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Long-Acting Injectable Antiretroviral Therapy for the Treatment of HIV

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espite advances in the efficacy and tolerability of antiretroviral therapy (ART) for the treatment of HIV, the Centers for Disease Control and Prevention (CDC) estimates that up to 34% of people with HIV (PWH) in the United States remain virally unsuppressed.¹ Long-acting injectable antiretroviral therapy (LAI-ART) offers a shift in the traditional HIV treatment paradigm by providing an alternative to daily oral HIV medication. Currently, two LAI-ART products have been FDA-approved for PWH:

 long-acting cabotegravir + rilpivirine (CAB/RPV-LA) administered every
 1 -2 months as an intramuscular injection,2

2) lenacapavir (LEN) administered every 6 months as a subcutaneous injection.²

CAB/RPV-LA is approved as a complete switch regimen for PWH who are virally suppression on their current ART regimen, whereas LEN is approved for use in conjunction with other antiretrovirals (ARVs) for the treatment of multidrug resistant HIV infection in PWH with limited treatment options. In this article, we review the efficacy, safety, and future developments of new LAI-ART products. While the focus of this review is on the current FDA-approved long-acting agents, other

novel long-acting treatments are in development, including islatravir and monoclonal antibodies, which may add further options for future long-acting therapies.

Benefits of Long-Acting Injectable Antiretroviral Therapy (LAI-ART)

There are several possible benefits to a LAI-ART regimen.³ This includes the potential to increase medication adherence with less frequent dosing requirements and an administration that is directly observed, relief from pill anxiety or pill fatigue, freedom from the daily reminder of one's HIV status, and

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TABLE 1: Clinical efficacy trials of long-acting injectable cabotegravir + rilpivirine for the treatment of HIV

Study	Trial Design	Study Population	Treatment Arms	Response Rate	Summary
ATLAS ⁴⁻⁵	Phase 3, randomized, multicenter, open-label, noninferiority switch trial	Adults with HIV on ART with suppressed HIV RNA (N=616)	Continue daily regimen (2 NRTI + [PI, NNRTI or INSTI]) versus CAB 30 mg daily + RPV 25 mg daily x4 weeks oral lead-in followed by CAB-LA 600mg IM x1 + RPV-LA 900mg IM x1 at week 4 followed by CAB-LA 400mg IM + LA RPV 600mg IM Q4W beginning at week 8	HIV-1 RNA level <50 copies/mL: Week 48: 92% in LA arm vs. 95% in oral arm Week 96: 100% in LA arm and 97% in switch arm	CAB/RPV-LA Q4W noninferior to stan- dard oral ART through week 96
FLAIR ⁶⁻⁷	Phase 3, randomized, multicenter, open-label, noninferiority trial	ART-naïve adults with HIV (N=629)	Oral induction (all participants): DTG/ABC/3TC daily x20 weeks Maintenance regimen: Continue daily oral regimen versus Oral lead-in CAB 30 mg daily + RPV 25mg daily x4 weeks followed by CAB-LA 600mg IM x1 + RPV-LA 900mg IM x1 at week 4 followed by CAB-LA 400mg IM + RPV-LA 600 mg IM Q4W beginning at week 8	HIV-1 RNA level <50 copies/mL: Week 48: 94% in LA arm vs. 93% in oral arm Week 96: 87% in LA arm vs. 89% in oral arm	CAB/RPV-LA Q4W noninferior to standard oral ART through week 96
ATLAS-2M ⁸⁻⁹	Phase 3b, randomized, multicenter, open label, noninferiority switch trial	Adults with HIV on ART with suppressed HIV RNA (N=1045)	CAB-LA 400mg IM + RPV-LA 600mg IM Q4W versus CAB-LA 600mg IM + RPV-LA 900mg IM Q8W	HIV-1 RNA level <50 copies/mL: Week 48: 94% in Q8W arm vs. 93% in Q4W arm Week 96: 91% in Q8W arm vs. 90% in Q4W arm Week 152: 87% in Q8W arm vs. 85% in Q4W arm	CAB/RPV-LA Q8W noninferior to Q4W regimen through week 152
SOLAR ¹⁰	Phase 3b, randomized, multicenter, open-label, noninferiority switch trial	Adults with HIV on BIC/ FTC/TAF with suppressed HIV RNA (N=670)	Continue daily oral BIC/TAF/ FTC versus CAB-LA 600mg IM + RPV-LA 900mg IM Q8W (with or without oral lead-in)	HIV-1 RNA level <50 copies/ mL: Month 12: 90% in LA arm vs. 92% in oral arm	CAB/RPV-LA Q8W noninferior to oral BIC/TAF/FTC through month 12

ART, antiretroviral therapy; BIC, bictegravir; CAB-LA, long-acting cabotegravir; FTC, emtricitabine; IM, intramuscular; Q4W, every 4 weeks; Q8W, every 8 weeks; RPV-LA, long-acting rilpivirine; TAF, tenofovir alafenamide; TDF, tenofovir disoproxil fumarate.

a reduced risk of inadvertent HIV status disclosure. Medications administered by injection may also reduce unwanted adverse effects or drug and drug—food interactions that can occur with oral administration.

Cabotegravir/Rilpivirine (CAB/RPV-LA)

The first all-injectable ART regimen, CAB/RPV-LA, was shown to be non-inferior to oral ART regimens in Phase

3 clinical trials (Table 1) and was FDA-approved in 2021 for monthly dosing and in 2022 for every-other-month dosing as an intramuscular gluteal injection by a health care provider.⁴⁻¹¹

CAB/RPV-LA is approved for adults and adolescents who have sustained viral suppression (<50 copies/mL) on their current oral ART regimen.¹¹ A one month lead-in with oral CAB and RPV is optional to assess drug tolerability before injection. Hepatitis

B virus (HBV) serologies and ART resistance/treatment failure history should be reviewed before initiation of CAB/RPV-LA, since CAB/RPV-LA is not recommended for persons with active or occult HBV who are not receiving concurrent oral HBV treatment or for those with known or suspected resistance to either CAB or RPV. Persons receiving medications that have significant drug interactions with injectable CAB or RPV (such as certain anticonvulsants and rifamycins)

continued on next page

should not receive CAB/RPV-LA.² It should be noted that CAB/RPV-LA has not been approved in pregnant persons or children less than 12 years of age, as it has not yet been studied in these populations. Perinatal guidelines currently recommend that persons who become pregnant while on CAB/RPV-LA be switched to an approved oral regimen.²

CAB/RVP-LA has been well-tolerated in early clinical trials.¹² The most commonly reported side effect was injection site reactions (pain, nodules, swelling, induration). Most of these reactions were mild to moderate in severity, and less than 1% were grade 3 (severe) or greater. The incidence of injection site reactions was highest with the first dose and then decreased over time. Other potential adverse reactions included musculoskeletal pain, nausea, sleep disorders, dizziness, depression, pyrexia, and rash.¹¹

CAB/RPV-LA has a long half-life, producing a "pharmacokinetic tail," which raises concerns that suboptimal adherence could lead to the selection of drug-resistant viral strains.¹³ To reduce the risk associated with subtherapeutic drug exposure, patients with doses delayed more than seven days should receive oral bridging therapy.¹¹ Early trials of CAB/RPV-LA excluded patients

with suboptimal ART adherence and ongoing viremia. However, some preliminary observational data has shown that CAB/RPV-LA may be safe and effective in vulnerable subpopulations with viremia or adherence difficulties when adequate adherence support is available. The LATITUTUDE trial is a randomized clinical trial currently underway evaluating CAB/RPV-LA in participants with a history of suboptimal adherence and control of their HIV that aims to further inform the safety and efficacy CAB/RPV-LA in this population. The safety and efficacy CAB/RPV-LA in this population.

Lenacapavir (LEN)

Lenacapavir is the first agent in a new antiretroviral class called capsid inhibitors. Capsid inhibitors bind two subunits of the viral capsid, disrupting the viral life cycle at several points and preventing the production of replication-competent virus. LEN was FDA approved on December 22, 2022, for the treatment of HIV infection in combination with daily oral antiretroviral agents in those with multidrug-resistant HIV infection or with an intolerance to or safety concerns with other drug classes. 16 This new class of ARVs offers therapeutic options for persons with limited treatment alternatives.

As with other medications, attention

to potential drug interactions should be considered prior to initiation of lenacapavir, a substrate of CYP3A enzymes; administration with strong CYP3A inducers is contraindicated. ¹⁶ Concurrent use of several other ART medications with lenacapacir, such as efavirenz, etravirine, nevirapine, or boosted tipranavir, is also contraindicated due to significant drug interactions.

Lenacapavir was wellgenerally tolerated in the CAPELLA trial, however, injection site reactions were common and were seen in 62% of trial participants.¹⁷ There is no crossresistance between capsid inhibitors and other classes of ART, however, mutations associated with decreased susceptibility to lenacapavir (primarily M66I) can occur with lenacapvir use. Resistance development and treatment failure were primarily attributed to poor adherence to the oral background regimen or having no fully active agents in the background regimen.¹⁷

Although lenacapavir was initially studied in treatment-experienced persons with multidrug-resistant HIV, ongoing investigations in treatment-naïve adults with HIV are currently underway. A recent phase 2 clinical trial (CALABRATE) randomized treatment-naïve PWH to BIC/FTC/TAF or lenacapavir administered orally daily or subcutaneously every 26 weeks in combination with other oral ART. The week 54 results found rates of virologic suppression to be similar between groups.¹⁸

Future Developments in Long-Acting ART

Ongoing studies are exploring new ART formulations and combinations with less frequent dosing. New classes of antiretroviral agents in clinical development include HIV maturation inhibitors, broadly neutralizing antibodies (bNAbs), and nucleoside reverse transcriptase translocation inhibitors (NRTTI), such as islatravir, that inhibit HIV RT through multiple



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mechanisms^{-2,19,20} Investigations into combinations of long-acting products to build complete regimens are also underway, such as with the phase 1b trial of lenacapavir and bNAbs (GS-5423 and GS-2872) dosed every 6 months.²² Also in development are novel mechanisms of administration of ART, including implants and patches.^{23,24}

Conclusion

LAI-ART provides exciting alternatives to oral therapy for the treatment of HIV and offers the potential to improve adherence and quality of life for PWH. Currently improved LAI-ART products include CAB/RPV-LA and LEN, with further investigation ongoing for new drug classes and mechanisms of drug administration. Implementation challenges persist, and further data is needed to expand inclusion to adolescents, pregnant persons, and those with barriers to medication access and adherence.

