HIV in the Latino Community

Beliefs, Borders & Barriers

Immigration Reform

Hard Times for Migrants

Addressing Diversity
INDICATION AND USAGE

COMPLERA (emtricitabine 200mg/rilpivirine 25mg/tenofovir disoproxil fumarate 300mg) is indicated for use as a complete regimen for the treatment of HIV-1 infection in antiretroviral treatment-naïve adult patients with HIV-1 RNA less than or equal to 100,000 copies/mL at the start of therapy.

This indication is based on safety and efficacy analyses through 96 Weeks from 2 randomized, double-blind, active controlled, Phase 3 trials in treatment-naïve subjects.

The following points should be considered when initiating therapy with COMPLERA:

• More rilpivirine-treated subjects with HIV-1 RNA greater than 100,000 copies/mL at the start of therapy experienced virologic failure (HIV-1 RNA ≥ 50 copies/mL) compared to rilpivirine-treated subjects with HIV-1 RNA less than or equal to 100,000 copies/mL

• Regardless of HIV-1 RNA level at the start of therapy, more rilpivirine-treated subjects with CD4+ cell count less than 200 cells/mm³ at the start of therapy experienced virologic failure compared to subjects with CD4+ cell count greater than or equal to 200 cells/mm³

• The observed virologic failure rate in rilpivirine-treated subjects conferred a higher rate of overall treatment resistance and cross-resistance to the NNRTI class compared to efavirenz

• More subjects treated with rilpivirine developed tenofovir and lamivudine/emtricitabine associated resistance compared to efavirenz

• COMPLERA is not recommended for patients less than 18 years of age

IMPORTANT SAFETY INFORMATION

BOXED WARNING: LACTIC ACIDOSIS/SEVERE HEPATOMEGALY WITH STEATOSIS and POST TREATMENT ACUTE EXACERBATION OF HEPATITIS B

• Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs, including tenofovir disoproxil fumarate, a component of COMPLERA, in combination with other antiretrovirals

• COMPLERA is not approved for the treatment of chronic hepatitis B virus (HBV) infection and the safety and efficacy of COMPLERA have not been established in patients coinfected with HBV and HIV-1. Severe acute exacerbations of hepatitis B have been reported in patients who are coinfected with HBV and HIV-1 and have discontinued EMTRIVA® (emtricitabine) or VIREAD® (tenofovir disoproxil fumarate), which are components of COMPLERA. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who are coinfected with HIV-1 and HBV and discontinue COMPLERA. If appropriate, initiation of anti-hepatitis B therapy may be warranted

Please see additional Important Safety Information and Brief Summary of full Prescribing Information, including BOXED WARNING, on the following pages.

NNRTI = non-nucleoside reverse transcriptase inhibitor.
For treatment-naïve adult patients with HIV-1 RNA $\leq 100,000$ copies/mL at the start of therapy

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**INDICATION AND USAGE**

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This indication is based on safety and efficacy analyses through 96 Weeks from 2 randomized, double-blind, active controlled, Phase 3 trials in treatment-naïve subjects.

The following points should be considered when initiating therapy with **COMPLERA**:

- More rilpivirine-treated subjects with HIV-1 RNA greater than 100,000 copies/mL at the start of therapy experienced virologic failure (HIV-1 RNA $\geq 50$ copies/mL) compared to rilpivirine-treated subjects with HIV-1 RNA less than or equal to 100,000 copies/mL.
- Regardless of HIV-1 RNA level at the start of therapy, more rilpivirine-treated subjects with CD4+ cell count less than 200 cells/mm$^3$ at the start of therapy experienced virologic failure compared to subjects with CD4+ cell count greater than or equal to 200 cells/mm$^3$.
- The observed virologic failure rate in rilpivirine-treated subjects conferred a higher rate of overall treatment resistance and cross-resistance to the NNRTI class compared to efavirenz.
- More subjects treated with rilpivirine developed tenofovir and lamivudine/emtricitabine associated resistance compared to efavirenz.
- **COMPLERA** is not recommended for patients less than 18 years of age.

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Please see additional Important Safety Information and Brief Summary of full Prescribing Information, including BOXED WARNING, on the following pages.
IMPORTANT SAFETY INFORMATION (CONT)

Contraindications
• Coadministration: COMPLERA should not be coadministered with drugs that induce CYP3A enzyme or increase gastric pH as loss of virologic response and possible resistance may occur. Use of the following drugs with COMPLERA is contraindicated: carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifabutin, rifampin, rifapentine, proton pump inhibitors (such as esomeprazole, lansoprazole, dexlansoprazole, omeprazole, pantoprazole, rabeprazole), dexamethasone (more than a single dose) and Hypericum perforatum (St. John’s wort).

Warnings and Precautions
• New onset or worsening renal impairment: Renal impairment, including cases of acute renal failure and Fanconi syndrome may occur. Assess creatinine clearance (CrCl) before initiating treatment with COMPLERA. Monitor CrCl and serum phosphorus in patients at risk for renal impairment, including patients who have previously experienced renal events while receiving adefovir dipivoxil. Avoid administering COMPLERA with concurrent or recent use of nephrotoxic drugs. Patients with CrCl below 50 mL per minute should not receive COMPLERA.

• Drug interactions: Use COMPLERA with caution when given with drugs that may reduce the exposure of rilpivirine or when coadministered with a drug with known risk of Torsades de Pointes. Supratherapeutic doses of rilpivirine have been shown to prolong the QTc interval of the electrocardiogram in healthy subjects. Please see the full Prescribing Information and below for more information about potential drug interactions with COMPLERA.

