Q3)	24.0 (21.5, 27.4)	24.0 (21.5, 27.1)	24.0 (21.5, 27.2)
OTHER USE OF ANTI-HTNs			
Yes	35 (2%)	53 (2%)	88 (2%)

- The mean age of the participants was 27 years, with 75% aged 45 years and older
- Participants with pre-existing HTN were 8 years older on average than those without
- 20% with pre-existing HTN were over the age of 45 compared to 4% among those without pre-existing HTN

HPTN 083: Hypertension

CAB-LA versus TDF-FTC PrEP

	CAB	TDF/FTC
Incident HTN	237 (12%)	213 (11%)
Confirmed Elevated DBP	26 (1%)	24 (1%)
Confirmed Elevated SBP	30 (2%)	25 (1%)
Initiation of New Anti-HTN med	7 (0%)	2 (0%)
Diagnosis of Hypertension	174 (9%)	162 (8%)
Severity Grade 1	161 (93%)	153 (94%)
Severity Grade 2	13 (7%)	9 (6%)

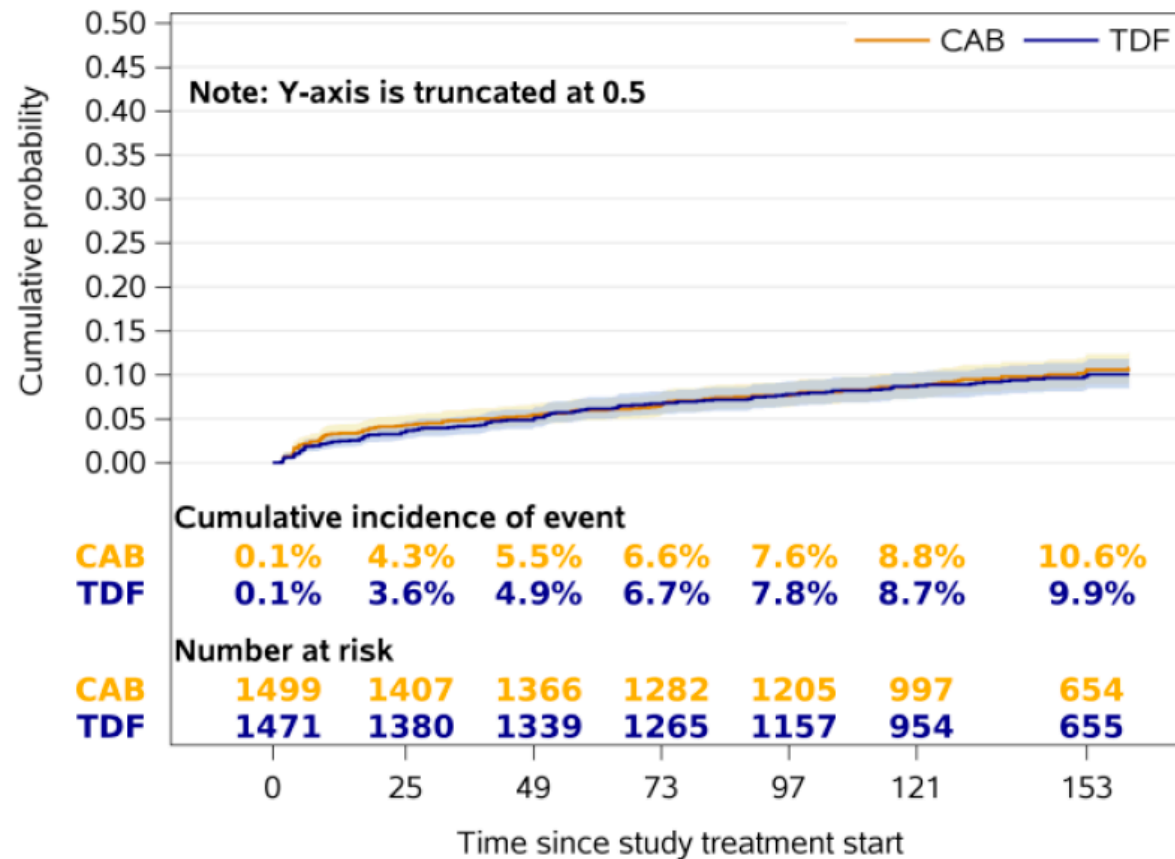


HPTN 083: Hypertension

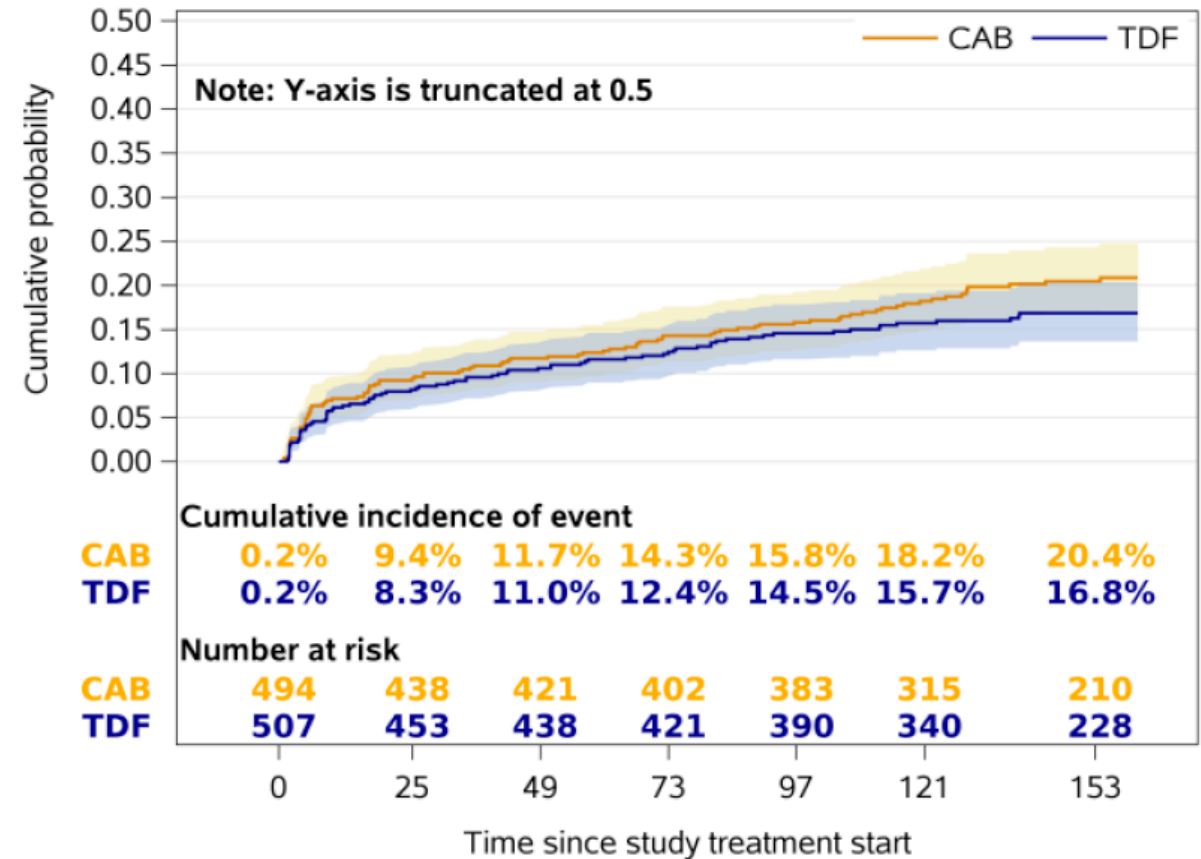
CAB-LA versus TDF-FTC PrEP

Figure 4.4: Cumulative Incidence of First Hypertension Event by Baseline Age Group

(a) Ages ≤ 30 Years



(b) Ages >30 Years



HPTN 083: STIs and Efficacy

BACKGROUND

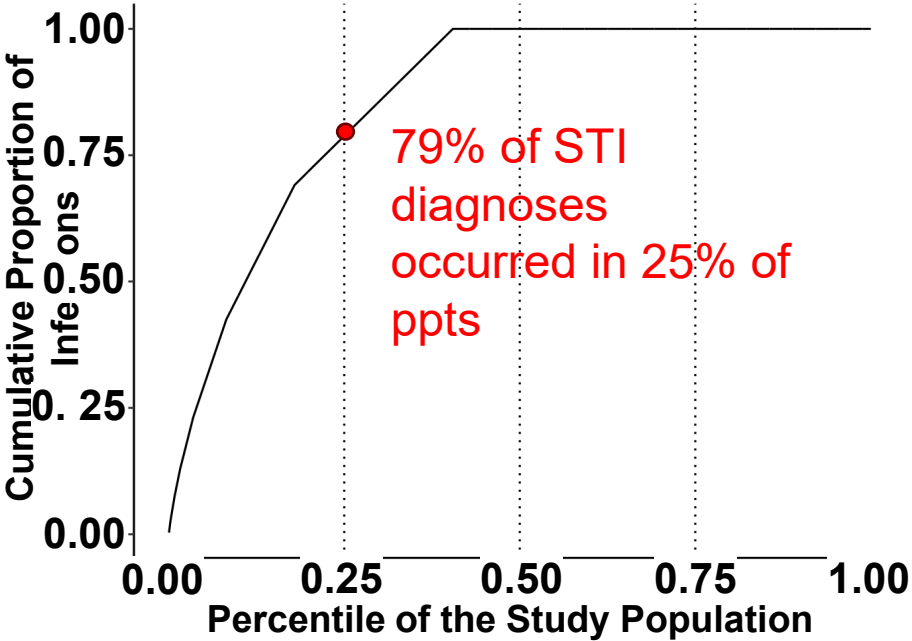
- Bacterial STIs facilitate HIV transmission by lowering barriers to infection through mucosal inflammation and genital ulcers.
- Evaluating the impact of STIs on PrEP efficacy is crucial.
- Previous studies show STIs do not reduce protection provided by TDF/FTC.
- CAB-LA has not been evaluated for similar effects.
- Secondary analysis of HPTN 083 blinded period.

