

SYLLABUS AND COURSE GUIDE

Disparities in HIV Care: The Mounting Epidemic Plaguing African Americans

A Free, 90-Minute Live and OnDemand Activity

Premier Date: Monday, April 26, 2021

6:30 PM -8:00 PM ET (live)

Credit Expiration Date: Tuesday, April 26, 2022

Log-In: www.cmeoutfitters.com/HIVcare

FACULTY:

Oni J. Blackstock, MD, MHS (Moderator)

Carlos Malvestutto, MD, MPH

Leandro A. Mena, MD, MPH

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INFORMATION FOR PARTICIPANTS

Statement of Need

The national response to HIV infection and advances in preventative therapies has meant that there are fewer new HIV infections nationally. Additionally, more people with HIV are diagnosed, on a treatment regimen, and leading longer, healthier lives. However, stark racial disparities remain for people living with HIV. Black and African Americans do not engage in more high-risk behaviors than persons of other races, yet they have the highest rates of new HIV infections. Black and African Americans also have poorer outcomes for diagnosis, linkage to care, retention in care, antiretroviral therapy (ART), treatment adherence, and viral suppression, which has led them to be the most affected population of new HIV diagnoses.

This CME Outfitters Live and OnDemand will address racial and ethnic health care disparities among at-risk individuals, with expert faculty discussing best practices for actively engaging Black/African Americans at risk for HIV, developing treatment strategies for older adults with HIV, and initiating and switching patients to ART based on safety and efficacy profiles, to optimize health and treatment outcomes throughout their lives.

Learning Objectives

At the end of this CE activity, participants should be able to:

- Actively engage Black/African Americans at risk for HIV in testing, treatment, and educational initiatives.
- Develop treatment strategies for older adults with HIV to optimize health outcomes.
- Integrate best practices for initiating and switching patients to ART based on safety and efficacy profiles.

The following learning objectives pertain only to those requesting CNE or CPE credit:

- Summarize ways to actively engage Black/African Americans at risk for HIV in testing, treatment, and educational initiatives.
- Explain treatment strategies for older adults with HIV to optimize health outcomes.
- Identify best practices for initiating and switching patients to ART based on safety and efficacy profiles.

Financial Support

This educational activity is supported by independent educational grants from Gilead Sciences, Inc., Janssen Therapeutics, Division of Janssen Products, LP, and ViiV Healthcare. These supporters were not involved in the development of content or selection of faculty for this educational activity.

Target Audience

Primary care physicians, infectious disease specialists, nurse practitioners, PAs, nurses, and pharmacists

CREDIT INFORMATION

CME Credit (Physicians):

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Live: 0376-0000-21-062-L02-P

Enduring:0376-0000-21-062-H02-P

Type: Knowledge-based

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Learning Formats: Live activity; Enduring material

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Dr. Malvestutto reports that he is on the advisory board for ViiV Healthcare.

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Dr. Mena reports that he receives grants from Gilead Sciences, Inc. and Merck & Co. He receives research support from Binx Health, Inc.; Gilead Sciences, Inc.; GlaxoSmithKline/ViiV Healthcare; Merck & Co.; and ThaiMed. He is on the speakers bureau for Gilead Sciences, Inc. He is a consultant for Gilead Sciences, Inc.; GlaxoSmithKline/ViiV Healthcare; and Merck & Co.

Tony Graham, MD (peer reviewer) has no disclosures to report.

Noreen Iftikhar, MD (planning committee) has no disclosures to report.

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FACULTY BIOS

Oni J. Blackstock, MD, MHS (Moderator)

Founder and Executive Director

Health Justice, LLC

New York, NY

Dr. Oni Blackstock is recognized as a thought leader and influencer in the areas of HIV and health equity. She is a primary care and HIV physician, and the founder and Executive Director of Health Justice, a consulting practice that helps health organizations to center anti-racism and equity in the workplace and reduce health inequities in the communities they serve. Dr. Blackstock recently served as an Assistant Commissioner at the New York City Health Department where she led the City's response to the HIV epidemic. She holds degrees from Harvard College, Harvard Medical School, and Yale School of Medicine and is passionate about ensuring that all individuals and communities have the resources and support they need to achieve optimal health and well-being.

Carlos Malvestutto, MD, MPH

Assistant Professor

Division of Infectious Diseases

Ohio State University Wexner Medical Center

Columbus, OH

Dr. Malvestutto completed his Bachelor of Science in Biology at Yale University in 1996 and a Master of Public Health at Johns Hopkins University College of Hygiene and Public Health in 2000. He obtained his medical degree at Ponce School of Medicine in Ponce, Puerto Rico in 2005 and completed residency in internal medicine at Mount Sinai Medical Center in New York, NY in 2008 and his fellowship in infectious diseases at New York University Medical Center in 2010. He remained on faculty at NYU until 2014 when he moved to Columbus, OH and joined the faculty at the Ohio State University Wexner Medical Center.

