Gender-affirming Care for Transgender and Gender Diverse Patients

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Several health disparities disproportionately impact transgender and gender diverse (TGD) individuals, including HIV. Because gender identity is a core element of personal identity, gender-affirming care is essential for improving health outcomes. This article reviews the key elements of gender-affirming care and how it can improve the quality of life for TGD patients seeking HIV prevention or treatment services.

What is gender-affirming care?
To understand gender-affirming care, it is important to start with some definitions, listed in Table 1. Notably, both sex and gender can manifest in many different ways and represent a rich diversity of human phenotype, expression, and identity. TGD individuals experience gender incongruence, which is a persistent dissonance between gender
Gender-affirming Care for Transgender and Gender Diverse Patients: The Key to Improving Health Outcomes Across the HIV Care Continuum

<table>
<thead>
<tr>
<th>Sex</th>
<th>The anatomic and physiologic characteristics that differentiate male, female, and intersex individuals, such as reproductive organs, chromosomes, and hormones.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assigned sex at birth</td>
<td>Sex determination assigned by chromosomal analysis or visual observation of the genitals at birth. Typical assignments include female, intersex, and male.</td>
</tr>
<tr>
<td>Differences in sexual development (DSD)</td>
<td>A heterogeneous group of congenital conditions in which the development of chromosomal, gonadal, or anatomic sex is atypical. The use of “differences” instead of “disorders” is less stigmatizing, as DSD represents a continuum of sexual development. Furthermore, the presence of DSD may or may not predispose patients to morbidity.</td>
</tr>
<tr>
<td>Intersex</td>
<td>Sex assignment at birth based on reproductive anatomy that does not meet the typical definition of female or male. Individuals with an intersex assignment may have DSD.</td>
</tr>
<tr>
<td>Gender</td>
<td>Psychological, behavioral, and cultural characteristics that are typically associated with the assigned sex at birth. Typical gender roles include man/boy and woman/girl.</td>
</tr>
<tr>
<td>Gender identity</td>
<td>Personal gender designation that is identified internally by self-knowledge and understanding. Typically falls on a spectrum and can include man/boy, gender non-binary, gender diverse, and woman/girl, among others. Because gender identity is internally defined, it cannot be assumed.</td>
</tr>
<tr>
<td>Transgender</td>
<td>Self-identity that encompasses anyone who differs from cultural norms for gender identity, expression, and/or role. Frequently, describes someone whose gender identity is different from the assigned sex at birth.</td>
</tr>
<tr>
<td>Transgender girl/woman</td>
<td>Someone whose assigned sex at birth was male and whose gender identity is girl or woman.</td>
</tr>
<tr>
<td>Transgender boy/man</td>
<td>Someone whose assigned sex at birth was female and whose gender identity is boy or man.</td>
</tr>
<tr>
<td>Cisgender</td>
<td>Anyone who is not TGD. Typically, someone whose assigned sex at birth aligns with their gender identity.</td>
</tr>
<tr>
<td>The gender binary</td>
<td>The idea that there are only two possible genders: man/boy and woman/girl. This idea problematically excludes and erases the experiences of TGD people and people with DSD.</td>
</tr>
<tr>
<td>Gender non-binary</td>
<td>Self-identity for people who feel the traditional gender binary does not accurately represent their gender.</td>
</tr>
<tr>
<td>Gender diverse</td>
<td>Umbrella term representing gender identities that demonstrate a diversity beyond the gender binary.</td>
</tr>
<tr>
<td>Gender incongruence(^1)</td>
<td>A marked and persistent incongruence between the gender felt or experienced and the assigned sex at birth.</td>
</tr>
<tr>
<td>Gender dysphoria(^2)</td>
<td>The discomfort or distress caused by incongruence between a person’s gender identity and assigned sex at birth and the associated gender role and secondary sex characteristics.</td>
</tr>
</tbody>
</table>
identity and the assigned sex at birth. People who identify as TGD may or may not experience gender dysphoria, an internal sense of discomfort or distress with a gender role or physical characteristics such as body shape, secondary sex characteristics, hair distribution, and/or facial structure, which are incongruent with their experienced gender. TGD people may also experience discrimination or violence from transphobia, which can greatly affect quality of life and opportunities for healthy living, and increase the risk for suicide. As a result, access to gender-affirming care, which is care that aligns a person’s physical and social gender experience with internal gender identity, can be life-saving.

Table 2 summarizes the key aspects of gender-affirming care. Gender-affirming care starts from the moment a patient has their first contact with the clinic. Even if your clinical practice does not provide gender-affirming hormone therapy or gender-affirming surgery, there are important considerations for meeting the healthcare concerns of TGD patients, who may have many health priorities beyond the treatment of gender incongruence. Because of prior adverse experiences with healthcare, patients may be reluctant to seek care or may experience high anxiety levels when presenting for services. A clinical space that creates a sense of belonging and affirmation for TGD patients ensures increased linkage and engagement in care. Furthermore, specific interventions to treat gender incongruence or dysphoria, including hormones and surgery, improve quality of life and depression symptoms, and reduce the use of mental health services. Detailed, evidence-based guidelines for gender-affirming care are available from the World Professional Association for Transgender Health Standards of Care. An updated version of the Standards of Care (version 8) will be available in the spring of 2022.

<table>
<thead>
<tr>
<th>Point of contact</th>
<th>Gender-affirming practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Greeting and reception</td>
<td>Ensure gender-neutral greetings from the first contact with the health facility, including on the phone, and with security and the front desk staff. Post welcoming and inclusive posters and materials.</td>
</tr>
<tr>
<td>Forms and registration</td>
<td>Create forms and registration materials that are inclusive of multiple options for assigned sex at birth, gender identity, chosen names (when different than legal names), and pronouns. Electronic forms filled out in advance can provide accurate information before the visit. Ensure the electronic medical record has the capacity to collect and accurately display this information.</td>
</tr>
<tr>
<td>Waiting area and associated spaces</td>
<td>Ensure access to inclusive reading materials and all-gender bathrooms. Create inviting spaces that make everyone feel welcome by including messaging and images supporting TGD, such as pride flags.</td>
</tr>
<tr>
<td>Use of names and pronouns</td>
<td>Create workflows that support addressing patients by the correct chosen name, greeting, and pronouns that are congruent with their gender identity. Importantly, this creates a space of respect and safety and sets the tone for the visit.</td>
</tr>
<tr>
<td>Patient-centered communication</td>
<td>Expect to encounter a diversity of gender expressions and gender identities. Recognize TGD patients for their unique individual perspectives. Make no assumptions about gender identity, gender norms, or sexuality.</td>
</tr>
<tr>
<td>Quality primary and preventive care</td>
<td>Provide guideline-based and organ-specific screening and preventive care, including cancer screening, vaccinations, and counseling on sexual health, fertility planning, family planning, and healthy behaviors.</td>
</tr>
<tr>
<td>Gender-affirming hormone therapy</td>
<td>Provide timely referrals for guideline-based gender-affirming hormone therapy and discuss realistic expectations, benefits, and the low risk profiles of treatment with medical supervision. Explore relevant drug interactions, and dispel misconceptions about interactions between hormones and antiretroviral medications.</td>
</tr>
<tr>
<td>Gender-affirming surgery</td>
<td>Refer to vetted gender-affirming surgery programs. Counsel about the benefits and risks of surgical procedures. Learn about common complications and how to counsel patients on their management.</td>
</tr>
<tr>
<td>Community-informed policies and practices</td>
<td>Establish reliable mechanisms for consumer feedback for the priorities of TGD patients, such as establishing a community advisory board or creating surveys or focus groups.</td>
</tr>
</tbody>
</table>

Why is gender-affirming care an essential element of HIV prevention and treatment services?

Transgender individuals are disproportionately affected by HIV globally. In a recent systematic review of 98 international studies, transgender women were 66 times more likely to be diagnosed with HIV, and transgender men were 6.8 times more likely compared to cisgender counterparts. This disparity is primarily driven by multiple levels of structural violence, marginalization, and discrimination. In many ways, this disparity reveals how public health and healthcare have failed to provide equitable access and care tailored for patient populations most affected by the HIV pandemic. Because gender-affirming care can help patients live and thrive authentically, addressing this core health priority allows patients and providers to focus on additional important health issues, such as...
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as preventive care and management of chronic illnesses. With respect to HIV, integration of gender-affirming care into HIV prevention and treatment programs improves outcomes across the HIV care continuum, including initiation of HIV pre-exposure prophylaxis, retention in care, and viral load suppression. An additional large longitudinal cohort study examining HIV-related health outcomes among TGD patients engaged in gender-affirming care is ongoing (LEGACY).

In our experience, the integration of gender-affirming care has improved the overall quality of care of our HIV practices. By creating inclusive and health-positive spaces, expanding our services, and focusing on community outreach, our practices have grown and thrived, which benefits patients of all genders. In addition, gender-affirming care leads to positive physical and mental health outcomes that are gratifying to manage on the part of providers.

Conclusion

Given the disproportionate prevalence of HIV among transgender individuals, gender-affirming practices are essential for HIV prevention and treatment services. Gender-affirming care integrated with HIV prevention and treatment improves outcomes across the HIV care continuum and can improve care delivery for patients of all genders.

References

Introduction:
Untreated HIV disease is linked to chronic inflammation and wasting syndrome, which is the reason it took us a while to realize that antiretroviral therapy (ART) could lead to excessive weight gain as an adverse event.1 Generally, providers assume that a person receiving ART with a decrease in viral load (VL) and improvement of their immune system will gain weight as a sign of a return to good health.

In the past few years, the incidence of obesity in persons with HIV (PWH) was higher than the general population, especially in those taking ART with suppressed VL. This is of particular concern since cardiovascular disease, along with type 2 diabetes mellitus and hypertension are some of the most common comorbidities that we see in PWH.

In this article, we present the current evidence for weight gain secondary to ART in different groups. We will start with HIV negative persons receiving ART as pre-exposure prophylaxis (PrEP), then we will present data in patients starting ART for the first time (ART-naïve), and finally, we will review switch studies in patients with a suppressed VL who changed ART within the same or to a different class. It is important to note that weight gain is usually multifactorial; pediatric HIV and weight changes in pregnant women with HIV will not be discussed, nor will the effects of rarely used medications (e.g., zidovudine, nevirapine, nelfinavir, etc.).

PrEP
PrEP may be started on people who are at high risk of contracting HIV. Current studies have analyzed the effect of various ART regimens on weight gain in patients using ART for HIV prophylaxis (Table 1). These studies compared different regimens and compared patients on PrEP to those on placebo.