METHODS

- STI Testing: Serologic tests for syphilis; NAAT for rectal/urethral gonorrhea and chlamydia every 6 months or with symptoms/exposures.
- Incidence: Incident STI rates per 100 person-years calculated from enrollment to final STI test.
- Analysis:
 - Poisson regression assessed baseline factors associated with STI incidence.
 - Cox proportional hazards modeling with STI status as a time-varying covariate

HPTN 083: STIs and Efficacy

Among 3859 participants, STIs were diagnosed in 1562 (40.5%), with multiple STIs reported for 691 (17.9%)



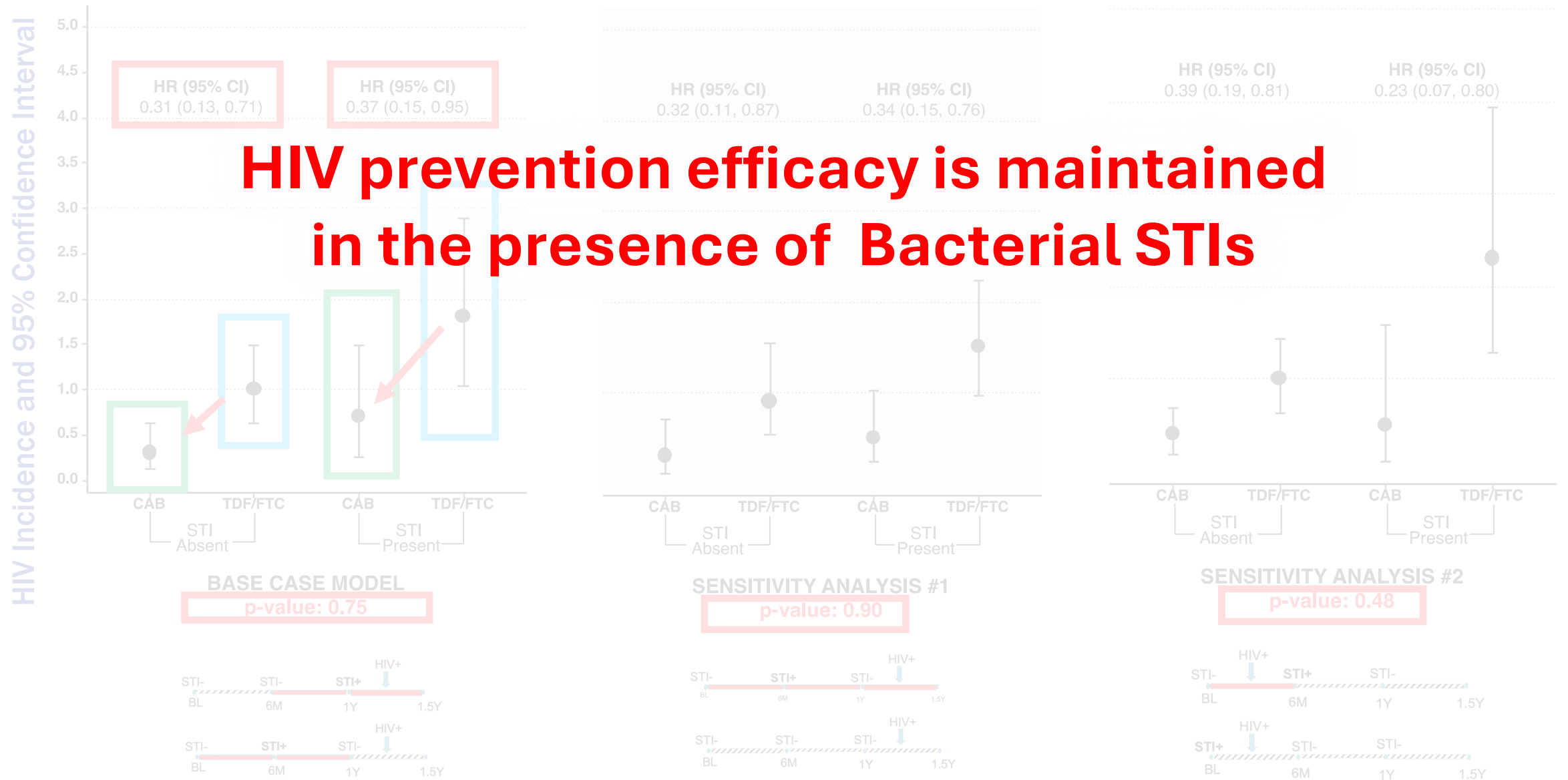
	# Positive Tests	IR (per 100 PY)
Any STI	2819	50.7
Syphilis	923	16.7
Urogenital Gonorrhea	134	2.4
Urogenital Chlamydia	249	4.5
Rectal Gonorrhea	600	11.0
Rectal Chlamydia	913	16.7

HPTN 083: STIs and Efficacy

- Univariate Model:** Age was significantly associated with STI incidence at the alpha = 0.10 level. This indicates that, when analyzed individually, age had a notable relationship with STI outcomes.
- Multivariable Model:** Age remained statistically significant ($p < 0.05$) when analyzed alongside other factors like region, education level, marital status, and baseline STI status. This highlights its independent influence on STI incidence, even after accounting for these variables.