FACULTY BIOS

Dr. Malvestutto is an Assistant Professor in the Division of Infectious Diseases at the Ohio State University Wexner Medical Center. He is the former Director of the Infectious Diseases Fellowship Training Program at OSU and is the former Medical Director of the Family AIDS Clinic and Education Services (FACES) program at Nationwide Children's Hospital. Dr. Malvestutto is an investigator at the OSU AIDS Clinical Trials unit and is involved in multiple HIV and hepatitis C clinical trials. His areas of clinical research include improving linkage to prevention and treatment care for underserved populations, cardiovascular complications of HIV, new modalities of HIV and PrEP, and use of broadly neutralizing antibodies for the treatment and cure of HIV.

Leandro A. Mena, MD, MPH

Chair and Professor of Population Health Science

Professor of Medicine, Division of Infectious Diseases

University of Mississippi Medical Center

Jackson, MS

Leandro Mena, MD, MPH, is a clinician-researcher and public health advocate with expertise in the prevention and clinical management of sexually transmitted diseases (STDs) and the human immunodeficiency virus (HIV). He is founding chair of the Department of Population Health Science at the University of Mississippi Medical Center John D. Bower School of Population Health and Professor of Medicine in the Division of Infectious Diseases. Dr. Mena also directs the Center for HIV/AIDS Research, Education & Policy at the Myrlie Evers-Williams Institute for Elimination of Health Disparities and serves as the STD Medical Director for the state of Mississippi. He is the Medical Director of the Five Points Clinic (Jackson's public STD clinic) and co-founded Open Arms Healthcare Center (first Lesbian, Gay, Bisexual, and Transgender [LGBT] clinic in Mississippi). In recognition of his work developing a model program of culturally-competent HIV prevention and care for Black men who have sex with men, which is being replicated in other clinics around the country, he was awarded the 2016 Achievement Award by the Gay and Lesbian Medical Association (GLMA). Dr. Mena is board certified in infectious diseases. He is a research fellow with the Rural Center for STD/HIV Prevention (Indiana University). His interests include understanding the dynamics of HIV transmission in racial/ethnic, gender, and sexual minorities as well as the development and provision of culturally competent quality health services to these populations.



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Learning Objective

Actively engage Black/African Americans at risk for HIV in testing, treatment, and educational initiatives.

Audience Response

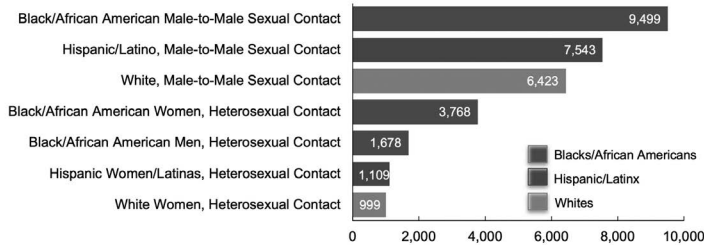
In the Trio Health Study report, which of these statements is NOT true regarding the differences in HIV viral suppression?

1. Black and other people of color have higher rates of viremia than Whites
2. People with HIV treated in the South have lower rates of viral suppression
3. Medicare and commercial insurance patients had equal rates of viremia
4. There were no differences between gender in rates of viral suppression
5. I'm not sure.



Black Communities Are Disproportionately Affected By HIV

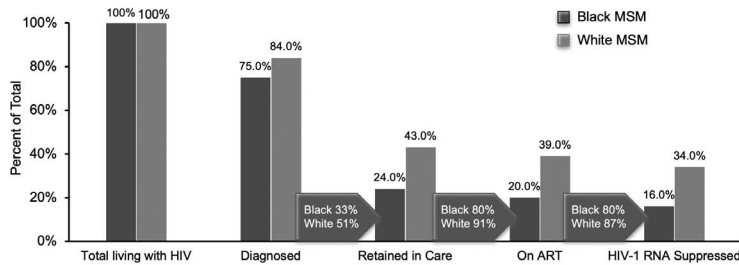
New HIV Diagnoses in the U.S. and Dependent Areas for the Most-Affected Subpopulations, 2018



Centers for Disease Control and Prevention. 2019. <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2018-preliminary-vol-30.pdf>. Accessed April 20, 2021.



Racial Disparities in HIV Cascade of Care for MSM in the US, 2009-2010

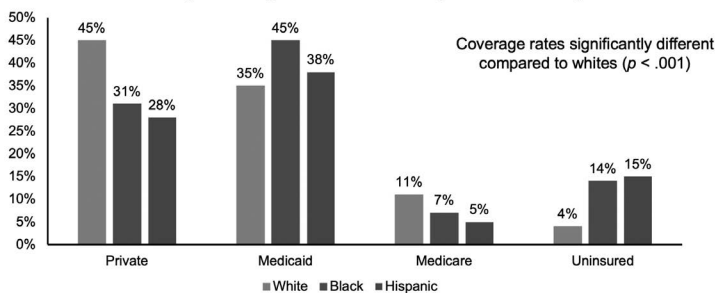


MSM = men who have sex with men
Rosenberg ES, et al. *Lancet HIV*. 2014;1:112-118



Disparities in Access to HIV Care

Insurance Coverage Among Adults with HIV by Race/Ethnicity 2018



Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. <https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/AdultandAdolescentGL.pdf>. Accessed April 20, 2021.



Key Disparities in Black Communities: Baltimore, MD Sample

- In a sample of 1,464 HIV-negative individuals, only 18% reported prior knowledge of PrEP
 - Awareness among Whites (34%) twice as high as awareness among Blacks (16%)

Why Does This Matter?