• Depressive disorders: Depressive disorders (depressed mood, depression, dysphoria, major depression, mood altered, negative thoughts, suicide attempt, suicidal ideation) have been reported with rilpivirine. The incidence of depressive disorders reported through 96 Weeks among rilpivirine (N=686) or efavirenz (N=682) was 9% and 8%, respectively, in Phase 3 trials. Most events were mild or moderate in severity. Grade 3 and 4 depressive disorders (regardless of causality) were reported at 1% in both study arms. Suicide attempt was reported in 2 subjects and suicide ideation was reported in 4 subjects treated with rilpivirine. Patients with severe depressive symptoms should seek immediate medical evaluation and the risks of continued therapy should be determined.

• Hepatotoxicity: Hepatic adverse events have been reported in patients on a rilpivirine regimen. Patients with underlying liver disease and those with marked elevations in serum liver biochemistries may be at increased risk. Appropriate laboratory testing and monitoring should be undertaken for all patients before and during therapy with COMPLERA, as hepatic toxicity has been reported in patients without underlying liver disease or risk factors.

• Decreases in bone mineral density (BMD) and cases of osteomalacia have been seen in patients treated with tenofovir disoproxil fumarate (DF). Consider monitoring BMD in patients with a history of pathologic fracture or risk factors for osteoporosis or bone loss.

• Coadministration with other antiretroviral products: Do not administer concurrently with other products containing any of the same active components (emtricitabine, rilpivirine, or tenofovir DF) or with products containing lamivudine or adefovir dipivoxil.

• Fat redistribution/accumulation has been observed in patients receiving antiretroviral therapy.

• Immune reconstitution syndrome, including the occurrence of autoimmune disorders with variable times to onset, has been reported.

Adverse Reactions
• The most common adverse drug reactions to rilpivirine (incidence greater than or equal to 2%, Grades 2-4) were depressive disorders, insomnia and headache.

• The most common adverse drug reactions to emtricitabine and tenofovir DF (incidence ≥10%) were diarrhea, nausea, fatigue, headache, dizziness, depression, insomnia, abnormal dreams, and rash.

Drug Interactions
• COMPLERA is a complete treatment regimen for treating HIV-1 infection and should not be coadministered with other antiretroviral agents.

• Drugs inducing or inhibiting CYP3A: Drugs which induce CYP3A enzymes should not be coadministered with COMPLERA due to potential for loss of virologic response and/or resistance. (See CONTRAINDICATIONS). Coadministration of COMPLERA with drugs that inhibit CYP3A may increase rilpivirine plasma concentrations.

• Potentially significant drug interactions may occur with azole antifungal agents and macrolide/ketolide antibiotics coadministered with rilpivirine by increasing plasma concentrations of rilpivirine (due to inhibition of CYP3A enzymes). Clinical monitoring is recommended when coadministering COMPLERA with methadone.

• Drugs increasing gastric pH may cause significant decreases in rilpivirine plasma concentrations (See CONTRAINDICATIONS).

• Antacids should be administered at least 2 hrs before or 4 hrs after COMPLERA.

• H, Receptor antagonists should be administered 12 hrs before or 4 hrs after COMPLERA.

• Drugs affecting renal function: Caution should be used when coadministering COMPLERA with drugs that reduce renal function or compete for active tubular secretion. Examples include acyclovir, adefovir dipivoxil, cidovir, ganciclovir, valacyclovir, and valganciclovir.

• QT prolonging drugs: Supratherapeutic doses of rilpivirine (75 mg once daily and 300 mg once daily) have been shown to prolong the QTc interval of the EKG in healthy subjects. Please see full Prescribing Information for more information about potential drug interactions with COMPLERA.

Pregnancy and Breastfeeding
• Pregnancy Category B: There are no adequate and well-controlled studies in pregnant women. Use during pregnancy only if potential benefits justifies the potential risk. An Antiretroviral Pregnancy Registry has been established.

• Breastfeeding: Mothers with HIV should be instructed not to breastfeed due to the potential for HIV transmission. Because emtricitabine and tenofovir have been detected in human milk, the risk to the infant is unknown.

Dosing and Administration
• Adults: The recommended dose of COMPLERA is one tablet taken orally once daily with a meal.

• Renal Impairment: Do not use with patients requiring dose adjustment or with patients with creatinine clearance below 50 mL per minute. Please see Brief Summary of full Prescribing Information, including BOXED WARNING, on the following pages.
**Warnings and Precautions**

Fat redistribution/accumulation, bone loss, osteomalacia have been seen in patients treated with tenofovir. Patients with HIV and those with marked elevations in serum liver enzymes have been reported (regardless of causality) were reported at 1% in both study arms. Mild or moderate in severity. Grade 3 and 4 depressive disorders was 9% and 8%, respectively in Phase 3 trials. Most events were observed in the first 96 weeks among rilpivirine (N=686) or efavirenz (N=682) treatment arms. The adverse drug reactions observed in the subset of patients who were generally consistent with those seen for the overall patient population participating in these studies (refer to the prescribing information). The proportion of subjects who discontinued treatment with rilpivirine or efavirenz, tenofovir DF for ADR, regardless of severity, was 2% and 3%, respectively. The most common ADR leading to discontinuation were psychiatric disorders: (5.4%) (the) subjects in the rilpivirine/tenofovir DF arm and 17 (2.2%) subjects in the efavirenz/tenofovir DF arm. Both related to discontinuation of a 3.2% (the) subject in the rilpivirine/tenofovir DF arm and 10 (1.8%) subjects in the efavirenz/tenofovir DF arm.

**Drug Interactions**

**Coadministration with Other Products:** COMPLERA should not be administered concurrently with other medicinal product containing any of the following: ritonavir-boosted tipranavir, atazanavir, efavirenz, darunavir/ritonavir, fosamprenavir/ritonavir, lopinavir/ritonavir, nevirapine, raltegravir, saquinavir/ritonavir, tipranavir/ritonavir, or voriconazole. For information about drug interactions, see table below.

