HIV Treatment, Prevention, Access and Advocacy

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Disclosures

- I have received an investigator initiated grant from Merck Pharmaceuticals
- I have served on an advisory board for Theratechnologies

Objectives

- Discuss current recommendations for initiating antiretroviral therapy in patients with newly diagnosed HIV infection
- Outline the approach for preventing HIV infection transmission with pre-exposure prophylaxis
- Describe new and ongoing challenges for patients and providers in terms of healthcare coverage and access to HIV care
- Identify opportunities to advocate for patients living with HIV in order to reduce barriers to HIV treatment and prevention services
- Discuss ACCP Advocacy resources on the website
- End with a call to advocate

Initiation of Antiretroviral Therapy
Current Recommendations

DHHS Panel's Recommendations for Initiating Antiretroviral Therapy in Treatment-Naive Patients
• Antiretroviral therapy (ART) is recommended for all individuals with HIV, regardless of CD4 T lymphocyte cell count, to reduce the morbidity and mortality associated with HIV infection (AI).
• ART is also recommended for individuals with HIV to prevent HIV transmission (AI).
• When initiating ART, it is important to educate patients regarding the benefits and considerations of ART, and to address strategies to optimize adherence. On a case-by-case basis, ART may be deferred because of clinical and/or psychosocial factors, but therapy should be initiated as soon as possible.

Rating of Recommendations: A = Strong; B = Moderate; C = Optional
Rating of Evidence: I = Data from randomized controlled trials; II = Data from well-designed nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion

US DHHS. Guidelines for Use of Antiretroviral Agents in HIV-1–Infected Adults and Adolescents. 2017. https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/10/initiation-of-antiretroviral-therapy. Accessed August 1, 2018.

Initiation of Antiretroviral Therapy

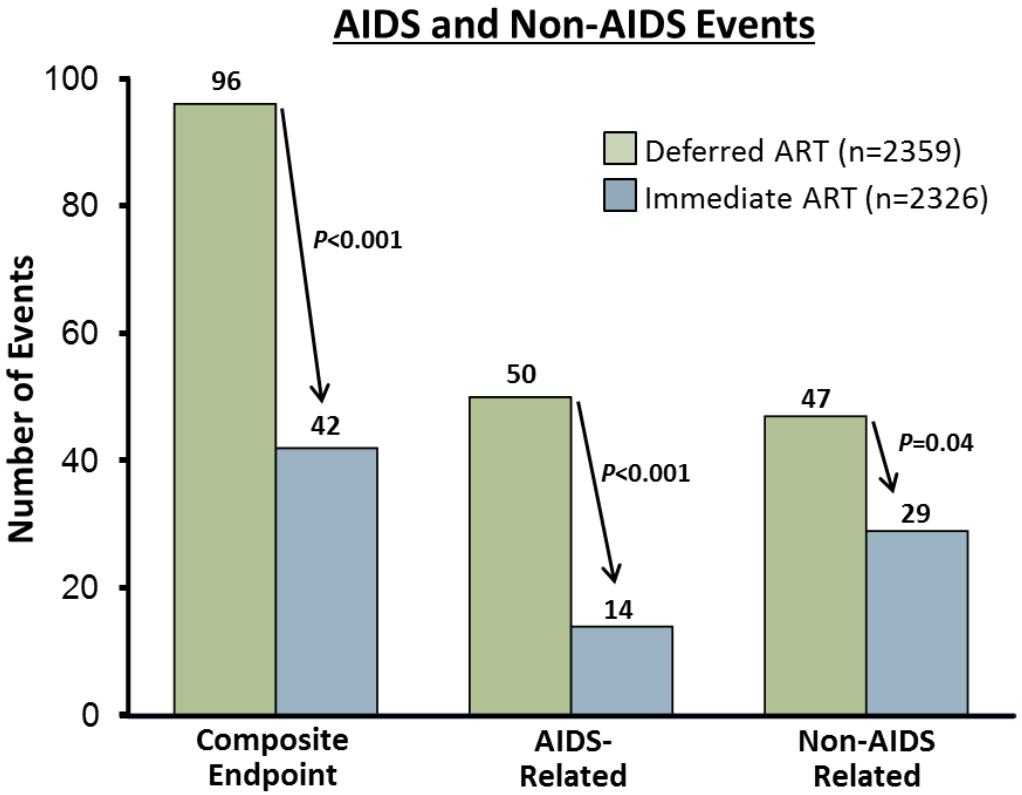
Recommendations Have Evolved

CD4 Count (cells/mm^3)	1998	2001	2006	2009	2012	Present
> 500	Treat if VL >20,000	Treat if VL >55,000	Consider if VL >100,000	Consider in certain patients	Consider in certain patients	**Treat**
350-500	Treat if VL >20,000	Consider if VL >55,000	Consider if VL >100,000	Consider in certain patients	**Treat**	**Treat**
200-350	Treat if VL >20,000	**Treat**	**Treat**	**Treat**	**Treat**	**Treat**
<200 or symptomatic	**Treat**	**Treat**	**Treat**	**Treat**	**Treat**	**Treat**

Early ART Reduces AIDS and Non-AIDS Events

The START Study

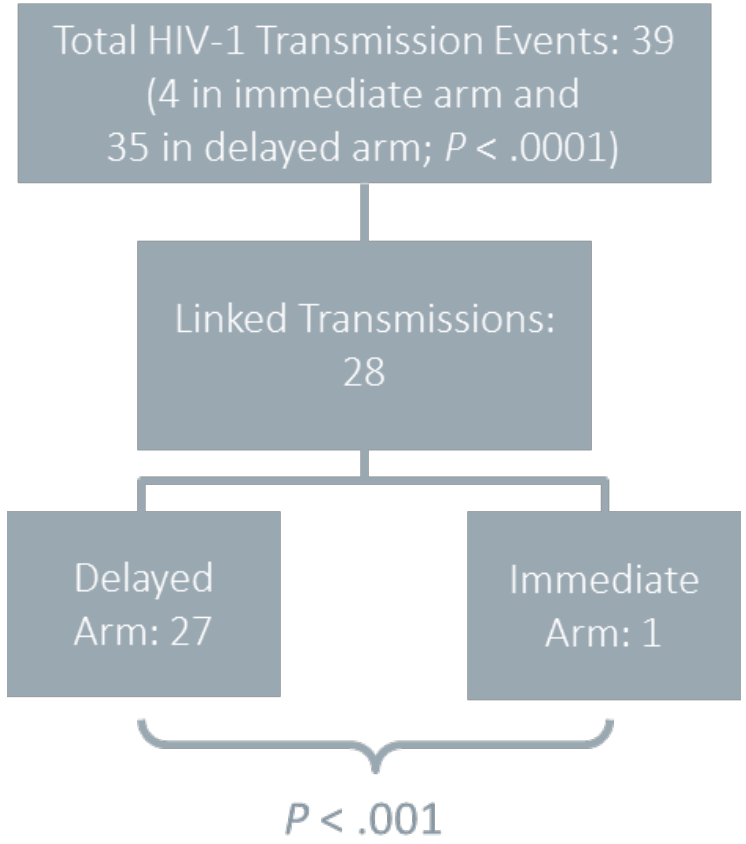
- ART-naïve adults (n=4685)
  - CD4 cell counts >500
  - Randomized to initiate ART immediately or after a CD4 count decline to <350
  - Primary endpoint was a composite of serious AIDS and non-AIDS events
- Immediate ART reduced risk of serious events or death by 57%
- Most events (59%) in the deferred ART arm occurred with CD4 counts > 500



ART Reduces HIV Transmission

The HPTN-052 Study

- HIV-serodiscordant couples (n = 1763)
  - Partner with HIV was ART naive with a CD4 count of 350 to 550 cells/mm3 at enrollment
  - Randomized to immediate ART versus delayed therapy (CD4 count <250)
  - Most (97%) reported to be in a heterosexual monogamous relationship
  - All were counseled on risk and condom use
  - Primary outcome: HIV transmission events
- A 96% reduction in transmission with early ART
  - HR 0.04; 95% CI, 0.01–0.27; P < 0.001



Cohen MS, et al. *N Engl J Med*. 2011;365: 493-505

ART Reduces HIV Transmission

Undetectable = Untransmittable (U = U)

- PARTNER-1 study
  - Assessed rate of HIV transmission within sero-different heterosexual and MSM couples during periods of condomless sex while HIV-positive partner had HIV-1 RNA < 200 copies/mL
    - No linked within-couple transmissions observed
    - Upper 95% CI for rate of transmission between MSM was 0.84/100 CYFU vs 0.46/100 CYFU in heterosexuals

- Opposites Attract study
  - Assessed rate of HIV transmission within sero-different MSM couples during periods of condomless sex while HIV-positive partner had HIV-1 RNA < 200 copies/mL
    - No linked within-couple transmissions observed
    - Upper 95% CI for rate of transmission was 1.59/100 CYFU

Rodger AJ, et al. JAMA. 2016;316:171-181.
Bavinton BR, et al. Lancet HIV. 2018. epub ahead of print

ART Reduces HIV Transmission

Undetectable = Untransmittable (U = U)

- PARTNER study enrolled sero-different couples in 75 European sites
  - PARTNER-1 followed heterosexuals and MSM from 2010-2014
  - PARTNER-2 followed MSM from 2014-2018 (included some MSM couples from PARTNER-1)

- Primary aim of PARTNER-2:
  - Improve accuracy of estimated within-couple HIV transmission risk among MSM during periods of condomless sex while HIV-positive partner had HIV-1 RNA < 200 copies/mL

- Eligibility for inclusion (all must apply within time period between HIV tests):
  - Couple reported within-couple CL sex
  - No PEP or PrEP use by HIV-negative partner
  - HIV-1 RNA < 200 copies/mL in HIV-positive partner at all assessments within prior 12 months

Rodger A, et al. IAS 2018; Abstract WEAX0104LB.

ART Reduces HIV Transmission

Undetectable = Untransmittable (U = U)

- PARTNER-2: Rate of HIV transmission according to sexual behavior reported by the negative partner

	Linked Transmissions	Upper 95% CL	Couple Years of Follow-up	Condomless Sex Acts
Any Sex	0	0.23	1,596	76,991
Anal Sex	0	0.24	1,546	70,743
Insertive anal Sex	0	0.27	1,345	52,572
Receptive Anal Sex with Ejaculation	0	0.57	652	20,770
Receptive Anal Sex without Ejaculation	0	0.43	867	23,153
Any Sex with a STI	0	2.74	135	6,301

- Among serodifferent gay couples who had sex ~77,000 times without condoms with an undetectable viral load, zero linked transmissions were identified

Rodger A, et al. IAS 2018, Abstract: WEAX0104LB.

Advocacy

Undetectable = Untransmittable (U = U)

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

People who take ART daily as prescribed and achieve and maintain an undetectable viral load have effectively no risk of sexually transmitting the virus to an HIV-negative partner.

September, 2017

https://www.preventionaccess.org/ and https://www.cdc.gov/hiv/risk/art/index.html

Initiation of Antiretroviral Therapy
Current Recommendations

DHHS Panel's Recommended Initial Regimens for Most People with HIV
• Dolutegravir/abacavir/lamivudine (AI)
• Dolutegravir plus tenofovir/emtricitabine (AI)
• Elvitegravir/cobicistat/tenofovir/emtricitabine (AI)
• Raltegravir plus tenofovir/emtricitabine (AI)
• Bictegravir/tenofovir alafenamide/emtricitabine (AI)

- An antiretroviral (ARV) regimen for a treatment-naive patient generally consists of two nucleoside reverse transcriptase inhibitors in combination with a third active ARV drug from one of three drug classes: an integrase strand transfer inhibitor, a non-nucleoside reverse transcriptase inhibitor, or a protease inhibitor

US DHHS. Guidelines for Use of Antiretroviral Agents in HIV-1–Infected Adults and Adolescents. 2017. https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/10/initiation-of-antiretroviral-therapy. Accessed August 1, 2018.