- Black men are > 6X more likely to acquire HIV during their lives compared to Whites
- Lifetime HIV risk is 17X greater among Black women than White women

PrEP = pre-exposure prophylaxis
 Yang C, et al. *J Health Care Poor Underserved*. 2021;32(1):537-549.

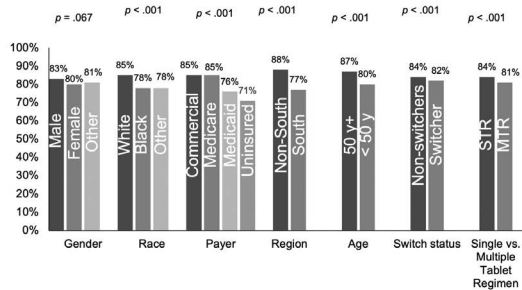


Regional and Racial Disparities in ART Response: Trio Health Study

Higher rates of viremia

- Younger
- Black or other people of color
- Treated in the South
- Medicaid or uninsured
- Multi-tablet regimen

Differences in Viral Suppression by Race and Region



ART = antiretroviral therapy; MTR = multiple tablet regimen; N = 20,2071; STR = single tablet regimen
 Rawlings KM, et al. *Open Forum Infect. Dis.* 2020;7:1:S835.



Audience Response

Which of these factors do not contribute to HIV disease burden among African-Americans / Black Americans?

1. Limited access to health care services
2. Health care inequities and inequalities
3. Higher rates of high-risk behaviors than persons of other races
4. Poorer rates of linkage and retention in ART care
5. I don't know



Social and Structural Factors Contributing to HIV Disease Burden Among African Americans

- Black and African Americans do not engage in any more high-risk behaviors than persons of other races, but have poorer outcomes for diagnosis, linkage and retention in care, ART prescription, adherence and viral suppression
 - Limited access to health care services
 - Lower levels of health insurance
 - HIV-related stigma
 - High rates of incarceration

Nunn A, et al. *AIDS Behav.* 2019;23(Suppl 3):319-330.



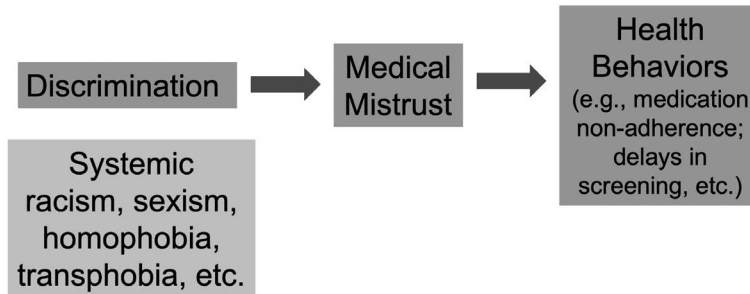
Patient, Provider, and System Factors that Affect Linkage to and Retention in Care

- Negative experience at HIV testing site
- Fear of disclosure, discrimination, stigmatization
- Gaps in follow-up/referral services
- Lack of motivation, denial
- Distrust of health care system
- Poor provider communication or lack of connection with provider
- Financial: housing, employment, food insecurity, transportation, lack of health insurance
- Alcohol/substance use
- Mental health needs
- Prioritizing health in the context of other social disparities
- Negative or no experience navigating health care system
- Lack of support system

Mugavero MJ, et al. *Clin Infect Dis*. 2011;52:S238-S246.



The Relationship Between Discrimination, Medical Mistrust and Health Behaviors



Bogart LM, et al. Medical mistrust, discrimination, and the domestic HIV epidemic. *HIV in US Communities of Color*. 2021; pp. 207-231. https://link.springer.com/chapter/10.1007%2F978-3-030-48744-7_12. Accessed April 23, 2021.



Medical Mistrust is Negatively Associated with Many HIV-Related Outcomes

- Lower uptake of HIV testing
- Lower uptake of condoms
- Less comfort talking to providers about PrEP
- Lower PrEP awareness and uptake
- Lower likelihood to believe HIV treatment is effective
- Lower antiretroviral adherence
- Less likelihood of viral suppression
- Engagement in HIV care?

Adapted from Bogart LM, et al. Medical mistrust, discrimination, and the domestic HIV epidemic. In *HIV in US Communities of Color*. 2021. https://link.springer.com/chapter/10.1007%2F978-3-030-48744-7_12. Accessed April 23, 2021.



JumpstART Program: New York City Sexual Health Clinics

Early HIV treatment = improved patient and public health outcomes

- Routine rapid antibody test; highest risk (eg. MSM) also screened for acute HIV infection (AHI) via pooled nucleic acid amplification testing
- 149 patient, >18 years, treatment naïve
 - 35% Hispanic
 - 32% Black
 - 20% White, non-Hispanic
 - 13% Other, non-Hispanic
- Immediate on-site ART with navigation and sustained linkage-to-care

Blank S, et al. Presented at CROI (virtual); 2018. Abstract No. 1108. https://2jg4quetidw2lbbq2ixwziw-wpengine.netdna-ssl.com/wp-content/uploads/sites/2/posters/2018/1430_Borges_1108.pdf. Accessed April 22, 2021.