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Bridging Social Media and Sexual Health

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power of social media is unmatched; the way we are consuming, sharing, and processing information is radically changing. In early 2023, the first Republican Party debate was watched by 24 million viewers, the largest audience in its history. Just five minutes before the debate and with a successful strategic tactic, the former president went on the platform "X," formally known as Twitter, with Tucker Carlson to conduct an interview. Within four minutes they had 10.7 million viewers; and within 14 hours, they had 205 million viewers. This example of how people access information is astounding.

Wong reported in Forbes,¹ that globally, 4.9 billion people use social media, and the average person spends 145 minutes a day viewing social media. At the beginning of 2023, the reigning social media giant, Facebook, had approximately 3 billion users; YouTube followed closely with 2.5 billion; Instagram and WhatsApp trailed at 2

billion; and TikTok at 1 billion. Social media use will continue to climb. It is predicted that if someone started using a social media platform at the age of 16 and lived to 70, they would spend 5.7 years of their life using social media.¹

By the end of 2023, TikTok reported 1.5 billion active monthly users and was downloaded over three billion times. With a primarily younger demographic and more adults tapping in, TikTok has the highest social media engagement of all platforms. In 2020, TikTok users spent 62 minutes a day on the app. Fast forward to 2022, and users averaged 95 minutes per day! Before diving further into TikTok and how a medical professional can use a social media platform for outreach, understanding the state of our young folks and their sexual health is essential.

Adolescents, Young Adults, and Sexual Health

Sexual health education among adolescents and young adults is

essential to avert sexually transmitted infections (STIs) and unintended pregnancies. There is sufficient evidence that culturally sensitive and age-appropriate programs are effective. Programs must educate about safe sex practices, the gender continuum and individual expression, sexual orientation, relationship building, sexual negotiation skills, consent, anatomy, and physiology, as well as connect them to health services.²⁻³ The World Health Organization (WHO) and United Nations International Children's Emergency Fund (UNICEF) strongly advise and support evidence-based science interventions to increase knowledge about sexual health and promote safe- sex practices.4-5

Adolescents represent one-sixth of the global population. As adolescents transition from childhood to adulthood, they face health challenges unique to risk-related behaviors. Risk-related behaviors include sexual intercourse or activities with multiple partners leading to the contraction of STIs and pregnancies.⁶ Worldwide, one million girls under 15 years of age and 12 million girls under 19 years give birth yearly. Within the United States, girls under the age of 19 years account for 150,000 unplanned births. Although the US rate is low globally, it is higher than in the UK and Canada, where pregnancy rates are significantly lower due to available birth control. The adolescent pregnancy rates signal a significant risk and highlight not only the need for women's safety but also comprehensive sexual health education and services.

Transgender and nonbinary individuals



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Figure 1: The percentage of high school students and sexual activity (Source: CDC)

The Percentage of High School Students Who:	2011 Total	2013 Total	2015 Total	2017 Total	2019 Total	2021 Total	Trend
Ever had sex	47	47	41	40	38	30	
Had four or more lifetime sexual partners	15	15	11	10	9	6	
Were currently sexually active	34	34	30	29	27	21	
Used a condom during last sexual intercourse [†]	60	59	57	54	54	52	
Used effective hormonal birth control ^{1,‡}	-	-	-	-	-	33	-
Used a condom and effective hormonal birth control (dual use) ^{1,‡}	-	-	-	7	2	10	-
Were ever tested for HIV	13	13	10	9	9	6	
Were tested for STDs during the past year ^s	-	-	7-1	4	9	5	

Among sexually active students

Survey question changed in the 2021 national YRBS; therefore, trends are not available.

Variable introduced in 2019.



represent 2% of adolescents in the United States, but they face discrimination and denial of their autonomy in their own health decisions. These individuals face potential lifelong psychological, medical, and social consequences that may lead to mental health issues, suicidal ideation, and death.⁷ It is vital to create a safe space for transgender and gender nonconforming people as we promote inclusive sexual health education and ameliorate disparities.⁸

Generation Z is diagnosed with more STIs while testing decreases. In 2020, the CDC reported, young people ages 13-24 accounted for 20% of all new HIV diagnoses in the US and more than half of the almost 20 million new STIs were among young people aged 15-24.9,10 The CDC acknowledged that although the proportion of high school students engaged in sexual activities

that increased their risks for HIV, STIs, and unintended pregnancy decreased from 2011 to 2021, there was a marked decrease in condom use, STI testing, and HIV testing. One third of high students have had a sexual encounter, and more than 20% are currently sexually active. The CDC concludes across all demographic groups, apart from Asian youth, there is no significant difference regarding those who have had sex, remain sexually active, or have had four or more encounters. ¹⁰

Adolescents and young adults face challenges getting accurate and trustworthy sexual health education and services, it is not surprising that the CDC reports that STI infection rates continue to rise. 10 For example, school is the primary source of sexual health education, presented via traditional teaching methodologies of lectures and classroom activities, which might

be outdated for Generation Z and Generation Alpha.^{2,3} Sex education in schools is variable and inconsistent and does not prepare young people adequately for the reality of sexual behaviors. Sexual health education also faces barriers with legislation, restrictive policies, lack of confidentiality, limited income, teachers and parents reluctant to openly discuss sexual health needs, parental control, and mis- and disinformation.⁶ Because of these limitations, young people are more easily persuaded by peers, norms, and social influences.¹¹ Those of us committed to providing accurate sexual health information to adolescents and young adults can overcome some of these barriers using social media like TikTok. This leaves one to think: Could scrolling be beneficial?

Approximately half of all young people say they've learned more about sex via TikTok than from their sex education lessons in school, and 89% of teens say they learn about various sexual health issues online.1 One in three Gen Z young folks trust TikTok more than their health care provider. 12 Young people are telling us they are not receiving patientcentered care or educated about sexual health openly, honestly, and without bias. To address this concern, some health care professionals, as popular content creators actively use TikTok to provide science-based content, answer questions posed by other users, and respond to misinformed viral videos.2 The key word is ACTIVELY!

Misinformation and Disinformation on Social Media

One example of misinformation on TikTok is a popular creator posting a statement that HIV is in the water, targeting an area of the world that needs significant resources. This example of misinformation does not explain that HIV is in fact a fragile virus, dying instantly when exposed to water,



air, or light. The poor word choice exacerbates stigma and fear surround HIV. Furthermore, some creators may manipulate information for an alternative motive and create content that is disinformation, by displaying inaccurate ultrasound images of abortions. One shows a fetus "fighting" not to be vacuumed out of the womb, and another uses a grimacing fetus' face and states, "a baby's reaction to an abortion," thus perpetuating increased stigma, persuading political voters, or emotionally sabotaging a person.

The quantity of content available on TikTok makes responding to misinformation and disinformation impractical. There is no guarantee a user will view a corrective video, however, there are advantages to responding:¹³

- (1) social media reaches at-risk or marginalized populations without compromising their privacy and safety,
- (2) it increases cost-effectiveness and efficiency for service

- providers with limited budgets for facilitator training and materials,
- (3) entertainment can engage the social media consumer,
- (4) influencers can provide timely feedback,
- (5) provides targeted messaging,
- (6) it is less threatening than a doctor's office, and
- (7) in areas where sexual issues are taboo, dissemination of sexual health information can be widespread to youth at low to no cost.

Identifying content that is questionable can be challenging. Not everyone has access to databases of peer reviewed scholarly journals; however, there are ways to verify information. One can ask themselves, are the statements made by a creator backed by government or accredited organizations? If statements are supported by an organization, does the organization present unbiased data? Does the creator provide links or images of articles supporting their claim or personal story? Is the creator a qualified, certified, or credentialed individual? Does the content appear to be an emotional response or an informative discussion? These questions are not to belittle a creator's personal story; but are to empower people to evaluate the content of the media they are viewing.

Storytelling is essential in creating

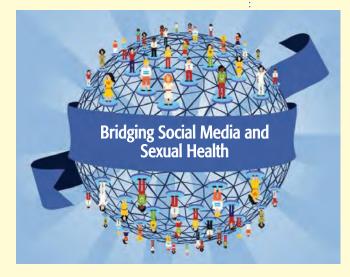


trusting relationships, but people must be cautious when viewing health information on social media. Some creators will share their personal story of their medical experiences and may include unverified health claims, intentional disinformation, and incomplete facts. 13 This is an opportunity for health care professionals to expand their outreach and education by meeting young people where they are - on social media! It takes more than just responding to misinformation disinformation: health professionals must use social media to actively listen and engage with young people.

How Health Care Practitioners can use Social Media

Plunging into the world of social media can appear daunting, overwhelming, technical, or seen as unobtainable.

However, the audience is looking for open and honest dialogue, representation, realness. Yes, throwing in a catchy audio bite, trending dance routine, or funny gimmick can add an extra flare of pizzazz; but it is in the realness of your content that will engage folks. For example, @mrwilliamsprek talks about his experience as a pre-K teacher



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social worker, @marcwinski puts stuttering awareness out in the limelight, @mercurystardust showcases her knowledge as the "Trans Handy Ma'am," @hauseofpetty uses his nursing knowledge to create awareness around political and current events, @ileavebreadcrumbs highlights his apparel product as he deconstructs stigmas social and supports community, and @thefrozenplantguy highlights his passion for plants and climate change while supporting the LGBTOIA2+ and HIV communities. Each of these creators has designed a platform that invites their audience into their professional or personal lives. These platforms are not overly edited, inorganic, or super polished.

On personal mv page, @freakbetweenthesheets, I create content that shares my personal journey with sexual health, substance use, and harm reduction. The videos describe my genuine experience or provide accurate sexual health or substance use information in an easily digestible format. This type of presentation tends to do better than polished and rehearsed TikTok. People like to see humans being... "human." It makes the TikTok creator relatable, and the audience feels heard, and represented.