Initiation of Antiretroviral Therapy
Current Recommendations

DHHS Panel's Recommended Initial Regimens in Certain Clinical Situations
• Darunavir plus tenofovir/emtricitabine (AI)
• Atazanavir plus tenofovir/emtricitabine (BI)
• Efavirenz plus tenofovir/emtricitabine (BI)
• Rilpivirine plus tenofovir/emtricitabine (BI)
• Darunavir plus raltegravir (CI)

- These regimens are effective and tolerable, but have some disadvantages when compared with regimens recommended to be used in most patients, or have less supporting data from randomized clinical trials. However, in certain clinical situations, one of these regimens may be preferred

US DHHS. Guidelines for Use of Antiretroviral Agents in HIV-1–Infected Adults and Adolescents. 2017. https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/10/initiation-of-antiretroviral-therapy. Accessed August 1, 2018.

Integrase inhibitors have high rates of virologic suppression and often greater tolerability than PI- or NNRTI regimens

Study	Integrase Agent	Comparator(s)	Follow-up	Efficacy
STARTMRK	Raltegravir	Efavirenz	192 Weeks	Raltegravir **superior** to efavirenz
ACTG 5257	Raltegravir	Darunavir/ritonavir	96 Weeks	Raltegravir **superior** to darunavir/ritonavir
		Atazanavir/ritonavir		Raltegravir **superior** to atazanavir/ritonavir
GS-102	Elvitegravir	Efavirenz	144 Weeks	Elvitegravir non-inferior to efavirenz
GS-103	Elvitegravir	Atazanavir/ritonavir	144 Weeks	Elvitegravir non-inferior to atazanavir
WAVES	Elvitegravir	Atazanavir/ritonavir	48 Weeks	Elvitegravir **superior** to atazanavir/ritonavir
SINGLE	Dolutegravir	Efavirenz	48 Weeks	Dolutegravir **superior** to efavirenz
FLAMINGO	Dolutegravir	Darunavir/ritonavir	48 Weeks	Dolutegravir **superior** to darunavir/ritonavir
GS-US-380-1489	Bictegravir	Dolutegravir	48 Weeks	Bictegravir non-inferior to dolutegravir
GS-US-380-1490	Bictegravir	Dolutegravir	48 Weeks	Bictegravir non-inferior to dolutegravir

US DHHS. Guidelines for Use of Antiretroviral Agents in HIV-1–Infected Adults and Adolescents. 2017. https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/10/initiation-of-antiretroviral-therapy. Accessed August 1, 2018.

Initiation of Antiretroviral Therapy

Choosing Between The Integrase Inhibitors

Agent	Advantages	Disadvantages
Raltegravir	• Longest experience • Fewest drug interactions • Twice or once daily dosing	• **Not a single tablet regimen** • Daily dose is two tablets in addition to nucleoside reverse transcriptase inhibitors
Elvitegravir	• Single tablet regimens • Once daily dosing	• **Requires boosting with cobicistat** • Many drug interactions • SCr elevations with cobicistat
Dolutegravir	• **Single tablet regimen** • Once daily dosing • **High barrier to resistance** • Few drug interactions • Can be given as a two-drug regimen?	• Risk of neural tube defects in pregnancy? • Co-formulated with abacavir • Co-formulated with lamivudine • SCr elevations with dolutegravir
Bictegravir	• **Single tablet regimen** • Once daily dosing • **High barrier to resistance** • Few drug interactions	• Only available in a single tablet • SCr elevations with bictegravir

Initiation of Antiretroviral Therapy

Recommendations - International Antiviral Society, USA Panel

Recommended Initial Regimens
• Dolutegravir/abacavir/lamivudine (AIa)
• Dolutegravir plus tenofovir/emtricitabine (AIa)
• Bictegravir/tenofovir/emtricitabine (AIa)

When Initial Regimens Are Not an Option
• Darunavir plus tenofovir/emtricitabine (AIa)
• Atazanavir plus tenofovir/emtricitabine (AIa)
• Efavirenz plus tenofovir/emtricitabine (AIa)
• Elvitegravir/cobi/tenofovir/emtricitabine (AIa)
• Raltegravir plus tenofovir/emtricitabine (AIa)
• Rilpivirine plus tenofovir/emtricitabine (AIa)

- Bictegravir and dolutegravir do not require boosting, have a high barrier to resistance, and are part of regimens with a low pill burden and toxicity.
- Raltegravir is well tolerated with few drug interactions, but has a low barrier to resistance and a high pill burden.
- Elvitegravir has a lower barrier to resistance and requires boosting, resulting in more drug interactions.

Saag MS, et al. JAMA 2018.

Initiation of Antiretroviral Therapy

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Initiation of Antiretroviral Therapy
Two versus Three Drug ART

- In single-arm pilot studies, first-line DTG plus 3TC was effective and well tolerated
  - PADDLE: 18/20 (90%) patients had HIV-1 RNA < 50 copies/mL at Week 48
  - ACTG A5353: 108/120 (90%) patients had HIV-1 RNA < 50 copies/mL at Week 24

- GEMINI-1 and GEMINI-2 (n = 1,433)
  - Two double-blind, Phase III studies comparing efficacy and safety of DTG+3TC to DTG+TDF/FTC in treatment-naïve adults with baseline HIV-1 RNA ≤500,000 copies/mL

Participants with HIV-1 RNA <50 c/mL at Week 48: Snapshot Analysis

	GEMINI-1	GEMINI-2	Pooled
DTG+3TC	320/356 (90%)	335/360 (93%)	655/716 (91%)
DTG+TDF/FTC	332/358 (93%)	337/359 (94%)	669/717 (93%)
Difference (95% CI)	-2.6 (-6.7, 1.5)	-0.7 (-4.3, 2.9)	-1.7 (-4.4, 1.1)

  - DTG+3TC demonstrated non-inferior efficacy to DTG+TDF/FTC
  - Both regimens were well tolerated. Biomarkers of bone turnover and renal function favored DTG+3TC

Cahn P, et al. J Int AIDS Soc. 2017, Taiwo BO, et al. Clin Infect Dis. 2018, Cahn P, et al. IAS 2018 Abstract: TUAB0106LB

Initiation of Antiretroviral Therapy

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Dolutegravir	• Single tablet regimen • Once daily dosing • High barrier to resistance • Few drug interactions • Can be given as a two-drug regimen?	• **Risk of neural tube defects in pregnancy?** • Co-formulated with abacavir • Co-formulated with lamivudine • SCr elevations with dolutegravir
Bictegravir	• Single tablet regimen • Once daily dosing • High barrier to resistance • Few drug interactions	• Only available in a single tablet • SCr elevations with bictegravir

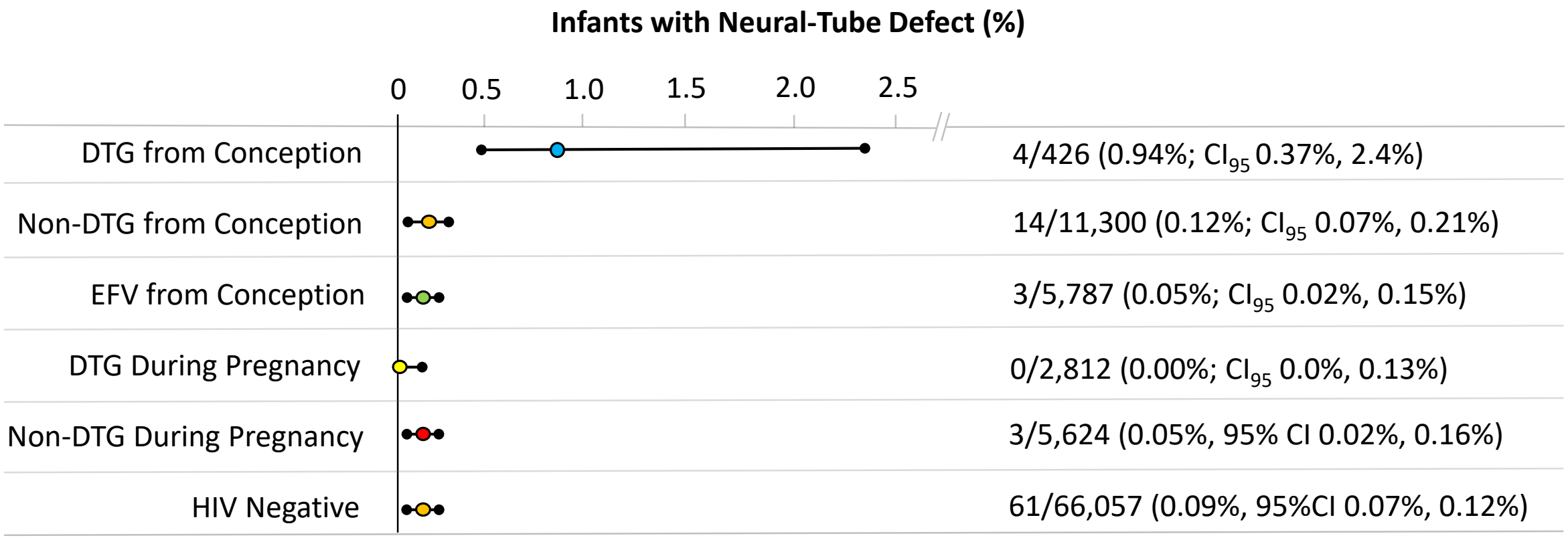
Dolutegravir and Neural Tube Defects
Evidence as of May 1, 2018

- NIH-funded surveillance study of birth outcomes in Botswana
- Originally began in 2014 as a 4-year study of the prevalence of neural tube defects in live-born and stillbirths among women on efavirenz at conception versus other exposure groups
- In 2016, Botswana switched first line ART from TDF/FTC/EFV to TDF/FTC/dolutegravir for all adults (including pregnant women)
- In April 2018, investigators were asked to provide preliminary data on outcomes for women who started DTG before pregnancy

Dolutegravir and Neural Tube Defects

Evidence as of May 1, 2018

- Neural tube defects found in 86 of 88,755 births (0.10%; CI_{95} 0.08%-0.12%) as of May 1, 2018.

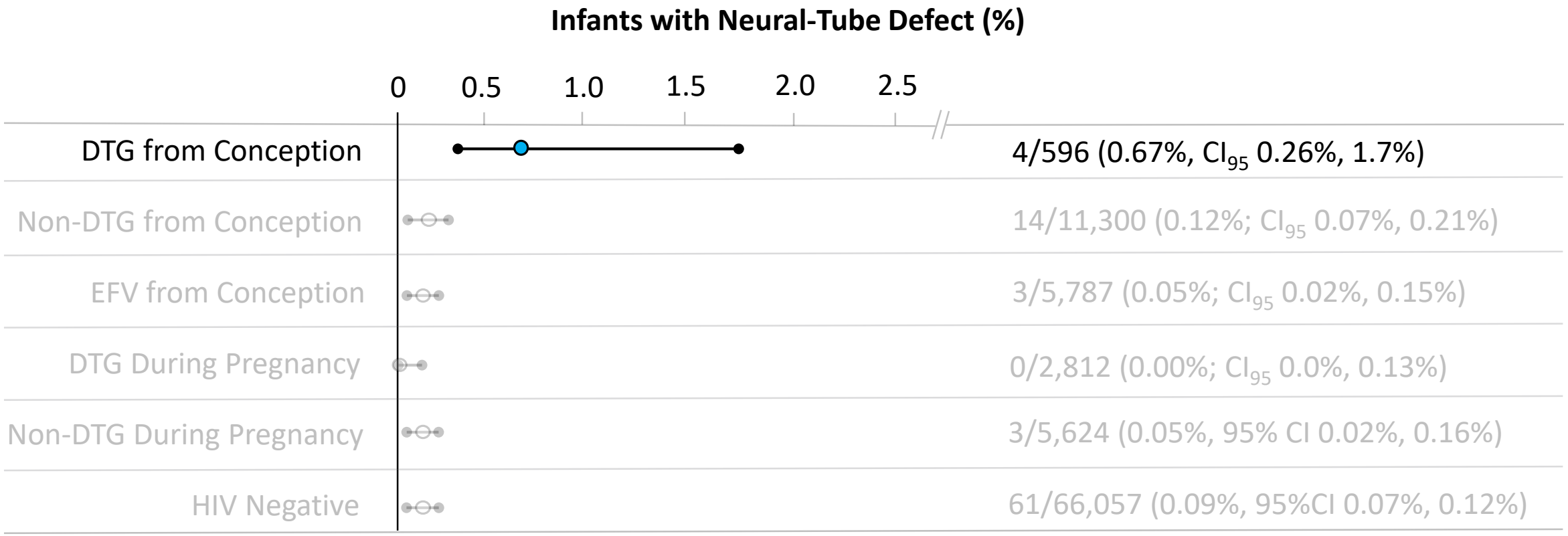


Zash R, et al. N Engl J Med 2018.