	Univariate Model		Multivariate Model	
	<i>IRR (95% Confidence Interval)</i>	<i>p-value</i>	<i>IRR (95% Confidence Interval)</i>	<i>p-value</i>
Age				
18-29	Reference		Reference	
30-39	0.76 (0.69, 0.83)	<0.001	0.77 (0.70, 0.85)	<0.001
40-49	0.69 (0.59, 0.80)	<0.001	0.73 (0.63, 0.86)	<0.001
50-59	0.58 (0.45, 0.75)	<0.001	0.68 (0.53, 0.89)	0.004
60+	0.84 (0.43, 1.61)	0.59	0.83 (0.43, 1.60)	0.573

HPTN 083: STIs








HPTN 083: Performance characteristics of HIV RNA screening with CAB-LA PrEP

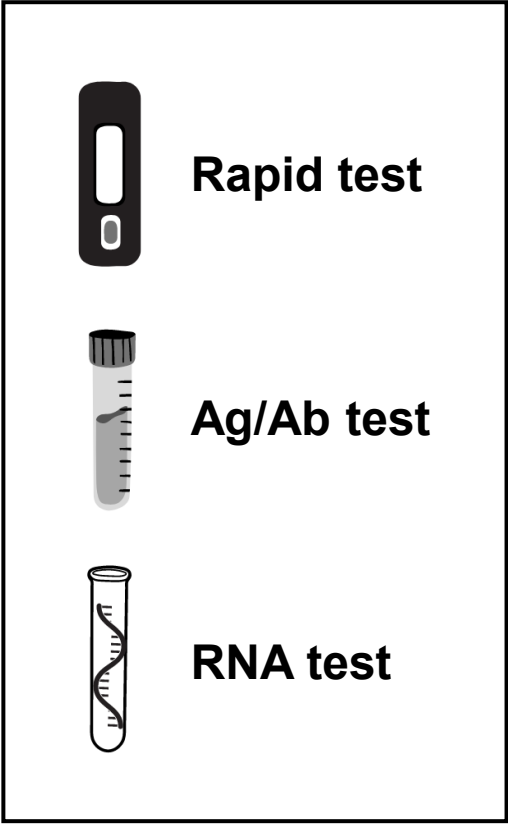
Study Design

Results

Population Characteristics

PPV of HIV Testing Algorithms with CAB-LA

HPTN 083			HPTN 084	
	TDF/FTC	CAB	TDF/FTC	CAB
	91%	84%	86%	40%
	95%	83%	100%	Insufficient data
and 	100%	100%	100%	100%
or 	80%	61%	62%	15%
	86%	66%	70%	17%
 < 6 months (on product)	N/A	9%	N/A	Data forthcoming
 > 6 months (initiation)	N/A	60%	N/A	Data forthcoming



Thank you!

Questions?
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HIV PREVENTION POLICY UPDATE

Terri L Wilder, MSW
twilder@sageusa.org
December 13, 2024



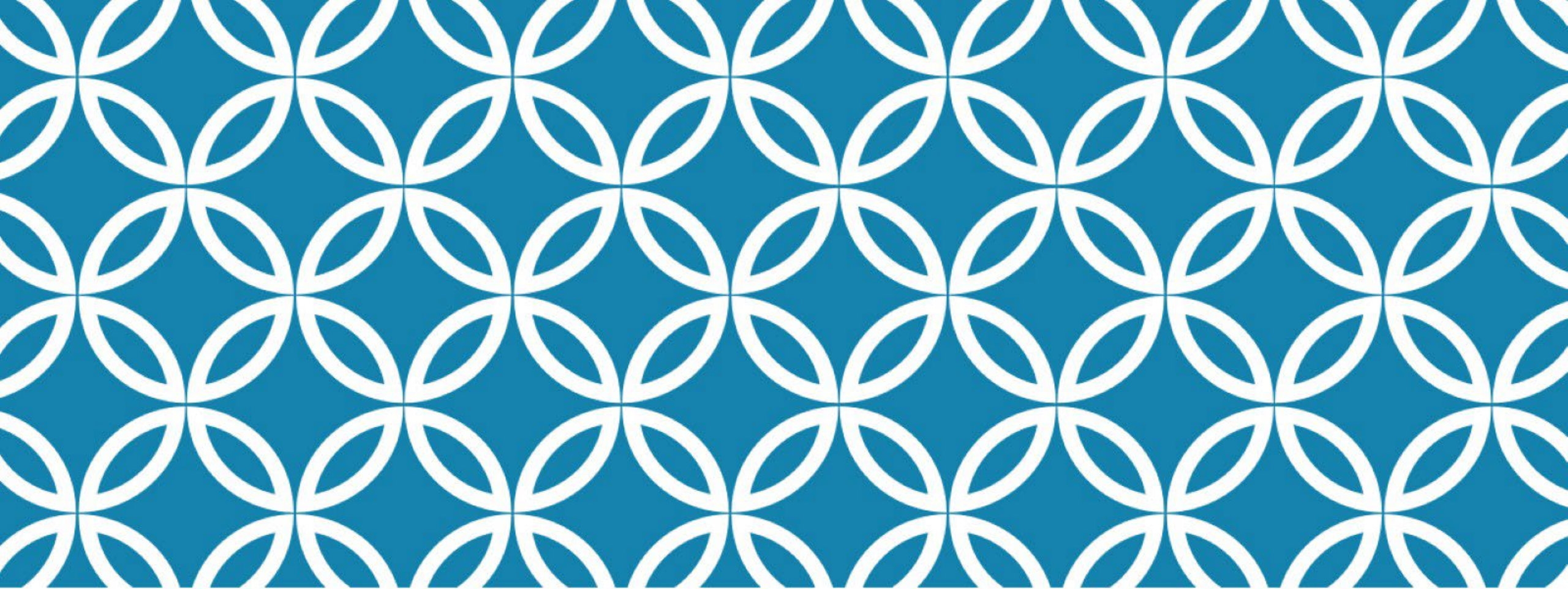
SAGE is the world's largest and oldest organization dedicated to improving the lives of LGBTQ+ elders.