Health care providers who want to consider social media as a form of outreach to our communities need to be aware of their organization's policy and procedures. Most importantly, keep patients' information private and follow Health Insurance Portability and



Accountability Act (HIPAA) guidelines. If you would like to see an example of my work, please scan the QR Code.

Conclusion

Social media is an art form. Social media can be a promising platform and can reach unique populations and provide science-based information that can positively influence perception, knowledge, and behavior centering around sexual health.14 Furthermore, Sexual health is an increasing health issue for our younger generation and has been targeted via digital media.15 Health care professionals need to level up our outreach and hit that record button. Practice makes progress; and the only way we are going to see positive progress is by meeting our communities where they are. Health care professionals who want to advocate and break down stigma around sexual health, substance use, and harm reduction, here is your call to action!

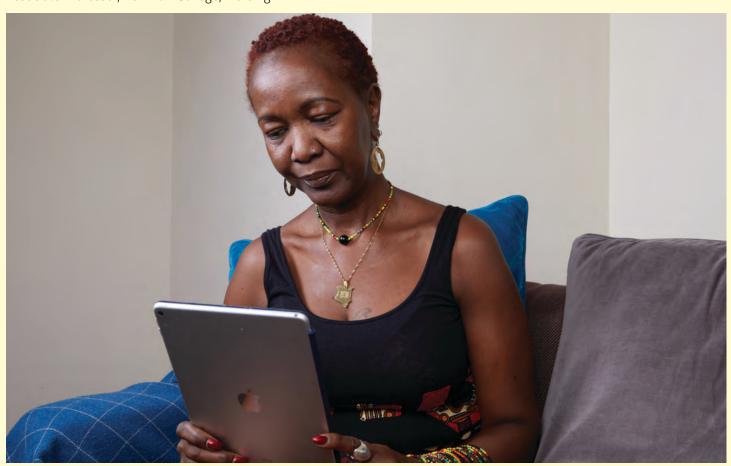
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Impact of Menopause on Older Women with HIV

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enopause is defined as the self-reported cessation of menstruation for 12 months or longer without any pathological or physiological cause. The average age for natural menopause is 52.5 years in women who do not have HIV. Generally, menopause between the ages of 40 and 45 is considered early menopause, and menopause before age 40 is considered premature menopause.

The number of women with HIV (WWH) transitioning through

menopause is increasing as the epidemic ages. WWH may transition to menopause at 40 to 47 years of age and have a threefold higher risk of amenorrhea in the absence of menopause compared to women without HIV.^{2,3} Other factors that contribute to early menopause in WWH include intravenous drug use, higher rates of the social determinants of health, smoking, early menarche, and Hepatitis C infection. Early menopause is not related to how the women acquired HIV or the stage of HIV. However, some recent research

indicates that lower nadir CD4 counts, a history of low weight, psychotropic medications, and methadone may be associated with early menopause.^{3,4}

WWH have unique challenges during menopause. WWH experience a more significant burden of menopausal symptoms, such as hot flashes and night sweats (vasomotor symptoms), sexual dysfunction, increased urogenital symptoms, fatigue, pain, and mood changes compared to women without HIV.⁵ They have difficulty distinguishing menopausal symptoms from HIV-related symptoms

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such as vaginal dryness, dyspareunia, and hot flashes with menopause, especially if they are experiencing menopause at a younger age. These women may not discuss menopause nor seek symptomatic treatment with their health care providers because they do not attribute their symptoms to menopause. Equally, providers may not recognize these symptoms as early menopause.6 WWH experience complex menopausal difficulties because of the impact of HIV stigma on intimate partner relationships, possible challenges with body image and HIV disclosure. For all women. earlier menopause increases the risk of cardiovascular and metabolic diseases, osteoporosis, depression, and cognitive decline.

Cardiovascular Disease Risk

Cardiovascular disease (CVD) rates are higher in WWH compared to women who do not have HIV, likely due to inflammatory response, hypercoagulability, altered arterial elasticity, and endothelial dysfunction.⁷ HIV and menopause have similar and added adverse effects of central lipodystrophy, adiposity, insulin resistance, and worse lipid profiles. A study using the Framington Risk Score (FRS) compared cardiovascular disease risk in postmenopausal African American and Latina women with and without HIV found that the FRS was not significantly affected by HIV status and may not be appropriate for use in this population.8

The risk for CVD in WWH experiencing menopause is due to increased follicle stimulating hormone and decreased progestin. In addition, increases inflammatory estrogen mediators, and HIV disease promotes increased immune activation in postmenopausal WWH, which promotes atherosclerosis.8,9 WWH have significantly higher triglycerides, impaired glucose tolerance, fasting insulin levels, lower high-density

lipoprotein, and body fat abnormalities than women without HIV, and more than half of both WWH and women without HIV are under-prescribed statin therapy.⁸ WWH have twice the risk of ischemic stroke compared to women without HIV, and risk is inversely proportional to the duration of ART.¹⁰ HIV also increases the risk of venous thromboembolism (VTE). For the WWH, providers should consider prescribing transdermal estrogen preparations, which have a lower risk of VTE compared to oral preparations.¹

Bone Disease

Menopausal WWH are at increased risk for osteoporosis (OP) or osteopenia due to HIV-related factors and traditional risk factors such as age, smoking, alcohol, family history, and medication such as glucocorticoids. WWH have significantly lower bone mass density (BMD) compared to women without HIV, and the difference is more pronounced in the postmenopausal stage than premenopause. In postmenopausal WWH, the prevalence of OP ranges from seven to 84%, compared to women living without HIV, who experience a prevalence of OP of 0.7 to 23%. Some HIV medications are associated with decreased BMD. Although the decrease in BMD may stabilize or reverse as the immune system improves, providers must consider the ART regimen when treating OP. For menopausal WWH who need treatment for OP, an HIV regimen with Tenofovir alafenamide (TAL) has less effect on BMD than tenofovir disoproxil fumarate (TDF).11

The recommendations for WWH include height assessment every one to two years, screening with the Fracture Risk Assessment Tool (FRAX), although it is known to underestimate fracture risk in HIV disease, and dual-energy X-ray absorptiometry (DEXA) scans after menopause.^{11,12} Treatment for OP is the same for WWH as for women without HIV and includes lifestyle

modifications, calcium and vitamin D supplements, and bisphosphonates. Guidelines recommend menopausal hormone therapy (MHT), but data about the effect on the health of WWH is scarce.¹¹

Vasomotor and Psychological Symptoms of Menopause

WWH have higher baseline levels of anxiety and report depression levels twice as high as women without HIV. Even when correcting for smoking status, history or substance use, current antidepressant prescribing rates may not adequately treat depression in WWH. Vasomotor symptoms during peri-menopause due to hormonal changes are correlated with anxiety and depression, sleep disturbances, and stress.4,13 WWH may experience greater severity and prevalence of hot flashes, mistaking them as night sweats associated with low CD4 counts or high viral load.13 As a result, the symptom severity experienced by WWH may result in less adherence to ART, elevated depression, decreased cognitive performance, and decreased quality of life.4,13

Hormonal Therapy

The decision to initiate MHT is a shared decision between the provider and WWH. Both the combination estrogen-progesterone pill micronized progesterone pill relieves symptoms. Current menopausal guidelines recommend the use of MHT for women in early menopause to counteract the loss of hormonal protection against cardiovascular disease, dementia, fractures, and other manifestations of premature aging. Lack of experience on the part of HIV specialists and primary care providers, pill burden, concern about drug-drug interactions, fear of adverse events, and inability to distinguish between early menopause and HIV symptoms prevent HIV clinicians from prescribing MHT.1

continued on next page

Feature Article

Use of a drug interaction website, such as Liverpool, can prevent drug-drug interactions. Consult the North American Menopause Society guidelines when considering MHT for WWH.14 Prescribing transdermal estradiol patches can reduce pill burden. Unopposed estrogen should not be used in women with a uterus because of the risk of endometrial cancer. For genitourinary symptoms, vaginal hormonal creams are useful. Providers should address lifestyle issues that impair overall health, such as smoking cessation, exercise, diet, and Vitamin D and calcium supplementation for bone health. Cognitive behavioral approaches can reduce or alleviate insomnia. Contraindications to hormonal therapy include liver dysfunction, unexplained vaginal bleeding, estrogen dependent cancers, DVT, heart disease, stroke, and triglycerides higher than twice the highest level, age over 60, and in menopause for more than 10 years.1

Summary

As the population of WWH ages, guidance is necessary for WWH to increase the identification and management of menopausal signs and symptoms unique to WWH. Providers should start monitoring WWH for vasomotor symptoms, cardiovascular risk, and OP at the age of 40. WWH should keep track of menstrual cycles and report any changes. Providers should educate WWH about their risk for earlier menopause, assess if she needs hormonal therapy, and offer counseling about the symptoms and effects of possible co-morbidities. Menopause can create distress and anxiety for every woman, but providers should address the HIV-related challenges experienced by WWH during their menopausal transition.