**Adverse Reactions from Clinical Trials Experience:**

The following adverse reactions were observed in clinical studies of emtricitabine/tenofovir DF or tenofovir DF in combination with other antiretroviral agents. The most common adverse reactions occurred in less than 1% of patients treated with COMPLERA. The most common adverse events associated with the use of tenofovir DF were:

- Nausea
- Headache
- Mild or moderate in severity.
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There is limited information available on the potential for a pharmacodynamic interaction between rilpivirine and drugs eliminated by active tubular secretion, including, but not limited to, acyclovir, adefovir dipivoxil, cidofovir, ganciclovir, valacyclovir, and valganciclovir.

Coadministration of rilpivirine with drugs that increase gastric pH may decrease plasma concentrations of the class of NNRTIs. Coadministration of rilpivirine and drugs that inhibit CYP3A may result in increased plasma concentrations of rilpivirine. Rilpivirine or inhibit CYP3A may thus affect the clearance of rilpivirine [See Clinical Pharmacology, Contraindications]

COMPLERA is a complete regimen for the treatment of HIV-1 infection; therefore, COMPLERA should not be administered with other antiretroviral drugs [See Drug Interactions].

In the study of patients treated with clopidogrel, the increase in the area under the plasma concentration-time curve for clopidogrel was approximately 20% after administration of only rilpivirine. This interaction is not considered clinically significant.

COMPLERA may be used in patients with mild or moderate renal impairment (creatinine clearance ≥50 mL per minute). Rilpivirine is extensively metabolized by CYP3A. In patients with mild or moderate renal impairment, the increase in plasma concentrations of rilpivirine was similar to those seen in patients with normal renal function.

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Addressing the Unique Needs of a Community

I WOULD BE REMISS to begin this column without acknowledging the recent passing of a hero in the HIV/AIDS community, Dr. C. Everett Koop. When I was a senior career policy official in the U.S. Public Health Service, I had the good fortune to work alongside Dr. Koop when he became the Surgeon General of the U.S. I found him to be so unlike the caricature of him the media had created. Yes, he was a stern conservative. He was also warm, friendly, thoughtful, and committed to caring for people—even if they were gay and infected with AIDS. His AIDS pamphlet mailed to every household in the U.S. in 1986 made that abundantly clear and was an important milestone in our HIV/AIDS history. The pamphlet conveyed more than the medical/scientific information in it. It changed the way our society thought about AIDS, and was another step in reducing the stigma associated with being gay in America. His leadership and courage will be his legacy.

It was also recently announced that another HIV champion, Dr. Deborah Parham Hopson, formerly the Director of the HIV/AIDS Bureau (HAB) in the Health Resources and Services Administration (HRSA), will be assuming new responsibilities. The Ryan White Program she headed provided infrastructure, education, resources and services to HIV patients across the United States. And not for just any HIV patients, but those HIV patients who needed it the most—those that did not have access to life saving healthcare. Again while I was in the U.S. Public Health Service, I knew Deborah even before she became a Hopson—before she completed her Ph.D. and before there was a HAB. She has always been a bright, committed caring healthcare professional. A couple of years ago, I had the honor of sitting next to Deborah’s mother at a Ryan White event. Her mother was rightfully proud of all that her daughter was achieving. There is no doubt that Deborah’s achievements will continue into the future.

Our members and the patients we serve owe a lot to these two individuals.

In this issue of HIV Specialist, you’ll learn the names of other HIV champions, working diligently to raise awareness of the growing epidemic in the Latino community. According to the new 2011 Centers for Disease Control (CDC) Surveillance Report, Latinos represent 21 percent of the new HIV infections while representing 16 percent of the population. In 2011 alone, 10,159 Hispanics were diagnosed with HIV. Far too many. But we know that there are cultural and language barriers that can make their care more challenging. A number of articles in this issue provide some guidance in addressing these challenges.

Working towards reducing the incident rate of HIV in at-risk populations has been the defining factor in the success of fighting the disease. When Dr. Koop began as Surgeon General, the educational and scientific focus was on the gay community. Since then, we have also focused efforts on women, mother-to-child transmission and the African-American community. History has shown that by tailoring outreach to address the unique needs of a population, we can make a bigger difference.

By educating ourselves on the cultural challenges within Latino communities, we can provide better communication, treatment and access to care.

James M. Friedman
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Prevention Research Update from CROI 2013

BY JEFFREY T. SCHOUTEN, MD, JD, AAHIVE

MAJOR HIV PREVENTION STUDIES were presented at the 20th Conference on Retroviruses and Opportunistic Infections (CROI). The VOICE study (MTN 003), conducted by the Microbicide Trials Network, enrolled women in a 5-arm, randomized, double-blind, placebo-controlled trial assessing the safety and efficacy of daily use of oral tenofovir (TDF), oral tenofovir/emtricitabine (TDF/FTC) and 1% vaginal tenofovir gel (TFV). Two of the arms had been closed prior to the completion of study for futility (oral TDF and TFV gel, in September and November 2011, respectively).

A total of 5,029 women were enrolled at 15 sites in South Africa, Uganda, and Zimbabwe. Broad eligibility criteria included report of vaginal intercourse in the prior 3 months, negative pregnancy test, and willingness to use effective contraception throughout study. HIV testing was done monthly and plasma TDF levels were measured quarterly. The mean age was 25.3 years and 79 percent of the women were unmarried.

Over follow-up of 5511 person-years, 334 HIV infections occurred, including 22 infections defined as acute HIV with RNA present at enrollment. Excluding these 22 participants, HIV incidence was 5.7 per 100 person-years, and ranged from 0.8 to 9.9 per 100 person-years by site. This was higher than projected in the study design. None of the interventions were effective at reducing HIV acquisition. Effectiveness was –48.8 percent for TDF (hazard ratio [HR] 1.49; 95% confidence interval [CI] 0.97, 2.29), –4.2 percent for TDF/FTC (hazard ratio [HR] 1.04; 95%CI 0.73, 1.49), and 14.7 percent for TFV gel (HR 0.85; 95%CI 0.6, 1.2).