Founded in 1978 and headquartered in New York City, SAGE is a national organization that offers supportive services and consumer resources to LGBTQ+ older people and their caregivers. SAGE also advocates for public policy changes that address the needs of LGBTQ+ elders, including people aging with HIV.

<https://www.sageusa.org/>

EXCITING POLICY NEWS!





MEDICARE AND PREP

Effective September 30, 2024

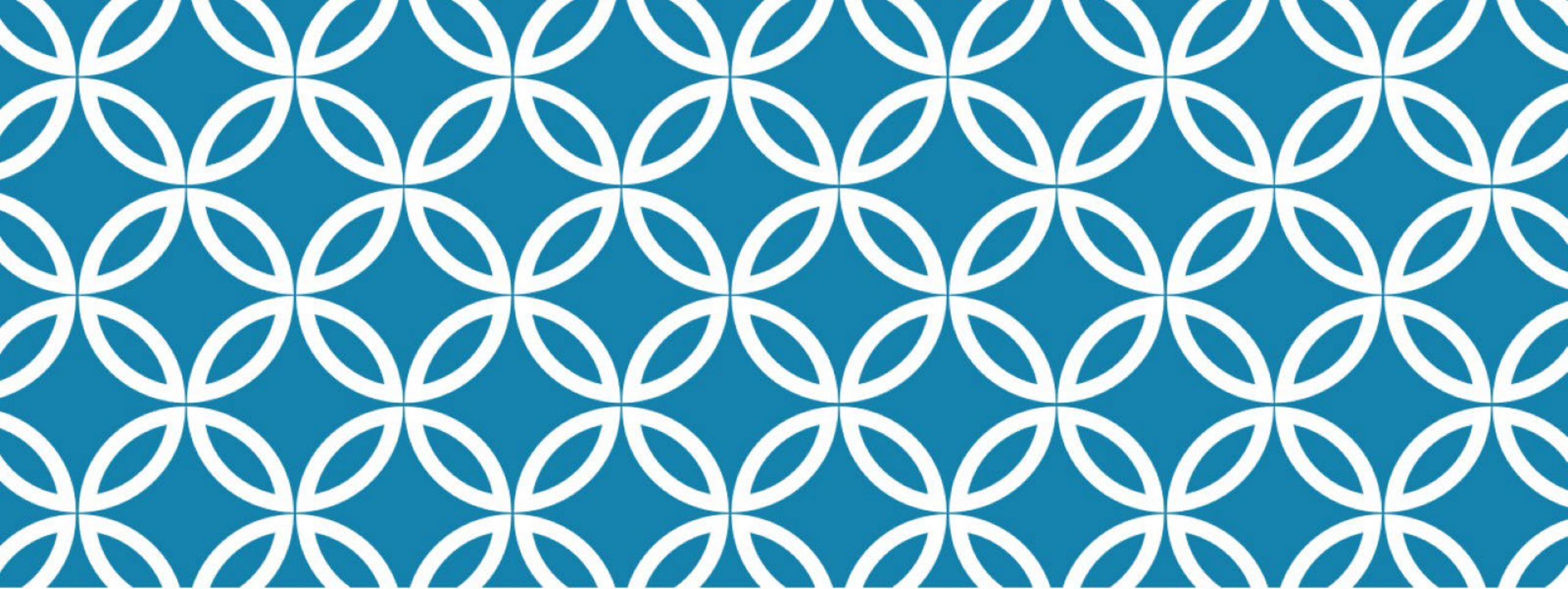
MEDICARE PRE-EXPOSURE PROPHYLAXIS (PREP) COVERAGE

- FDA-approved oral or injectable PrEP medication.
 - Medicare Part B also covers the fee for injecting the drug.
- Up to 8 individual counseling sessions (including HIV risk assessment, HIV risk reduction, and medication adherence) every 12 months.
- Up to 8 HIV screenings every 12 months.
- A hepatitis B virus screening