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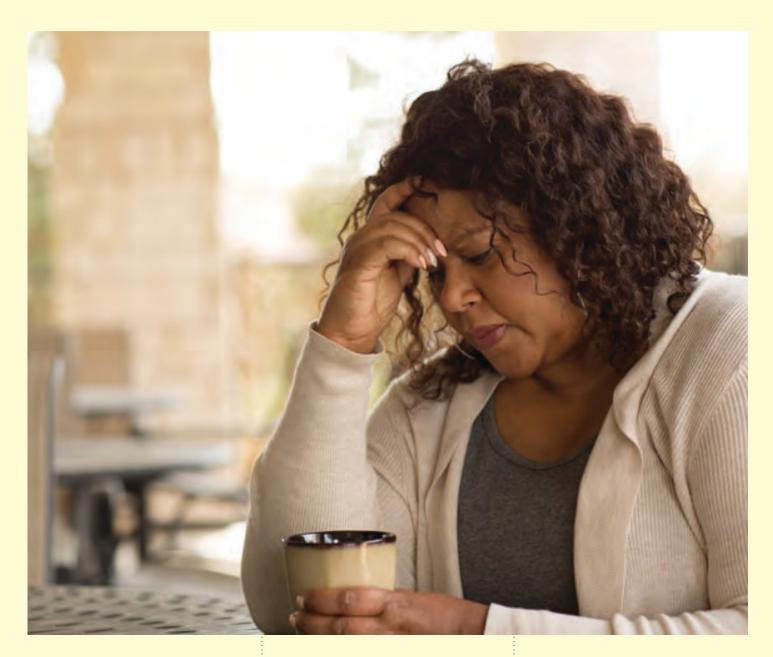
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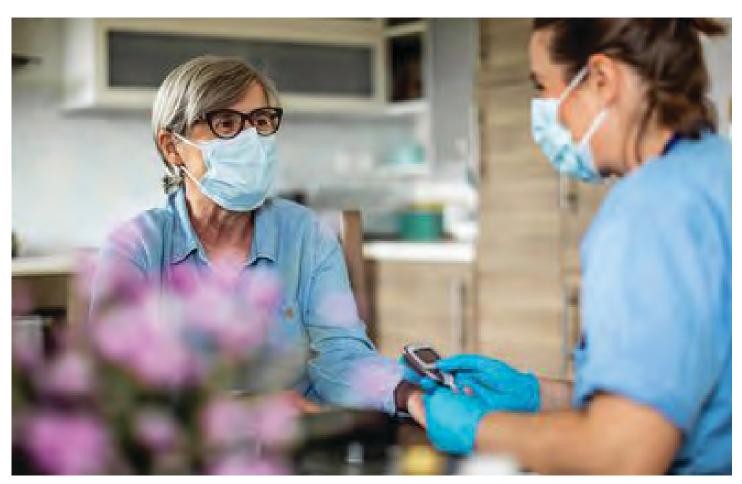
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Type 2 Diabetes Mellitus: An HIV Comorbidity on the Rise

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Background

iabetes mellitus (DM) is a group of metabolic disorders primarily characterized by chronic hyperglycemia secondarily to a decrease or cessation of autonomous insulin production (e.g., type 1 DM), and/or insulin resistance or insensitivity (type 2 DM).¹ Chronic hyperglycemia, whether intermittent or constant, leads to systemic inflammation and other metabolic changes over time. Obesity and limited physical activity commonly

exacerbate the inflammatory process leading to increased resistance to

circulating insulin.² DM is associated with resultant comorbidities

Table 1—Diagnostic criteria for DM in nonpregnant individuals¹

Fasting (0 caloric intake for ≥ 8 hours*) Plasma Glucose ≥126 mg/dL (≥7.0 mmol/L)

2-hour Plasma Glucose ≥**200 mg/dL** (≥11.1 mmol/L) during an oral glucose tolerance test performed using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water

In an individual with classic symptoms of hyperglycemia or hyperglycemic crisis (eg, polydipsia, polyuria, ketoacidosis), **a random plasma glucose** \geq **200 mg/dL** (\geq 11.1 mmol/L)

Hemoglobin A1C ≥**6.5%** (≥48 mmol/mol) via a laboratory based National Glycohemoglobin Standardization Program certified and Diabetes Control and Complications Trial assay standardized method

In the absence of **unequivocal hyperglycemia**, diagnosis **requires two abnormal test results** obtained at the same time (eg, hemoglobin A1C and fasting plasma glucose) or at two different time points

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including but not limited dyslipidemia, metabolic dysfunctionassociated steatotic liver disease (MASLD) or metabolic dysfunctionassociated steatohepatitis (MASH), hypertension, cardiovascular disease, stroke, renal disease, immune compromise, neuropathy, depression, and anxiety disorders. 1,3,4 While aging, excessive body fat, and genetics play a role in the development of type 2 diabetes, (T2DM),⁵ people with HIV (PWH) are at higher risk. As the population of PWH ages, the incidence of T2DM comorbidity has increased.6 It is estimated that one out of five PWH or 22.1%, have T2DM;7 the national prevalence of T2DM is 14.9% among people without HIV.⁴ In addition to aging, excessive weight, environmental, and genetic factors, another contributing factor associated with recognized increases in T2DM in PWH is HIV antiretroviral therapy (ART).^{8,9} In particular, tenofovir alafenamide fumarate (TAF) and its combination with integrase inhibitors (INSTIs) have been found to have the strongest association with T2DM and MASLD development.¹⁰

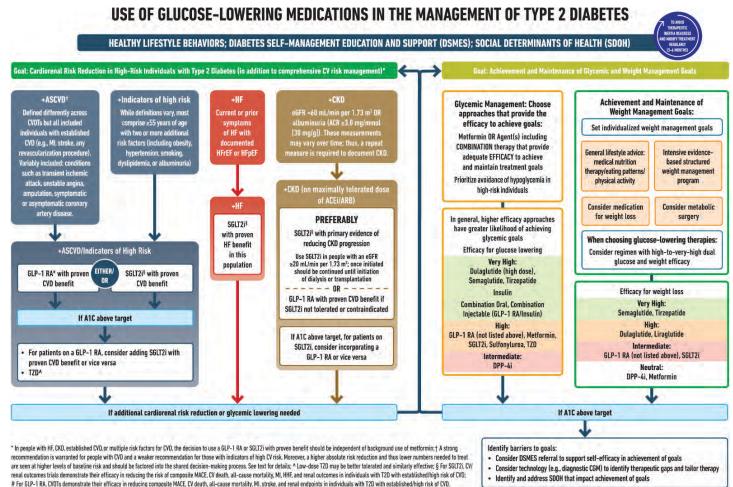
Like DM, HIV infection is also associated with chronic inflammation, dyslipidemia, and increased risks of cardiovascular disease, renal disease, bone density loss, peripheral neuropathy, MASLD, depression, and anxiety disorders.¹¹⁻¹³ The recommendations for both T2DM and HIV are to take preventive measures if

not already diagnosed with either or both diseases, to be diagnosed as early as possible, and to initiate treatment as early as possible. For T2DM, this includes dietary measures, physical activity, self-blood glucose monitoring, and medication(s) as needed to maintain euglycemic status. For PWH this includes initiation and adherence to HIV antiretroviral therapy (ART) to achieve and maintain undetectable blood levels of HIV.

Screening for Diabetes in PWH

Prediabetes is defined as having any of the following results: fasting plasma glucose (FPG) of 100 - 125 mg/dL, or two-hour plasma glucose

Figure 1



Concomitant Drug	INSTI	Effect on INSTI or Concomitant Drug Concentrations	Dosing Recommendations and Clinical Comments
Metformin	BIC	Metformin AUC ↑39%	Monitor for adverse events of metformin.
	DTG	DTG 50 mg Once Daily plus Metformin 500 mg Twice Daily	Start metformin at the lowest dose and titrate based on glycemic control. Monitor for adverse events of metformin.
		Metformin AUC ↑79% and Cmax ↑66%	When starting/stopping DTG in patients on metformin, dose
		DTG 50 mg Twice Daily plus Metformin 500 mg Twice Daily	adjustment of metformin may be necessary to maintain optimal glycemic control and/or minimize adverse events of metformin.
		Metformin AUC ↑2.4-fold and C _{max} ↑2-fold	medomin.
	CAB (PO and IM), RAL	← metformin expected	No dose adjustment needed.
Saxagliptin	BIC, CAB (PO and IM), DTG, RAL	← saxagliptin expected	No dose adjustment needed.
	EVG/c	↑saxagliptin expected	Limit saxagliptin dose to 2.5 mg once daily.
Dapagliflozin/	BIC, CAB (PO and IM), DTG, RAL	→ dapagliflozin or saxagliptin expected	No dose adjustment needed.
Saxagliptin	EVG/c	↑saxagliptin expected	Do not coadminister. Dapagliflozin is available only as a co-formulated drug that contains 5 mg of saxagliptin. When coadministered with EVG/c, the dose of saxagliptin should not exceed 2.5 mg once daily; thus, this combination is not

(PG) of 140 - 199 mg/dL following a 75-gram oral glucose tolerance test (OGTT), or a hemoglobin A1c (HbA1c) of greater than or equal to 5.7% but less than 6.5%.1 Other conditions that correlate to prediabetes in PWH include hypertension and hyperlipidemia.6 Among PWH, HbA1c test results must be used with caution.7 HIV is one of several conditions known to affect the hemoglobin A1c result. Other conditions include hemoglobin variants, second and third trimester pregnancy, postpartum period, glucose-6phosphate dehydrogenase deficiency (G6PD), hemodialysis, recent blood loss or transfusion, or erythropoietin therapy.1 Therefore, plasma glucose criteria should be used to diagnose DM people with these conditions. 1,6,7

Treatment of PWH and T2DM

General guidance exists for the evaluation and treatment of renal cardiovascular disease, disease, hyperglycemia, hyperlipidemia, and neurological pathologies in PWH

and separately in people with DM.^{1,15} However, it is important to note that the recommendations in these guidelines have not all been validated in persons with HIV and T2DM comorbidities. For instance, cardiovascular risk prediction programs developed for the general population likely underestimate the risk in persons with HIV.¹⁵ Similarly, peripheral neuropathy may manifest in persons with HIV¹¹ as well as in persons with T1DM or T2DM, and in persons with HIV and DM.¹⁶ The validity and reliability of hemoglobin A1c test result in a PWH are not the same as in a person without HIV.

recommended.

Treatment of T2DM, as with HIV, needs to be patient-centered, accounting for social determinants health (e.g., housing, food access, insurance, and income), comorbidities, support systems or persons, age, and the complexity of DM literacy.^{1,8} The key components DM management include glycemic control to prevent severe hyperglycemia and hypoglycemia as

well as the prevention and treatment of comorbidities associated with DM including hypertension, dyslipidemia, kidney disease, and vascular diseases including retinopathy, mvocardial disease, strokes, and peripheral tissue disease. Exercise and dietary measures are commonly the first recommended interventions assuming hyperglycemia is not current based on random plasma glucose nor prior, reflected in elevated hemoglobin A1C levels. Pharmacological interventions are needed if chronic hyperglycemia occurs despite nutritional and physical activity interventions or if the hyperglycemia is severe. Metformin is usually the first agent unless other risk factors for complications or contradictions exist (see Figure 1). Metformin use with integrase strand transfer inhibitors (INSTIs) must be closely monitored (see Table 2).