In a case-cohort subset, TFV was detected on average in only 28 percent of available quarterly plasma samples among participants randomized to TDF, 29 percent to TDF/FTC, and 22 percent to TFV gel. The drug assay sensitivity was very low so should have detected recent or intermittent use. Most women self-reported high rates of adherence, in the range of 90 percent. Product use was so low that the study could not even measure the effectiveness in the subset of regular users determined by drug levels. No safety concerns were identified.

The VOICE results are consistent with the FemPreP study in a population of women in southern Africa at high risk for HIV acquisition. Qualitative research is forthcoming from the VOICE study to attempt to understand the discordance with self-report and product use determined by objective measure, as well as perception of risk. In contrast, the Partners PrEP study, which showed high efficacy of TDF and TDF/FTC, was conducted in serodiscordant couples.

Another major prevention study presented was Project Accept (HPTN 043) conducted by the HIV Prevention Trials Network. It was a large community randomized trial testing whether HIV incidence can be reduced in communities receiving community-based voluntary counseling and testing (CBVCT) relative to communities receiving standard clinic-based voluntary counseling and testing (SVCT). Included in the study were 16 communities in South Africa, 10 in Tanzania, 8 in Zimbabwe, and 14 in Thailand randomized in matched pairs to either CBVCT or SVCT.

CBVCT was designed to: make VCT more available in community settings; engage the community through outreach; and provide post-test support. These strategies targeted change in community norms to reduce the risk for HIV infection among all community members, regardless of direct participation in the intervention. The post-intervention assessment was conducted using a single cross-sectional random survey of 18- to 32-year-old community residents who provided blood samples (N = 54,327) for HIV incidence analysis. HIV incidence was estimated using a multi-assay algorithm developed by the HPTN Network Laboratory that included the BED assay, an avidity assay, CD4+ cell count, and HIV viral load. This incidence assay and algorithm is a major contribution of this study.

During the 36-month intervention phase of the study, 15,603 units of community mobilization, 71,842 units of voluntary counseling and testing, and 51,787 units of post-test support services were delivered. The estimated reduction in incidence in intervention vs. control communities was 13.9 percent (relative risk [RR] = 0.861, 95% confidence intervals [CI] 0.725–1.023; p = 0.08). HIV incidence was reduced by 1.5 percent among the 18- to 24-year-olds and by 25.4 percent (RR = 0.75; 95%CI 0.54–1.04, p = 0.08) in 25- to 32-year-olds.

Incidence was reduced by 11.6 percent in women (95%CI 0.73–1.07, p = 0.17) and by 19.3 percent in men (95%CI 0.57–0.15, p = 0.19). Women older than 24 years had a 30.2 percent reduction in incidence (95%CI: 0.54–0.90, p = 0.009). Younger men, older men, and younger women did not have enough incident cases to evaluate the intervention effect reliably. These results suggest a modest reduction in incidence in the intervention versus control communities and support new studies adding enhanced linkage to care and treatment as prevention to reduce community viral load and transmission.

ABOUT THE AUTHOR: Dr. Schouten, MD, JD, AAHIVE, is director of the Office of HIV/AIDS Network Coordination Project, Fred Hutchinson Cancer Research Center, Seattle, WA. He is a member of the HIV Specialist Editorial Advisory Group.
New US Report Suggests New Steps for Anti-AIDS Program

The U.S. initiative to fight AIDS should increase its programs, better target resources and focus more on prevention, says a new report from the Institute of Medicine (IOM) released in late February.

The report praised the President’s Emergency Plan for AIDS Relief (PEPFAR), citing the “millions of lives worldwide” that have been saved and improved by U.S. investments against AIDS. It also laid out a path for PEPFAR to build on its progress and increase effectiveness as countries seek to “sustainably manage the response to HIV.”

“PEPFAR has achieved—and in some cases surpassed—itself ambitious aims,” the report said. “That success has in effect ‘reset’ the baseline and shifted global expectations for what can be achieved in partner countries.”

The IOM said PEPFAR should take the long view in its efforts to fight HIV and AIDS, fostering delivery systems and best practices that will serve AIDS-ridden countries in the future. It also recommended that new policies tighten the links between diagnosis and treatment for HIV/AIDS patients and encourage treatment adherence. PEPFAR must also encourage a greater focus on prevention, targeted services and program monitoring in partner countries, the report said.

“As it moves forward, PEPFAR must continue to be bold in its vision, implementation, and global leadership,” said international health expert Robert Black, who led the study.

PEPFAR was launched by President George W. Bush in 2003 with $15 billion to spend against AIDS worldwide. It was subsequently reauthorized in 2008 with up to $39 billion through this year.

The HIV/AIDS Community Pays Tribute to the Surgeon General That Changed the Face of AIDS

BY VERONICA MILLER, PHD, EXECUTIVE DIRECTOR, THE FORUM FOR COLLABORATIVE HIV RESEARCH

As the nation and indeed the world says goodbye to Dr. C. Everett Koop, the 13th Surgeon General of the U.S., and one of the greatest public health leaders of all time, it is a good time to reflect on Dr. Koop’s leadership from the first days of the AIDS crisis to the end of Dr. Koop’s life when he advocated for accelerated HIV testing.

During to the 2010 National Summit on HIV Diagnosis, Prevention and Access to Care in Washington, Dr. Koop gave an hour-long and very candid address to the HIV/AIDS community reflecting his lessons learned over 25 years in combating HIV/AIDS. He talked about June 1981, when he first learned that five homosexual men in Los Angeles who were dying from Pneumocystis Carinii pneumonia, which he called “a disease so rare that a handful of cases in a single year is like an epidemic.” He then recounted learning a month later of 26 cases of homosexual men who were diagnosed with Kaposi’s sarcoma, an equally rare form of skin cancer.

Dr. Koop called these first cases “ground zero in the fight against HIV/AIDS” and recounted the rapid progression of this disease during the 1980s. By 1985, 12,000 cases had been reported; by 1986, the number had jumped to 16,000. A year later, there were 30,000 cases. He likened the contagion to the arrival and spread of smallpox and the bubonic plague in Europe in the Middle Ages.