IMPORTANT INFORMATION

Billing is Medicare Part B vs Medicare Part D

- **IMPORTANT:** Make sure pharmacy can bill Medicare Part B.
- If pharmacy can't bill Part B, Medicare will help you find another pharmacy where you can get your PrEP.
- **Call 1-800-MEDICARE (1-800-633-4227). TTY users can call 1-877-486-2048.**



CDC HIV TESTING GUIDELINES

CDC Recommendations For Routine Screening

Infection	Recommendation	Last Update
HIV	<ul style="list-style-type: none">• 13-64 yrs• Vulnerability factors	2006
Hepatitis B	<ul style="list-style-type: none">• Universal screening 18 yrs and older• Vulnerability factors• Anyone who asks for test	2023
Hepatitis C	<ul style="list-style-type: none">• Universal screening \geq 18 yrs• Recognized Exposure• Ongoing vulnerability• Anyone who asks for test	2020

Updating the CDC HIV Testing Guidelines

The CDC Should Remove Upper Recommended Age Limit for HIV Testing

Current US Centers for Disease Control and Prevention (CDC) Guidelines state:

Screening for HIV Infection - In all health-care settings, screening for HIV infection should be performed routinely for all patients aged 13--64 years. Health-care providers should initiate screening unless prevalence of undiagnosed HIV infection in their patients has been documented to be <0.1%. In the absence of existing data for HIV prevalence, health-care providers should initiate voluntary HIV screening until they establish that the diagnostic yield is <1 per 1,000 patients screened, at which point such screening is no longer warranted.^[1]

GOAL: Have the upper age limit removed, i.e., "In all health care settings, screening for HIV should be performed routinely for all patients aged 13 year and older." (OFFER)

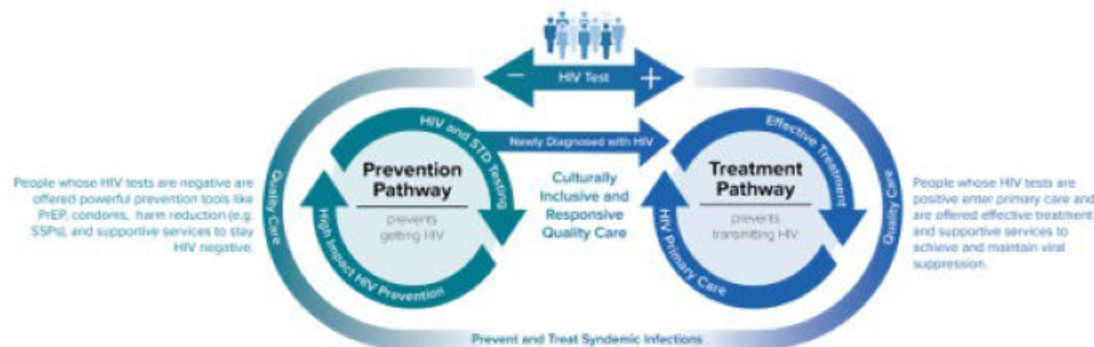
Why is this needed? Many older adults (and their providers) don't think that older people are vulnerable to HIV, yet the most recent data shows that approximately 17% of new HIV diagnoses in the United States occurred among people aged 50 years and older. 55 and older is 10%. While the CDC has not recommended routine HIV testing for adults over the age of 64, there are experts around the country who argue that HIV testing should be a routine part of healthcare for all adults, regardless of age. People over 64 are being diagnosed late...with advanced disease...and some have died. This is not ok.

^[1] <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm>

How is removing the upper age limit related to other prevention (and care) services?

The status neutral approach to HIV prevention and care defines the entry point to care as the time of an HIV test.

Status Neutral HIV Prevention and Care



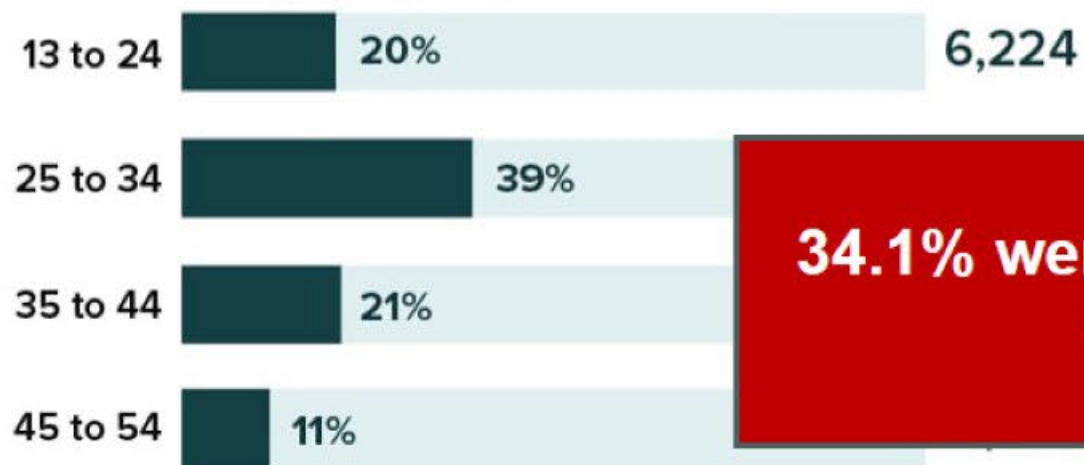
Follow CDC guidelines to test people for HIV. Regardless of HIV status, quality care is the foundation of HIV prevention and effective treatment. Both pathways provide people with the tools they need to stay healthy and stop HIV.