The iPrEx study compared Emtricitabine 200 mg/Tenofovir Disoproxil Fumarate 300 mg tablet (FTC/TDF) to placebo for prevention of HIV infection over 96 weeks.1 In this study, 2,499 patients were enrolled from 2007 through 2009 in eleven sites spanning 6 different countries (in descending order according to percentage Peru, Ecuador, Brazil, USA, Thailand, South Africa) and randomly placed into the FTC/TDF group or placebo group. Inclusion criteria were male sex at birth, age 18 years or older, HIV-seronegative status, and evidence of high risk for acquisition of HIV. Participants’ ages ranged from 18 to 67 years of age. Participants identified as multiracial or other (68%), Hispanic (72%), black (9%), white (10%).

<table>
<thead>
<tr>
<th>Name</th>
<th>Drugs</th>
<th>Design</th>
<th>Number</th>
<th>Gender</th>
<th>Race</th>
<th>Ethnicity</th>
<th>Age</th>
<th>Location</th>
<th>Results</th>
<th>Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>iPrEx</td>
<td>FTC/TDF vs placebo</td>
<td>Prospective, randomized, blinded</td>
<td>2499</td>
<td>100% Male</td>
<td>68% mixed</td>
<td>72% Hispanic</td>
<td>Age 18-67</td>
<td>Multi-national</td>
<td>No significant weight difference</td>
<td>96 weeks</td>
</tr>
<tr>
<td>DISCOVER</td>
<td>FTC/TDF vs FTC/TAF</td>
<td>Prospective, randomized, double-blinded</td>
<td>5857</td>
<td>100% Male</td>
<td>84% white</td>
<td>25% Hispanic</td>
<td>Age 29-44</td>
<td>Multi-national (50% US)</td>
<td>FTC/TAF significant increase in weight</td>
<td>48 weeks</td>
</tr>
<tr>
<td>HPTN083</td>
<td>CAB vs TDF/FTC</td>
<td>Prospective, randomized, double blind, double dummy</td>
<td>4566</td>
<td>100% Male</td>
<td>49% black, 51% white</td>
<td>Mean Age: 26</td>
<td>Multi-national</td>
<td>No significant weight difference</td>
<td>153 weeks</td>
<td></td>
</tr>
<tr>
<td>HPTN084</td>
<td>CAB vs TDF/FTC</td>
<td>Prospective, randomized, double blind</td>
<td>3224</td>
<td>100% Female</td>
<td>40% black</td>
<td>Mean Age: 35, Range 22-30</td>
<td>Africa</td>
<td>Initial significant weight increase with CAB</td>
<td>3 years</td>
<td></td>
</tr>
<tr>
<td>HPTN077</td>
<td>CAB vs placebo</td>
<td>Prospective, randomized, blinded</td>
<td>177</td>
<td>66% Female</td>
<td>36% Hispanic</td>
<td>Mean Age: 31</td>
<td>Multi-national</td>
<td>No significant weight difference</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: iPrEx, pre-exposure prophylaxis initiative trial; FTC, Emtricitabine; TDF, Tenofovir disoproxil fumarate; TAF, tenofovir alafenamide; CAB, Cabotegravir
Does Antiretroviral Therapy Cause Weight Gain?

(18%), and Asian (5%). The majority of participants completed post-secondary education or had secondary degrees (76%). Data showed that both groups gained 1.5% of baseline weight per year, with no significant difference in weight gain between the two groups. Overall weight loss of more than 5% for both groups, intentional and unintentional, was 15%.

The DISCOVER study was a randomized, double blind, active-controlled phase 3 PrEP trial comparing FTC/TDF to Emtricitabine 200mg/ Tenofovir Alafenamide 300 mg tab (FTC/TAF). This study enrolled adult cisgender men who have sex with men (MSM) and transgender women who have sex with men deemed to be at high risk for contracting HIV based on reported sexual behavior over the last 12 weeks or a history of a sexually transmitted infection in the last 24 weeks. The trial was a randomized, double-blinded, multicenter, active-control study conducted in Europe and North America. Participants in this study ranged in age from 29 to 44 years old with an average age of 34 years. They were 84% white, 9% black, and 25% Hispanic. Overall, 60% of participants were in the US, 33% were in Europe, and 7% were in Canada. In both groups, 16% of participants were on FTC/TDF at the time of study initiation.

The DISCOVER study showed that participants taking FTC/TAF had a statistically significant (p<0.0001) increase in weight compared to those taking FTC/TDF. Individuals taking FTC/ TAF had an average of a 1.1 kg increase in weight after 48 weeks while those taking FTC/TDF had a decrease in weight followed by an increase resulting in an overall 0.1 kg change in weight at the end of 48 weeks. The average baseline body mass index (BMI) was 25 kg/m² with a range of 23 to 29.

In the HPTN083 study, researchers compared long acting cabotegravir (CAB-LA), an integrase strand inhibitor (INSTI), with TDF/FTC for the prevention of HIV in at risk cisgender men who have sex with men and at risk transgender women who have sex with men. This was a multicenter, randomized, double blind, double dummy, non-inferiority trial with 4,566 participants; 570 participants were transgender women. The median age was 26 years; 49% of participants were black and 51% white. The majority of participants in this study completed college or university or higher (68%). Study locations were the US, Latin America, Asia, and Africa. Researchers found no significant difference in weight gain; both groups gaining approximately 1 kg over one year.

In the HPTN084 study, a sample of 3,224 females who were at high risk of contracting HIV were randomized to one
of two groups to determine the efficacy and effects of CAB-LA compared to TDF/FTC. In this double-blind trial, women were randomized and received either CAB-LA or TDF/FTC. The average age of women in the sample was 25 years old and approximately 55% of women had a BMI of >25 kg/m² at baseline. Women started on CAB-LA experienced a statistically significant higher amount of weight gain than the TDF/FTC group, with an increase of about 0.42 kg. Over time, however, patients on TDF/FTC also gained weight. After three years, participants on CAB-LA gained 2.4 kg/year and participants on TDF/FTC gained 2.2 kg/year. The final weight gain between the two groups after three years was not statistically significant.

Finally, The HPTN077 study compared CAB-LA to a placebo for people without HIV starting PrEP therapy. The study enrolled 177 people without HIV in a randomized phase 2 trial. The study population included participants from three continents, with 55% from the US. The median age was 31 years old and 66% were female, 40% black, and 36% Latino. The sample population demographics were balanced between study arms (CAB-LA and placebo). Results indicated no statistically significant weight change at 41 weeks between the two groups. However, it should be noted that this was a relatively small study and powered to detect weight differences greater than 2.4 kg between arms.

**ART-naïve**

Generally, providers believe that patients diagnosed with HIV will have weight gain when starting ART due to the return of health phenomenon. Regardless of the ART class that prescribed, the largest proportion of weight gain (>10% of initial weight) is seen in those with a low CD4 count. However, recent studies indicate variability in weight gain is based on the type of ART (Table 2). Various studies indicate that the class of ART may result in statistically significant variations in weight gain, which can be further broken down into different medications within a single class.

In a retrospective observational cohort study that took place in the Vanderbilt comprehensive care clinic, researchers started participants on either an INSTI (Dolutegravir (DTG) based therapy, Elvitegravir (EVG)- based therapy, Raltegravir (RAL) based therapy), non-Nucleoside reverse transcriptase inhibitors (NNRTI) based therapy or Protease inhibitors (PI) based therapy and measured weight gain over 18 months. This sample was 86% men, with 49% of the participants identifying as white. The average age was 35 years old with an average BMI of 25.1 kg/m². In this study, the weight gain at 18 months was highest in the DTG group (6.0 kg) and the lowest in the EVG group (0.5 kg); the remaining groups’ weight varied from a 2.6 to a 4.1 kg increase in weight. There was a statistically significant difference in weight gain between the DTG and EVG groups (p <0.05). The lack of adjustment for the two nucleoside reverse transcriptase inhibitors (NRTI) used was the main limitation in this study.

Data were analyzed from the NA-ACCORD study, which collected data from 26 cohort studies representing over 200 clinical and research facilities in the US and Canada. Researchers looked at patients starting HIV therapy with NNRTI, PI, and INSTI based regimens and followed the data at two and five years. The cohort was 87% males, and 41% were white; 49% started NNRTI, 31% started PI and 20% started INSTI-based regimen with a two NRTI drug base. Results after two years indicated that weight gain in the NNRTI class was 3.1 kg, the PI class was 4.9 kg and the INSTI class was 4.9 kg. However, the weight gain in the INSTI class was further divided into RAL, DTG, and EVG. For RAL, the weight gain was 5.8 kg, for DTG the weight gain was 7.2 kg and for EVG the weight gain was 4.1 kg. There was a wide variability in weight changes, which likely reflects the return to health phenomenon coupled with the additional effect of the medication. Higher changes in weight (>10% of body weight) were seen in patients with lower CD4 counts, also in women and those starting INSTI-based regimens compared to those starting NNRTI-based regimens.

The Gemini I and II trials, which consist of a Phase III, randomized, double blind, non-inferiority study looked at the effects of DTG plus Lamivudine (3TC) versus DTG plus FTC/TDF. In this trial, the sample population was 85.3% male and 68.6% identified as white. The study compared weight and BMI at week 0 to week 96. The DTG+3TC group had a 3.1 kg increase in weight compared to a 2.1 kg increase in the DTG+FTC/TDF with BMI changes of 1.04 kg/m² and 0.67 kg/m², respectively. There were comparable weight changes between men and women within the two groups. Men had a 3.43 kg increase in the DTG+3TC group and a BMI increase of 1.11 kg/m² compared to a 2.18 kg weight increase and a BMI increase of 0.69 kg/m² in the DTG+FTC/TDF group. For women, the weight gain was 1.5 kg increase with a BMI increase of 0.62 kg/m² in the DTG+3TC group compared to a 1.56 kg weight increase with a BMI increase of 0.60 kg/m² in the DTG+FTC/TDF. Although both groups experienced weight gain during the 96 weeks, these changes in weight between the two groups were not statistically significant.

The ADVANCE trial, a randomized, open-label, non-inferiority phase 3 trial, studied the weight changes in participants started on three different ART regimens. The study was conducted at two research sites in Johannesburg, South Africa, with participants from 11 public health clinics. The three arms of the study compared DTG+FTC/TDF versus DTG+FTC/TAF versus Efavirenz (EFV)+FTC/TDF. Baseline demographics among groups consisted of a mean age of 32 years old, 59% of participants were women and 99%
of the participants identified as black. At 96 weeks compared to the start of therapy, a mean weight gain of 7.1 kg was seen in the DTG+FTC/TAF group, compared to a 4.3 kg increase in weight in the DTG+FTC/TDF group and a 2.3 kg increase in the EFV+FTC/TDF group. Weight changes were also found to be more significant in men than in women, with the largest weight gain found in black females.