But what makes Dr. Koop so remarkable is how he responded to this escalating crisis. Even though the virus remained a mystery for many years, Dr. Koop focused on the science, which showed that HIV is not contagious but rather, transmitted via blood or semen. And he used this understanding and his compassion as a physician to respond to politicians who called for a quarantine of AIDS patients and to overcome public fear at a time when Americans worried about contagion through casual contact in schools, restaurants and public restrooms.

In the face of a deadly epidemic, Dr. Koop was also bold. In 1986, he issued the famous Surgeon General’s report to the American people on just what the AIDS threat was all about. And long before there was the Internet, he turned the report into an eight-page pamphlet and sent it to all American households – 107 million at the time. He said that as Surgeon General, his job was to wage all-out war against disease, not people – which he did by giving Americans the facts in plain English, dispelling rumors and educating the public about how the disease is transmitted, who is at risk and what people could do to protect themselves.

After antiretroviral therapy changed the course of AIDS from a deadly disease to a chronic condition, Dr. Koop continued to press for research and became a vocal advocate for accelerated routine testing. And late in his life, he spoke out about against ignorance and complacency, which he called the “new front in the war against HIV/AIDS.” His takeaway observation was that the nation must remain aware and knowledgeable about HIV and the public health community must always be vigilant in its prevention and early detection efforts.

From this first days as Surgeon General to his last years of life, Dr. Koop was the Surgeon General that changed the face of AIDS. And he did it with candor, compassion and a respect for all people—gay and straight, married and unmarried, regardless of their race or creed. In every way, he was the “nation’s doctor” and the straight talk he gave to the American public combined with the care he gave to people with HIV/AIDS must always be what we in the HIV/AIDS community must aspire to.
The addition of Selzentry (maraviroc) and Isentress (raltegravir) to a standard triple drug antiretroviral cocktail rapidly suppresses HIV viral load in semen and significantly reduces the likelihood of intermittent, low level shedding of the virus in seminal fluid, aidsmap reports.

Researchers published their findings in the online edition of The Journal of Infectious Diseases of this study of 13 gay men who began this intensified therapy and 25 controls who took a standard triple-drug regimen of antiretrovirals (ARVs). None of the participants had a sexually transmitted infection (STI), which has been shown to cause viral shedding in semen.

After recent studies have shown that suppressing viral load drastically reduces the likelihood of transmissions, other research has identified individuals who maintain an undetectable viral load in their blood, but who still experience isolated HIV shedding (IHS) in their semen, raising the possibility that they still may be intermittently infectious. There have indeed been isolated reports of such transmissions.

Those taking the intensive therapy experienced more rapid viral suppression in their semen. IHS was found in more than one clinic visit in two participants (15 percent) on intensive therapy compared with 12 of the controls (48 percent). After one of the participants maintained an undetectable viral load in his blood but a detectable seminal viral load for 14 months after beginning intensified treatment, the investigators observed another cohort to find if there was viral shedding in men taking long-term therapy. They examined blood and semen samples from 26 men who had been on long-term standard ARVs, all of whom had no STIs and an undetectable viral load in the blood.

Among those in this group taking ARVs for less than six months, about half had intermittently detectable virus in their semen. Meanwhile, only 20 percent of those taking therapy for one to three years had detectable seminal virus; and none of those on treatment for more than three years did.
A RESEARCH TEAM from Case Western Reserve University School of Medicine has discovered an approach that could make gene therapy dramatically more effective for patients.

Led by professor Eric Arts, PhD, the scientists discovered that the process of gene therapy is missing essential elements thereby reducing the effectiveness of this treatment. Re-introducing this element into their model system suggests that improvements for gene therapy are on the horizon.

The findings are detailed in the article, “A new genomic RNA packaging element in retroviruses and the interplay with ribosomal frameshifting,” published February 15 in the journal Cell Host & Microbe.

Failure to distribute enough modified genetic information to the patient’s body has prohibited gene therapy from being more widely used, the article points out. Gene therapy relies mainly on viruses—which transport genomes inside the cells they infect—to deliver genetic material into a patient’s cells.

Unfortunately, the success rate of viral vectors is uneven. For instance, adenoviruses, a cause for the common cold, and lentiviruses, such as HIV-1, are routinely converted into viral vectors. But adenovirus vectors don’t last long, so therapy must be frequently re-administered. And lentiviral vectors, while stable, fail to deliver genetic material to enough defective human cells.

Dr. Arts, a professor of medicine in the Division of Infectious Diseases and HIV Medicine, learned that lentiviral carriers lack sufficient genetic material necessary for treatment. HIV-1, when converted from virus to lentiviral vector, loses a specific RNA element required to pack its “container” with its own genetic material to be effective. After identifying the problem, researchers introduced the element into a lentiviral vector, successfully and significantly improving the quality and quantity of the gene therapy.

Dr. Arts and colleagues named the genetic element, Genomic RNA Packaging Enhancer element (or GRPE). During virus production, GRPE coordinates the production and filling of the container with the genetic material of HIV-1, or the desired human gene.

Delivery and success of gene therapy for human cells has the potential of increasing five to ten times with the introduction of the GRPE into the lentiviral vector, according to the article.

“Using lentivirus for gene transfer appears to be a safe option,” said Stanton L. Gerson, MD, director of the Case Comprehensive Cancer Center and the Asa and Patricia Shiverick-Jane Shiverick (Tripp) Professor of Hematological Oncology at Case Western Reserve School of Medicine and director of the Seidman Cancer Center at University Hospitals Case Medical Center, who is not involved in the study. “This discovery could greatly advance the recent successes ongoing in cancer and childhood congenital diseases. Improvements in the technology of gene delivery identified by Arts and his colleagues could lead to many more effective studies that help patients with many different diseases, including cancer. Its impact could be felt in a few short years.”