Based on the results of the Randomized Trial to Prevent Vascular Events in HIV (REPRIEVE),¹⁷ moderateintensity statin use is recommended

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for non-pregnant PWH aged 40 to 75 years who have a 10-year ASCVD risk estimate are 5% to less than 20% (an Al recommendation).15 The REPRIEVE study showed a 35% reduction in major adverse cardiovascular events (MACE) over a median follow-up duration of five years for those treated with pitavastatin 4 mg PO once daily versus placebo.¹⁵ Other studies support the treatment effect of other moderate-intensity statins for lipid lowering, reductions in inflammation, and immune activation. The Panel on Antiretroviral Guidelines for Adults and Adolescents¹⁵ recommends the following regimens:

- Pitavastatin 4 mg once daily (AI)
- Atorvastatin 20 mg once daily (All)
- Rosuvastatin 10 mg once daily (All).

These recommendations complement the standard recommendations for

adults inclusive of PWH.15

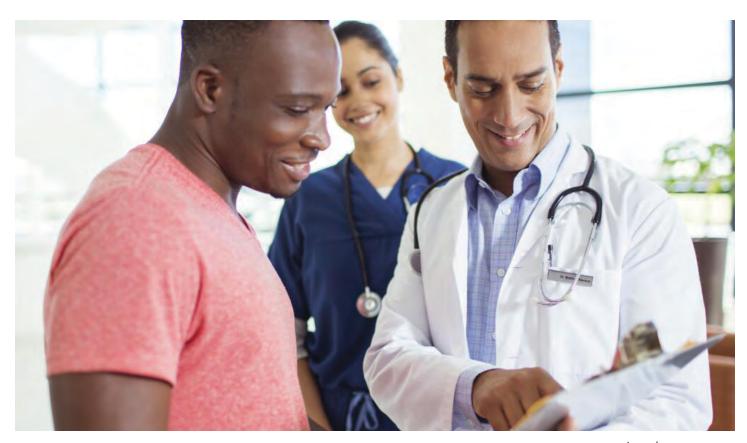
- For adults aged 40 to 75 years who have high (≥20%) 10-year ASCVD risk estimates, initiate high-intensity statin therapy.
- For adults aged 20 to 75 years who have low-density lipoprotein cholesterol (LDL-C) ≥190 mg/dL, initiate high-intensity statin therapy at the maximum tolerated dose.
- For adults aged 40 to 75 years with DM, initiate at least moderate-intensity statin therapy. Perform a further risk assessment to consider using a high-intensity statin.

However, statin use has been associated with an increased incidence of T2DM among PWH^{17,18} as well as among people without HIV. The increased risk of developing T2DM may be related to the use of specific ARVs,¹⁹ aging, and having two or more DM risk factors among PWH^{20,21} and/

or to statin-specific increases in plasma glucose. 19,22 Nonetheless, DM and ASCVD are both linked with HIV, and risk reductions are essential.

Another component of T2DM and HIV metabolic dysfunction that may need to be additionally managed is that of MASLD which may lead to MASH. In two recent clinical trials, the use of semaglutide (self-injected weekly) in virally suppressed PWH who had MASLD (n=49) resulted in a mean liver fat decrease of 31%, along with decreases in body weight, reduced fasting blood glucose (FBG), and fasting triglycerides, and 29% experiencing a complete resolution of MASLD.^{23,24} Although the sample sizes were small, there is hope that treatment options available for treating the metabolic dysfunction-associated outcomes for PWH and T2DM are being recognized and used successfully.

Other essential factors to include in the



Practice Tips

care plan of PWH who have DM include tobacco use cessation counseling and treatment as needed, dental visits at least once every six months, ophthalmology (retinal experts) visits every six to 12 months, mental health screening at least annually, nutritional support and counseling, and monitoring labs every four to six months. For HIV disease, the achievement and maintenance of viral suppression is critical, and for maintenance of plasma glucose within a range of 80 - 180 is ideal. Maintaining pre-prandial capillary plasma glucose readings of 80-130 mg/dL, peak post-prandial capillary plasma glucose readings of >180 mg/ dL, and hemoglobin A1cs >7.0% while experiencing non-significant episodes of hypoglycemia are the goals.1 Similar to obtaining and maintaining HIV viral suppression, maintaining blood sugars is associated with fewer complications. Both conditions influence other metabolic and immunological functions that result in risk factors for complications including MACE, MASH, and mental health issues.

Conclusion

In summary, T2DM is becoming more common among older PWH, and like HIV, it is best to prevent, diagnose as early as possible, and treat immediately to limit associated morbidity and mortality. The AIDS Education and Training Center Program created an HIV comorbidities awareness tool in 2023 which includes monitoring for hypertension, cardiovascular disease, hyperlipidemia, and DM: HIV Health Outcomes: It's More Than Just Viral Suppression. It is important for entire clinical care teams to proactively work to prevent, diagnose, and treat not only HIV but T2DM as well.

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Update on Cardiovascular Disease and HIV – Focus on the REPRIEVE Study

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eople with human immunodeficiency virus (PWH) have at least a two-fold higher risk of cardiovascular disease (CVD) including myocardial infarction, stroke, and heart failure; rates are even higher in females.^{1,2} Reasons for increased rates of CVD in PWH are likely multifactorial and include traditional risk factors, such as smoking and hyperlipidemia, and may include ongoing inflammation and immune activation related to chronic HIV disease. Statin therapy has been shown to be effective in reducing CVD risk not only due to their reduction in low density lipoprotein (LDL) reductions, but also their effect on inflammatory markers. The JUPITER study demonstrated that in persons without HIV and increased levels of highly sensitivity C-reactive protein, statin therapy with rosuvastatin significantly reduced the incidence of major CVD events. Event rates were also reduced in patients without hyperlipidemia which highlights the anti-inflammatory benefits of statins beyond their reductions in cholesterol.³

Clinicians can estimate the CVD risk by using the American College of Cardiology atherosclerotic cardiovascular disease (ASCVD) Risk Estimator, which evaluates patient related factors to determine the 10-year risk of heart disease or stroke. The 2018 cholesterol guidelines suggest that for patients with borderline risk (5% to less than 7.5%) providers should engage PWH in a risk discussion to determine if moderate-intensity statin therapy is appropriate, as HIV is listed as an ASCVD risk enhancer.

prior to the REPRIEVE study results, there was a concern about PWH and their increased risk of CVD.

REPRIEVE Study

In an attempt to evaluate the role of statin therapy in PWH with lower (mild to moderate) ASCVD scores, the Randomized Trial to Prevent Vascular Events in HIV (REPRIEVE), a large phase 3 study was conducted. The results were recently published in 2023.⁵ REPRIEVE compared pitavastatin use to placebo in PWH with low to moderate risk for cardiovascular events. The hypothesis for the study was that people with HIV are at a higher risk for cardiovascular disease and that pitavastatin would reduce CVD events in this population.

Researchers randomized people to receive oral pitavastatin 4mg daily or a placebo. The primary endpoint of the study was major adverse cardiovascular events (MACE), which was included in a broad range of cardiovascular

diagnoses, including CVD, death, myocardial infarction, stroke, and peripheral vascular disease. Secondary outcomes included MACE or death from any cause, and other parameters such as LDL, non-HDL cholesterol, targeted safety events, including incidental diabetes mellitus, myalgia, muscle weakness and Grade 3 myopathy.

The study enrolled over 7,500 PWH ages 40 to 75 (median 50 years) from diverse backgrounds including high income and poor countries, males (68%), cisgender (95%), and black participants (40%). The median baseline 10-year ASCVD risk score was relatively low at 4.5, with 55% of subjects below 5%; median LDL cholesterol level was 108 mg/dL. As it relates to HIV infection, the current CD4 count was over 500 cells/mm³ for 68% of participants; 88% had undetectable viral loads. Patients were excluded with a history of statin use in previous 90 days and those with prior

	REPRIEVE Study Summary
Study Purpose	Assess the role of pitavastatin to prevent cardiovascular events in PLWH at low-moderate risk for atherosclerotic cardiovascular disease
Population	7,769 PLWH between 40 and 75 years of age, from diverse racial, ethnic, geographic backgrounds
Randomization	1:1 pitavastatin 4mg or placebo
Study Duration	5.1 years
Major Results	Rate of major cardiovascular events were 35% lower in the pitavastatin group compared to placebo (HR=0.65; 95% CI 0.48-0.9) Rate of major cardiovascular events or death were 21% lower in the pitavastatin group compared to placebo (HR=0.79, 95% CI=0.65 to 0.96)
Safety implications	Patients in the pitavastatin group more likely to experience newly diagnosed diabetes mellitus and myalgias
Application to PWH	Providers should discuss the role of pitavastatin with PWH with lower ASCVD risk scores where statins may not have been used previously

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atherosclerotic cardiovascular disease events.

The study was discontinued after just over five years. The use of pitavastatin was associated with a reduction of MACE by 35% for patients receiving pitavastatin compared to placebo (HR=0.65,95% Cl=0.48-0.9). When they evaluated secondary outcome of first MACE or death, researchers also found a significant 21% reduction (HR=0.79, 95% CI=0.65 to 0.96) in events for patients receiving pitavastatin therapy compared to placebo. Even for patients with low ASCVD risk there was a significant benefit to the use of pitavastatin therapy in PLWH. The majority of MACE occurred in patients with ASCVD risk scores of over 5%.

The number needed to treat (NNT), a statistical calculation helpful for determining whether an intervention is going to benefit patients, was also calculated for the REPRIEVE study and is available in the manuscript appendix.^{5,12} The NNT calculation determines the number of people needed to treat with an intervention to prevent one event. For example, an NNT of 50 means 50 people need to be treated with the intervention to prevent one event. In REPRIEVE, the



Table 1 Number Needed to Treat for Pitavastatin to Prevent One MACE, Overall and Based on Baseline ASCVD Risk Score

Overall	N	5 Year NNT
Overall	7769	106
ASCVD 0%-<2.5%	2156	199
ASCVD 2.5%-<5%	2055	149
ASCVD 5%-10%	2995	53
ASCVD >10%	563	35

NNT to prevent one MACE episode was 106 overall. Even in subjects with a 10-year ASCVD risk score of less than 5%, the NNT was less than 199, better than many common preventive interventions. Clearly the NNT is much lower for people at higher ASCVD risk. Given the rare risk of myalgias and incident diabetes in the study, these results further support the clinical role for this intervention (see Table 1).