JumstART Program: Results

- Baseline testing (CD4, VL, genotype; kidney, liver function tests, CBC, HBV, HCV screen) & other STIs
- Initiating ARV at diagnosis feasible = higher initiation rates
- Early treatment for people at-risk (ie. MSM of color)
- 20% met criteria for AIDS and able to access treatment without delay or loss

	N	%
Critical labs		
Hepatitis B	3	2%
Hepatitis C	0	0
Abnormal kidney	11	7%
Abnormal liver	8	5%
CD4 < 200 (stage 3)	25	17%
Baseline Quantitative Viral Load		
> 100,000 (c/ml)	46	31%
< 100,000 (c/ml)	101	69%

AIDS = acquired immunodeficiency syndrome; CBC = complete blood count; CD4 = cluster of differentiation 4; HBV = hepatitis B virus; HCV = hepatitis C virus; N = number of patients; STI = sexually transmitted infections; VL = viral load
Blank S, et al. Presented at CROI (virtual); 2018. Abstract No. 1108. https://2jg4quetdvw2blbbq2xwzwwpengine.netdna-ssl.com/wp-content/uploads/sites/2/posters/2018/1430_Borges_1108.pdf. Accessed April 22, 2021.



Optimize ART Adherence for Black Americans with HIV

- Biases and stereotypes about adherence among HIV-positive people of color
 - Affect provider's treatment decisions and failure to treat some minorities
 - Delay timing of ART initiation
- Most studies show that Black Americans and other people of color have similar adherence to ART as other patients (after controlling for other key factors known to be predictors of poorer adherence)
- Yet, in "real-life," Black Americans are more likely to experience one or more barriers to adherence compared with their White counterparts

Stone VE, et al. *HIV/AIDS in U.S. Communities of Color*. 2009.



Training Health Care Professionals on Cultural and Racial Discrimination

- Proactively combat biases among HCPs
- Acknowledge and address racism
- Educate on how to respond to mistrust
 - Empathy, reflective listening
 - Encourage questions
 - Non-judgmental, non-confrontational
- *Structural competency*: Acknowledge historical and current context of discrimination and racism as root cause
- Diversify HCPs
- Hire and train PrEP and HIV ambassadors
- Incorporate peer/patient navigators and educators into visits



Takeaways and Action Steps

- Identify opportunities in your practice or health care setting to improve HIV testing and linkage to care for Black Americans
- Educate your health care team about the historical and present-day context of medical mistrust
- Confront biases and stereotypes about adherence among HIV-positive people of color to mitigate treatment delays



Learning Objective

Develop treatment strategies for older adults with HIV to optimize health outcomes.

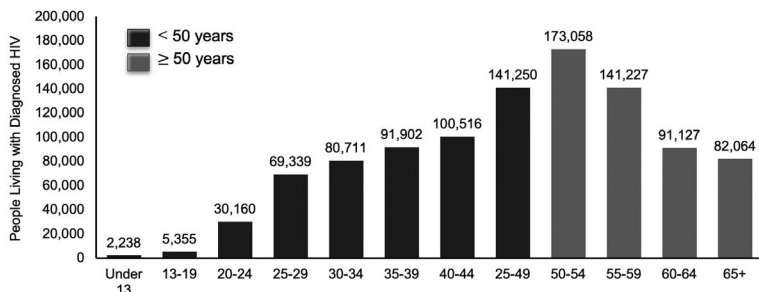
Audience Response

Bone health is a concern among older adults on ART. Which of the following is not a DHHS guideline recommendation about osteoporosis?

1. TAF and ABC are associated with smaller declines in bone mineral density than TDF.
2. TDF has been associated with increases in bone mineral density, renal tubulopathy, and resultant osteomalacia
3. ABC may be used if patient is HLA-B*5701 negative
4. If HIV RNA is > 100,000 copies/mL, do not use ABC/3TV + (EFV or ATV/r)
5. I don't know



48% of People Diagnosed with HIV in the United States are ≥ 50 Years Old¹

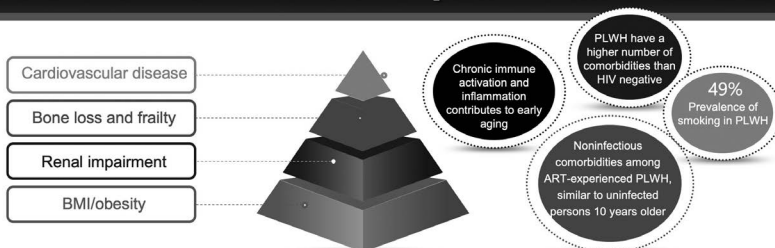


1. Centers for Disease Control and Prevention. 2020. <https://www.cdc.gov/hiv/group/age/olderamericans/index.html>. Accessed April 22, 2021.

2. Shah M, et al. *Lancet HIV*. 2016;3(3):e140-e146.



Comorbidities in People with HIV



As HIV-positive population ages, increasingly important to identify and manage comorbidities that may increase the risk of cardiovascular complications, renal disease, osteoporosis, and bone fracture. Comorbidities are an important consideration when optimizing treatment decisions.

BMI = body mass index; PLWH = people living with HIV
Gallant J, et al. *J Infect Dis*. 2017;216(12):1529-1533.