ViiV Healthcare announces FDA priority review designation for dolutegravir as a potential treatment for HIV infection

ViiV Healthcare announced February 15 that the U.S. Food and Drug Administration (FDA) has granted a priority review designation to dolutegravir submitted for the treatment of HIV infection, in combination with other antiretroviral agents, in adults and adolescents. A priority review designation is granted to drugs that, if approved, have the potential to offer significant improvement compared to marketed products or provide a treatment where no adequate therapy exists. The FDA has assigned dolutegravir a Prescription Drug User Fee Act (PDUFA) target date of 17 August, 2013.

The new drug application (NDA) for dolutegravir was received by the FDA on 17 December 2012, and includes the results of four pivotal phase III clinical trials that treated a total of 2553 patients with HIV/AIDS across the treatment spectrum, from therapy naïve to salvage patients. Dolutegravir is in development and subject to evaluation of the benefits and risks by the regulatory authorities before it can be approved and made available on prescription.

ViiV Healthcare submitted a Marketing Authorisation Application (MAA) for dolutegravir to the European Medicines Agency (EMA) on 17 December, 2012.
HIV Prevention in Practice: Teachable Moments

SOME HIV-INFECTED PERSONS continue to engage in high-risk sexual behaviors, particularly unprotected anal or vaginal sex with multiple partners; and sex with anonymous partners. Some HIV-infected persons continue to participate in these unsafe behaviors even when they are knowledgeable about modes of HIV transmission and STD acquisition risks.

Among the reasons for persistent high-risk behavior in HIV-infected persons are a lack of critical information or motivation, inadequate skills needed to practice safer sex behaviors, uncertainty about specific behavior prevention, uncertainty about factors that may affect the risk of transmission with different sexual partners, and alcohol, drug use, or mental health issues. More effective prevention messages are needed to educate and motivate HIV-infected persons who engage in high-risk sexual behaviors to modify these behaviors.

Sexual Risk Modification

Sexual risk modification begins with a sexual history, which is taken at the initial visit and then at routine HIV medical care visits. A more recent sexual history should be obtained when patients present with STDs or are at risk for an STD. Our clinic participated in a study to improve understanding of the increasing incidence of bacterial STDs and to determine the potential effect of STDs on increased risk of HIV transmission in HIV-discordant partnerships among MSM. The results showed that STDs were diagnosed in a similar proportion of HIV-infected and HIV-negative MSM, and the rates did not differ between men with HIV-concordant and HIV-discordant partnerships.

These findings emphasize the need for interventions to foster serostatus discussion, condom use, fewer anonymous partners, and STD screening. STD testing itself can be a behavior education maneuver. For example, HIV-negative patients who present with gonorrheal or chlamydial urethritis should be told that HIV is transmitted in exactly the same way as these STDs are acquired, and that the event that transmitted this infection could transmit HIV in the future. So the clinical setting of STD diagnosis provides an opportunity to talk about the mode of HIV transmission and prevention.

Many HIV providers do not provide protracted risk reduction discussions because they assume that most MSM already know the mantra about condom use and other risk reduction strategies. Most conversations about risk reduction actually take place as the sexual history is elicited, asking patients: 1) whether they use condoms, 2) about the number of sexual contacts, 3) if they know the people with whom they are having sex, and 4) how they encounter partners. Risk screening can actually serve as the intervention, as patients realize that their behaviors put them at risk.

Brief HIV Prevention Messages Can Reduce High-Risk Behaviors

Studies have indicated that even brief interventions by HIV providers during routine clinical care can modify sexual risk behaviors. Fisher et al showed that a clinician-delivered “behavioral prescription” using the information-motivation-behavioral skills model of HIV prevention significantly (P<0.05) reduced unprotected sex among HIV-infected persons during 18 months of follow-up.

Gardner et al screened HIV-infected persons for behavioral risks and delivered targeted prevention messages at all routine visits. They found a significant (P<0.001) decline in unprotected intercourse that was directly related to the frequency of receipt of safer sex discussions.

Rose et al determined the effectiveness of assessing sexual risk behavior and delivering risk-reduction-oriented prevention messages over 6 months of follow-up to patients who reported risk behaviors with HIV-uninfected or unknown-status partners. Patients who received the risk-reduction intervention reported a significant (OR = 0.49; 95% CI = 0.26 to 0.92) decrease in the number of sexual partners.

Finally, Patel et al showed that routine brief risk-reduction messages by medical providers with biannual STD testing significantly reduced the incidence of STDs (including syphilis, chlamydia, and gonorrhea).

STD ACQUISITION IS RELATED TO BEHAVIORAL RISK

Because many STDs are asymptomatic, routine screening for STDs—especially syphilis, gonorrhea, and chlamydia—should be performed at baseline and at least annually for all sexually active HIV-infected persons. Diagnosis of an STD in an HIV-infected person indicates ongoing or recurrent high-risk behavior and should prompt prevention discussions or referral for counseling.

The majority of persons who acquire STDs, however, continue to become infected with new STDs, while a smaller percentage acquire only one STD. Persons in the former group are in the high-risk category and may be somewhat refractory to provider messages, while those in the latter group may simply have “slipped up” and are candidates for refresher discussions and debriefing about what led to the exposure despite generally practicing safe sex.

A new STD in an HIV-positive person has serious clinical implications, particularly because STDs can facilitate HIV transmission, increase viral load, and reduce the CD4 count. HCV can be a sexually transmitted infection. There has been a recent rapid and significant rise in the incidence of HCV...
in HIV-infected populations of MSM, particularly in some localities, and some data suggest transmucosal HCV transmission as a result of high-risk sexual behaviors. This is important, because HCV infection complicates the treatment of HIV. For example, HCV coinfection in patients with HIV infection may impair CD4-cell reconstitution in those who receive antiretroviral therapy.