➤ PEP

➤ PrEP

HIV Diagnosis (2022)

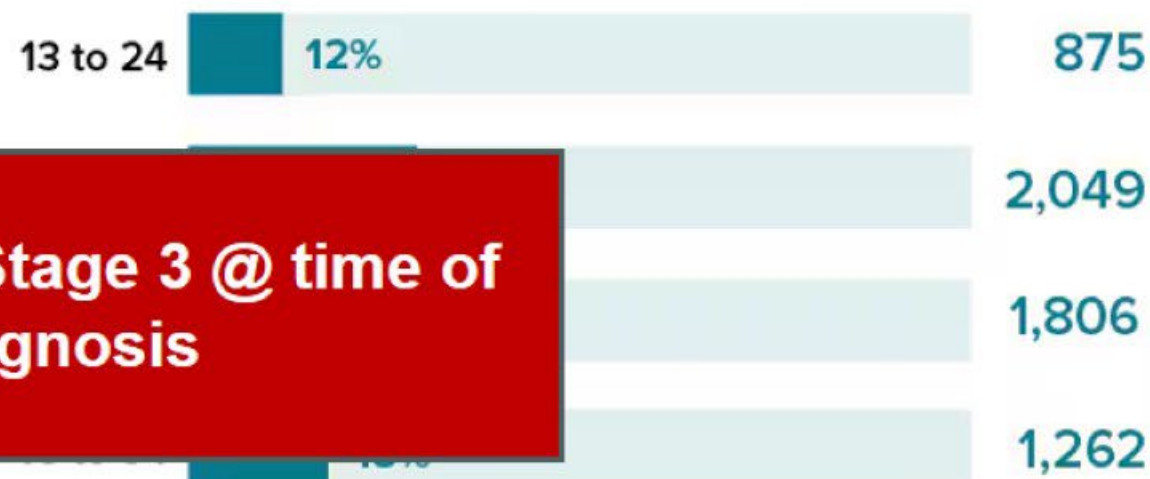
MEN



34.1% were Stage 3 @ time of diagnosis



WOMEN



Presidential Advisory Council on HIV/AIDS

Presidential Advisory Council on HIV/AIDS (PACHA) Resolution on Removing the Upper Age Limit of CDC Testing Guidelines

In recognition of National HIV/AIDS Awareness Day, September 18th, the Presidential Advisory Council on HIV/AIDS (PACHA) stands united in our commitment to address the unique challenges faced by older adults aging and vulnerable to HIV. It is imperative that we recognize and attend to the intersecting issues of aging and HIV, ensuring that older adults receive the support, care, and respect they deserve.

Whereas, the Centers for Disease Control and Prevention (CDC) currently recommends that in all healthcare settings, HIV testing should be performed at least once as part of routine healthcare for all individuals between ages 13 and 64, and further recommends that people at heightened vulnerability to HIV acquisition get tested for HIV at least once a year;

Whereas, HIV acquisition is not confined to specific age groups, necessitating a comprehensive and inclusive approach to HIV testing;

Whereas, barriers to HIV testing among people over 50 include low perceived HIV risk and clinician preconceptions about older people;

Whereas, according to CDC data in 2019, 17% of new HIV diagnoses were among persons aged 50 and older;

Whereas, older people are at the highest risk of all age groups for having Stage 3 disease (AIDS) at the time of diagnosis such that in 2021, 34% of people 55 and older were diagnosed with Stage 3 disease (AIDS) at time of HIV diagnosis;

Whereas, older adults are at increased risk for immunocompromising conditions such as cancer, which can further increase risk of mortality if HIV is undiagnosed;



PACHA RESOLUTION September 2023

Wyden, Casey, Fetterman, Merkley Urge CDC to Update HIV Testing Guidelines

Washington, D.C. — U.S. Senators Ron Wyden, D-Ore., Bob Casey, D-Pa., John Fetterman, D-Pa., and Jeff Merkley, D-Ore., today called on the Centers for Disease Control and Prevention to update HIV testing guidelines.

The senators' letter to CDC Director Mandy Cohen also requests the agency remove the upper age limit of HIV testing recommendations to protect the health of older Americans. Currently, the CDC guidelines recommend routine HIV testing for people between the ages of 13 and 64 years old.

GUESS WHAT HAPPENED?