A retrospective analysis of the ACTG A5257 study analyzed weight gain and BMI changes in a phase III randomized clinical trial in which ART-naïve patients were started on either Atazanavir/Ritonavir (ATV/r), darunavir/ritonavir (DRV/r), or RAL with the same NRTI backbone of TDF/FTC. The sample of 1,809 participants was 76% male and 41.1% black. The average age was 37 years old, and the average weight was 79 kg and BMI was 26 kg/m². The average weight gain over 96 weeks was 3.8 kg with an average BMI increase of 1.8 kg/m². When comparing each specific ART therapy, participants taking RAL had a statistically significant higher change in weight than those taking ATV/r \((p=0.043)\) and a statistically significant higher BMI increase than those taking DRV/r \((p=0.041)\). Overall, it suggests that the use of PIs may result in less weight gain than RAL. Data were analyzed by race; black non-Hispanic participants had a 1.55-fold higher weight gain compared to white non-Hispanic participants \((p=0.013)\). Also, those with a higher HIV viral load and lower CD4 count were found to have more weight gain.

A pooled analysis of weight gain in eight randomized controlled clinical trials of treatment naive PWH, treatment classes were broken down into INSTI based, NNRTI based, and PI based therapy. The participant sample was 88.3% men, 61.6% white, 25.9% black, with an average age of 37 years old and average BMI of 25.7 kg/m². The average weight gain based on medication class at 96 weeks was 3.24 kg in the INSTI class, 1.93 kg in the NNRTI class, and 1.72 kg in the PI class (with a fluctuation in weight noted by a decrease in weight at 48 weeks). Analysis of the data based on race and ethnicity noted that the greatest weight gain was seen in black females, followed by black males, non-black males, and then non-black females. The statistically significant weight gain variation between those who identified as black and those who did not was an average of 0.99 kg \((p<0.001)\). Weight gain in females was smaller with only a 0.23 kg difference but still found to be

### Table 2: Weight Change in ART-Naïve HIV-positive Patients on Various Therapies

<table>
<thead>
<tr>
<th>Title</th>
<th>Drugs</th>
<th>Design</th>
<th>Number</th>
<th>Gender</th>
<th>Race</th>
<th>Ethnicity</th>
<th>Age</th>
<th>Location</th>
<th>Results</th>
<th>Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>INSTI vs PI vs NNRTI</td>
<td>Retrospective, observational study</td>
<td>1152</td>
<td>85.5% male</td>
<td>42% black, 48.5% white</td>
<td>Mean Age: 35</td>
<td>Nashville, TN</td>
<td>Statistically significant higher weight gain in patients on DTG vs EVG with non significant variability in other groups (RAL, NNRTI, PI therapies)</td>
<td>18 months</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NA-ACCORD</td>
<td>NNRTI vs PI vs INSTI</td>
<td>Observational cohort study</td>
<td>22,972</td>
<td>87% male</td>
<td>41% white 42% black</td>
<td>Mean Age: 41</td>
<td>North America</td>
<td>NNRTI had more weight gain compared to NNRTI, primarily DTG and RAL</td>
<td>2 and 5 year intervals</td>
<td></td>
</tr>
<tr>
<td>Gemini I and II</td>
<td>DTG/STC vs DTG/FTC/TDF</td>
<td>Phase III, randomized, double blind, non-inferiority study</td>
<td>1,433</td>
<td>85.3% male</td>
<td>68.6% white 31.2% Hispanic</td>
<td>Mean Age: 33</td>
<td>Multi-national</td>
<td>STC more weight gain than FTC/TDF</td>
<td>96 Weeks</td>
<td></td>
</tr>
<tr>
<td>ADVANCE NCT03122262</td>
<td>DTG/FTC/TDF vs DTG/FTC/TAF vs EFV/FTC/TDF</td>
<td>randomized, open-label, non-inferiority phase 3 trial</td>
<td>1,053</td>
<td>59% Female</td>
<td>100% Black 20% Hispanic</td>
<td>Mean Age: 32</td>
<td>Johannes-burg, South Africa</td>
<td>DTG + FTC/TAF &gt; DTG + FTC/TDF &gt; EFV + FTC/TDF</td>
<td>96 weeks</td>
<td></td>
</tr>
<tr>
<td>ACTG A5257</td>
<td>ATV/r vs DRV/r vs RAL</td>
<td>Retrospective analysis of randomized trial</td>
<td>1,809</td>
<td>76% male</td>
<td>41.9% Black</td>
<td>Mean Age: 37</td>
<td>RAL is associated with more weight gain/ increase in BMI than Protease Inhibitors (ATV/r and DRV/r)</td>
<td>96 weeks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>INSTI vs NNRTI vs PI</td>
<td>Pooled analysis of 8 RCT</td>
<td>5,680</td>
<td>88.3% male</td>
<td>61.6% white</td>
<td>Mean Age: 37</td>
<td>INSTI&gt;PI and NNRTI</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: INSTI, Integrase strand transfer inhibitor; NNRTI, non-nucleoside reverse transcriptase inhibitor; PI, protease inhibitor; FTC, Emtricitabine; TDF, Tenofovir disoproxil fumarate; TAF, Tenofovir alafenamide; STC, lamivudine; DTG, dolutegravir; EFV, efavirenz; ATV/r, atazanavir/ritonavir; DRV/r, darunavir/ritonavir; RAL, raltegravir

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The average weight gain when a patient was continuously on the TDF therapy was calculated, a major confounding variable was the lack of direct comparison between TDF and TAF because all patients switched from TDF to TAF.

In a cohort study based on five university hospitals in Switzerland, participants were either maintained on TDF therapy or switched to TAF therapy, while maintaining the rest of the regimen. In this study, the control group was 30.5% female, 20% identified as black and the average age was 49 years old. In the control group, 21.2% were on an INSTI, 9.4% were on a PI, and 68% were on an NNRTI. In the experimental group, in which TDF was changed to TAF, the group was 24.7% female, 13.3% identified as black and the average age was 50 years old. Regimens in the experimental group consisted of 38.3% on an INSTI, 21.3% on PI, and 39.3% on an NNRTI. Follow up over 18 months showed that both groups gained statistically significant weight (p=0.001); the control group gained 1.1 kg and the experimental group gained 1.7 kg. Analysis by subgroups determined that weight gain was highest in black women, followed by non-black women, and did not vary significantly based upon the third drug used in the treatment.

In a single center retrospective study that focused on the use of TDF/FTC/RPV versus TAF/FTC/RPV, data were collected on 252 participants. In this study, the participants were 65.5% men, with an average age of 51.2 years old, and 98.8% of participants identified as white. The average BMI was 25.3 kg/m² and the average weight was 73.8 kg. The documented weights for six months before the start of the change in medication did not show any significant difference. When patients switched to the TAF-based therapy, weight documented at three months averaged 77.7 kg and weight documented at six months averaged 75.5 kg with a statistically significant difference from the weight at the start of therapy compared to six months later (p<0.0001). The most drastic weight gain was in women, patients with a BMI > 25 kg/m², and patients with a low CD4 count of < 200 cells/ml.

<table>
<thead>
<tr>
<th>Title</th>
<th>Drugs Design</th>
<th>Number</th>
<th>Gender</th>
<th>Race</th>
<th>Ethnicity</th>
<th>Age</th>
<th>Location</th>
<th>Results</th>
<th>Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>OPERA</td>
<td>TDF to TAF</td>
<td>Retrospective cohort</td>
<td>6,908</td>
<td>82% Men</td>
<td>39% Black</td>
<td>Mean Age 45</td>
<td>United States</td>
<td>Increased weight after TAF switches</td>
<td>20.5 months</td>
</tr>
<tr>
<td>TDF vs TDF to TAF switch</td>
<td>Retrospective cohort</td>
<td>4,375</td>
<td>74.1% male</td>
<td>82% Men</td>
<td>Mean Age 50</td>
<td>Switzerland</td>
<td>Switch from TDF to TAF was associated with weight gain</td>
<td>18 months</td>
<td></td>
</tr>
<tr>
<td>TDF/FTC/RPV vs TAF/FTC/RPV</td>
<td>Retrospective study</td>
<td>252</td>
<td>65.5% male</td>
<td>74.1% male</td>
<td>Mean Age 51.2</td>
<td>Italy</td>
<td>Increased weight in the TAF group</td>
<td>6 months</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: TDF, tenofovir disoproxil fumarate; TAF, tenofovir alafenamide; FTC, emtricitabine; RPV, rilpivirine
the switch in ART therapy was 0.63 kg/year and the average weight gain post-switch was 0.68 kg/year. There was no statistically significant weight gain noted between treatments or based on the pre-switch regimen (PI vs non-PI). Furthermore, although there are reports of differences between drugs in the same class for weight changes, this study found no significant difference in weight changes between DTG and RAL.

In a single-center, retrospective cohort study conducted in Illinois studied incarcerated individuals who were switched from any non-INsti therapy to an INSTi therapy. Of the participants, 95% were men, and 86% identified as black. The average age was 44 years old, with an age range of 19 to 79 years old. In the study, 40% of patients were switched to EVG-based therapy, 29% to DTG-based therapy, 18% to RAL-based therapy, and 13% to Bictegravir (BIC)-based therapy. All patients started on an INSTi therapy had an increase in weight and BMI that was statistically significant (p<0.01 and p<0.03 respectively). Participants on the DTG therapy had the largest weight gain of 6.5 kg over one year and a BMI change of 2.8 kg/m². RAL had the lowest increase in weight with an average of 2.6 kg/year and EVG had the lowest average BMI increase at 1 kg/m². However, about 32% of participants also had an associated switch from TDF to TAF, which may skew the data. When analyzing participants solely on concurrent TDF therapy who did not switch to TAF, the average weight gain with starting INSTi therapy was 2.1 kg. Overall, the switch from non-INsti based therapy to INSTi based therapy was statistically significant over one year when data controlling for changes in the NRTI backbone (p=0.02).