Dolutegravir and Neural Tube Defects

Evidence as of July 15, 2018

- From May 1st to July 15th, there were **2 more NTDs;** 1 in an infant exposed to **DTG *started during pregnancy*** and 1 birth to an **HIV-uninfected** woman



Zash R, et al. IAS 2018

Dolutegravir and Neural Tube Defects

Current Recommendations

ART history	Clinical Scenario	Recommendations/Comments
ARV-naive or On ART (but not DTG) and contemplating switching to a DTG-based regimen	Pregnant, less than 8 weeks from last menstrual period	•**Do not initiate a DTG-based regimen**
	Pregnant, 8 weeks or longer from last menstrual period	•If ARV-naive, use DTG or another ARV drug •If currently on a non-DTG regimen, continue current regimen or switch to DTG or another option
	Those who desire pregnancy or are not using effective contraception	•**Do not initiate a DTG-based regimen**
	Those who do not desire pregnancy and who are using effective contraception	•DTG can be considered as part of an ARV regimen •Pregnancy testing is recommended prior to initiation of DTG •Discuss the potential of DTG to the fetus and the effective use of contraception
Currently receiving DTG	Pregnant, less than 8 weeks from last menstrual period	•Switch DTG to an alternative option or continue DTG after weighing risks and benefits •Do not stop DTG without replacing it with another effective ARV drug •Discuss the potential risk of DTG to the fetus, and explain that switching regimens after the neural tube has formed is unlikely to confer benefits

US DHHS. Guidelines for Use of Antiretroviral Agents in HIV-1–Infected Adults and Adolescents. 2017. https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/10/initiation-of-antiretroviral-therapy. Accessed August 1, 2018.

Advocacy
Women and Children

Start Free, Stay Free, AIDS Free is a unified framework to end vertical HIV transmission, cut new infections among adolescents and young women, and increase and sustain access to antiretroviral treatment by children and adolescents.

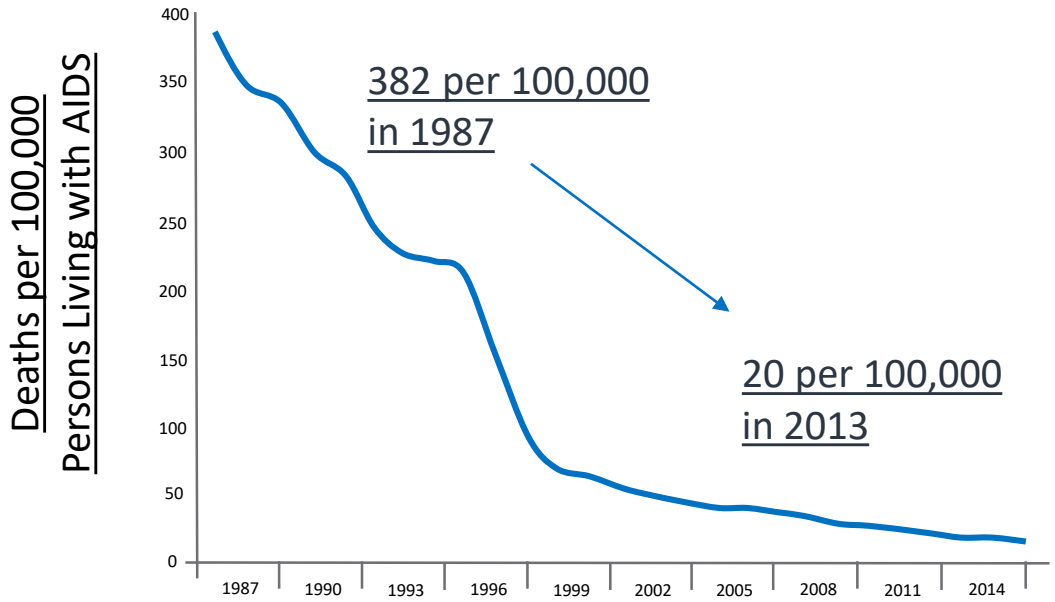
Led by the Joint United Nations Program on HIV/AIDS (UNAIDS) and the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), Start Free, Stay Free, AIDS Free brings together a coalition of partners to build on the tremendous progress achieved under the Global Plan towards the elimination of new HIV infections among children by 2015 and keeping their mothers alive (Global Plan).

https://free.unaids.org/ and http://www.pedaids.org/

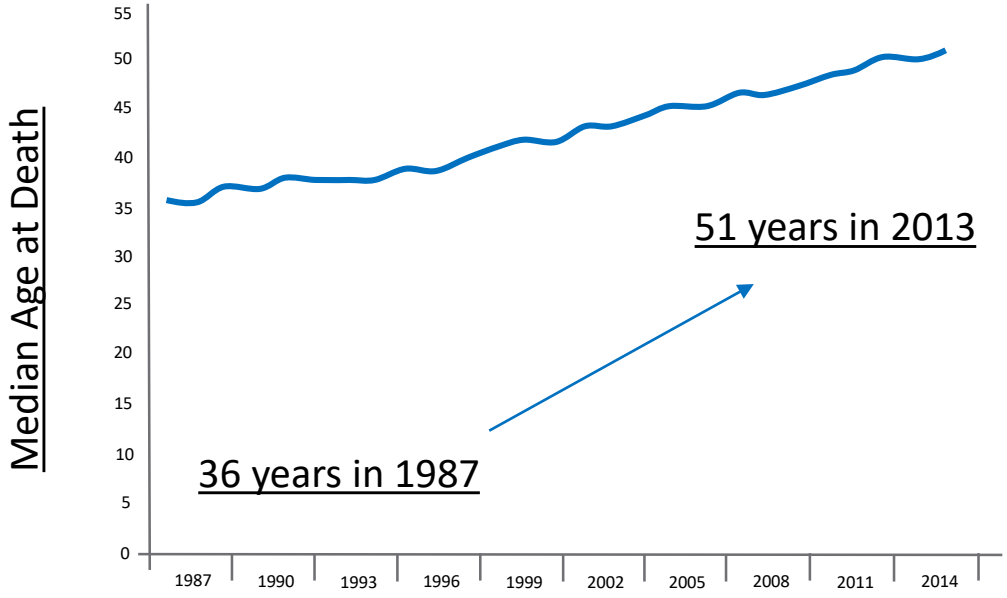
Access To Antiretroviral Therapy

The Benefits

Death Rate, Ever AIDS



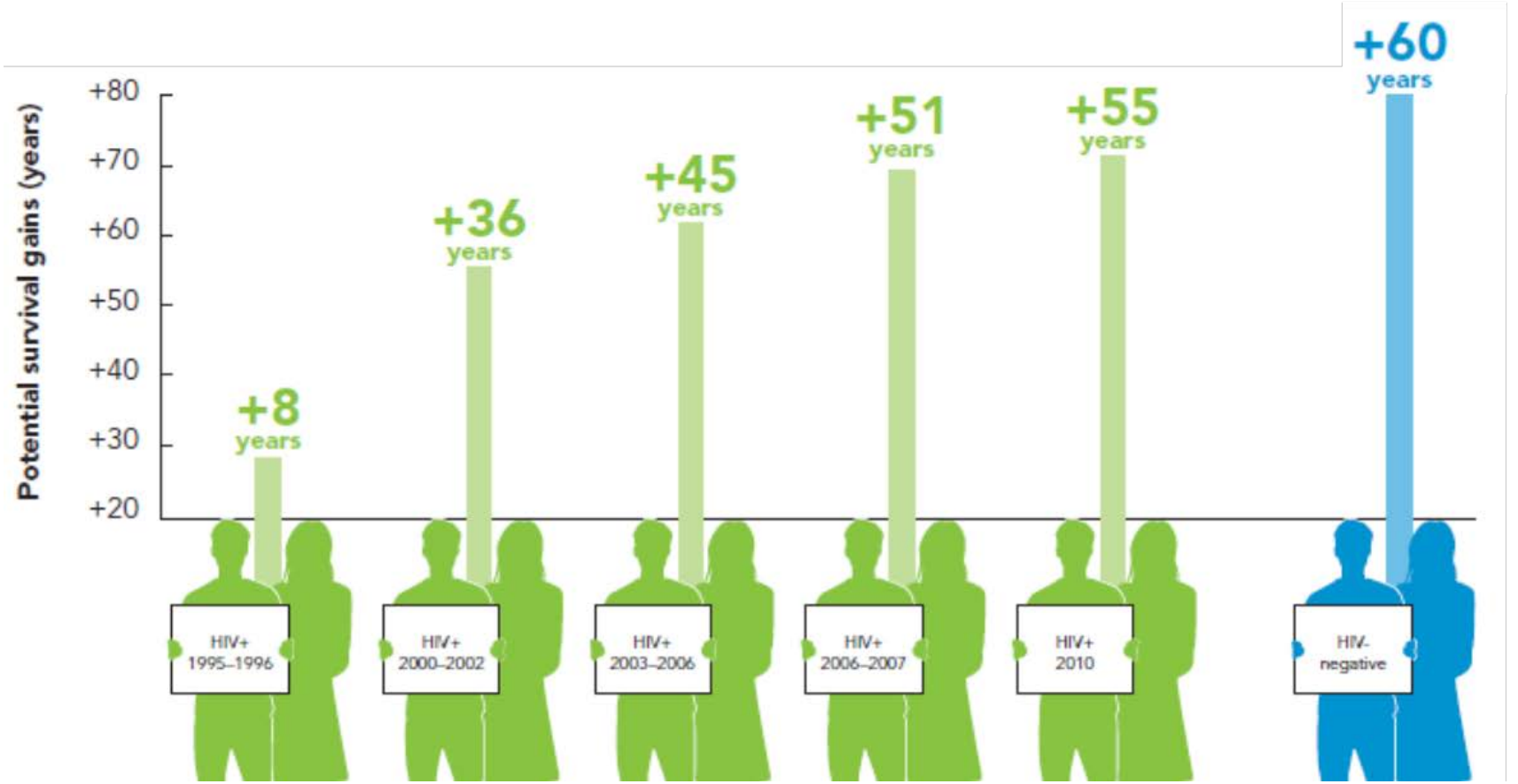
Age at Death, HIV Infection



Centers for Disease Control and Prevention. https://www.cdc.gov/hiv/statistics/overview/index.html

Access To Antiretroviral Therapy

The Benefits



Adapted from Lohse et al, 2007; Hogg et al, 2008; May et al, 2011; & Hogg et al, 2013