The U.S. Centers for Disease Control and Prevention (CDC) has developed draft [Recommendations for HIV Screening in Clinical Settings](#) and is requesting public input until January 2, 2025.

*In this draft, CDC proposes recommending at least one HIV test in a lifetime for all persons 15 years of age or older. **These draft recommendations update the ages for HIV screening including eliminating an upper age limit.***

--Dec 3, 2024

YES! YES! YES!



CDC HIV Testing Guidelines

Public Comment Due January 2, 2025

<https://www.federalregister.gov/documents/2024/12/03/2024-28294/draft-cdcs-recommendations-for-hiv-screening-in-clinical-settings>

<https://nastad.org/savehivfunding>

TELL CONGRESS ***#SAVEHIVFUNDING***

Our leaders in Congress are calling for \$767 million in cuts to HIV funding in the U.S.

Tell your your representatives in Congress
to **#SaveHIVFunding!**



ADVOCACY AT SAGE

We are committed to continuing the legacy that our LGBTQ+ pioneers ignited by raising our voices and taking meaningful action. From the spark at Stonewall that started it all, our elders remain at the forefront to demand equal treatment and opportunity.

The types of policies we advocate for...

- Discrimination protections in long-term care
- Requiring training in LGBTQ+ and HIV cultural competency for providers
- Inclusive data collection
- HIV care and prevention
- Equal access to inclusive programs and services through the Older Americans Act
- Legal definition of family that includes chosen family and domestic partners
- Restoration of benefits to veterans with Other-Than-Honorable Discharges



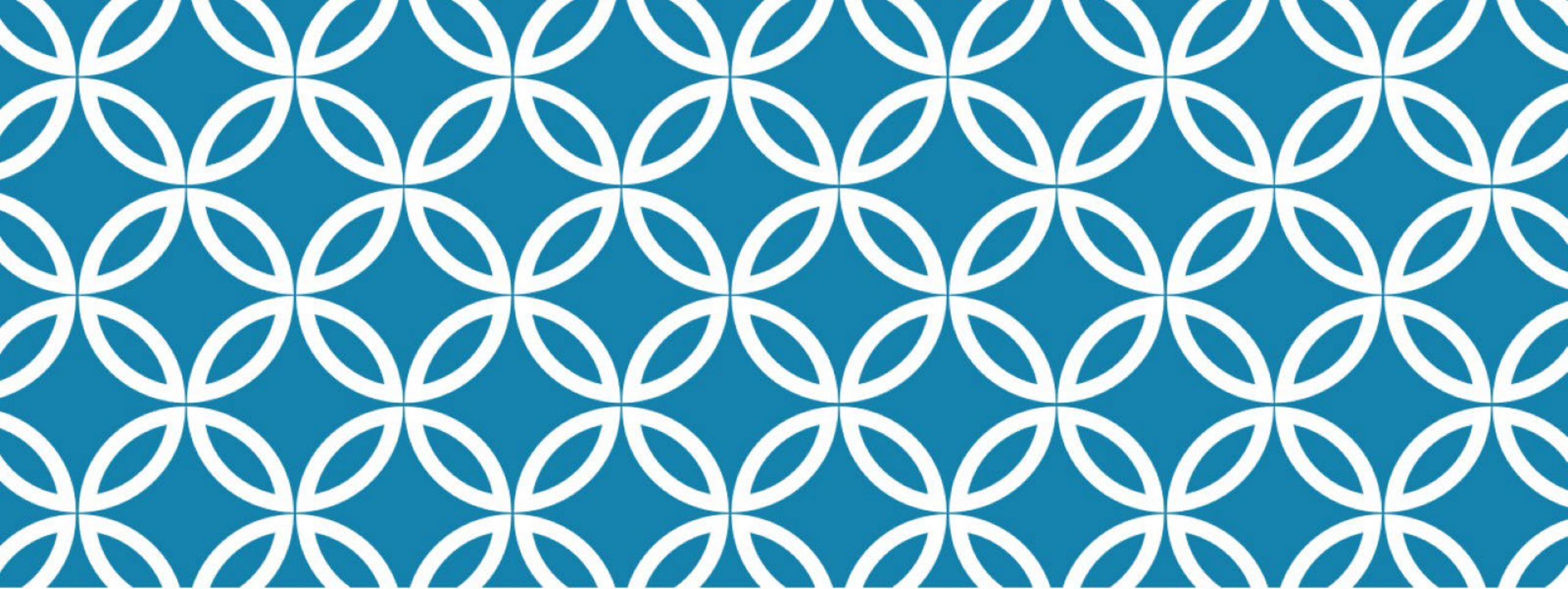
Join our email list
for action items
and updates!

sage | Advocacy &
Services for
LGBTQ+ Elders
We refuse to be invisible™

Members of this ever-growing group are notified of breaking news and action alerts. We will provide tangible steps for moving your local community and our country towards greater justice, like:

1. Sending a letter to your representatives or calling to share why legislation matters to you
2. Joining a training to learn how to leverage the power of your personal story for positive impact
3. Attending an event or webinar to become more informed

Contact Us!
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THANKS!

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