ProjEcting Age, MultimoRbidity and PoLypharmacy: How Big Will the Morbidity Burden Grow?

- PEARL model projects increasing number of ART users over time, reaching 928,000 U.S. adults by 2030
 - Overall median age increases from 50 to 53 years of age by 2030
 - Large projected growth in ART users 60 – 70 yrs, with 25% of ART users ≥ 65 yrs in 2030
- Predicts increasing burden of ≥ 2 physical comorbidities among PLWH
 - Projected increase from 30% in 2020 to 36% by 2030 (~ 251,000 additional cases)

Comorbidity	Projected Prevalence Change From 2020 to 2030
Anxiety	+ 0.113
Chronic kidney disease	+ 0.094
Diabetes	+ 0.086
Myocardial infarction	+ 0.059
Depression	+ 0.02
Cancer*	+ 0.006
End-stage liver disease	+ 0.001
Hyperlipidemia	- 0.016
Hypertension	- 0.042

*Primarily among males who inject drugs.

Kasale P, et al. Presented at CROI; 2021. Abstract 102. Available at



Treatment Considerations for Older PLWH

- Modifiable contributing factors for quantity and quality of life:¹
 - Burden of harmful health behaviors
 - Smoking, alcohol, substance use
 - HIV treatment toxicity
- Among 266 PLWH, physical function impairment and pre-frailty were present in nearly 50%²
 - Hypertension (28%), overweight (38%), obesity (30%)
 - Older age, Black race, 10 years on ART, greater BMI, high waist circumference, hypertension, and physical inactivity were risk factors

1. Althoff KN, et al. *Curr Opin HIV AIDS*. 2016;11(5):527-536. 2. Umbleja T, et al. CROI; 2020. Abstract No. 707. Available at <https://www.croiconference.org/wp-content/uploads/sites/2/resources/2020/ebook/croi2020-boston-abstract-ebook.pdf>. Page 259.



Cardiovascular Risk in PLWH

- Cardiovascular disease leading causes of mortality in virally suppressed PLWH, and leading challenges in good health outcomes in elderly PLWH¹
- Factors driving risk of cardiovascular disease in PLWH are multiple and may differ from those of general population
- Veterans Aging Cohort Study (n = 82,000) consisted of participants with and without HIV, in which HIV infection linked to increased risk of acute myocardial infarction, even after adjustment for traditional cardiovascular disease risk factors²
- Ongoing REPRIEVE trial: 7500 PLWH; average age: 50 years³

1. McGillick P, et al. *Expert Rev Anti Infect Ther*. 2020;18(7):677-688. 2. Friberg MS, et al. *JAMA Intern Med*. 2013;173(6):614-622.

3. National Institute of Allergy and Infectious Diseases. Randomized Trial to Prevent Vascular Events in HIV-REPRIEVE. ClinicalTrials.gov Identifier: NCT02344290. 2015.



Bone Health in Older PLWH

- Prevalence of frailty in HIV-positive individuals age 40-50 ranges from 5% to 28%^{1,2}
- In Veterans Aging Cohort Study, frailty increased 5-year risk of hospitalization (78%) and mortality (75%) in HIV-positive individuals^{3,4}
- Earlier diagnosis and initiation of ART as well as reinforcement of adherence to therapy can decrease frequency of risk factors¹
- ART treatment decision-making should factor in impact on bone health

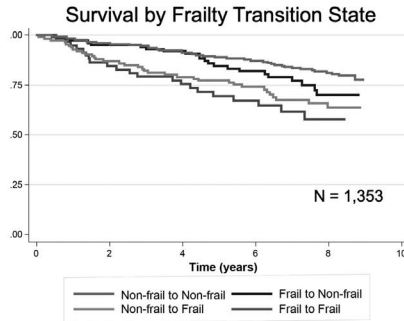
1. McMillan JM, et al. *Can Geriatr*. 2019;22(4):190-198. 2. Piggott D, et al. *AIDS*. 2020;34:1217-1225.

3. Kooji KW, et al. *AIDS*. 2016;30(2):241-250. 4. Akgun K, et al. *J Acquir Immune Defic Syndr*. 2014;67(4):397-404.



ALIVE Study: Frailty in HIV Linked to Survival Rates

- Adjusting for sociodemographic factors, number of comorbid conditions, and HIV disease status, being frail at 1 of 2 consecutive visits was associated with significantly higher mortality rates than those who maintained a non-frail state



Piggott D, et al. *AIDS*. 2020;34:1217-1225.



DHHS Guidelines: Treatment of Older Adults with HIV in the Presence of Comorbidities

Clinical Scenario	Considerations	Rationale
Osteoporosis	<ul style="list-style-type: none"> Avoid TDF ABC may be used if patient is HLA-B*5701-; If HIV RNA is > 100,000 c/mL, do not use ABC/3TC with EFV or ATV/ritonavir 	<ul style="list-style-type: none"> TDF has been associated with decreases in BMD along with renal tubulopathy, urine phosphate wasting, and resultant osteomalacia TAF and ABC are associated with smaller declines in BMD than TDF

3TV = lamivudine; ABC = abacavir; ATV = atazanavir; BMD = bone mineral density; c = copies; EFV = efavirenz; HLA = human leukocyte antigen; RNA = ribonucleic acid; TAF = tenofovir alafenamide; TDF = tenofovir disoproxil fumarate
 Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. <https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/AdultandAdolescentGL.pdf>. Accessed April 20, 2021.