Access To Antiretroviral Therapy

The Benefits

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

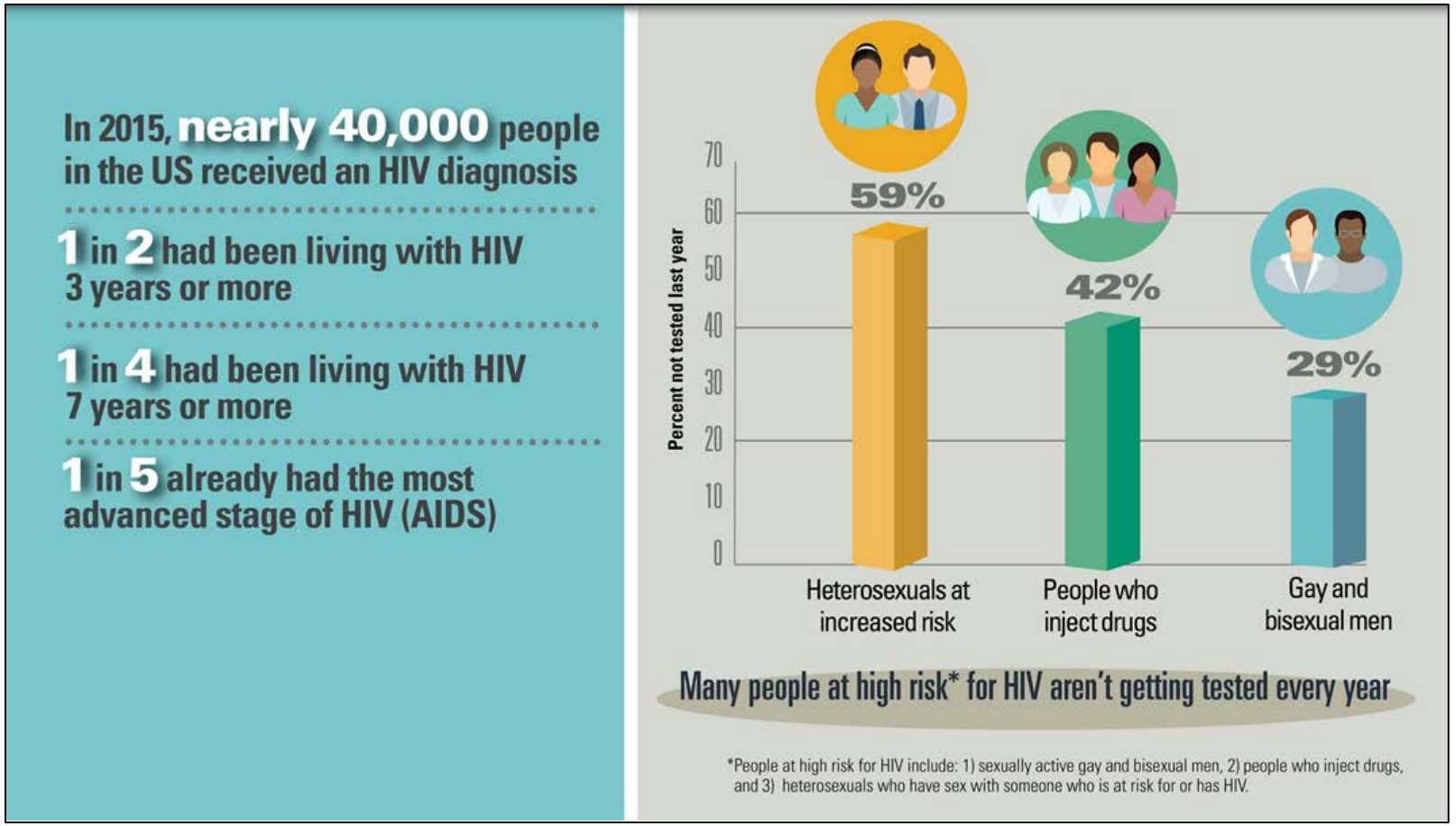
People who take ART daily as prescribed and achieve and maintain an undetectable viral load have effectively no risk of sexually transmitting the virus to an HIV-negative partner.

September, 2017

https://www.preventionaccess.org/ and https://www.cdc.gov/hiv/risk/art/index.html

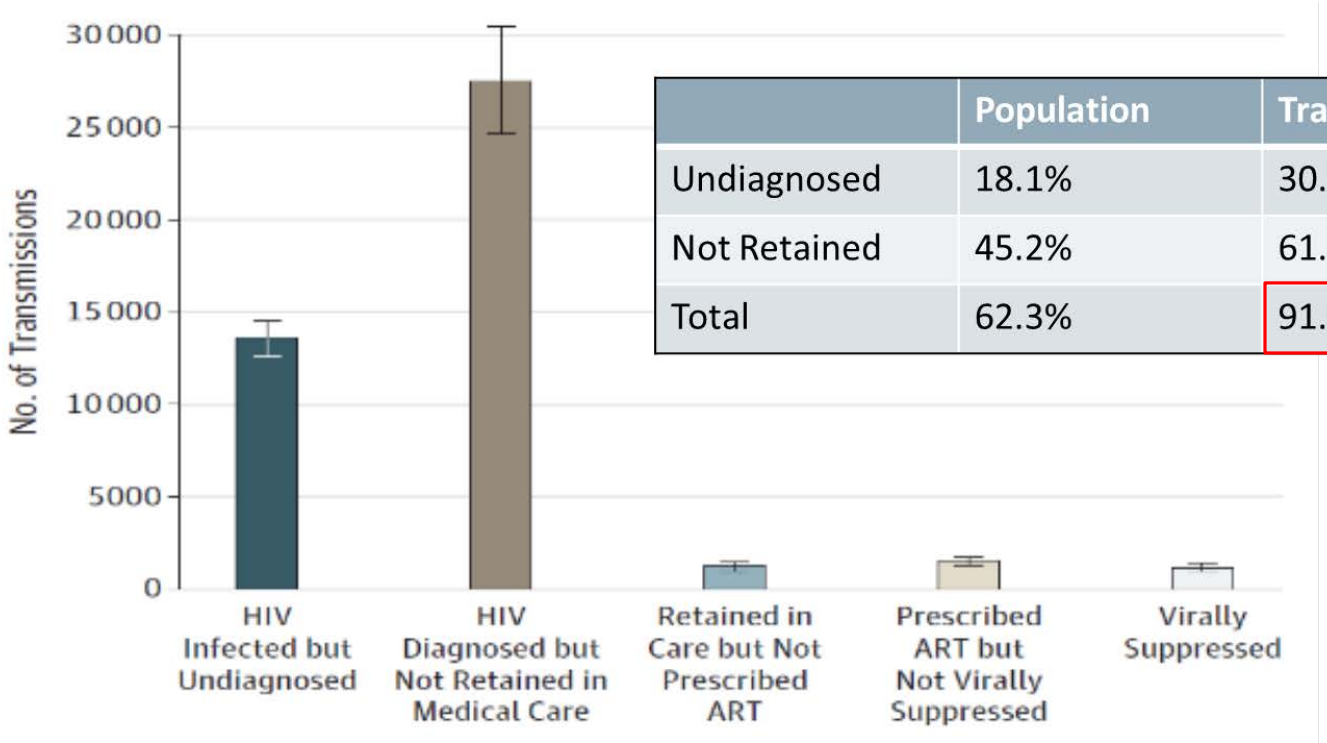
Access To Antiretroviral Therapy

The Barriers – Not Being Tested



HIV Transmission is Most Common from Persons Undiagnosed or Not in Care

Estimated Number of HIV Transmissions Along the HIV Care Continuum, U.S. 2009

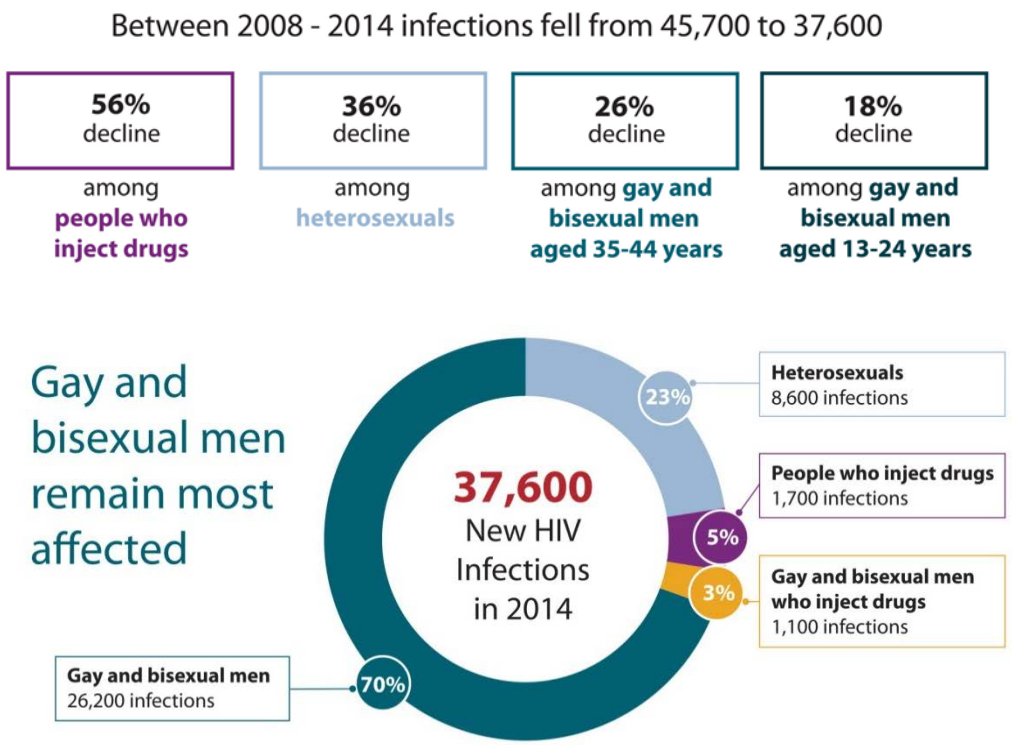


	Population	Transmission
Undiagnosed	18.1%	30.2%
Not Retained	45.2%	61.3%
Total	62.3%	91.5%

Skarbinski et al., JAMA, 2015; 175(4):588-596, Gopalappa et al., Med Decision Making, 2017; 37:224-233

The Overall Incidence of HIV has Declined, But Progress is Uneven

Annual incidence of HIV in the US declined 18%



Progress is Uneven

- Gay/bisexual men were the only group that did not have an overall decline in annual HIV infections from 2008 to 2014.
- Reductions in infections among whites and young gay and bisexual men were offset by increases in other groups.
- Annual infections remained stable among gay/bisexual men overall and among black gay/bisexual men
- **Most concerning are trends among groups, where the annual rate of infections are increasing:**
  - 35% among 25-34 year-old gay/bisexual males
  - 20 % among Latino gay/bisexual males

Centers for Disease Control and Prevention: US Public Health Service. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf.

Improving Diagnosis
Can Pharmacists Be Part of the Solution?

- Partnership between the Virginia Department of Health and Walgreens
- Incorporated HIV testing into 32 retail pharmacies located in high-minority and high-poverty areas of Virginia
- Walk-in testing using the 1-minute finger-stick Insti® rapid HIV test during all pharmacy hours
- Clients testing positive were referred to confirmatory testing at a health department

• Number of tests performed	3,221
• Never been tested or unsure	1,481 (46%)
• Positive Tests*	25 (0.8%)
• Those with positive tests that had never been tested or unsure	16 (64%)
• Tests provided at night or over the weekend	1,965 (61%)
• Cost per positive test**	$4,300

*Nearly all linked to confirmatory testing and medical care
**$14,900 at other community based health centers

Collins BC, et al. CROI 2017. February 13–16, 2017; Seattle, WA. Abstract 962.

Improving Diagnosis

Can Pharmacists Be Part of the Solution?

J Am Pharm Assoc (2003). 2014 Sep-Oct;54(5):486-92. doi: 10.1331/JAPhA.2014.14045.

HIV testing in community pharmacies and retail clinics: a model to expand access to screening for HIV infection.

Weidle PJ, Lecher S, Botts LW, Jones L, Spach DH, Alvarez J, Jones R, Thomas V.

Abstract

OBJECTIVE: To test the feasibility of offering rapid point-of-care human immunodeficiency virus (HIV) testing at community pharmacies and retail clinics.

DESIGN: Pilot program to determine how to implement confidential HIV testing services in community pharmacies and retail clinics.

SETTING: 21 community pharmacies and retail clinics serving urban and rural patients in the United States, from August 2011 to July 2013.

PARTICIPANTS: 106 community pharmacy and retail clinic staff members.

INTERVENTION: A model was developed to implement confidential HIV counseling and testing services using community pharmacy and retail clinic staff as certified testing providers, or through collaborations with organizations that provide HIV testing. Training materials were developed and sites selected that serve patients from urban and rural areas to pilot test the model. Each site established a relationship with its local health department for HIV testing policies, developed referral lists for confirmatory HIV testing/care, secured a CLIA Certificate of Waiver, and advertised the service. Staff were trained to perform a rapid point-of-care HIV test on oral fluid, and provide patients with confidential test results and information on HIV. Patients with a preliminary positive result were referred to a physician or health department for confirmatory testing and, if needed, HIV clinical care.