Teachable Moments
The doctor-patient relationship is a key factor in reducing the risk of HIV transmission by HIV-infected persons. Long-standing, trusting professional relationships related to HIV treatment offer a particular opportunity to integrate prevention into care, but HIV-infected patients rarely initiate prevention discussions with their HIV care providers.

For this reason, it is imperative that medical providers make time during appointments to build this relationship and initiate prevention discussions. Prevention messages can be brief, and shorter messages are often better than longer ones. Although—as noted above—HIV-infected patients rarely initiate discussion of prevention, providers can take advantage of opportunities that may arise during clinical interviews.

To initiate a prevention discussion with an HIV-infected patient, clinicians must be alert for “teachable moments,” which can be defined as an opportunity to stimulate patient action, particularly with regard to health behavior change.

But physicians caring for HIV-positive patients often miss opportunities to deliver routine HIV prevention messages. For example, clinicians may be less likely to discuss prevention during ongoing care than during initial visits, and the delivery of prevention messages often drops off over time. Prevention messages should be given at every visit, and it should be considered a missed opportunity if prevention is not discussed. Prevention of HIV transmission is pertinent at all stages of HIV infection, so, please, listen for opportunities to deliver routine HIV prevention messages during all patient visits. Prevention topics can include condom negotiation, how to practice safer sexual behavior, limiting sex partners, and how to talk to partners about safer sex and HIV status.

Disclosure of HIV status is important because it allows partners to be included in the decision-making process by either allowing or not allowing potentially unsafe sex to occur. Tieu et al conducted a study to assess factors associated with serodiscordant or serostatus-unknown, unprotected intercourse among MSM, including disclosure of HIV status. A substantial proportion of the study participants did not reveal their HIV status, highlighting the need for interventions to encourage communication between HIV-infected patients and their partners.

Conclusions
HIV providers can help prevent HIV transmission by talking to their patients about HIV risk reduction, discussing the risky behaviors associated with HIV transmission and STD acquisition, and sharing the facts with patients so they can make informed and safer decisions about sexual behaviors.

References

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POLITICIANS IN WASHINGTON and business executives across the nation have come to learn that the Latino population in the United States is growing and is rapidly becoming a powerful force in both the political arena and the marketplace.

One major political candidate learned that the hard way last November, and businesses that fail to respond are losing share to those that recognize the importance of this growing economic powerhouse.

But there is another side to that story as Washington struggles with immigration reform and the corporate world tries to adapt and appeal to this expanding and diverse market, one with unique traditions, desires, and needs.

That is the story of millions of men and women who are disproportionately affected by HIV and whose unique traditions and needs must be recognized, understood, and effectively addressed by the HIV specialists who treat them—many of whom are not of their culture and may not speak their language.

On February 28, the Centers for Disease Control and Prevention (CDC) issued its 2011 HIV Surveillance Report, which details the state of HIV/AIDS in the United States through 2011. The report includes these conclusions and, thus, illustrates the challenges that confront HIV specialists every day:

- Latinos are disproportionately affected by HIV, and the rate of new infections among Latino men was two-and-one-half times as high as that of white men.
- In 2009, Latino MSM accounted for 81 percent (6,000) of new HIV infections among all Latino men and 20 percent among all MSM. Among Latino MSM, 45 percent of new HIV infections occurred in those under age 30.
- While Latina women accounted for 21 percent (2,000) of new infections among Latinos in 2009, their rate of HIV infection was more than four times that of white women.
- At some point in life, one in 36 Latino men will be diagnosed with HIV, as will one in 106 Latina women.
- In 2009, Latinos accounted for 19 percent of the 42,959 new diagnoses of HIV infection in the 40 states and five U.S. territories with long-term confidential name-based HIV infection reporting.
- By the end of 2008, an estimated 111,438 Latinos with an AIDS diagnosis had died in the U.S. and dependent areas. In 2007, HIV was the fourth leading cause of death among Latinos aged 35-44 and the sixth leading cause of death among Latinos aged 25-34 in the U.S.

Prevention Challenges
The report cites several factors that contribute to the HIV epidemic in Latino communities.

Behavioral risk factors for HIV infection differ by country of birth. Data suggest that the highest percentages of diagnosed HIV infections among Latino men are attributed to sexual contact with other men, regardless of place of birth, but men born in Puerto Rico have a substantially larger percentage of diagnosed HIV infections attributed to injection drug use than Latino men born in other countries.

Latino men and women are most likely to be infected with HIV as a result of sexual contact with men. Latina women may be unaware of their male partner’s risk factors.

Injection drug use continues to be a risk factor for Latinos, particularly those living in Puerto Rico. In addition, both casual and chronic substance users may be more likely to engage in risky sexual behaviors, such as unprotected sex, when they are under the influence of drugs or alcohol.

The presence of certain sexually transmitted infections (STIs) can significantly increase one’s chances of contracting HIV infection. A person who has both HIV infection and certain STIs has a greater chance of infecting others with HIV. The rates of STIs remain high among Latinos.

Cultural factors may affect the risk of HIV infection. Some Latinos may avoid seeking testing, counseling, or treatment if infected out of fear of discrimination, stigmatization or...
immigration status. Traditional gender roles and the stigma around homosexuality may add to prevention challenges.

Greater acculturation into the US culture has both negative (engaging in behaviors that increase the risk for HIV infection) and positive (communicating with partners about practicing safer sex) effects on the health behaviors of Latinos.

Socioeconomic factors such as poverty, migration patterns, lower educational attainment, inadequate health insurance, limited access to health care or language barriers add to Latino HIV infection rates. These factors may limit Latinos’

Due to fear of disclosure, undocumented immigrants may be less likely to access HIV prevention services, get an HIV test, or receive adequate treatment and care if living with HIV.

In the following pages, you will find articles written by your peers from around the nation who are meeting these challenges. They include physicians, a nurse practitioner, a pharmacist—all of whom discuss the obstacles they confront and how they are responding. You will find an overwhelming sense of satisfaction expressed in their words, as well as words of concern, even outrage, as they discuss the challenge of treating patients, many of whom must live in the shadows for fear of deportation and separation from their loved ones.