Reducing CVD Risk for PWH in Clinical Practice

Studies also have shown that certain medications used to treat HIV may be associated with increased risks of CVD. The use of abacavir has been associated with increased risk of myocardial infarction in the DAD Study.⁶
Data from other cohorts have also

found this association with abacavir use was not explained by preferential use of abacavir in individuals at increased CVD or CKD risk.^{7,8} While retrospective studies demonstrate this risk, data from prospective clinical trials evaluating the risk of MI in persons receiving abacavir in clinical trials did not show this association.9 Data also demonstrates an association with CVD events in PWH receiving the protease inhibitor darunavir/ritonavir, when compared to atazanavir/ritonavir.10 Although it is difficult to determine causality of certain ARV medications in these retrospective studies, providers are encouraged to evaluate these associations carefully when selecting HIV regimens for patients, especially those with elevated ASVCD risk scores. The current Department of Health and Human Services (DHHS) Guidelines for the Use of Antiretroviral Therapy in Adults and Adolescents also provide some guidance around selection of HIV medication selection in PWH with high CVD risk or hyperlipidemia (see Table 2).11 Most importantly, providers should stress modifiable risk factors such as smoking and obesity to reduce CVD risk in PWH.

In addition to regimen selection and lifestyle modifications, the REPRIEVE results provide evidence that statin therapy in PWH (beyond their LDL reductions) can provide additional significant reductions in MACE and all cause mortality. The benefit of the pitavastatin in REPRIEVE was evident in almost all participant subgroups across

continued on next page

	Table 2				
	Select Guidance from DHHS Guidelines on Regimen Selection in PWH with High CVD risk or Hyperlipidemia (adapted from DHHS Guidelines)				
High cardiac risk	Consider avoiding ABC-based regimens. If a boosted PI is the desired option, an ATV-based regimen may have advantages over a DRV-based regimen.	An increased risk of CV events with ABC has been observed in some studies. Observational cohort studies reported an association between some Pls (DRV and LPV/r) and an increased risk of CV events; this risk has not been seen with ATV.			
Hyperlipidemia	The Following ARV Drugs Have Been Associated With Dyslipidemia: • Pl/r or Pl/c • EFV • EVG/c BIC, DOR, DTG, RAL, and RPV have fewer lipid effects. TDF lowers lipids; therefore, switching from TDF to TAF is associated with increased lipids.	TDF has been associated with lower lipid levels than ABC or TAF.			

gender, race, ethnicity, CD4 count, and region of residence. Importantly, they found a reduction in MACE with pitavastatin even in participants who were in the youngest age group (40 to 49 years) and those with low 10-year ASCVD risk and low LDL cholesterol. Almost all MACE occurred in high income countries and while they still did occur in low-income countries, places like sub-Saharan Africa had extremely low rates of MACE. However, the benefits of statin therapy were still demonstrated in Asia and Africa, which highlights the potential broad applicability of the results. Women also had higher rates of CVD in the placebo group – especially in those with higher ASCVD risk scores, perhaps reflecting a heightened focus for statin therapy use in women living with HIV.

As a result, REPRIEVE results should compel providers to closely evaluate patients with low to moderate ASCVD risk scores to determine whether the use of a statin should be initiated for primary prevention. The study results suggest that providers should be considering statin therapy earlier in PWH — or at least provide a shared discussion with patients regarding statin use — and consider statin use even in patients with low to moderate risk for CVD, a place where historically we may

not have used a statin.

DHHS Guidelines Update

Based upon the REPRIEVE study result, in February 2024 the U.S. Department of Health and Human Services Guidelines Panel for the Use of Antiretroviral Agents in Adults and Adolescents developed recommendations statin use to reduce CVD risk in PWH 11 These recommendations were established in collaboration with American College of Cardiology (ACC), the American Heart Association (AHA), and the HIV Medicine Association. The recommendations are listed below:

PWH with low-tointermediate (<20%) 10-year ASCVD risk estimates:

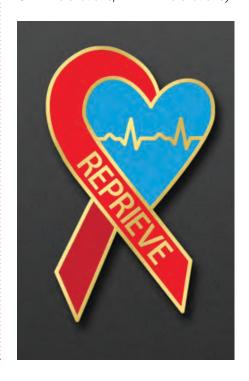
- Age 40 to 75 years
- ° If 10-year ASCVD risk estimates are 5% to less than 20%, initiate at least a moderate intensity statin therapy **(AI)**.
- o If 10-year ASCVD risk estimates are less than 5%, initiate at least a moderate intensity statin therapy. The benefit of statin use is not as clear in this population, therefore the decision should take into the presence or absence of HIV-related factors that can increase ASCVD risk.

- ° Recommended options for moderate intensity statin therapy include Pitavastatin 4mg once daily (AI), Atorvastatin 20mg once daily (AII), or Rosuvastatin 10mg once daily (AII)
- Age younger 40 years
- ° For PWH, there is insufficient data for or against statin therapy as primary prevention of ASCVD.

For patients with higher ASCVD risk (high risk, 20% or greater), providers should initiate high intensity statins for PWH ages 50 to 75 and for those who are 20 to 75 with LDL greater than 190 mg/dl. For persons with diabetes mellitus, ages 40 to 75, initiate at least moderate intensity and if further risk is identified, consider use of high intensity statins.

Drug to Drug Interactions and Statin Use

Co-administration of certain statins and antiretroviral drugs may result in significant drug—drug interactions. When evaluating these interactions, providers may be required to adjust the statin dose, switch to another statin, or monitoring closely for toxicity (myalgias, CPK elevations, LFT elevations).



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Online databases can be helpful in assisting providers with statin and HIV medication interactions. Providers are also reminded to be particularly cautious when combining statins with ritonavir or cobicistat-boosted regimens, or when stopping these regimens, as the dose and or statin drug selection may require adjustment. Investigators selected pitavastatin because it does not interact with ARV therapy.

Conclusions

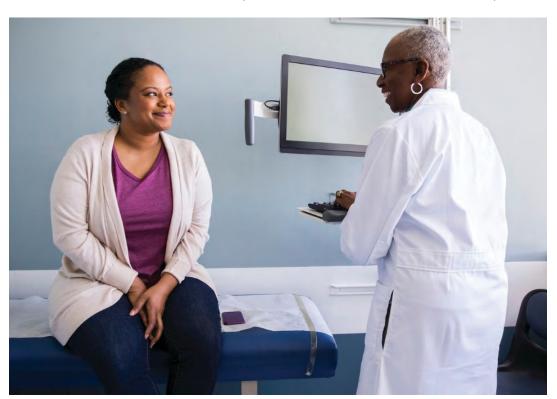
Interventions to reduce CVD risk in PWH are essential in this population, given their increased risk of CVD events, even at lower ASCVD risk scores. Since certain HIV treatments may be associated with increased CVD risk in retrospective studies, HIV providers should carefully select regimens, especially for PWH who have higher ASCVD risk. In persons with lower CVD risk, providers should also be cognizant of CVD risk, select medications appropriately. The REPRIEVE study provides evidence for statin use to reduce CVD risk across a large, diverse population of PWH,

reflecting various races, ages, CVD risk and geographic regions. Based on this study, recent additions to the DHHS guidelines provide guidance on statin use in PWH.11 Persons 40 to 75 years of age with a 10 year ASCVD risk score of 5% up to 20% should be started on a moderate intensity statin to reduce risk of CVD events. In PWH who have a 10-year ASCVD risk estimate of less than 5%, providers should initiate at least a moderate intensity statin therapy, with the caveat that the benefit of is not as clear in this population. Providers are encouraged to follow consensus guidelines which establish an evidence-based framework for this important intervention.

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Updated Recommendations for Infant Feeding for Parents with HIV in the U.S.

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Introduction

hoosing what to feed their infant is one of the most important decisions new parents have to make. The decision can be complicated by mixed messages from care team members who are uncomfortable talking about infant feeding for people with HIV (PWH). In general, pregnant people are often told that "breast is best" since breastfeeding offers numerous benefits to both the infant and the mother. Breast milk is designed to meet the nutritional needs of a growing baby, containing a perfect balance of proteins, carbohydrates, fats, and antibodies that support the baby's optimal development and immune function. Breastfed infants are less likely to suffer from respiratory, ear infections, and sudden infant death syndrome (SIDS); later in life they are at lower risk of asthma, allergies, and obesity than formula-fed infants. ¹⁻⁶ Breastfeeding also has benefits to the mother (See Table 1) and promotes bonding between mother and child. ⁷ Strong early bonding can have longlasting positive effects on the child's emotional and social development.

HIV Transmission through Breastmilk in the Pre-ART Era

Early guidelines released by organizations in the United States (U.S.) discouraged breastfeeding for PWH for good reason. Prior to the availability of antiretroviral therapy (ART), the

risk of HIV transmission via breastmilk was high. For those with established infection an average of 14% (95% CI, 7%-22%) transmitted HIV to the infant via breastfeeding.⁸ Risk can be even higher under specific circumstances. For example, based on a meta-analysis, the frequency of HIV transmission during acute seroconversion was estimated to be 29% (95% CI, 16%-43%).⁹

In 1992, a randomized clinical trial conducted in Nairobi compared HIV acquisition in breastfed versus formula fed infants born to women with established HIV. The primary outcome was HIV-1 transmission in each arm during the first two years of life. For the primary analysis, 401 mother-infant pairs were included. The median duration of breastfeeding was 17 months. The cumulative probability of acquiring HIV at 24 months was 36.7% (95% CI, 29.4%-44.0%) in the breastfeeding arm and 20.5% (95% Cl, 14.0%-27.0%) in the formula feeding arm (p=0.001; prevalence of breast milk transmission 16.2% (95% Cl, 6.5%-25.9%)).10

Does U=U Apply to Breastfeeding?