MAIN OUTCOME MEASURES: Number of HIV tests completed and amount of time required to conduct testing.

RESULTS: The 21 participating sites administered 1,540 HIV tests, with 1,087 conducted onsite by staff during regular working hours and 453 conducted at 37 different HIV testing events (e.g., local health fairs). The median amount of time required for pretest counseling/consent, waiting for test results, and posttest counseling was 4, 23, and 3 minutes, respectively. A majority of the sites (17) said they planned to continue HIV testing after the project period ended and would seek assistance or support from the local health department, a community-based organization, or an AIDS service organization.

CONCLUSION: This pilot project established HIV testing in several community pharmacies and retail clinics to be a feasible model for offering rapid, point-of-care HIV testing. It also demonstrated the willingness and ability of staff at community pharmacies and retail clinics to provide confidential HIV testing to patients. Expanding this model to additional sites and evaluating its feasibility and effectiveness may serve unmet needs in urban and rural settings.

Improving Diagnosis

Can Pharmacists Be Part of the Solution?

J Pharm Pract. 2014 Dec;27(6):578-81. doi: 10.1177/0897190013514090. Epub 2013 Dec 10.

Pharmacist testers in multidisciplinary health care team expand HIV point-of-care testing program.

Sherman EM[1], Elrod S[2], Allen D[3], Eckardt P[4].

Author information

Abstract

Knowledge of HIV serostatus is the first step to accessing treatment, reducing transmission, and mitigating public health challenges. We describe the expansion of an HIV point-of-care testing (POCT) program within a health care system utilizing pharmacists as testers. The testing program's expansion is detailed and its impact assessed. The POCT program was evaluated by comparing the number of traditional HIV venipuncture tests to the number of POCTs performed across the health system as well as comparing the number of POCTs performed by clinical pharmacists to the number of tests at other POCT locations. Although pharmacists' contributions to HIV prevention are well documented, pharmacists' involvement in HIV testing initiatives is still nascent. Our POCT program demonstrates an effective HIV testing initiative driven by pharmacists and other health care providers.

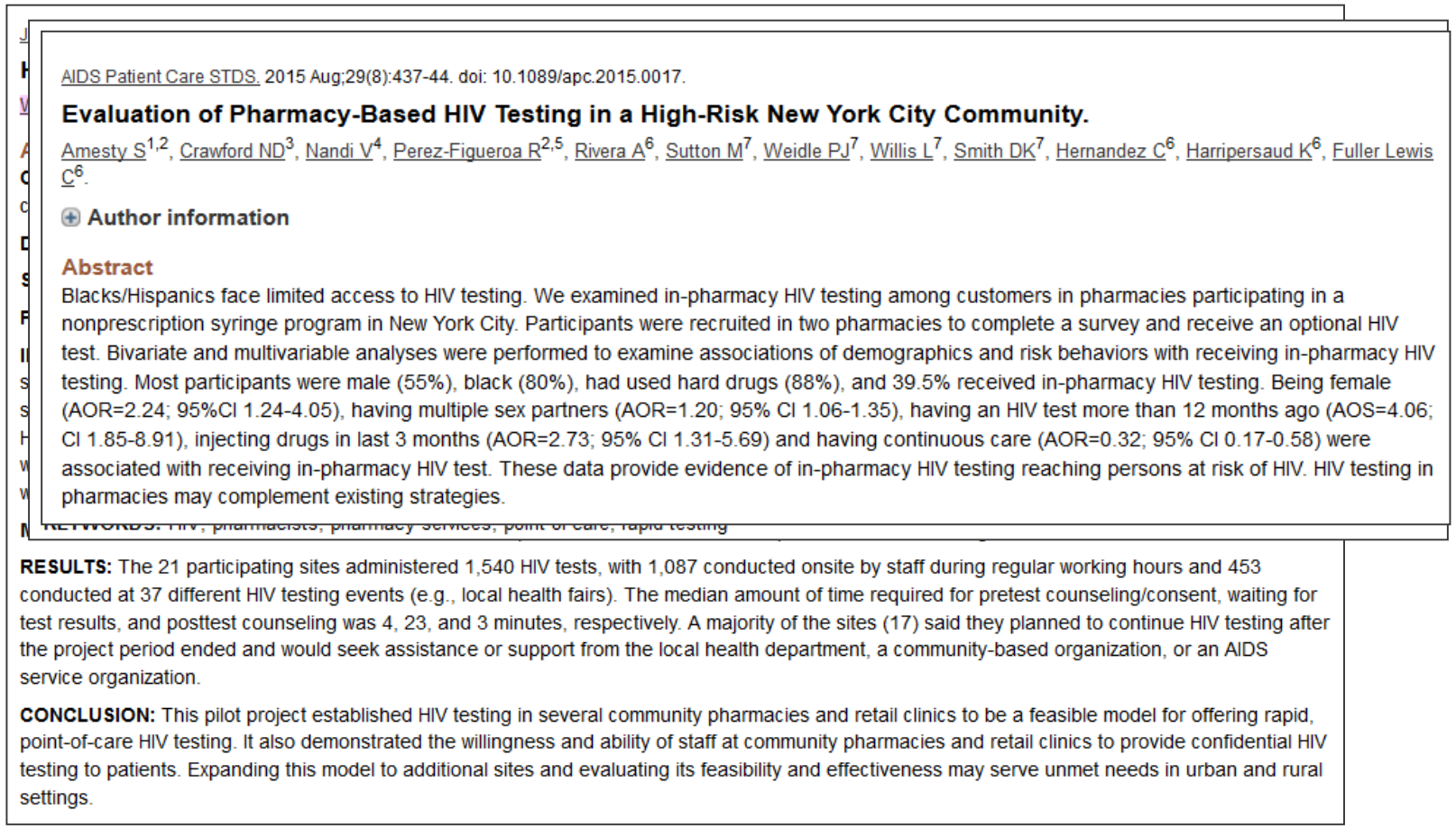
KEYWORDS: HIV; pharmacists; pharmacy services; point of care; rapid testing

RESULTS: The 21 participating sites administered 1,540 HIV tests, with 1,087 conducted onsite by staff during regular working hours and 453 conducted at 37 different HIV testing events (e.g., local health fairs). The median amount of time required for pretest counseling/consent, waiting for test results, and posttest counseling was 4, 23, and 3 minutes, respectively. A majority of the sites (17) said they planned to continue HIV testing after the project period ended and would seek assistance or support from the local health department, a community-based organization, or an AIDS service organization.

CONCLUSION: This pilot project established HIV testing in several community pharmacies and retail clinics to be a feasible model for offering rapid, point-of-care HIV testing. It also demonstrated the willingness and ability of staff at community pharmacies and retail clinics to provide confidential HIV testing to patients. Expanding this model to additional sites and evaluating its feasibility and effectiveness may serve unmet needs in urban and rural settings.

Improving Diagnosis

Can Pharmacists Be Part of the Solution?



AIDS Patient Care STDS. 2015 Aug;29(8):437-44. doi: 10.1089/apc.2015.0017.

Evaluation of Pharmacy-Based HIV Testing in a High-Risk New York City Community.

Amesty S[1,2], Crawford ND[3], Nandi V[4], Perez-Figueroa R[2,5], Rivera A[6], Sutton M[7], Weidle PJ[7], Willis L[7], Smith DK[7], Hernandez C[6], Harripersaud K[6], Fuller Lewis C[6].

Author information

Abstract

Blacks/Hispanics face limited access to HIV testing. We examined in-pharmacy HIV testing among customers in pharmacies participating in a nonprescription syringe program in New York City. Participants were recruited in two pharmacies to complete a survey and receive an optional HIV test. Bivariate and multivariable analyses were performed to examine associations of demographics and risk behaviors with receiving in-pharmacy HIV testing. Most participants were male (55%), black (80%), had used hard drugs (88%), and 39.5% received in-pharmacy HIV testing. Being female (AOR=2.24; 95%CI 1.24-4.05), having multiple sex partners (AOR=1.20; 95% CI 1.06-1.35), having an HIV test more than 12 months ago (AOS=4.06; CI 1.85-8.91), injecting drugs in last 3 months (AOR=2.73; 95% CI 1.31-5.69) and having continuous care (AOR=0.32; 95% CI 0.17-0.58) were associated with receiving in-pharmacy HIV test. These data provide evidence of in-pharmacy HIV testing reaching persons at risk of HIV. HIV testing in pharmacies may complement existing strategies.

RESULTS: The 21 participating sites administered 1,540 HIV tests, with 1,087 conducted onsite by staff during regular working hours and 453 conducted at 37 different HIV testing events (e.g., local health fairs). The median amount of time required for pretest counseling/consent, waiting for test results, and posttest counseling was 4, 23, and 3 minutes, respectively. A majority of the sites (17) said they planned to continue HIV testing after the project period ended and would seek assistance or support from the local health department, a community-based organization, or an AIDS service organization.

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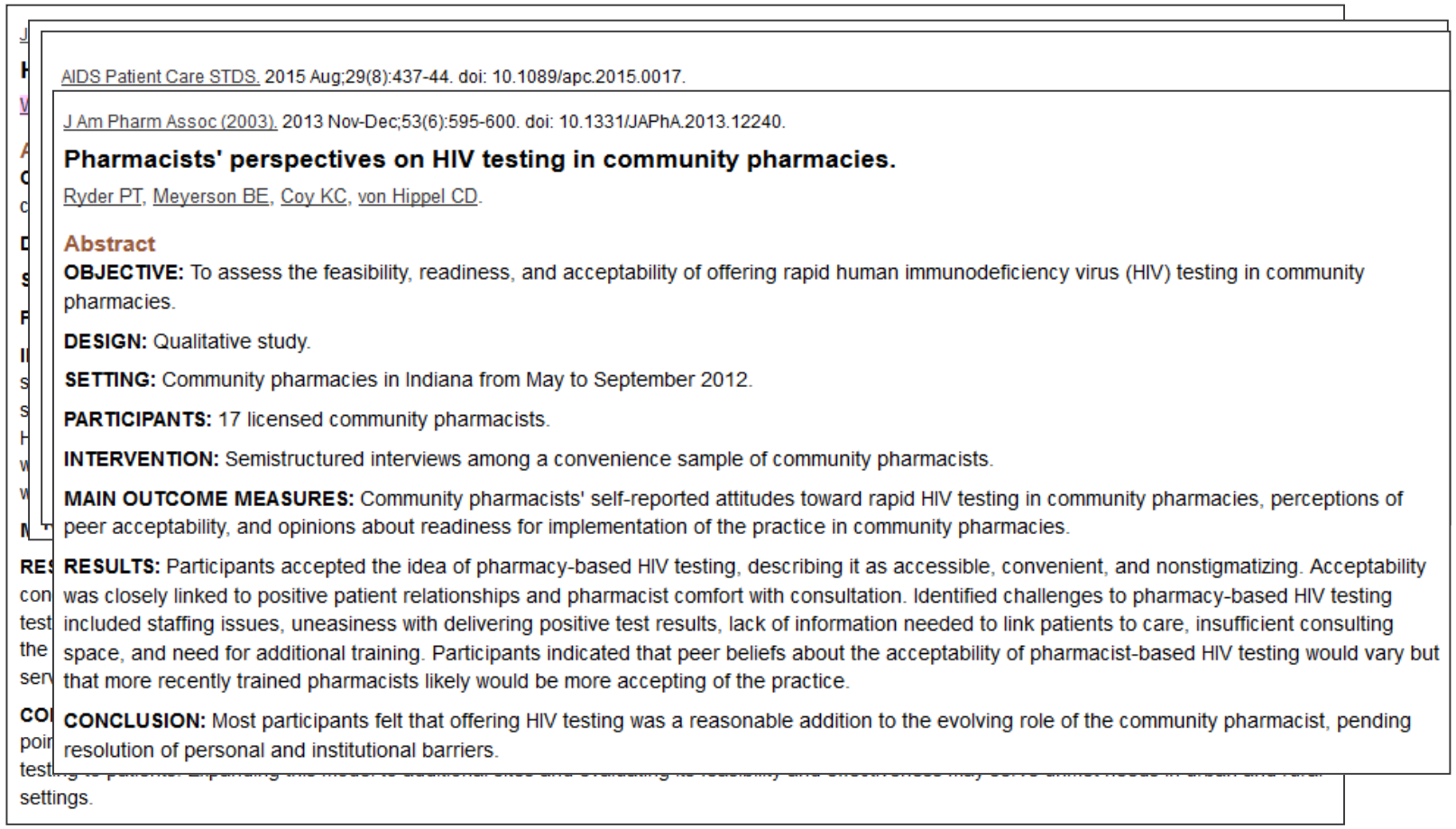


AIDS Patient Care STDS. 2015 Aug;29(8):437-44. doi: 10.1089/apc.2015.0017.