In a longitudinal retrospective study based on the Symphony Health Integrated Dataverse database, patients who met the criteria to start either Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide (DRV/c/FTC/TAF) or Bictegravir/Emtricitabine/Tenofovir Alafenamide (BIC/FTC/TAF) were compared to determine weight gain in patients on a PI-based therapy versus INSTi-based therapy. After switching, participants’ weights at three, six, nine, and 12 months were analyzed. The study sample was 71% men, 33.8% white, 28.9% black, and 8.6% Hispanic; the average age was 53 years old. In this study, some patients had previously been on a PI or INSTi therapy, but the individual drug regimen was changed. Patients started on BIC/FTC/TAF had a greater weight gain compared to those started on DRV/c/FTC/TAF at all time intervals, but the weight gain was only statistically significant at nine months with an average difference of 2.5 kg (p<0.005). BMI increases were also noted to be

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Table 4. Weight Gain in HIV+ Patients on ART in Different Classes (NNRTI, INSTI, PI)

<table>
<thead>
<tr>
<th>Title</th>
<th>Drugs</th>
<th>Design</th>
<th>Number</th>
<th>Gender</th>
<th>Race</th>
<th>Ethnicity</th>
<th>Age</th>
<th>Location</th>
<th>Result</th>
<th>Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-INsti to DTG or RAL</td>
<td>Retrospective cohort</td>
<td>378</td>
<td>81.2% male</td>
<td>70.1% white</td>
<td></td>
<td>Mean Age: 49</td>
<td></td>
<td>United States</td>
<td>No overall increase in average weight gain per year.</td>
<td>1.26 years</td>
</tr>
<tr>
<td>Non-INsti to EVG, DTG or RAL or BIC</td>
<td>Retrospective cohort; All patients incarcerated</td>
<td>103</td>
<td>95% Male</td>
<td>86% Black</td>
<td></td>
<td>Mean Age: 44</td>
<td></td>
<td>United States</td>
<td>Significant increase in weight and BMI.</td>
<td>12 months</td>
</tr>
<tr>
<td>Symphony Health, IDV Database</td>
<td>DRV/c/FTC/TAF vs BIC/FTC/TAF</td>
<td>Retrospective cohort</td>
<td>949</td>
<td>71% Male</td>
<td>33.8% white, 28.9% black</td>
<td>8.6% Hispanic</td>
<td>Mean Age: 53</td>
<td></td>
<td>United States</td>
<td>INI&gt; PI</td>
</tr>
<tr>
<td>TROP</td>
<td>TDF to RAL</td>
<td>Non-randomized open label study</td>
<td>37</td>
<td>97% male</td>
<td>84% white</td>
<td></td>
<td>Mean Age: 49</td>
<td></td>
<td>Australia</td>
<td>No difference in weight gain</td>
</tr>
<tr>
<td>ALLRT study and HAILO study</td>
<td>PI, NNRTI or other to INSTI</td>
<td>Sequential, longitudinal, observational</td>
<td>691</td>
<td>82% male</td>
<td>26% Black</td>
<td>19% Hispanic</td>
<td>Mean Age: 51</td>
<td></td>
<td>United States</td>
<td>INST&gt; PI and NNRTI</td>
</tr>
<tr>
<td>Women’s Inter-agency HIV Study</td>
<td>INSTI vs non-INSTI</td>
<td>Longitudinal cohort</td>
<td>1118</td>
<td>100% women</td>
<td>61% black</td>
<td>23.8% Hispanic</td>
<td>Mean Age: 49</td>
<td></td>
<td>United States</td>
<td>Significant weight gain with INSTI.</td>
</tr>
</tbody>
</table>

Abbreviations: TDF, Tenofovir disoproxil fumarate; TAF, Tenofovir alafenamide; INSTI, Integrase strand transfer inhibitor; NNRTI, non-nucleoside reverse transcriptase inhibitor; PI, protease inhibitor; DTG, Duloxetinevira; EVG, elvitegravir; RAL, raltegravir; BIC, bictegravir; DRV/c, darunavir/cobicistat

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significant at that time with an average difference of 0.66 kg/m² ($p=0.027$). Among patients started on DRV/c/FTC/TAF, female gender was associated with an increased BMI of greater or equal to 5%. Also, a higher initial BMI was associated with a lower likelihood of having a BMI increase of greater than or equal to 5%. The 12-month interval data lacked the power due to inadequate sample sizes to evaluate differences in weight gain between the two regimens.

The Tenofovir to Raltegravir for Osteopenia (TROP) study was a 96-week, non-randomized, open-label study in which participants on a TDF based regimen were changed to RAL based regimen.\(^{18}\) The study population consisted of 37 patients, 36 of whom were men, and 84% identified as white. The average age was 49 years old and patients had a mean initial weight of 79.6 kg and a mean BMI of 26.1 kg/m². All patients were previously on TDF-based therapy with no prior exposure to INSTIs. As part of the study protocol, weight was measured at baseline, 24, 48, and 96 weeks. When analyzed, this data showed no statistically significant change in weight at 96 weeks for the participants.

A study that analyzed data from two sequential, longitudinal, observational AIDS Clinical Trials Groups A5001 and A5322 did find weight gain after switching to INSTI.\(^{20}\) This study analyzed 691 patients with a suppressed viral load (defined as <200 copies) who switched to an INSTI from either PI (68%), NNRTI (31%), or other (2%). Participants were started on either DTG, ETV, or RAL. This study was mostly male 82%, with 26% identifying as black. The median age at the switch was 51 years old. BMI at randomization 26.9 kg/m². The median time for follow up post switch in this study was two years. The outcome of this study showed that switching from PI to DTG was associated with weight gain of +0.9 kg/yr ($p=0.04$). However, when switching from a PI to other INSTIs, no significant weight gain was seen. Switching from an NNRTI to DTG or ETV, showed a significant weight gain of 1.2 kg/yr ($p=0.01$) and 1.3 kg/yr ($p=0.01$) respectively. This study also analyzed the type of NRTI backbone used and noted that the switch to any INSTI with ABC was associated with significant weight gain of 0.9 kg/year ($p=0.004$). The switch to ETV with TAF was associated with significant weight gain ($p=0.01$). Findings indicated that women older than 60 years of age with a BMI of 30 kg/m² or greater had a higher likelihood of weight gain regardless of race. Men who were 60 years or older also showed an increased risk of weight gain.

In a study focused on women with HIV, data from the Women's Interagency HIV Study, a large longitudinal cohort study analyzed the weight change in women who started on an INSTI versus women who were not on an INSTI.\(^{21}\) In this all female study, 61% of participants identified as black and the average age was 49 years old. In women started on an INSTI, 42% switched to/added DTG, 23% switched to/added ETV, and 36% switched to/added RAL. In this group, 15% added ABC, 8% added TDF and 12% added TAF. In women who did not start an INSTI, 97% of women stayed on their current regimen and 3% switched to or added an NNRTI or a PI. For women on an INSTI, after 18 months a statistically significant difference was seen in the weight gained compared to those not on INSTI therapy. The INSTI group had an average of 2.4 kg increase in weight compared with a 0.2 kg increase in weight in the non-INSTI group. Women started on an INSTI also had an average BMI increase of 0.9 kg/m² compared with 0.1 kg/m² in the non-INSTI group. Women who were members of a minority population, women with CD4 counts greater than or equal to 350 cells/µl and undetectable viral loads experienced a more significant increase in weight. Also, women 50 years of age and older and those with a BMI of less than 30 kg/m² experienced more weight gain. There was no significant difference in weight gain based on the specific INSTI medication.

**Discussion**

The major advantage of studying non-HIV infected patients receiving ART in the form of PreP is that it does not take into consideration the wasting related to chronic inflammation from HIV infection. Hence, weight gain related to the return to normal health is not a factor. The disadvantage, however, is that most studies were conducted in relatively young, healthy, sexually active men. Despite this, the summarized findings in Table 1 suggest that weight gain in patients on PreP is not significant in patients started on FTC/TDF or CAB- LA as they had similar weight gain to the placebo group. Patients on PreP on FTC/TAF, however, did have a statistically significant increase in weight compared to those taking FTC/TDF.

In ART-naïve patients, the summarized findings in Table 2 suggest that weight gain is influenced by gender, race, CD4 count, as well as the class of medication. Those who are at highest risk of weight gain seem to either be women, identify as black, or have a low CD4 count. The ART associated with most weight gain were the INSTIs, more specifically the second generation INSTI medications, and TAF use.

In virologically suppressed individuals switching ART, the return to normal health is less of a consideration. The summarized findings in Tables 3 and 4 suggest that a switch from TDF to TAF as well as a switch to an INSTI seems to carry a significant risk for weight gain, mainly seen in the first nine months of the new therapy.

Providers should pay attention to weight gain in PWH, while monitoring for other comorbidities related to weight gain, including hypertension, diabetes mellitus, cardiovascular disease, obstructive sleep apnea, fatty liver, osteoarthritis, and cancers associated with obesity. At this time, there is no proven strategy to reverse weight gain secondary to ART, but standard
Does Antiretroviral Therapy Cause Weight Gain?

recommendations for regular exercise along with a low calorie diet may help. Although an early switch to a different regimen may curb an excessive weight gain, there are no current clinical trials to support this approach at this time.

References


The concept of implicit bias sparked much discourse in the 2016 presidential debate when presidential candidate Hillary Clinton spoke on race and policing.

"I think implicit bias is a problem for everyone, not just police. Unfortunately, too many of us in our great country jump to conclusions about each other. And therefore, I think we need all of us to ask hard questions about, you know, why am I feeling this way?"1

The term "implicit bias" was coined twenty years ago by scholars Mahzarin Banaji and Tony Greenwald.2 Today, many people are still wondering, "What exactly is Implicit Bias?" Implicit bias involves instinctual behaviors or survival instincts that allow humans to adapt to an environment and quickly respond to different types of stimuli. Our brains use automatic cues informed by what we have learned over time to process so much information. However, these cues can be biased. Automatic responses combined with social conditioning can result in implicit bias against people, often based on race and gender.3 Studies have shown that people have implicit biases that align with general social hierarchies.4 Unconscious, implicit bias results in a preference for a person or group of people. For example, people may have an implicit bias for men over women, youth over elderly, straight over gay. Human beings experience implicit bias when we have attitudes or associate stereotypes with groups of people without our conscious knowledge. We are all biased: Racial biases significantly impact who gets access, helped, hired, and promoted; often, these individuals tend to be similar in culture and identify with those wielding power.

Recent national events have propelled discussions about implicit bias, health inequities, intersectionality, and critical race theory in classrooms, break rooms, newsrooms, and symposiums across America. Healthcare organizations, industries, and academia are grappling with the inequities that result from implicit bias and asking tough questions, such as, "What will it take to reduce our reliance on generalizations and stereotypes?" Questions about bias reflect this moment in which people, historically silenced and excluded from places of power, dismantle the processes by which decisions are made and demand institutional change.