Increasing Burden of Renal Disease

- PLWH have 2-20x greater risk of end-stage renal disease than general population
- Prevalence of chronic kidney disease in PLWH increasing, often related to hypertension and diabetes, may impact QoL and survival
- Long-term ART exposure contributes to the burden of renal disease, highlighting need to choose treatment that has demonstrated renal safety

QoL = quality of life
 Heron JE, et al. *AIDS Res Ther*. 2020;17:11.



DHHS Guidelines: Treatment of Older Adults with HIV in the Presence of Comorbidities

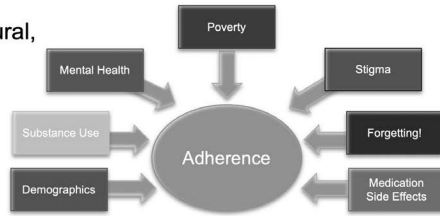
Clinical Scenario	Considerations	Rationale
Chronic kidney disease (defined as CrCl < 60 mL/min)	<ul style="list-style-type: none"> In general, avoid TDF ABC may be used if patient is HLA-B*5701-; If HIV RNA is > 100,000 c/mL do not use ABC/3TV with EFV or ATV/ritonavir TAF may be used if CrCl > 30 mL/min or if patient is on chronic hemodialysis Consider avoiding ATV ART options when ABC, TAF, or TDF cannot be used <ul style="list-style-type: none"> DTG/3TC (if HIV RNA < 500,000 c/mL and no HBV coinfection) DRV/r + 3TC DRV/r + RAL (if CD4 count > 200 cells/mm³ and HIV RNA < 100,000 c/mL) 	<ul style="list-style-type: none"> TDF has been associated with proximal renal tubulopathy; higher rates of renal dysfunction have been reported with TDF with RTV-containing regimen An adjusted dose of TDF can be used in patients with ESRD or those on hemodialysis TAF has less impact on renal function and lower rates of proteinuria than TDF ATV has been associated with chronic kidney disease in observational studies ABC has not been associated with renal dysfunction

CrCl = creatinine clearance; DTG/3TC = dolutegravir/lamivudine; DRV/r = darunavir/ritonavir; ESRD = end-stage renal disease; RAL = raltegravir; RTV = ritonavir.
 Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. <https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/AdultandAdolescentGL.pdf>. Accessed April 20, 2021.



Determinants of ART Adherence in Older Adults

- Socio-demographics; economic factors
- Education; psychosocial: cultural, stigmas
- Age-related cognitive decline
- Mental health
- Substance abuse
- Social support
- Health care access; HCP relationship
- Health insurance; social services



Mann SC, et al. *Curr Opin HIV AIDS*. 2020;15(2):134-141.



HIV-Associated Neurocognitive Disorder (HAND)

- Approximately 50% of adults living with HIV will experience HAND, which can compromise everyday function and quality of life
- With the aging HIV population, age-related cognitive declines may exacerbate HIV-related cognitive deficits
- PLWH may not know about or incorporate lifestyle and health behaviors into their lives in order to improve cognition
- Adults with HIV may benefit from education about how lifestyle and health behaviors may improve brain health and cognition as they age

Vance DE, et al. *J Assoc Nurses AIDS Care*. 2017;28(6):862-876.



Audience Response

Bone health is a concern among older adults on ART. Which of the following is not a DHHS guideline recommendation about osteoporosis?

1. TAF and ABC are associated with smaller declines in bone mineral density than TDF.
2. TDF has been associated with increases in bone mineral density, renal tubulopathy, and resultant osteomalacia
3. ABC may be used if patient is HLA-B*5701 negative
4. If HIV RNA is > 100,000 copies/mL, do not use ABC/3TC + (EFV or ATV/r)
5. I don't know



Takeaways and Action Steps

- Factor comorbidities such as cardiovascular disease, hyperlipidemia, bone health, chronic kidney disease, and neurologic disorders treatment decisions in older adults with HIV
- Screen for cognitive-decline and mental health as contributors to poor outcomes
- Be aware of social determinants of health that may negatively impact outcomes in patients with HIV



Learning Objective

Integrate best practices for initiating and switching patients to ART based on safety and efficacy profiles.



Audience Response

Which of the following statements is NOT correct regarding RAPID initiation of ART?

1. RAPID ART initiation should only be offered to people living with HIV who do not have other comorbidities
2. Delaying ART may impact transmission, opportunistic infections, morbidity and mortality
3. In a pilot program in a publicly insured clinic in San Francisco, 96% of patients accepted RAPID-start ART on the first day of diagnosis
4. Barriers to patients adhering to treatment were substance use, mental illness and homelessness
5. I don't know



Goals of Rapid ART

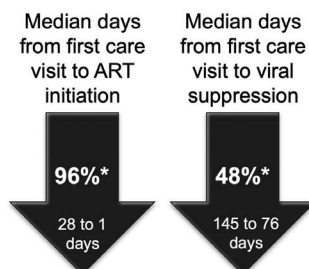
- Rapid-start ART: key strategy¹
- Early, maximal and durable viral suppression rate < 200 c/ml
- Improved health outcomes²
- Reduced HIV transmission; U=U
- Restored and preserved immune function (CD4 count)
- Reduce HIV-related opportunistic infections
- Reduced morbidity and mortality

1. Boyd MA, et al. *HIV Med.* 2019;20(Suppl 1):3-11. 2. Bacon O, et al. *Clin Infect Dis.* 2020 May 25. [Epub ahead of print].