J Am Pharm Assoc (2003). 2013 Nov-Dec;53(6):595-600. doi: 10.1331/JAPhA.2013.12240.

Pharmacists' perspectives on HIV testing in community pharmacies.

Ryder PT, Meyerson BE, Coy KC, von Hippel CD.

Abstract

OBJECTIVE: To assess the feasibility, readiness, and acceptability of offering rapid human immunodeficiency virus (HIV) testing in community pharmacies.

DESIGN: Qualitative study.

SETTING: Community pharmacies in Indiana from May to September 2012.

PARTICIPANTS: 17 licensed community pharmacists.

INTERVENTION: Semistructured interviews among a convenience sample of community pharmacists.

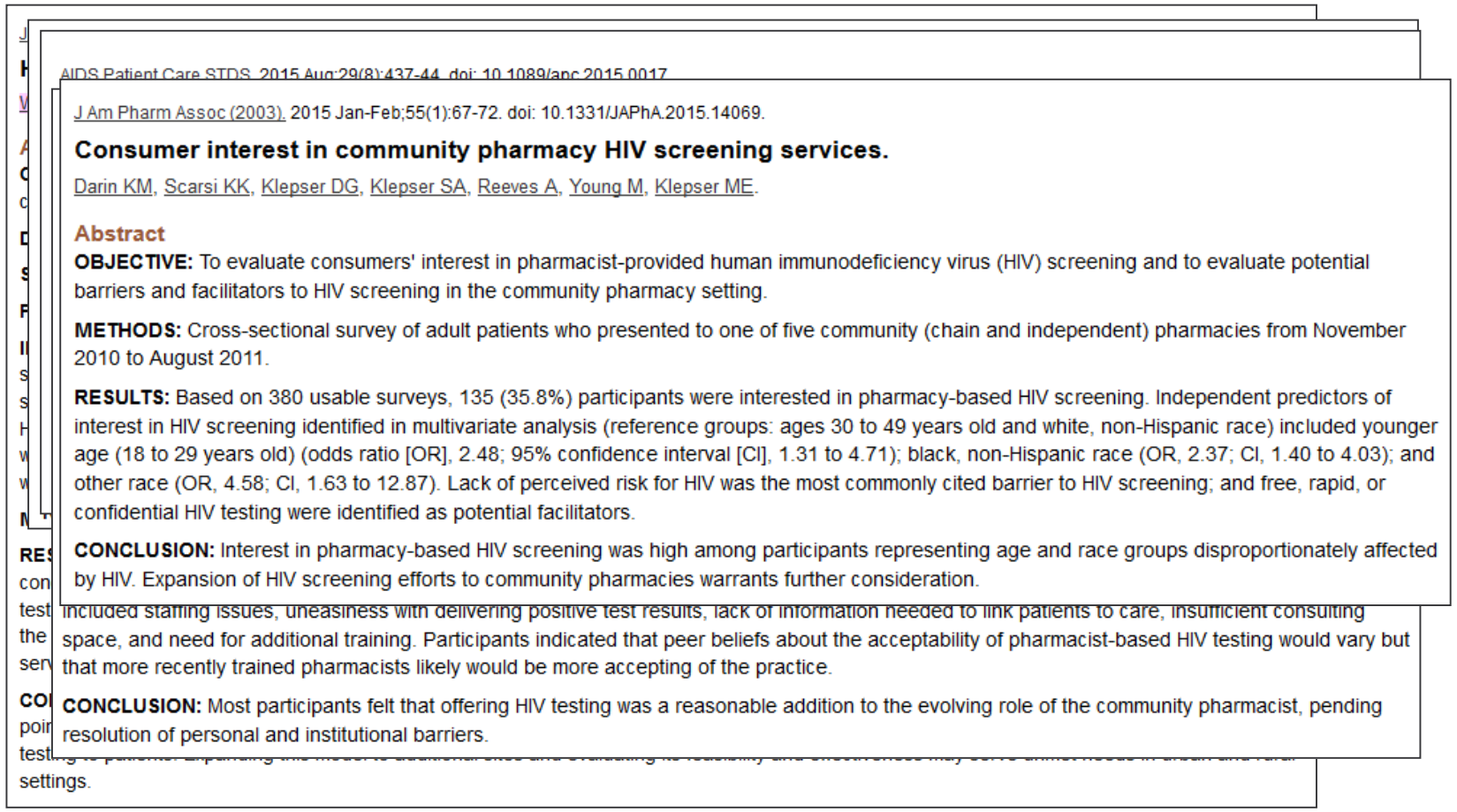
MAIN OUTCOME MEASURES: Community pharmacists' self-reported attitudes toward rapid HIV testing in community pharmacies, perceptions of peer acceptability, and opinions about readiness for implementation of the practice in community pharmacies.

RESULTS: Participants accepted the idea of pharmacy-based HIV testing, describing it as accessible, convenient, and nonstigmatizing. Acceptability was closely linked to positive patient relationships and pharmacist comfort with consultation. Identified challenges to pharmacy-based HIV testing included staffing issues, uneasiness with delivering positive test results, lack of information needed to link patients to care, insufficient consulting space, and need for additional training. Participants indicated that peer beliefs about the acceptability of pharmacist-based HIV testing would vary but that more recently trained pharmacists likely would be more accepting of the practice.

CONCLUSION: Most participants felt that offering HIV testing was a reasonable addition to the evolving role of the community pharmacist, pending resolution of personal and institutional barriers.

Improving Diagnosis

Can Pharmacists Be Part of the Solution?



J Am Pharm Assoc (2003). 2015 Jan-Feb;55(1):67-72. doi: 10.1331/JAPhA.2015.14069.

Consumer interest in community pharmacy HIV screening services.

Darin KM, Scarsi KK, Klepser DG, Klepser SA, Reeves A, Young M, Klepser ME.

Abstract

OBJECTIVE: To evaluate consumers' interest in pharmacist-provided human immunodeficiency virus (HIV) screening and to evaluate potential barriers and facilitators to HIV screening in the community pharmacy setting.

METHODS: Cross-sectional survey of adult patients who presented to one of five community (chain and independent) pharmacies from November 2010 to August 2011.

RESULTS: Based on 380 usable surveys, 135 (35.8%) participants were interested in pharmacy-based HIV screening. Independent predictors of interest in HIV screening identified in multivariate analysis (reference groups: ages 30 to 49 years old and white, non-Hispanic race) included younger age (18 to 29 years old) (odds ratio [OR], 2.48; 95% confidence interval [CI], 1.31 to 4.71); black, non-Hispanic race (OR, 2.37; CI, 1.40 to 4.03); and other race (OR, 4.58; CI, 1.63 to 12.87). Lack of perceived risk for HIV was the most commonly cited barrier to HIV screening; and free, rapid, or confidential HIV testing were identified as potential facilitators.

CONCLUSION: Interest in pharmacy-based HIV screening was high among participants representing age and race groups disproportionately affected by HIV. Expansion of HIV screening efforts to community pharmacies warrants further consideration.

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CONCLUSION: Most participants felt that offering HIV testing was a reasonable addition to the evolving role of the community pharmacist, pending resolution of personal and institutional barriers.

settings.

Improving Diagnosis

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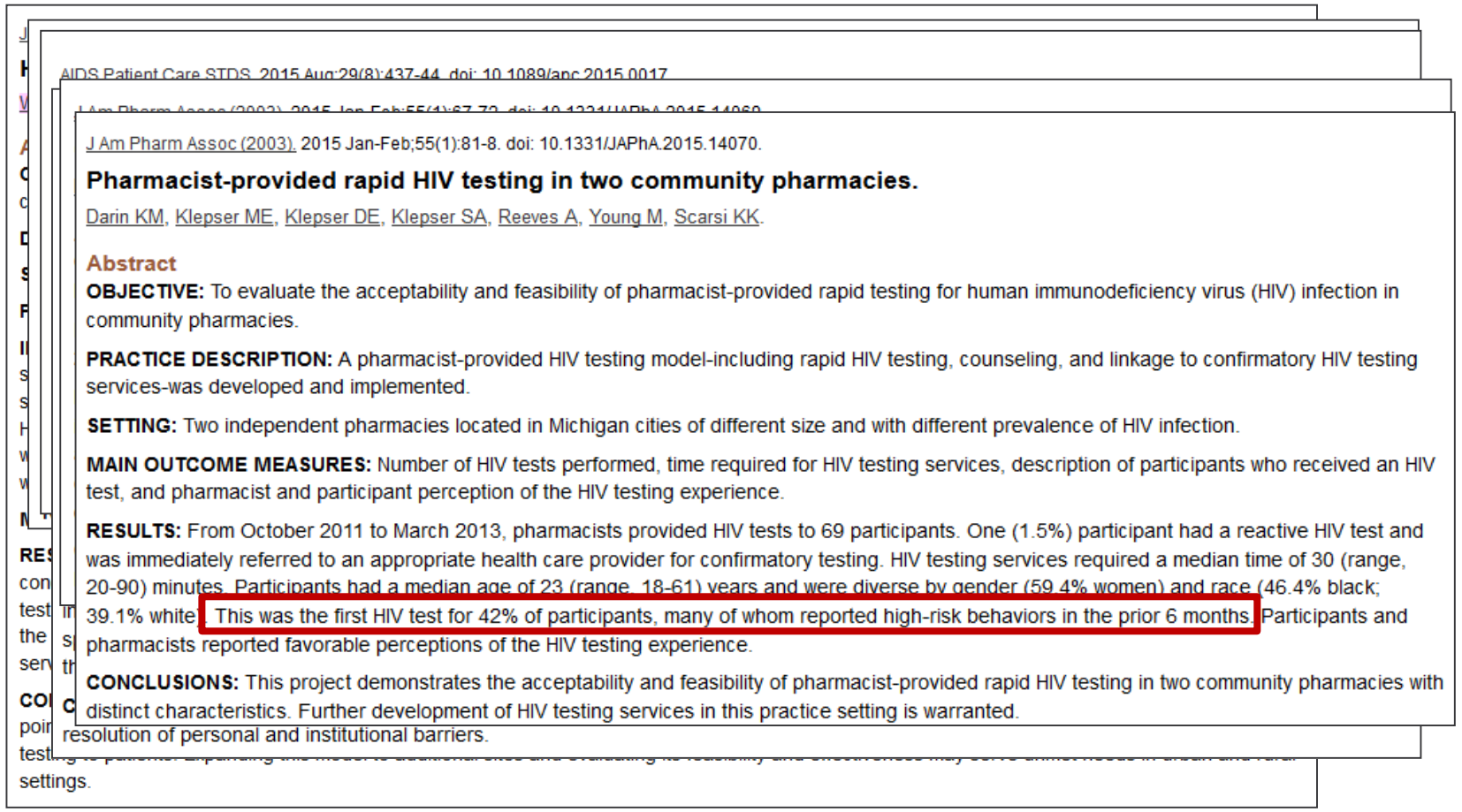


AIDS Patient Care STDS. 2015 Aug;29(8):437-44. doi: 10.1089/apc.2015.0017.

J Am Pharm Assoc (2003). 2015 Jan-Feb;55(1):81-8. doi: 10.1331/JAPhA.2015.14070.

Pharmacist-provided rapid HIV testing in two community pharmacies.

Darin KM, Klepser ME, Klepser DE, Klepser SA, Reeves A, Young M, Scarsi KK.