For example, consider an organization that serves vulnerable populations such as men who have sex with men and transgender individuals. To bring these people into a clinic for care, the organization may need to train staff in cultural humility, competency, and trauma-informed care to meet the needs of these populations. Despite all the training, if the organization’s hiring practices excluded the very individuals with whom it wanted to build a rapport, would it be able to provide appropriate care? The cultural identity reflected in the clinic staff needs to expand to be more inclusive and reflect its patient population. A cultural change is necessary. The organization can strengthen its inclusion and equity efforts if it is willing to examine, question, and confront why certain applicants or identities were considered great candidates and others were not. The organization needs to ask critical questions, such as:

- Who was afforded the privilege of showing up authentically in the workplace?
- What identities were excluded?
- Which cultural representation or aesthetic was deemed professional or idealized and why?

If, in contrast, the organization recycles notions of acceptability rooted in racism and oppression, even with the best intentions of serving its patient population, implicit bias can influence organizational norms and get in the way of diversity, equity, and inclusion initiatives.

How Does Implicit Bias Affect Patients?

Studies show that students who enter health professions harbor implicit bias toward minority patients, and their level of bias remains constant or increases over time.5 There is evidence that rates of implicit bias among healthcare workers are similar to the general population and are related to the following demographic characteristics: race, ethnicity, gender, socio-economic status (SES), age, mental illness, weight, HIV infection, and intravenous drug use.6 Implicit bias affects how clinicians and other healthcare providers communicate with patients, the number of diagnostic tests ordered or referrals made for a patient, and fewer treatment recommendations.7 The result is poorer health outcomes because provider bias reduces patients’ confidence and diminishes their ability
Implicit Bias: Asking Tough Questions

to adhere to treatment plans.\textsuperscript{8} Many racial and ethnic health disparities can be traced to implicit bias.\textsuperscript{8,9} Among women with a college education or higher, African American women have a higher pregnancy-related mortality rate than White women. An African American woman with a college degree is 1.6 times more likely to die in childbirth than a White woman with less than a high school education.\textsuperscript{10} A large cross-sectional study found that Latino men were 21\% less likely to receive definitive high-risk localized prostate cancer treatment compared to non-Latino white men.\textsuperscript{11} LGBTQ populations experience disparities in physical and mental health outcomes, including higher rates of anal cancer, asthma, cardiovascular disease, obesity, substance use, and suicide. Lesbians have fewer lifetime Pap tests, and transgender youth have less healthcare access. LGBTQ individuals are more likely to delay or avoid necessary medical care related to perceived discrimination. Biases among health care professions students and providers toward LGBTQ patients are common. A large study of heterosexual first-year medical students demonstrated that about half of students had negative attitudes towards lesbian and gay people.\textsuperscript{12} Implicit bias is the basis for stigmatizing groups of people and PWH are a prime example. A systematic review of stigma and HIV found that providers’ perceptions of stigmatizing attitudes were based on historically negative portrayals of persons at risk for HIV, PWH, and those seeking HIV prevention and care services.\textsuperscript{13} These outdated perceptions of PWH led to reduced quality of care, refusal of care, and anxiety when providing services to PWH. As a result, implicit bias correlates with psychological distress in people with HIV.\textsuperscript{14} Implicit bias affects HIV prevention efforts; a recent study found implicit bias influenced providers’ willingness to prescribe PrEP, apprehension about prescribing PrEP, and providers prescribed it only when the patient initiated the conversation.\textsuperscript{15} One of the more telling examples of the effects of implicit bias is the experience of Susan Moore. On November 29, 2020, she tested positive for COVID-19 and was admitted to Indiana University Hospital. On December 04, 2020, she posted a video on Facebook detailing her treatment by the attending physician. In her video post, Dr. Moore expressed that the physician refused to give her additional doses of antiretroviral medication to treat COVID. He also refused to provide Dr. Moore with adequate pain medication. Susan Moore was a Black woman. She was also a physician. In her Facebook post, Dr. Moore said, "He made me feel like a drug addict. And he knew I was a physician. I don’t take narcotics. I was hurting. If I was white, I wouldn’t have to go through that. This is how Black people get killed." Dr. Moore died two weeks later, at age 52. An investigation followed her death. Indiana University Hospital President and CEO Dennis Murphy acknowledged "that the hospital system has to do more to address implicit racial bias, weave diversity, equity, and inclusion training into staff education and create more opportunities for all patients to have a voice."\textsuperscript{16} Unfortunately, Dr. Moore’s story is all too familiar, reflecting a systemic problem in the healthcare system.

Implicit Bias Training

The research of Banaji and Greenwald led to the 1998 Implicit Association Test (IAT), which detects and measures unintentional biases, attitudes, beliefs, and stereotypes about gender, race, ethnicity, age, sexuality, and other group identifiers.\textsuperscript{17} Organizations often use the IAT as part of an implicit bias training program. Inequities such as the pay gap or gender gap in science, technology, engineering, mathematics, and medicine (STEMM) fields led many institutions to mandate implicit bias training.\textsuperscript{18,19} Implicit bias training creates a space that allows people to express their concerns and experiences with bias. It also invites discussion about how people participate, interpret, and internalize messages that impact those who have historically been marginalized, oppressed, and “othered.”\textsuperscript{20} There is little scientific data supporting bias awareness training results in less implicit bias. Some people find it challenging to accept the evidence that people harbor unconscious bias that influences behaviors, decisions, culture, and systems.\textsuperscript{5,6} Frequently, organizations address diversity, equity, and inclusion initiatives using implicit bias training as a solution. Implicit bias is challenging to change, and training does not yield more diversity in organizations.\textsuperscript{21} Although promoting awareness of gender and racial inequities is essential, the focus on implicit bias training misses the broader historical, social, structural, and political factors that prevent inclusion and advancement.\textsuperscript{9} Organizations and programs becoming aware of their implicit biases do not ensure a justice centered environment. After we take the IAT test, participate in implicit bias training, and come face to face with our biases, what do we do? We still live in a heteronormative, transphobic, sexist, racist, patriarchal, ableist society, and we are all impacted or stunted by it. Though bias affects everyone, some people possess more power and social capital than others, and our systems, institutions, and structures are sustained and supported by these inequities.\textsuperscript{19} Women can devalue other women; Black people can be biased against other Black people because bias can be deep-rooted and embedded in our institutions.\textsuperscript{19}

Beyond Implicit Bias Training

Acknowledging the relationship between implicit bias and patient outcomes is critical because it can continued on next page
motivate policymakers, physicians, nurses, social workers, healthcare personnel, and educators to mitigate bias in healthcare and social services delivery. Additionally, the curricula of university healthcare profession programs need to address bias, stereotyping, and stigmatization of patients; otherwise, devalued communities will continue to be traumatized by the healthcare system and its practitioners.\textsuperscript{20,21}

Despite implicit bias training goals of raising awareness about bias and its health implications, it often falls short of political and policy discussions and implementation.\textsuperscript{18} To develop more justice based social and political structures, systems, and norms, we must do more than confront our biases. Implicit bias training as a solution or tool to ensure culturally competent healthcare is not enough if the organization’s policies, procedures, and hiring practices do not reflect diversity, inclusion, and equity. Our historical and cultural genocide persist in human resource departments, courtrooms, universities, board rooms, and across all healthcare disciplines. The good news is that these conversations are happening; but dialogue and awareness are only the first steps. Next, we need action, policies, and budgets to support systemic changes resulting in better health outcomes and less bias.

Implementing structural solutions allows for a more human-centered lens to address systemic racism, implicit bias, and health disparities. And that is where we have yet to venture. How else do we begin to dismantle systems and structures that purport, sustain, and produce such inequities?

**Tips to Begin Organizational Change**

- Institute mechanisms to report and document bias incidents and investigate discrimination and unfair treatment reports.
- Investigate reports of subtle or overt discrimination and unfair treatment.
- Establish monitoring systems in which outcomes are compared by demographic variables (race, gender, sexual identity, and ethnicity) to monitor the effectiveness of the organization’s progress in eliminating inequities in treatment.
- Promote racial, ethnic, gender, and sexual identity diversity at all levels of the organizational hierarchy.
- Beyond implicit bias training, implement and evaluate training that ensures clinicians have the evidence-based knowledge to prevent racial, ethnic, gender, and sexual identity biases from affecting the quality of care.\textsuperscript{22}

**Conclusion**

Even after implicit bias training, implicit bias remains a problem for all of us. Discussion about implicit bias is often limited to personal awareness and self-mitigation. The paradigm shift and systemic changes needed to improve the gaps in health outcomes for devalued communities are too expansive or challenging to tackle. A justice centered environment that honors and invests in all human potential can only be made possible through system wide changes.

We are only as healthy as our policies and healthcare systems allow. Healthier communities cannot evolve without a radical shift in how organizations make decisions and how communities are involved. With a group-centered approach to organizing and leadership, we can become leaders for change in the tradition of luminaries such as Ella Baker. We can also exercise our power and privilege in support of those who have historically been discriminated against, silenced, and excluded by continuing to ask tough questions of our agencies, institutions, policies, and ourselves.

Becoming more aware of our bias is progress. Still, it will not erase or reimagine a culture rooted in racism, anti-Black, anti-immigrant, anti-woman, homophobia, patriarchy, and classism that result in inequities in care. History sets the context for the present, but this lack of acknowledgment hinders our ability to discuss what ails us and develop sound solutions. We need to understand how our collective historical traumas are inherited and how that trauma resurfaces. We need meaningful and institutional solutions that will result in real community healing.

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Jerry, the Flight Attendant*

Jerry, a person with HIV (PWH), works as a flight attendant. Recently, he engaged in unprotected sex with a man he met at a party while furloughed in Spain. Upon returning to New Jersey, Jerry called his provider complaining of painful "pimples" or "blisters" that appeared on his forehead, behind his ear, and neck. He also reported generally feeling ill and had muscle aches. Jerry said he had a fever before the pimples appeared. Jerry was concerned because the pimples were spreading to other parts of his body and were painful. Jerry shared a house with his 68 year old mother and wondered if the rash was contagious and if his mother could get it.

Jerry’s healthcare provider asked him to come in for an evaluation based on the CDC advisory of May 20, 2022, which confirmed monkeypox cases in Europe, North America, South America, the Middle East, Australia, and at least one non-endemic country in Africa. Most, but not all, cases were among self-identified gay, bisexual, and other men who have sex with men, including transgender, gender nonconforming, and non-binary individuals. It is important to emphasize that monkeypox can affect anyone—regardless of sexual orientation or gender identity.