Despite Benefits of Early Treatment, ART Initiation is Often Delayed: Positive Impact of Rapid ART Initiation

- Pilot program at safety-net hospital in San Francisco (2013-2014) expanded citywide in 2015 as part of the *San Francisco Get to Zero* initiative
- Protocol optimized linkage to care and training of providers on **why** and **how** to initiate ART at the first care visit recognizing diversity in care, patient populations, insurance plans, and testing



By 2017, 28% of new diagnoses had rapid start

N = 1354, *p < .00001
Bacon O, et al. *Clin Infect Dis.* 2020 May 25. [Epub ahead of print].



What Do the Guidelines Recommend for Rapid ART?

- **DHHS:** ART should be started as immediately or as soon as possible following diagnosis¹
 - Should not include an NNRTI, ABC, or DTG/3TC
- **IAS-USA:** Initiate ART as soon as possible after diagnosis, including same day if the patient is ready²
 - Caveats in setting of possible opportunistic infection
 - Should not include NNRTI, ABC, or DTG/3TC

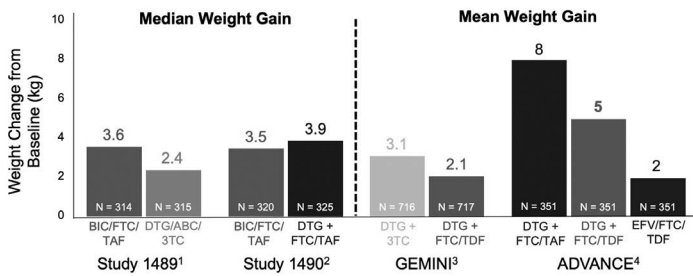
Recommended Rapid ART Regimens
BIC/TAF/FTC ^{1,2}
DTG + (TAF or TDF)/(FTC or 3TC) ^{1,2}
DRV/r or DRV/c + (TAF or TDF)/(FTC or 3TC) ^{1,2}

Rapid ART, or initiation of ART immediately or as soon as possible following diagnosis, can be started without labs or resistance testing

1. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. <https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/AdultandAdolescentGL.pdf>. Accessed April 14, 2021.
 2. Saag MS, et al. *JAMA*. 2018;320(4):379-396



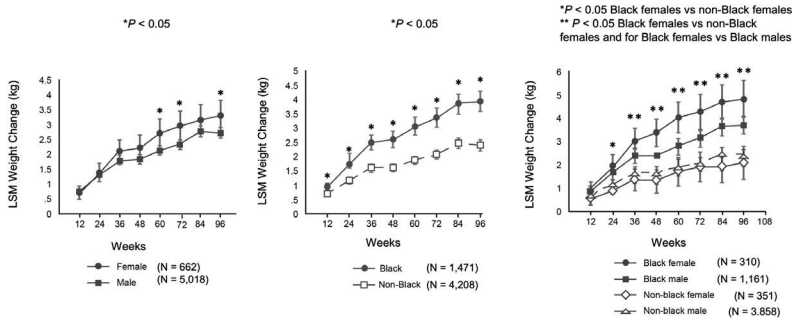
Weight Change at Week 96 Across First-Line Randomized Controlled Trials



1. Wohl D, et al. *Lancet HIV*. 2019;6:e355-e363. 2. Stellbrink HJ, et al. *Lancet HIV*. 2019;6:e364-e372. 3. Cahn P, et al. 2019 International AIDS Society Conference on HIV Science. Abstract No. WEAB0404LB. <http://programme.ias2019.org/Abstract/Abstract/4767>. 4. Hill A, et al. 2019 International AIDS Society Conference on HIV Science. Abstract No. MOAX0102LB. <http://programme.ias2019.org/Abstract/Abstract/4772>.



Pooled Data Evaluating Effect of Sex and Race on Weight Change in Individuals Initiating ART



Sax P, et al. *Clin Infect Dis*. 2020;71(6):1379-1389.



Long-Acting injectables Improve Health Outcomes for PLWH?

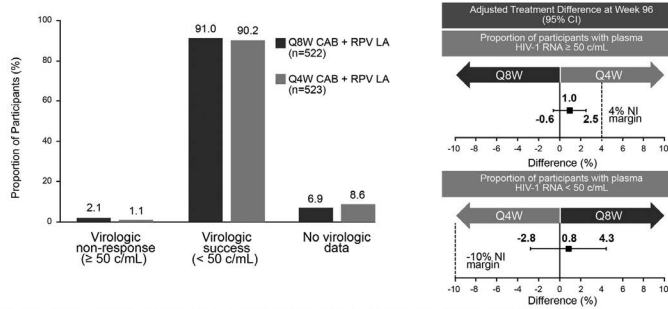
What's the attraction of LAI?