The concept of undetectable equals untransmittable (U=U) is well

Table 1. Breast milk Feeding Considerations for Individuals with HIV				
Health Benefits	Infant: lower risk of infants developing severe lower respiratory disease, otitis media, sudden infant death syndrome, gastrointestinal infections, necrotizing enterocolitis, asthma, obesity, and type 1 diabetes,			
	Breastfeeding parent: decreased risk of hypertension, type 2 diabetes; and breast and ovarian cancers			
Equity Considerations	People of color are disproportionately affected by HIV			
	People of color experience a greater burden of many health conditions that may be mitigated by breastfeeding			
Cultural Considerations	Environmental, social, familial, and personal pressures to breastfeed			
	Fear that not breastfeeding would lead to disclosure of their HIV status			

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established for sexual transmission of HIV when a person with HIV has an undetectable HIV viral load for more than six months. 11 If a person conceives on ART with an undetectable HIV viral load and maintains that undetectable viral load through pregnancy and delivery and the infant receives postnatal prophylaxis, perinatal HIV transmission is virtually zero. 12 Although many small studies of breastfeeding women on suppressive ART have shown no HIV transmissions, others have shown that a few transmissions do still occur with an average rate of HIV transmission of 0.3% at six months and 0.6% at 12 months.13 With an average of three infants of every thousand acquiring HIV with six months of breastfeeding, it cannot be said that U=U in this context.

In women who are not on ART, infant

prophylaxis during breastfeeding can protect against transmission, but it is also not 100% effective. A 14 site randomized open-label clinical trial with 2,431 mother-infant pairs, Promoting Maternal Infant Survival Everywhere (PROMISE), was conducted in women with HIV with CD4 counts greater than 350 cells/mm³ and their breastfed newborns who were born without HIV. They were randomized six to 14 days postpartum to receive either ongoing maternal ART (mART) or a daily dose of infant nevirapine prophylaxis (iNVP), and that continued until breastfeeding cessation, infant HIV transmission, toxicity, or 18 months postpartum. Not all mothers maintained full viral suppression. In the mART arm, seven of 1,219 (0.57%) analyzed infants acquired HIV and seven of 1,211

(0.58%) analyzed infants in the iNVP arm acquired HIV (hazard ratio 1.0, 96% repeated confidence interval 0.3-3.1). Neither mART nor iNVP resulted in rates of transmission of approximately six per 1000 over with a median period of breastfeeding of 16 months. To date, no study has been conducted to determine whether combining maternal ART and infant ART can lower the risk further.

Current U.S. Guidelines

Acknowledging that the risk of transmission of HIV through breastmilk can be made very low with modern ART and that there are compelling benefits, in January 2023, the U.S. Department of Health and Human Services (HHS) perinatal HIV guideline panel released their annual update and

for the first time do not recommend a specific feeding choice for people with well-controlled HIV.¹⁴ With an emphasis on education about risks and benefits of feeding options, there is now a focus on patient-centered, shared decision making around infant feeding choices.

Many gaps persist in our knowledge regarding how to best support PWH who choose to breastfeed their infants in order to mitigate risks and maximize benefits. For the breastfed infants, key areas to stress during decision-making include:

- Maintaining viral suppression postpartum is more challenging for some parents; studies have shown high rates of maternal viremia in the postpartum year.¹⁵
- "Mixed feeding" with breastmilk <u>and</u> formula (or other foods) may increase the risk of HIV transmission over exclusive breastfeeding.
- We do not know the extent to which adding infant prophylaxis may further decrease risk of transmission in the context of continuous maternal suppressive ART

With regards to mixed feeding, in the pre-ART era, the risk of transmission of HIV through breastfeeding was up to 11 times higher in infants exposed to both breastmilk and infant formula or solid foods compared to those who were exclusively breastfed. However,

the extent to which mixed feeding may increase the risk of HIV transmission compared with exclusive breastfeeding when the breastfeeding parent is on suppressive ART is uncertain. Exclusive breastfeeding beyond six months of age is rare since older infants require complementary foods. Thus, results of the meta-analysis of breastfed infants with mothers on ART showing rates of transmission of 0.3% at six months and 0.6% at 12 months suggest that for older infants adding complementary foods does not multiply risk as it did in the pre-ART era. These results cannot be extrapolated to the newborn period when gut permeability is higher, and establishment of the intestinal microbiome is strongly influenced by inclusion of formula in the diet.¹⁶

Antiretroviral Prophylaxis for Newborns

There is no consensus on antiretroviral (ARV) prophylaxis for breastfeeding infants of PWH with sustained viral suppression. Even in the absence of breastfeeding, the duration of postpartum prophylaxis has become controversial due to the lack of data comparing shorter versus historically accepted rates of infant prophylaxis. Most HHS perinatal HIV guideline panel members agreed on adopting the British HIV Association recommendation of only two weeks of infant zidovudine (ZDV).¹⁷ However, several Panel members prefer to maintain a duration

of ZDV prophylaxis of four to six weeks. For longer durations of prophylaxis during breastfeeding, nevirapine (NVP) has a better side effect profile than ZDV and is similarly effective. 17 Approaches to infant prophylaxis range from no prophylaxis as long as maternal suppression is maintained, to daily prophylactic NVP dosing or three-drug prophylaxis throughout breastfeeding. Prophylaxis decisions may change throughout the time of breastfeeding, depending on maternal circumstances (e.g., the presence of cracked nipples, mastitis, or maternal missed medication doses may prompt consideration of adding or increasing infant prophylaxis). Thus, ongoing discussions between the care team and parents are key to ongoing collaborative decision-making.

Child Protective Services

The new HHS guidelines specifically state that "parents' feeding choice alone is not a reasonable justification for involving child protective services (CPS) for persons with HIV who want to breastfeed." While HIV can be a serious health concern, it is not the only important consideration driving feeding choices. When a breastfeeding parent is effectively managing her HIV through medication and regular medical care, and has received appropriate counseling breastfeeding precautions, it is **not necessary** to involve child protective services. Instead, supporting the mother's informed decision to breastfeed and providing ongoing health care support with collaboration between maternal providers, infant providers, and a lactation consultant, can ensure that both receive the benefits of breastfeeding while effectively mitigating the risk of HIV transmission. It is essential to recognize that CPS involvement has disproportionately impacted marginalized populations, including people of color and PWH, and can result in punitive rather than supportive actions. 18 CPS exists to protect children at risk of abuse and neglect; it is not a natural partner in

Table 2. Key Recommendations on Infant Feeding for Individuals with HIV

-People should receive evidence-based, patient-centered counseling to support shared decision making about infant feeding. This counseling should ideally begin prior to conception.

-Replacement feeding with formula or banked pasteurized donor human milk is recommended to eliminate the risk of HIV transmission through breastfeeding when people with HIV are not on ART and/ or do not have a suppressed viral load during pregnancy (at a minimum throughout the third trimester), as well as at delivery

-Individuals with HIV who are on ART with a sustained undetectable viral load and who choose to breastfeed should be supported in this decision

-Individuals with HIV who choose to formula feed should be supported in this decision. For families desiring to formula feed, providers should ask about potential barriers to formula feeding (e.g., familial pressures or financial consideration) and explore ways to address them

-Engaging Child Protective Services or similar agencies is not an appropriate response to the infant feeding choices of an individual with HIV

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promotion of the well-being of the breastfeeding child with well-informed and engaged parents with HIV.

Counseling and Management

An interprofessional team consisting of HIV providers, lactation consultants, pediatricians, obstetricians, nurses, pharmacists, and counselors provides comprehensive information guidance to PWH regarding the benefits and risks of breastfeeding as well as data on risk-mitigation. Table 2 highlights key recommendations that need to be included in counseling. Ideally, the team collaborates to ensure that parents have accurate and up-todate information about the transmission risks associated with breastfeeding, the role of ART, and strategies to minimize transmission risk while promoting infant health. Table 1 highlights infant feeding considerations.

Conclusions

The approach to breastfeeding in the context of HIV has evolved over time, reflecting a more nuanced understanding of the risks and benefits involved. While breastfeeding carries a potential low risk of HIV transmission, exclusive formula feeding carries a different set of risks. A comprehensive approach aims to balance immunological, nutritional, psychological benefits of breastfeeding with the need to minimize the risk of HIV transmission. By providing ongoing support and monitoring, the care team can help PWH make informed decisions about breastfeeding that consider their individual circumstances and prioritize the health and well-being of both mother and child.

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New Jersey Nurses in HIV Care: Working to End the Epidemic

Christie Lyn Costanza - ANAC-NJ Chapter President Peter Oates, National ANAC Board Member, ANAC-NJ Director-at-Large

On December 12, 1991, at the height of the HIV/AIDS epidemic, 10 New Jersey nurses met to discuss the formation of a regional chapter of the Association of Nurses in AIDS Care (ANAC). Like many nurses around the country at this time, these 10 nurses felt the need to come together to share knowledge, raise concerns, network, mobilize the community, and find comfort and support with each other during a challenging time.

On November 11, 1992, at the ANAC annual conference in Orlando, Fla. the newly formed ANAC-Central New Jersey Chapter was presented with its official chapter charter. As membership in the chapter increased, chapter leadership decided to expand the region to become a statewide chapter. In September 1999, the national organization approved the change of

the chapter name to the Association of Nurses in AIDS Care – New Jersey Chapter (ANAC-NJ). Since its formation, members of the ANAC-NJ chapter have impacted the delivery of care in the State of New Jersey. Their leadership and involvement in patient care, policy, education, activism, advocacy, guideline development, research, and community involvement continue to this day.

ANAC is the leading nursing organization responding to the HIV epidemic. Since its founding in 1987, ANAC has been meeting the needs of nurses and other health care professionals in HIV care, research, prevention, and policy. ANAC has over 40 chapters of dedicated nurses, health care professionals, and others committed to HIV nursing. Affiliate members include social workers, pharmacists, physicians,



ANAC-NJ Board Members

Left to right: Liz Woodfield, Debbie Mohammed, Eileen Scarinci, Peter Oates, Christie Lyn Costanza, Nancy Peterson.



physician assistants, lawyers, and anyone involved in the care and support of people with HIV.