Who is at Risk for Monkeypox?
The first known outbreak of monkeypox in the United States occurred in 2003 and was traced to contact with pet prairie dogs that were housed during transport from Ghana with infected rodents. Contact with wild animals (including live animals, meat for consumption, and other products) are known potential risk factors in enzootic countries. Prolonged physical contact with an infected person can also result in person-to-person transmission. Anybody can get monkeypox. However, due to social networks and patterns of exposure, cases in the current outbreak have been mainly but not exclusively among self-identified gay, bisexual, and other men who have sex with men, including transgender, gender nonconforming, and non-binary individuals. It is important to emphasize that monkeypox can affect anyone—regardless of sexual orientation or gender identity.

How is Monkeypox Transmitted?
The good news is that monkeypox is not easily transmitted, and transmission via respiratory secretions is uncommon. People infected with monkeypox report close, sustained physical contact with the infected person. Transmission occurs in the following situations:

- Direct or indirect contact with body fluids or lesion materials
- Contact with fomites
- Exposure to respiratory secretions during prolonged, face-to-face contact
- Shared towels and bedding (infectious body fluids and scabs may be present)
- Skin-to-skin contact with a person who has monkeypox
- Being inside the patient’s room or within 6 feet of a patient during any procedures that may create aerosols from oral secretions, skin lesions, or resuspension of dried exudates, without wearing an N95 or equivalent respirator (or higher) and eye protection.

Monkeypox Symptoms
Monkeypox virus is part of the same family of viruses as smallpox. After the initial infection, there is an incubation period of roughly 1-2 weeks. The development of initial symptoms (e.g., fever, malaise, headache, weakness, etc.) marks the beginning of the prodromal period. Shortly after the prodrome, a rash appears. Lesions typically begin to develop simultaneously and evolve together on any given part of the body. The evolution of lesions progresses through four stages—macular, papular, vesicular, to pustular—before scabbing over and resolving. The illness typically lasts 2-4 weeks. Sometimes, people get a rash first, followed by other symptoms. Others only experience a rash. Prodromal symptoms may be mild or not occur at all. The symptoms are similar to smallpox but milder, and monkeypox is rarely fatal. Monkeypox is not related to chickenpox. Signs and symptoms of monkeypox can include:

- Fever
- Headache
- Muscle aches and backache
- Swollen lymph nodes may be generalized (involving many different locations on the body) or localized to several areas (e.g., neck and armpit).
- Chills
- Exhaustion

Monkeypox: It’s Not a Gay Disease or an STI!

Darcel M. Reyes, PhD, ANP-BC
Clinical Associate Professor, Rutgers University School of Nursing
A rash that can look like pimples or blisters appears on the face, inside the mouth, and on other parts of the body, like the hands, feet, chest, genitals, or anus. The lesions may start in the perianal or genital area and may be localized or disseminated throughout the body. The rash goes through different stages before healing completely. Patients are infectious once symptoms begin, whether prodromal or rash, and remain contagious until the lesions form scabs, the scabs fall off, and a fresh layer of skin forms.3

**Epidemiologic Criteria**
Within 21 days of illness onset, the patient:
- Reports having contact with a person or people with a similar appearing rash or who received a diagnosis of confirmed or probable monkeypox
- Close or intimate in-person contact with individuals in a social network experiencing monkeypox activity; this includes men who have sex with men who meet partners through an online website, “apps,” or social event
- Traveled outside the US to a country with confirmed cases of monkeypox or where the monkeypox virus is endemic OR
- Had contact with a dead or live wild animal or exotic pet that is an African endemic species or used a product derived from such animals (e.g., game meat, creams, lotions, powders, etc.3)

**Distinguishing Monkeypox from Other Rash Illnesses**
Clinicians working in outpatient clinics may be the first to suspect monkeypox and should be vigilant about the possibility of monkeypox if the characteristic rash is present. Monkeypox can be confused with sexually transmitted infections (STIs) and varicella zoster virus infection. An STI diagnosis does not exclude monkeypox infection; infections may be concurrent. The patient encounter should consist of:
- Comprehensive history: Obtain sexual and travel history; determine if any contacts have/has a similar rash
- History of present illness:
  - The patient usually experiences fever, malaise, headache, sore throat, cough, lymphadenopathy

- Complaints of pain and pruritis may be prominent

**Physical Examination:**
- The CDC recommends that clinicians don Personal Protective Equipment (PPE) before examining the patient
- Perform a thorough exam of all skin in a room with good lighting
- Lesions may be present in other areas of the body for persons presenting with genital/perianal complaints
- The rash evolves from macules to papules to vesicles to pustules to scabs. The patient may present with a rash at any of these stages.
- In some patients, lesions may be scattered or localized, rather than diffuse, and not involve the face or extremities. Lesions are typically similar in size, and at the same stage; lesions may become umbilicated.
- Inspect the tongue, mouth, face, arms, legs, hands and feet (including palms and soles).
- The clinical presentation in the current outbreak may not be typical.3

Clinicians who confirm a case of monkeypox should take the following steps:
- Notify the local NJ health department or the CDC:
  - Obtain specimens (follow specimen collection instructions at the CDC website or the New Jersey DOH)
  - Initiate contact tracing and monitoring
- Further information for NJ: [https://www.nj.gov/health/cd/topics/monkeypox.shtml](https://www.nj.gov/health/cd/topics/monkeypox.shtml)
- Further information from the CDC: continued on next page
Practice Tips

https://www.cdc.gov/poxvirus/monkeypox/clinicians/index.html or the CDC Emergency Operations Center (770-488-7100) or at poxvirus@cdc.gov.

Be aware that NJ DOH and the CDC regularly update monkeypox guidance; healthcare providers should review the websites regularly to stay updated on treatment guidelines.

Jerry’s Clinic Visit

Jerry’s physical exam showed evidence of monkeypox. He was experiencing significant pain from a lesion in the rectal area and mild discomfort from the other lesions. His axillary lymph nodes were palpable, and new lesions had appeared on his arms and legs. The lesions on his forehead, behind his ears, and neck were umbilicated. There were no lesions on his hands or feet. Because Jerry was immunocompromised and had anal lesions, his healthcare provider contacted the CDC for guidance regarding Jerry’s treatment.

Clinical Guidance for the Treatment of Monkeypox

Monkeypox typically lasts 2-4 weeks. Currently, there is no treatment explicitly approved for monkeypox virus infections and most people have a mild, self-limiting course that does not require specific treatment. However, multiple factors, including initial health status, concurrent illnesses, and comorbidities, may indicate further treatment. Tecovirimat (also known as TPOXX, ST-246), used for the treatment of smallpox, is available from the Strategic National Stockpile (SNS) and can be released via the CDC’s expanded access protocol, or “compassionate use” to treat monkeypox infections in people who meet specific criteria.

Tecovirimat is available as an oral capsule (200 mg) and injection for intravenous (IV) administration. The capsule can be opened for children weighing less than 28.6 pounds, and caretakers can mix the medicine with semi-solid food. Patients should take tecovirimat with a full, fatty meal. Intravenous (IV) tecovirimat should not be administered to patients with severe renal impairment (CrCl <30mL/min); these patient should be treated with oral tecovirimat. IV tecovirimat should be used with caution in patients with moderate (CrCl 30-49 mL/min) or mild (CrCl 50-80 mL/min) renal impairment as well as pediatric patients less than 2 years of age.

Patients eligible for treatment with tecovirimat following consultation with the CDC include people who may be at risk for severe disease: (e.g., hemorrhagic disease, confluent lesions, sepsis, encephalitis, or other conditions requiring hospitalization)

- People who are immunocompromised, such as those with HIV. PWH who are well controlled are NOT candidates for treatment unless they meet other criteria (e.g., confluent lesions, painful lesions proctitis on the genitals or anus).
- Pediatric populations, particularly patients younger than eight years of age
- People with a history or presence of atopic dermatitis, persons with other active exfoliative skin conditions
- Pregnant or breastfeeding women
- People with one or more complications such as secondary bacterial skin infection; gastroenteritis with severe nausea/vomiting, diarrhea, or dehydration; bronchopneumonia; concurrent disease or other comorbidities.
- People with monkeypox virus aberrant infections that include accidental implantation in eyes, mouth, or other anatomical areas where monkeypox virus infection might constitute a particular hazard (e.g., the genitals or anus)
- Those with hemorrhagic diseases, confluent lesions, sepsis, encephalitis, or requiring hospitalization.

EA-IND Protocol for Tecovirimat Treatment

Healthcare providers must obtain informed consent before starting treatment with tecovirimat. Healthcare providers must follow the EA-IND protocol required by the CDC. It should be noted that the EA-IND protocol is evolving and is subject to change as the CDC learns more about tecovirimat’s effectiveness in treating monkeypox. To learn more about the criteria for treatment with
Monkeypox: It's Not a Gay Disease or an STI!

tecovirimat and the protocol, contact the NJ health department (LINCS-updated-monkeypox-guidance.pdf (nj.gov)) or CDC (Emergency Operations Center 770-488-7100; Poxvirus@cdc.gov or https://www.cdc.gov/poxvirus/monkeypox/clinicians/obtaining-tecovirimat.html.

Jerry’s Case: Treatment
Because of his HIV status, the pain Jerry was experiencing, and the rectal lesion, he was a candidate for treatment with tecovirimat. To be treated with tecovirimat, Jerry was required to sign a consent. After taking tecovirimat for a few days, Jerry reported a headache and nausea but no abdominal pain or vomiting (common adverse effects of the medication). He experienced a reduction in pain and itching from the lesions, and the lesions were becoming smaller and some were beginning to form scabs. As per the CDC protocol for EA-IND, Jerry provided pictures of his lesions before starting treatment with tecovirimat, and one week later, this confirmed the lesions’ evolution. Jerry’s provider monitored his treatment and the progress of his disease via telehealth. Jerry is expected to make a full recovery.

To prevent transmission to his mother, Jerry isolated in his bedroom, used a separate bathroom and kept his bed linens and towels separate. Jerry remained isolated until all the scabs had fallen off all lesions and new skin formed. To date, Jerry’s mother remains symptom-free, however as a precaution, she came to the clinic and consented to receive the JYNNEOS™ vaccine.

People Exposed to Monkeypox
People exposed to monkeypox should monitor their temperature twice daily and be monitored for symptoms for 21 days after exposure. If symptoms develop, they should self-isolate and contact the health department for further guidance. If a person exposed to monkeypox remains asymptomatic, they can continue daily activities. People exposed should not donate blood, cells, tissue, breast milk, semen, or organs while under symptom surveillance.

Healthcare workers who experience an unprotected exposure to monkeypox patients do not need to be excused from work but should undergo active surveillance for symptoms. Exposed healthcare workers should take their temperature at least twice daily for 21 days following the exposure. Before reporting for work each day, the healthcare worker should be interviewed regarding evidence of fever or rash.