- Infrequent dosing
- Improved ART adherence
- Lower overall drug dose
- Overcome pill burden / treatment fatigue
- Potential of directly observed therapy
- Protect privacy/prevent stigma

LAI = long-acting injectables. Soriano V, et al. *Nat. Mater*. 2020;19:826-827.



ATLAS-2M: LAI CAB + RPV Q4W vs Q8W in Patients With Viral Suppression



CAB = cabotegravir; CI = confidence interval; NI = non-inferiority; RPV = rilpivirine; Q4W = every 4 weeks; Q8W = every 8 weeks
Jaeger H. Presented at CROI 2021. Abstract 401. Available at <http://www.croiwebcasts.org/console/player/47431?mediaType=slideVideo&Accessed April 16, 2021>.



Reasons to Switch ART in the Setting of Viral Suppression

- Managing or preventing short-term or long-term adverse events
- High pill burden or dosing frequency impacting adherence
- Pregnancy
- Difficulties with food or fluid requirements
- Prevent or mitigate DDIs
- Reduce cost

Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. <https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/AdultandAdolescentGL.pdf>. Accessed April 20, 2021.



Factors to Consider Before Switching or Simplifying Therapy

- Review of a patient's full treatment history is critical before initiating a treatment switch¹
 - History of multiple virologic failures or pre-treatment drug resistance
 - Review of cumulative resistance test results
 - Clinical response to prior regimens
 - Past treatment-associated intolerance, toxicities, or AEs
- Review active medication list, including herbal supplements and over-the-counter medications, for DDIs¹
- Always consider patient preference

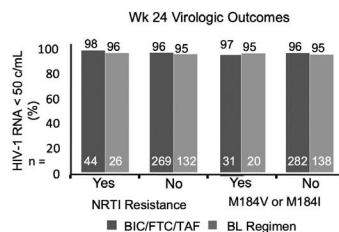
Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. <https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/AdultandAdolescentGL.pdf>. Accessed April 20, 2021.



BRAAVE 2020: Impact of BL Resistance on Outcomes Following Switch to BIC/FTC/TAF in Black PLWH

- Randomized, open-label, active-controlled phase III study evaluated switch from BL regimen (2 NRTIs + third agent) to BIC/FTC/TAF in virologically suppressed Black PLWH (N = 495)
 - NRTI backbone: FTC/TAF (67%), FTC/TDF (19%), ABC/3TC (14%)
 - 3rd agent: INSTI (59%), NNRTI (29%), PI (6%), other (6%)
- Switch to BIC/FTC/TAF non-inferior to remaining on BL regimen at wk 24
- Patients with BL NRTI resistance remained suppressed at wk 24

BL ARV Resistance, %	BIC/FTC/TAF (n = 330)	Continue BL Regimen (n = 165)
NRTI	13	16
M184V/I	9	12
NNRTI	21	19
PI	11	15

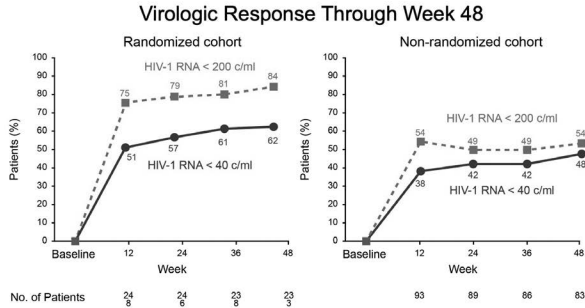


BL = baseline; INSTI = integrase strand transfer inhibitor; n = adults with HIV; N = number of participants; PI = protease inhibitors; wk = week.
Hagins DP. Presented at CROI (virtual), 2020. Abstract No. 36. Available at <http://www.croiwebcasts.org/pr2020croi/croi/36>. Accessed April 22, 2021.



Fostemsavir in Adults with Multi-Drug Resistant HIV-1 Infection

- Patients with multidrug-resistant HIV-1 infection, who received fostemsavir had a significantly greater decrease in the HIV-1 RNA level than placebo during first 8 days
- At wk 48, a virologic response (HIV-1 RNA level, < 40 c/mL) occurred in 54% of patients in the randomized cohort and 38% of those in the non-randomized cohort



No. = number
Kozal M, et al. *N Engl J Med.* 2020;382(13):1232-1243.



Monitoring Patients After Switching

- Recommendation of DHHS guidelines is to monitor patients within 3 months after a regimen switch
 - Assess tolerability
 - Viral suppression
 - Adherence
 - Safety¹
- When switching from a stable regimen, even if the new agent has a better safety profile, monitor potential side effects that could result when starting a new regimen

¹ Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. <https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/AdultandAdolescentGL.pdf>. Accessed April 20, 2021.



Audience Response

Which of the following statements is NOT correct regarding RAPID initiation of ART?

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4. Barriers to patients adhering to treatment were substance use, mental illness and homelessness
5. I don't know



Takeaways and Action Steps

- Rapid ART, or initiation of ART immediately or as soon as possible following diagnosis, can be started without labs or resistance testing
- Optimize and simplify treatment for patients with HIV while maintaining virologic suppression and considering key issues
 - Improve short-term and long-term efficacy, safety, and tolerability
 - Decrease high pill burden and difficulties with food requirements that may positively impact adherence
 - Prevent or mitigate DDIs
- Engage patients in shared decision-making, always considering patients' past experiences, preferences, and expectations



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