Part of the ANAC enterprise is the HIV/AIDS Nursing Certification Board (HANCB), a nonprofit professional organization whose mission is to improve the quality of HIV nursing care, foster HIV prevention, promote competency of nurses caring for persons with HIV, and recognize professional achievement through the certification and recertification process. Certifications offered by HANCB include:

- HIV/AIDS Certified LPN/LVN (ACLPN)
- HIV/AIDS Certified Registered Nurse (ACRN)
- Advanced HIV/AIDS Certified Registered Nurse (AACRN).

The ANAC-NJ Chapter welcomes new members. To join, you must first have ANAC National membership. The ANAC-NJ chapter holds meetings throughout the year. For ANAC-NJ, please visit their Facebook page: ANAC New Jersey Chapter. The chapter may also be contacted via email at anacjnj1992@gmail.com.

Save the date for the annual ANAC conference, ANAC2024, in Indianapolis, Nov. 14-16, 2024! The theme is *Race for the Cure*. For more information about ANAC and the annual conference, please visit www.nursesinaidscare.org. This site also has a link to the HANCB.



Nurses Are Gonna Nurse

Bridgette Picou, LVN, ACLPN Stakeholder Liaison, The Well Project National ANAC Board Member, Director-at-Large

Nurses are gonna nurse. I heard that for the first time in nursing school and it became a bit of a mantra for the hard days and a celebration for the good ones. Nurses do what's needed. For me, it's not only about the idea that I get to help people. I believe in the healing power of touch and showing empathy and care. It is that I also get to build relationships. Not all nurses can take that time. It depends in part on the area of nursing you choose. A nurse in an emergency room has very little time to establish rapport, stabilize, and treat a patient and then it's on to the next. A clinic nursing experience is different. You have opportunities to connect. It's one of the reasons I love HIV nursing so much.

I am an HIV nurse and an advocate. I say it often and proudly. If you were to ask most nurses in a specialty, they could tell you all the reasons they love it. I get to see my patients every three months or so, and help them with medications and services they may need. I make it a point to know about biomedical advances and HIV cure and clinical trials, so they can be informed on those things. All that means I get to know them well and they can get to know me. Nursing in HIV has not only been a learning experience, but in many ways, it has shaped my relationship with my own HIV diagnosis. I have been living with HIV for a little over 11 years and working in HIV nursing for 10 of those. I have experienced some of my most profound moments working in an HIV clinic, not all of them directly related to the Human Immunodeficiency Virus, but all of them related to the human part of the equation. Some of the experiences I have encountered during my life process with the virus have been

hurtful and stigmatizing. More than a few of these have been at the hands of a medical "professional." It can be devastating to go to an ostensibly safe space and leave feeling the opposite.

Moments of stigma were defining and underscored the type of nurse (and person) I would be. HIV involves amounts of guilt and shame and is peppered with myths, so people hide their status-- including those that work in health care. There are countless times when I have heard or been a part of conversations when other nurses refer to those living with HIV as "those people" or "dirty". Still, in 2024, some nurses think gloves are needed to touch HIV patients or tell each other in whispered tones to "be careful with that one". It's a stark reminder that nurses are people and old myths are hard to break when backed up by fear. Sometimes it's the woeful ignorance of just not knowing. Other times it's willful ignorance; opportunities to know and do better and choosing not to. The beginning of my nursing journey gave me chances to be taught by patients

so I could do better. I heard firsthand accounts of how fear and some of that ignorance caused nurses to treat them poorly and doctors to refuse to treat them. Listening to them helped me heal and to cheat stigma through empathy and advocacy. By fighting for them and their health care needs, I did so for myself. When I hugged them through the hurt, I was hugging all of us with HIV.

When I went public with my status it was because I was driven to do more for people living with HIV. Standing in the gap between nursing and those living with HIV made sense. It didn't occur to me that I would also be standing in the gap for health care professionals living with HIV in silence until the first time another positive nurse thanked me for being open about my status. Fear of reprisal from employers or rejection from patients keeps health care workers with HIV from being able to live fully open with their status. Nurses are humans away from the bedside, with lives they set aside to help other people. I wonder sometimes; because so much of my nursing identity is tied to HIV if I would be "allowed" to do a different kind of nursing. If an employer googled me and saw HIV all over my profile and resume, would they hire me? Sure, nurses are gonna nurse, but at what cost when they can't be in their full authentic selves? It's worth a thought, and definitely worth me continuing to do what I do.

Be well. You matter.



Hydeia Broadbent, the Legacy of an HIV Activist

Sunrise June 14, 1984 - Sunset February 20, 2024

Michelle Thompson, Program Manager Rutgers School of Nursing-François Xavier Bagnoud (FXB) Center

"I want people to know that we're just normal people. I just want people to know I'm normal."

Those were the tearful words of 7-year-old Hydeia Broadbent in 1992 at the height of the HIV epidemic, when she appeared on the Nickelodeon special "A Conversation with Magic," hosted by Magic Johnson and Linda Ellerbee as they talked to a group of children about HIV. Hydeia, the first African American youth to speak up and speak out about the epidemic, was a pioneer in the HIV movement. She became a warrior in the fight against the stigma surrounding children with HIV and their treatment at home, in schools, and the community.

Hydeia was born with undiagnosed

HIV in Las Vegas, Nevada, on June 14, 1984, and abandoned by her birth mother. Loren and Patricia Broadbent took her in as a foster child and later adopted her. In 1987, they learned that Hydeia had HIV. Her parents enrolled her in a research trial in hopes of finding a treatment that would work for Hydeia. Physicians predicted that she would die by the age of five. **Despite all predictions, she survived.** However, when she was five, she developed AIDS.

In 1996, 11-year-old Hydeia appeared on the *Oprah Winfrey Show* to talk about living with AIDS and all the medical emergencies she experienced in her young life. Hydeia regularly had blood infections, pneumonia, and

fungal infections in her brain. When Oprah asked Hydeia what the most challenging part for her was, Hydeia tearfully answered, "When your friends die. That's the hardest part because you love them, and you always lose a friend to AIDS." But Hydeia also delivered a message of hope and resilience by stating:

"No one really knows how long anybody's going to live; I don't tell myself, Oh, you have AIDS, or I could go outside and get hit by a bus tomorrow. If you stay in your bed and feel sorry for yourself, and don't get up with the birds and just sit there and say I'm going to die, why get up and try to make a difference? But when you say today's another day, I can get up. I can do something, make something positive."

That same year, Hydeia addressed the Republican National Convention with a poem declaring:

"I am the future, and I have AIDS.
I can do anything I put my mind to.
I am the next doctor.
I am the next lawyer.
I am the next Maya Angelou.
I might even be the first woman president.
You can't crush my dreams.
I am the future, and I have AIDS."

In 2002, Hydeia and her mother cowrote a book entitled *You Get Past the Tears: A Memoir of Love and Survival* about their experience as a family. As she got older, Hydeia continued to work in HIV advocacy; she always talked about the impact of HIV on the



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African American community, reducing stigma, educating the community about practicing safer sex or abstinence, and getting tested regularly. She spoke to young people about stopping the spread of HIV. In a 2012 CNN interview, Hydeia said:

"I have dedicated my whole life to this fight. I don't hate my life. I feel like I'm really blessed, but at the same time, my life doesn't have to be their life. I didn't have a choice when it came to HIV/AIDS, and people do have a choice."

In 2018, on her 34th birthday, Hydeia wrote a blog post on her website to celebrate the milestone as someone in "the first generation of children born HIV positive" whose parents were told she would not live past five years old.

"These last few years have been extremely difficult; struggles with depression, which reached scary points. A depression so dark I was not sure how I would see the beauty in life again. I was unsure of how I'd pull myself back up. I now have a new outlook. I'm now able to see the blessings and lessons from my valley. I am a warrior. I raise each day with purpose while still being a work in progress."

Hydeia was known national-

ly and internationally for her

advocacy work. Prominent publications such as the

New York Times, People,

Essence, Ebony, Health Quest, POZ, Nation-

most respected educational institutions, including Duke University, Morehouse School of Medicine, University of California, Los Angeles, University of Southern California, and Howard University, to name a few. Hydeia was a featured speaker at the International AIDS Conference in 2006, at the 2000 and 2007 Essence Music Festival, and at the 2007 AIDS Rally at Potters House led by Bishop TD Jakes in Dallas, Texas. Ebony Magazine named Hydeia one of the Most Influential 150 African Americans in 2008. She was honored with an American Red Cross Spirit Award and an Essence Award.

Magic Johnson, who had worked with Hydeia at the age of seven and continued to do so through the works of Magic Johnson Foundation wrote a tribute on X, that in part read:

"By speaking out at such a young age, she helped so many people, young and old, because she wasn't afraid to share her story and allowed everyone to see that those living with HIV and

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- New Jersey rapid testing site: www.njhiv1.org
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HIV/AIDS Training & Information Resources

AIDS Education and Training Center (AETC) Program

- National Coordinating Resource Center: www.aidsetc.org
- Northeast/Caribbean AETC: www.necaaetc.org
- National Clinician Consultation Center:
 http://www.nccc.ucsf.edu/
 HIV Warmline: (800) 933-3413
 Post-Exposure Prophylaxis Hotline/PEPline:
 (888) 448-4911
 Perinatal HIV Hotline: (888) 448-8765
 Pre-Exposure Prophylaxis Hotline (PrEPline):
 888-HIV-PREP
 Substance Use Warmline: (855) 300-3595
 Hepatitis C Warmline: 844-437-4636

HIVinfo: a service of the US Department of Health and Human Services, offers access to the latest, federally approved HIV/AIDS medical practice guidelines, HIV treatment and prevention clinical trials, and other research information. www.hivinfo.nih.gov US National Institutes of Health: a registry and results database of publicly and privately supported clinical studies conducted around the world. http://clinicaltrials.gov

US Centers for Disease Control and Prevention (CDC): http://www.cdc.gov/hiv/default.html

Health Resources and Services Administration (HRSA): http://www.hrsa.gov

FDA MedWatch: (800) FDA-1088; Subscribe to e-bulletin: www.fda.gov/medwatch/elist.htm

Center for Quality Improvement and Innovation: no-cost, technical assistance for Ryan White funded grantees to improve the quality of HIV care nationwide. www.cqii.org

TargetHIV Center: technical assistance and training resources for the Ryan White HIV/AIDS Program community. https://targethiv.org

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