Currently, in New Jersey, the JYNNEOS™ vaccine (approved by the FDA "for treatment of smallpox") is being administered only to people known to have had close contact with someone infected with monkeypox. The vaccine uses weakened live vaccinia virus and cannot cause smallpox or monkeypox. JYNNEOS™ is usually administered as two injections, four weeks apart. People who have received the smallpox vaccine in the past might only need one dose.

Conclusion
Healthcare providers must monitor for monkeypox among the affected population while remaining alert for monkeypox among all patients who report symptoms regardless of sexual orientation or gender identity. It is important to remember that full PPE should be worn while examining or treating a patient with symptoms or confirmed monkeypox disease. Healthcare providers should consult with the CDC to determine treatment if they identify or suspect a patient may have monkeypox. The CDC website, https://www.cdc.gov/poxvirus/monkeypox/clinicians/index.html, should be consulted on a regular basis for any updates or changes to the protocol.

Taking lessons from past epidemics, it is important to inform and empower patients and the general public about monkeypox. Healthcare providers must educate people to avoid stigma and the association of monkeypox as a “gay illness” or an STI. We know from the HIV epidemic and the early days of the COVID-19 pandemic that such a narrow-minded lens, in the absence of evidence, not only creates stigma but it underestimates potential risks to all communities.

*On July 23, 2022, the World Health Organization declared monkeypox a global health emergency.

References
2. https://www.who.int/emergencies/disease-outbreak-news/item/monkeypox---the-united-states-of-america
3. Centers for Disease Control and Prevention, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of High-Consequence Pathogens and Pathology (DHCPP)

*This is a composite case that does not represent a specific person.
In July 2021, the Centers for Disease Control and Prevention (CDC) published updated guidelines for the treatment of sexually transmitted diseases (STD); the first update since 2015. Clinicians should consult the complete 2021 CDC STD Treatment Guidelines before treating a patient for an STD. The guidelines can be found at https://www.cdc.gov/std/treatment-guidelines/default.htm. Selected highlights of the updated guidelines are described below.

Updated recommendations for the treatment of chlamydia in adolescents and adults:
- Doxycycline 100mg 2x/day for 7 days.
- Alternative treatment: Azithromycin 1 gm orally, single dose OR levofloxacin 500 mg orally 1x/day for 7 days.

Updated recommendations for uncomplicated gonorrhea in adolescents and adults:
- Uncomplicated infections of cervix, urethra, and rectum in adults and adolescents: ceftriaxone 500 mg IM, single dose. Alternatives: gentamicin 240 mg IM, single dose plus 2 gm azithromycin, orally single dose.
- Uncomplicated pharyngeal infections in adults and adolescents: ceftriaxone 500 mg IM, single dose. No alternative regimen is recommended.

Uncomplicated infections in pregnant patients: ceftriaxone 500 mg IM, single dose. No alternative regimen is recommended.

Expanded risk factors for syphilis testing among pregnant patients:
Pregnant patients with positive treponemal tests should have additional titers drawn throughout pregnancy to monitor treatment response. The guidelines recommend serologic testing twice in the third trimester (28 weeks gestation and at time of delivery) for pregnant patients who meet any of the following criteria:
- live in areas with high rates of syphilis,
■ have multiple sex partners,
■ history of drug use,
■ have transactional sex,
■ incarcerated,
■ no prenatal care or late entry to prenatal care (first prenatal appointment during the second trimester or later),
■ have a partner who uses drugs or is incarcerated,
■ vulnerable housing or homelessness.

Additional updated recommendations include:
■ Two-step serologic testing for diagnosing genital herpes simplex virus
■ Recommended universal hepatitis C testing in alignment with the CDC’s 2020 hepatitis C testing recommendations.

Additional information and resources for providers, such as print-friendly versions of wall charts and pocket guides, can be found at [https://www.cdc.gov/std/treatment-guidelines/default.htm](https://www.cdc.gov/std/treatment-guidelines/default.htm)

Reference:
Over the past decade, the United States (US) saw alarming increases in rates of sexually transmitted infections (STIs). In 2019, the Centers for Disease Control and Prevention (CDC) Sexually Transmitted Disease Surveillance Report showed increases for the sixth consecutive year in chlamydia, gonorrhea, and syphilis. From 2014 to 2018, rates of primary and secondary syphilis, congenital syphilis, gonorrhea, and chlamydia rose 71%, 185%, 63%, and 19%, respectively. Human papillomavirus (HPV), the most common STI, accounts for 14 million new infections each year.1

New Jersey rates of primary and secondary syphilis, gonorrhea, and chlamydia increased by 39%, 36%, and 22%, respectively, from 2014 to 2018. There were zero cases of congenital syphilis cases reported in New Jersey in 2014. However, between 2016 and 2020, New Jersey cases of congenital syphilis increased by 100%.2 When left untreated, STIs can lead to serious long-term health issues such as chronic pain, fertility issues, infant death, fetal abnormalities, and an increased risk for HIV infection.1

Further revealed health disparities and inequities experienced by people of color and SGM populations such as lower rates of health insurance, lack of access to transportation or childcare, lack of access to affirming healthcare, discrimination, stigma, and less trust in health care providers.3 The COVID-19 pandemic further revealed health disparities and inequities experienced by people of color and SGM populations such as lower rates of health insurance, lack of access to transportation or childcare, lack of access to affirming healthcare, discrimination, stigma, and less trust in health care providers.3

In January 2021, the CDC announced a 5-year strategic plan to address sharp increases in STIs across the United States, emphasizing lessening the burden on communities disproportionately impacted. The Sexually Transmitted Infections National Strategic Plan 2021-20253 serves as a roadmap to guide the development of new STI prevention policies, initiatives, and actions through five overall goals:

■ Prevent new STIs,
■ Improve the health of people by reducing adverse outcomes of STIs,
■ Accelerate progress in STI research, technology and innovation,
■ Reduce STI-related health disparities and health inequities,
■ Achieve integrated, coordinated efforts that address the STI epidemic.

Each goal includes objectives, strategies, and indicators designed to be accessible to a broad audience of stakeholders, including professionals in public health, health care, government, community-based organizations, research, and academia. While the plan targets the four STIs identified as the most pervasive and causing the most significant disparities, namely chlamydia, gonorrhea, syphilis, and HPV, the elements of the plan apply to all STIs. Below is a summary of each goal as particularly relevant to health care providers.3

Goal 1: Prevent New STIs.
This goal emphasizes primary prevention of STIs or preventing STIs before they occur through clinical measures and increasing patients’ knowledge and awareness. This goal calls on healthcare providers to assess a patient’s sexual behaviors that may increase the risk for infection with an STI. Objectives include:

■ Raising awareness of STIs and sexual health,
■ Expanding quality primary prevention activities,
■ Increasing completion rates for the HPV vaccine,
■ Increasing public health, healthcare delivery, and the healthcare workforce related to STIs and sexual health.

Strategies include techniques for obtaining sexual histories, client-centered prevention/risk-reduction counseling including abstinence, reduction of sex partners, condom use, and implementing recommended prevention methods such as pre-
exposure vaccination for STIs when applicable (e.g., HPV, HBV, HAV) and PrEP to reduce the risk for contracting HIV. Primary prevention approaches should always be inclusive, stigma reducing, linguistically and culturally appropriate, developmentally appropriate, and grounded in evidence-based science and medicine.

Goal 2: Improve the Health of People by Reducing Adverse Outcomes of STIs.

This goal emphasizes secondary and tertiary prevention approaches to thwart the progression of an STI from infection to disease, including treatment before serious and irreversible health outcomes occur. Objectives include:

- Expanding quality,
- Affordable STI screening, care and treatment,
- Providing holistic care to those diagnosed with an STI,
- Expeditiously identifying individuals infected with an STI to ensure appropriate and timely treatment.

Thorough screening, care, and treatment for people with STIs are essential to preventing adverse health outcomes associated with untreated STIs and preventing further spread. Effective achievement of Goal 2 requires the expansion of STI testing and treatment into settings beyond medical clinics, expanding the role of Disease Intervention Specialist (DIS), reducing barriers to testing and care, and increasing linkage to care across applicable programs.

Goal 3: Accelerate Progress in STI Research, technology, and Innovation.

This goal includes:

- Objectives to invest in the development of STI vaccines,
- Support the development and use of STI prevention technologies (such as prophylaxis and other technologies),
- Support the development and use of new STI diagnostic and treatment...
technologies, increase and evaluate best practices in STI prevention and treatment.

The National Institutes of Health (NIH) has recently provided recommendations regarding biomedical research goals to advance innovative diagnostics, vaccines, and treatments for STIs. Investment in research and translation of this research into practice will lead to additional evidence-based prevention models, technologies, and products to reduce the incidence and burden of STIs. The affordability and supply of new and existing preventive and therapeutic techniques need to be considered so that these can be translated into practice in ways that are accessible. For example, innovations in payment models can support access to required tests and therapies. In addition, the strategic plan calls for the development of major biomedical interventions—such as vaccines for chlamydia, gonorrhea, and syphilis—to be prioritized.

**Goal 4: Reduce STI-related health disparities and health inequities.**

This goal includes:

- Reducing stigma and discrimination associated with STIs,
- Expanding culturally and linguistically appropriate STI care,
- Addressing STI-related social determinants of health.

To effectively address the STI epidemic, it is essential to recognize the negative impacts of stigma and the importance of cultural competence. To this end, quality healthcare should be patient-centered, ensure awareness and attention to issues that unduly impact vulnerable populations, and be accessible to all. Fostering and creating health care environments that are more tailored to affected populations’ needs can help address stigma and discrimination. In addition, attention to social determinants of health and comorbidities can help lessen some of the negative impacts of STIs.

**Goal 5: Achieve integrated, coordinated efforts that address the STI epidemic.**

Coordination of organizations and programs at all levels, including national, state, and local public health, healthcare systems and practices, and community-based organizations, is key to integrating efforts and reducing duplication of efforts. STI prevention, care, and treatment integrated across services and programs are also central to other national strategic plans developed by Health and Human Services, namely the HIV Plan and the Hepatitis Plan. Objectives under this goal include:
Integrating STI, HIV, hepatitis, and substance use programs,

Improving/increasing the use of data on STIs and social determinants of health,

Improving mechanisms to monitor, evaluate and share progress toward achieving the goals in this plan.

This strategic plan highlights priority populations and areas that STIs have disproportionately impacted. The focus on these identified populations will reduce health disparities that have had the most significant impact on the nation’s overall health. Based on national data, the populations identified as priority populations include adolescents and young adults, men who have sex with men, and pregnant women. Within each population, particular focus should be given to racial and ethnic minorities who have higher rates of STIs, such as black and Hispanic populations.