Abstract

OBJECTIVE: To evaluate the acceptability and feasibility of pharmacist-provided rapid testing for human immunodeficiency virus (HIV) infection in community pharmacies.

PRACTICE DESCRIPTION: A pharmacist-provided HIV testing model-including rapid HIV testing, counseling, and linkage to confirmatory HIV testing services-was developed and implemented.

SETTING: Two independent pharmacies located in Michigan cities of different size and with different prevalence of HIV infection.

MAIN OUTCOME MEASURES: Number of HIV tests performed, time required for HIV testing services, description of participants who received an HIV test, and pharmacist and participant perception of the HIV testing experience.

RESULTS: From October 2011 to March 2013, pharmacists provided HIV tests to 69 participants. One (1.5%) participant had a reactive HIV test and was immediately referred to an appropriate health care provider for confirmatory testing. HIV testing services required a median time of 30 (range, 20-90) minutes. Participants had a median age of 23 (range, 18-61) years and were diverse by gender (59.4% women) and race (46.4% black; 39.1% white). This was the first HIV test for 42% of participants, many of whom reported high-risk behaviors in the prior 6 months. Participants and pharmacists reported favorable perceptions of the HIV testing experience.

CONCLUSIONS: This project demonstrates the acceptability and feasibility of pharmacist-provided rapid HIV testing in two community pharmacies with distinct characteristics. Further development of HIV testing services in this practice setting is warranted.

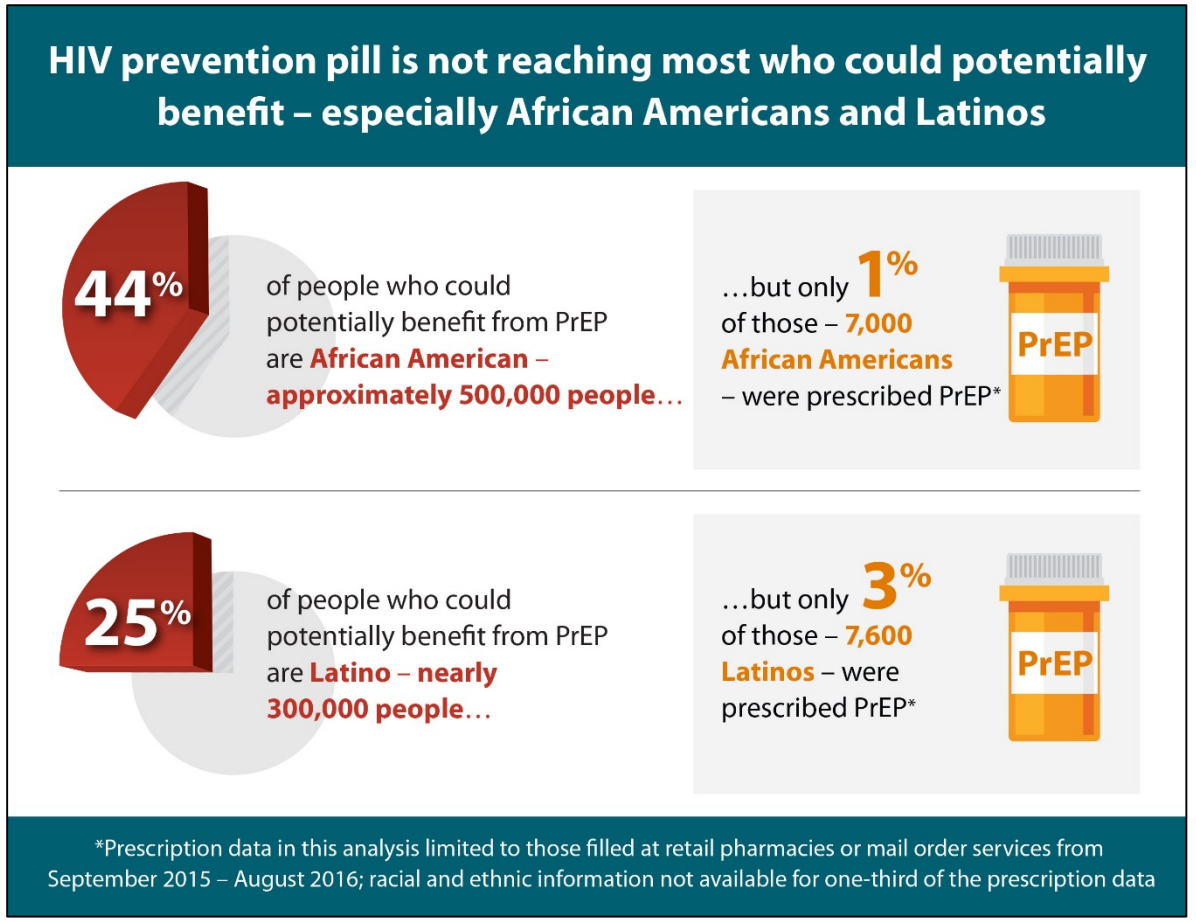
resolution of personal and institutional barriers.

settings.

HIV Prevention

Access to Pre-Exposure Prophylaxis (PrEP)

- About 1.1 million Americans overall are at substantial risk for HIV and should be offered PrEP.
- However, only 90,000 PrEP prescriptions were filled in commercial pharmacies in 2015.
- Two-thirds of people who could potentially benefit from PrEP are African-American or Latino
  - They account for the smallest percentage of prescriptions to date.



https://www.cdc.gov/nchhstp/newsroom/2018/croi-2018-PrEP-press-release.html

Improving Prevention with PrEP

Can Pharmacists Be Part of the Solution?

Kelley-Ross Pharmacy in Seattle, WA

Pharmacist-run comprehensive HIV PrEP clinic in a community-based pharmacy

Collaborative drug therapy agreement allows pharmacists to perform all necessary duties:

- Screen for qualified patients, order labs, prescribe PrEP, and dispense the medication

Protocol-guided services provided under a physician medical director

Between March 2015 – March 2016	Number (%)
Patients seeking service	373
Patient evaluated in the clinic	251
Patients qualified for PrEP at their initial visit	245 (97%)
Patients with primary care provider	57 (23%)
Male	241 (98%)
Age (mean)	34 y
MSM	210 (84%)
HIV-positive tests	2
Clinic retention rate	75%

Tung E, et al. CROI 2017; February 13–16, 2017; Seattle, WA. Abstract 961.

New PrEP Guidelines Recently Published by the Centers for Disease Control

	Men Who Have Sex with Men	Heterosexual Women and Men	Persons Who Inject Drugs
Detecting substantial risk of acquiring HIV infection	HIV-positive sexual partner Recent bacterial STI† High number of sex partners History of inconsistent or no condom use Commercial sex work	HIV-positive sexual partner Recent bacterial STI‡ High number of sex partners History of inconsistent or no condom use Commercial sex work In high HIV prevalence area or network	HIV-positive injecting partner Sharing injection equipment
Clinically eligible	Documented negative HIV test result before prescribing PrEP No signs/symptoms of acute HIV infection Normal renal function; no contraindicated medications Documented hepatitis B virus infection and vaccination status		
Prescription	Daily, continuing, oral doses of TDF/FTC (Truvada), ≤90-day supply		
Other services	Follow-up visits at least every 3 months to provide the following: HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, STI symptom assessment At 3 months and every 6 months thereafter, assess renal function Every 3-6 months, test for bacterial STIs		
	Do oral/rectal STI testing	Assess pregnancy intent Pregnancy test every 3 months	Access to clean needles/syringes and drug treatment services

Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2017 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf. Published March 2018.

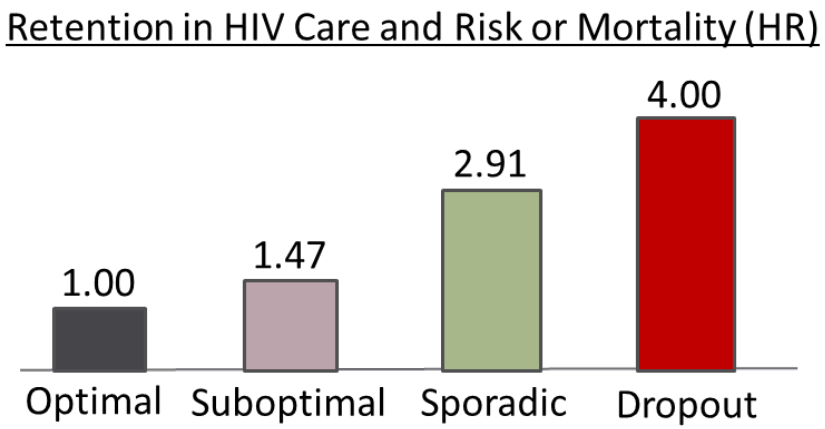
Access To Antiretroviral Therapy

The Barriers – Engagement in Care and Adherence

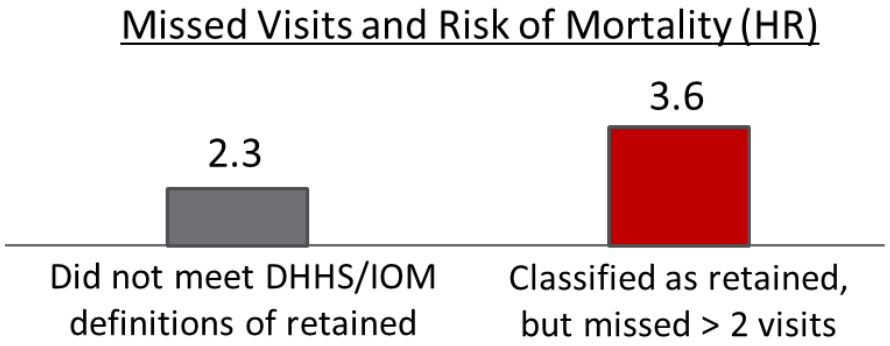
Dailey et al., MMWR Morb Mortal Weekly Rep, 2017; 66(47): 1300-1306

Poor Engagement and Adherence are Linked to an Increased Risk of Mortality

- A retrospective study of 2197 persons in the state of South Carolina examined newly diagnosed patients for 2-year intervals from 2004-2009
  - Poor retention was linked to an increased risk of mortality



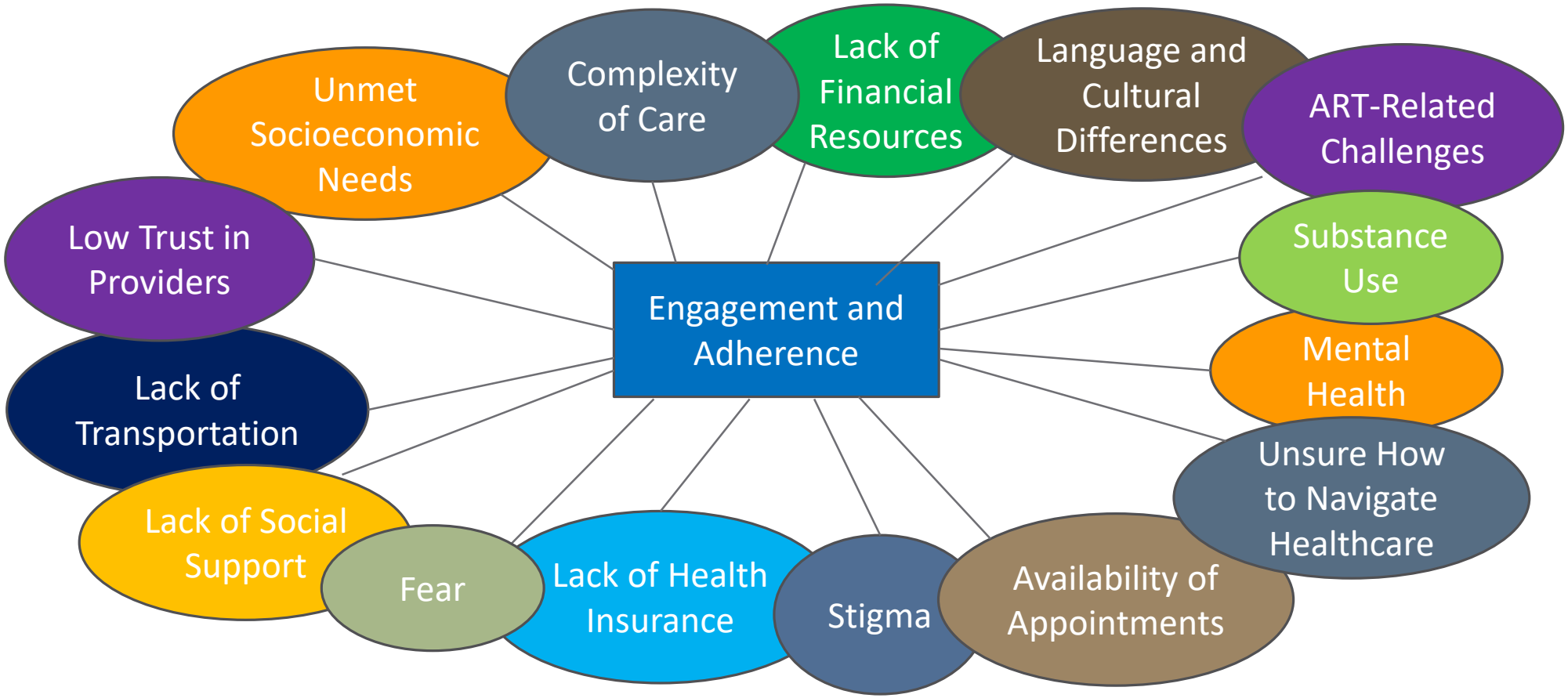
- Retrospective analysis of 3,672 patients establishing care for HIV at the University of Alabama from 2000-2010
  - The risk of mortality was increased in patients missing visits despite meeting DHHS and IOM definitions of retained



Tripathi A, et al. AIDS Res Hum Retroviruses. 2011. Mugavero MJ, et al. Clin Infect Dis 2009.