**Implementing the STI National Plan in New Jersey**

The plan acknowledges that each community stakeholder will bring their perspective to addressing STIs. To this end, using the goals and overall vision of the national plan adapted to their plan for addressing STIs is encouraged. Stakeholders are encouraged to implement goals and strategies most relevant to their patients or populations and ground strategies in data. Integrating efforts with other emerging public health issues, such as COVID, is strongly encouraged.

In conjunction with this plan, new Federal funding was released in 2021 to increase DIS capacity across the nation to address infectious diseases, including COVID and STIs. The New Jersey Department of Health is currently in the process of onboarding and training new DIS staff to address increasing rates of STIs, with particular focus on congenital syphilis, as well as other infectious diseases.

While we still may not have a clear picture of the overall impact of COVID-19 on the STI epidemic, HIV, and other public health issues, it is encouraging that we are seeing increased momentum on a national level to address the STI epidemic with this inaugural national STI strategic plan. We are encouraged to see this momentum in New Jersey. We hope to use this plan in conjunction with the National HIV and Hepatitis Strategic plans to improve and expand our efforts to improve the health of all New Jersey communities.

**References**


Black and African American persons with HIV (PWH) exhibit high levels of medical mistrust contributing to increased risk of HIV and a lack of access to health services.\textsuperscript{1, 2} There is a documented history of medical abuse and discrimination towards Black and African Americans that manifests as historical trauma with generational effects.\textsuperscript{3} In addition, HIV-related stigma and discrimination has a negative effect on both physical and mental health of PWH.\textsuperscript{4}

Research has highlighted the need for a more diverse workforce as well as social and educational support to reduce health disparities, address social determinants of health for stigmatized communities, and build credibility for the health system.\textsuperscript{5-8} To foster renewed trust in healthcare institutions, health systems can invest in and support a more culturally responsive workforce, equipped with the resources needed to address barriers and poor experiences by leveraging community members who have a shared lived experience with their clients and patients.\textsuperscript{9}

**What is a Community Health Worker?**

Variations of lay community workers have bridged the gap between individuals and health systems, including providing outreach, system navigation, and advocacy.\textsuperscript{10} Community Health Workers (CHWs) are an evidence-based model of leveraging individuals with shared lived experience to provide health services to their own communities.\textsuperscript{7} The American Public Health Association defines a community health worker as "a frontline public health worker who is a trusted member of or has an unusually close understanding of the community served."\textsuperscript{11}

CHWs’ shared lived experience can be expressed as a combination of shared racial or ethnic identities, common languages, similar socioeconomic statuses, or living with particular diseases such as HIV.\textsuperscript{12} This familiarity allows CHWs access to community members outside of the traditional healthcare setting. These shared lived experiences foster a different level of trust and confidence in healthcare systems, making CHWs effective in addressing the lack of trust that has led to decreased access to services and adverse health outcomes for minority communities.\textsuperscript{2, 13} In addition, CHWs as integral members of health care and service provider teams, can leverage their community expertise to assist other professionals in understanding the social determinants of health and community context that impact their clients.

CHWs can improve systems and patient indicators of success such as satisfaction, trust, and respect, allowing for a truly patient-centered approach in care delivery. Typical CHW roles include providing health coaching, linking clients and patients to needed resources and services, case and care management, follow-up on referrals and care plans, and health education and promotion.\textsuperscript{10} The relationship between the CHW and the client fosters positive health outcomes including improved access to health care services, increased rates of health screenings, better adherence to treatment plans, and more communication between clients and providers of care.\textsuperscript{14} Clients who engage with a CHW are more likely to report higher-quality care than clients who have not worked with a CHW.\textsuperscript{15} Clients with multiple chronic healthcare conditions have also reported improved mental health and quality of care.\textsuperscript{16}
The New Jersey Community Health Worker Program

Leveraging an evidence-based model to improve retention in HIV care and viral suppression, New Jersey (NJ) established the New Jersey Community Health Worker Program. The program model and materials were adapted from the PREParing Peers for Success program, a Health Resources and Services Administration HIV/AIDS Bureau Special Project of National Significance. The New Jersey Department of Health partnered with the South Jersey Regional Partner of the Northeast Caribbean AIDS Education and Training Center (NE/CA AETC) to develop and implement a five-day training program for CHWs to support linkage, retention, and most importantly, engagement in HIV care and treatment services for PWH. The CHW program used the ECHO model to support continued education for NJ CHWs with quarterly full-day trainings and a monthly community of practice meetings. NJ CHWs provide services in multiple health care settings, including community-based organizations, outpatient ambulatory clinics, and federally qualified health centers. The NJ CHW scope of practice was recently expanded to include services for individuals at risk for HIV, transforming the CHWs into full HIV Service Systems Navigators.

Conclusion

CHWs are an integral part of a care team to address barriers faced by PWH. The ability of CHWs to serve as a bridge between clients and the care team allows for renewed trust in the medical system as well as an improved understanding of the community by service providers. CHWs continue to be an effective intervention to engage communities to support themselves and each other.

References:

Michael’s Story: The Journey to Recovery, Redemption and Healing

Michelle Thompson,  
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Michael is a 60-year-old Caucasian male who was diagnosed with HIV 14 years ago. He is currently a Peer Counselor for a Medicaid Managed Care Provider in New York. He works with PWH and homeless members.

I interviewed Michael for this article. This is Michael’s story as told to me in his own words...

In 2005 I was married with three children and in the middle of a divorce. I was very depressed. At this same time, I began to explore my sexuality and my attraction to men. I had no gay friends to turn to or confide in to help me understand my feelings. I turned to the internet and hook-up sites and met with a good deal of rejection. I found it difficult to engage with men. The depression deepened.

I had smoked a little weed in high school and college but never had a taste for alcohol or tried any hard drugs. In 2006, I was introduced to a group of men by a guy who had become a regular hook-up that I had met on a site who happened to be the person that introduced me to crystal meth, one of whom became my dealer. They became my close-knit circle and most of my use and sexual escapades were linked to them in some manner shortly after we met. I tried meth out of curiosity and to feel included. I was gainfully employed, having spent 30 years in a family business selling heating and plumbing supplies, so I had money. Every other weekend I would show up with the “party favors”. I had a need to be accepted. In 2007 I moved out of my house, which led to my downward spiral of depression and increased meth use. After time, the meth exacerbated my depression. I attempted suicide in 2007 and 2008 on two occasions, each of which led to in-patient psychiatric admissions.

My suicide ideation intensified over time. I was a father who was very involved until the drugs and depression took over my life. I used about two years while I was still in the home, while trying to hold it together. I became unreliable and unrecognizable. I didn’t want to do anything extreme and leave a terrible image for my children or do...
something that would impact them and cause trauma for the rest of their lives. I wallowed in my depression and fueled it with meth.

Everything I knew about HIV and AIDS came from watching the Tom Hanks movie “Philadelphia”. Tom Hank’s character portrayed a man diagnosed with AIDS. In the movie there were other infections like KS and pneumonia that I could contract. I wanted a quick death. If I got sick and died from an incurable disease, that would have been easier for my family. People die from illness every day. I put myself in harm’s way.

When I was diagnosed in March of 2008, I shared my story with my doctor, who has devoted his entire career to HIV care, and he told me that my information about AIDS was incorrect and bluntly told me I had chosen a way that might not be quick or guarantee death. He said it could take a decade or more and could possibly be a slow excruciating way to die. There were ARVs available that could extend my life way beyond that if I entered treatment.

I attended several crystal meth recovery programs between 2011 and 2013 with limited success, but several periods of abstinence.

Things started to turn around in 2013. I started to pull myself together. About nine years ago I was finishing up a 48 week treatment regimen for Hep C, taking 15 pills a day and weekly injections of Interferon. The treatment itself was grueling, and syringes around the house was triggering for an intravenous drug user.

After finishing my course of treatment, I was asked by my doctor and a Health Educator to speak with a group of patients about Hep C and my journey. I agreed.

There were five to seven people in the room. It felt good, and little did I know I was being vetted for a Peer position. I was invited to work part-time as a Hep C Peer. I worked a couple of days a week doing outreach to patients receiving Hep C treatment, using my lived experience. I was also engaging with patients who had not yet committed to treatment, with education and support. This led to a full-time position. My role expanded to an HIV Peer.

In that role, I provided outreach, helping peers by providing medication reminder calls and working with people struggling with viral suppression, medication adherence and keeping their medical appointments. I also facilitated groups. Since then, I’ve held positions in medical, substance use treatment, and currently Medicaid Managed Care settings as a case manager, drawing on my lived experiences to provide services to the patients or members that I serve. This is much more rewarding than selling plumbing and heating supplies (LOL), which incidentally was a job I came to hate.

This is an opportunity to make a difference in my life possibly the life of others.

I can help someone who may be where I was at.

My experiences have led me to the life I live now. I have my family, my sobriety and my work. I really enjoy what I do.

My family comes first. My relationship with my three children has gotten so much better in the past five to six years. I have a two-year-old granddaughter and every Friday I spend a half day with her. There is a now a level of trust from my daughter and my son-in-law, as well as my other children. My parents are great. They have always stood behind me even during my worst times.

I’m happy. Life is good. It serves as a reminder that recovery is a lifelong endeavor, and I will always be one bad decision away from relapse. I continue with my mental health therapy three times a week, and I’m currently taking a deep dive into exploring what makes me. I believe that I have made some good progress. I highly recommend it!

**Commentary**

Michael is very interested in issues surrounding the aging population of PWH. He is also very passionate about his HIV advocacy endeavors.

He is a New York State Certified Peer Worker (HIV, Hepatitis C and Harm Reduction Tracks), a member of the New York State Peer Certification Review Board, a Council Member – HIV Planning Council (New York EMA) and a member of the Social, Cultural and Economic Ending the HIV Epidemic (EHE) Workgroup of the Northeast Caribbean AIDS Education and Training Center.
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(609) 984-5874 • www.state.nj.us/health/hivstbtb

HIV/AIDS Training & Information Resources

AIDS Education and Training Center (AETC) Program
- National Coordinating Resource Center: www.aidsetc.org
- Northeast/Caribbean AETC: www.necaetc.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: 844-457-4636

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


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

New Jersey HIVLinks Mailing List.
If you would like to be added to our mailing list, please contact Michelle Thompson at ccthomps@sn.rutgers.edu. To be deleted from the mailing list, please contact FXBCenter@sn.rutgers.edu. Current and past issues of NJ HIVLinks can be found at FXBCenter.org.