Access To Antiretroviral Therapy

The Barriers – Engagement in Care and Adherence



US DHHS. Guidelines for Use of Antiretroviral Agents in HIV-1–Infected Adults and Adolescents. 2017. https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/10/initiation-of-antiretroviral-therapy. Accessed August 1, 2018.

Improving Engagement and Adherence

Can Pharmacists Be Part of the Solution?

12-month ART Adherence: Multidisciplinary Care Teams vs. HIV Physician Specialist Only	
New Regimen Starts (n=10,601) from 1996–2006 at Kaiser Permanente California (ART Naïve: n=7071; Treatment Experienced: n=3730)	
Reference: HIV Physician Specialist only	Difference Over Reference, %*
Pharmacist plus care coordinator plus PCP	8.1
Nurse plus social worker plus PCP	7.5
Specialist plus mental worker	6.5
Pharmacist plus social worker plus PCP	5.7
Pharmacist plus PCP	3.3

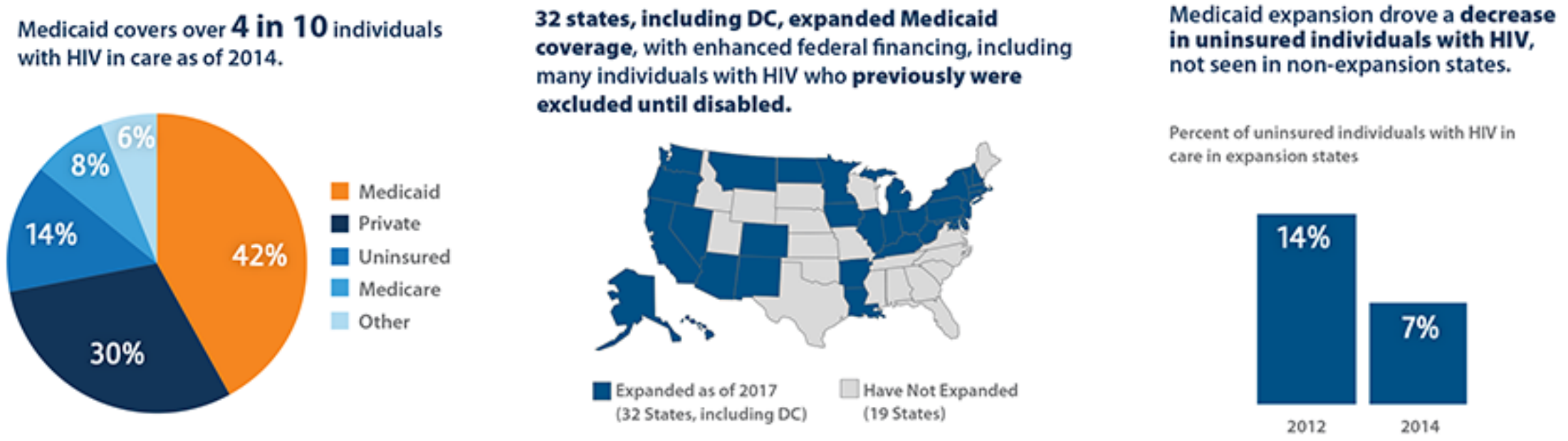
*$P<0.05$ for each combination

Horberg M, et al. J Acquir Immune Defic Syndr. 2012; 60(2):183-190.

Access To Antiretroviral Therapy

The Barriers – Payment

- Medicaid is the largest source of coverage for individuals with HIV – The ACA's Medicaid expansion, with enhanced funding, covers many with HIV who were previously excluded until they became disabled



https://kaiserfamilyfoundation.files.wordpress.com/2017/04/infographic-medicaids-role-for-individuals-with-hiv1.png

Access To Antiretroviral Therapy

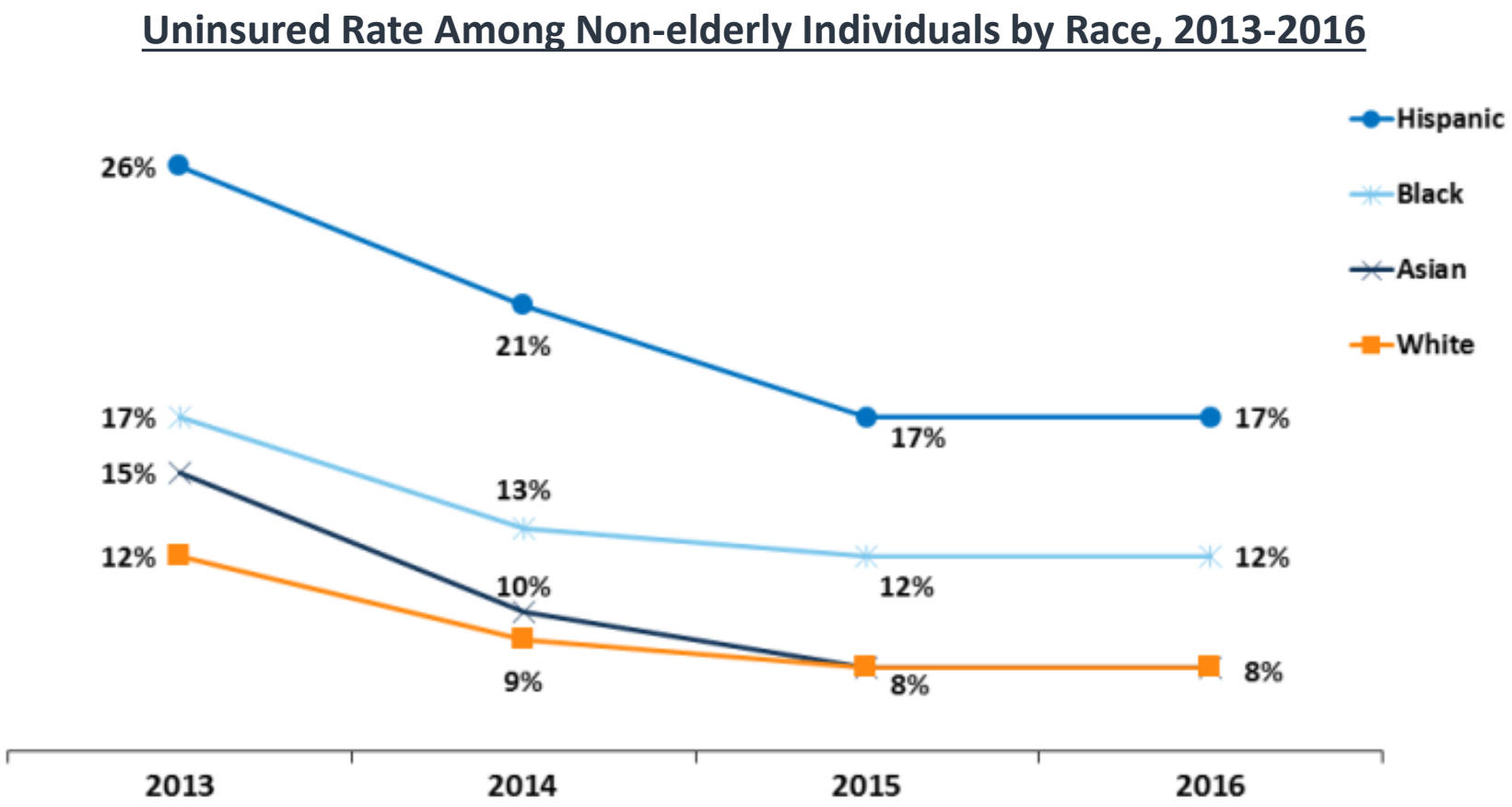
The Barriers – Payment

- Prior to the ACA, people with HIV faced limited access to insurance coverage due to barriers, including pre-existing condition exclusions, high costs, and Medicaid eligibility limitations.

- The ACA has played a significant role in increasing insurance coverage for people with HIV through Medicaid expansion.
  - Prior to expansion, most states required persons living with HIV to become disabled by AIDS before being Medicaid eligible.

- To the extent that ACA repeal efforts include elimination of the Medicaid expansion option for states, most people with HIV who gained coverage would likely lose it unless states adopt alternative approaches to retaining the newly covered population in the program.

People of color have experienced the largest gains in coverage since ACA implementation



https://www.kff.org/report-section/health-coverage-by-race-and-ethnicity-changes-under-the-aca-issue-brief/

Access To Antiretroviral Therapy
Current Threats

- ACA Repeal
  - A full or partial repeal that includes the elimination of the Medicaid expansion option for states, would cause most people with HIV who gained coverage to lose it
  - This will increase pressure on safety net programs like Ryan White and AIDS Drug Assistance Programs

- Short Term, Limited Duration Insurance Plans
  - Designed to provide temporary coverage, are less costly because they provide little insurance
  - Limited under the ACA to 3 months, are now available for 1 year and renewable for up to 3 years
  - Can exclude individuals with pre-existing conditions and impose annual/lifetime limits
  - Could increase costs for those relying on coverage through the ACA

- Copay accumulators
  - A practice health insurance and pharmacy benefit managers are instituting that prevents manufacturer copay assistance from counting towards a member's deductible and out-of-pocket maximum

Advocacy

Access to Care and Antiretroviral Therapy

- The AAHIVM Policy Department and Policy Committee
  - https://aahivm.org/advocacy-and-policy/
- HIVMA Policy and Advocacy
  - https://www.hivma.org/Policy-Advocacy.aspx
- Advocacy in Action – POZ
  - https://www.poz.com/tag/advocacy
- ADAP Advocacy Association
  - http://www.adapadvocacyassociation.org/
- The International HIV/AIDS Alliance
  - http://www.aidsalliance.org/about/policy-and-advocacy
- AIDS United
  - https://www.aidsunited.org/Policy-0024-Advocacy.aspx
- AVAC – Global Advocacy for HIV Prevention
  - https://www.avac.org/
- Elizabeth Glaser Pediatric AIDS Foundation
  - http://www.pedaids.org/

Summary

- ART is recommended for all individuals with HIV, regardless of CD4 T lymphocyte cell count, to reduce HIV-related morbidity and mortality as well as HIV transmission.

- Integrase inhibitor-based ART regimens are currently preferred; bictegravir and dolutegravir have few drug interactions, low pill burdens and higher barriers to resistance.

- Multidisciplinary teams are best to improve patient access and maintain engagement in care or preventative services that can improve outcomes due to HIV infection

- Advocacy remains essential to ensure that ALL patients living with HIV have access to life saving treatment without interruption