Yes, there are language problems that can become a barrier to care if not addressed appropriately. But there are cultural issues, traditions, and economic factors, even some unique medical conditions that must be understood, recognized and dealt with. Indeed, racism, classism, sexism, homophobia, all must be confronted. Some of our authors are Latinos themselves, but not all, and those practitioners share their experiences as they treat patients desperately in need of help who are so different from themselves.

We hope you find the following pages enlightening and informative, as they bring the cold, hard facts found in this latest CDC report to life. We invite your comments—and express our deep appreciation to our authors who have shared their experiences with us.

Please note: Many of the articles that follow were written before the release of the CDC’s 2011 Surveillance Report and cite statistics available prior to that time. While the numbers have changed in some instances, the circumstances and the facts surrounding them remain the same.

Bob Gatty, Editor, HIV Specialist, can be reached at bob@gattyedits.com.
Gustavo had initially left his native Michoacan (Mexico) in 2007, fleeing the increasingly violent drug war and its surrounding poverty. His hope, like all those who had migrated north (el Norte) before him, was to find steady work in the United States, enabling him to send money back to his impoverished family.

After an arduous, life-threatening crossing of the border, he found employment in housekeeping at a hotel in the rural South. Gustavo’s hopes were crushed in 2009 when after several weeks of increasing fatigue and fever, he was hospitalized and told he had AIDS, and was subsequently treated for extra-pulmonary tuberculosis.

With this life-changing event, Gustavo joined the over 7000 Latinos in the U.S. who were diagnosed with AIDS in 2009 (CDC). HIV/AIDS has now become the fourth leading cause of death among Latinos in the 35-44 age group, and the rate of new infections among Latino men today far exceeds that of white me.

As those of us who provide HIV care on a regular basis see more and more Latino men and women in our clinics, new challenges surface as we deal with a disease that we know so well, but now in a people and culture which for many of us are quite new and foreign.

Why is the rate of infection among Latinos increasing? Why do so many, like Gustavo, present to us at such late stages of the disease? What new challenges do their cultural differences, language and belief systems bring to our established ways of providing care and understanding this epidemic? How can these challenges be seen instead as the unique gifts to our practices, which they truly are?

HIV Among Latinos in the United States

It is clear that Latinos are disproportionately affected by HIV/AIDS in the U.S. Statistics show that 10,159 Hispanics were diagnosed with HIV in 2011. In 2011, Latinos accounted for 21 percent of new infections in this country while representing only 16 percent of the population. This infection rate is most dramatically affecting the Latino men who have sex with men (MSM) population. In the same year, Latino MSMs accounted for nearly 7 in 10 (68 percent) new HIV infections.
among Latinos overall and nearly 8 in 10 (79 percent) new infections among Latino men. Among women, Latinas accounted for 1,400, or 15 percent of new HIV infections, and their HIV incidence rate was more than 4 times the rate for white women according to the CDC 2011 Surveillance Report.

More concerning than even these startling demographics are the number of late testers we encounter in the Latino community. A “late tester” is defined as a person whose HIV+ diagnosis is made through HIV testing less than one year before they receive an AIDS diagnosis—defined by the CDC as a CD4+ count of less than 200, or through the development of an AIDS-defining opportunistic infection.

In 2006, 42 percent of Latinos diagnosed with HIV infection developed AIDS within 12 months. This rate, approaching 50 percent, was higher than any other racial or ethnic group. Like Gustavo, most of these individuals sought testing or had an HIV test performed because of a presenting illness or hospitalization.

### Barriers to Care

What are the cultural and societal barriers that prevent these high-risk Latinos from receiving more effective HIV prevention education? What are the cultural taboos and stigmas attached to HIV/AIDS, and the risk behaviors that cause it, which might be unique to the Latino population? What accounts for the remarkably high rate of late HIV testers in the Latino population?

A key resource in beginning to understand these issues lies in Rafael Diaz’ and George Ayala’s landmark study, “Social Discrimination and Health: The Case of Latino Gay Men and HIV Risk.”

Diaz and Ayala, building on the well-known work of Dr. Paul Farmer, place both HIV/AIDS disease prevalence and care outcomes in the context of existing social inequalities, commenting that “preventable diseases and deaths are far more common among the poor and the disenfranchised” (p vi). They identify three primary forms of social discrimination found within varying Latino communities—homophobia, racism and poverty—and they describe these as further “borders” to care. These borders are different from “la frontera,” the existing U.S. border, but they can be as dauntingly insurmountable.

“Borders are embedded in racism, sexism, homophobia and classism,” Juan Carlos Velazquez points out in the study’s preface (Diaz & Ayala, p. iv).

Border “patrols,” found both within and without the cultural group in the form of critical parents, church, homophobia, Immigration and Customs Enforcement (ICE), a wave of anti-immigrant and English-only laws... all slowly chip away at the self-esteem of the Latino immigrant community and even more specifically at gay Latino men, the group with the highest HIV infection rate (Diaz & Ayala, p.v).

Their research substantiates their theory that all of these border issues can lead to higher rates of risky behavior among gay Latino men. In the end, these factors can ultimately result in a prevailing sense of doom and an overriding perception...
individual within a regional setting can provide one with "Where are you from" ("De donde es?). This locating of an individual's country of origin and its unique culture. One of cultural beliefs, background and story.

approaching each patient as an individual, with unique cultural beliefs, background and story.

A primary factor driving these differences is the Latino patient's country of origin and its unique culture. One of the first questions Latinos will often ask of each other is "Where are you from" ("De donde es?"). This locating of an individual within a regional setting can provide one with an immense amount of information, including a sense as to the historical politics and economics of the country they have left behind, including poverty, war, persecution and vital family members.

If the Latino patient is native to the U.S., his or her parents' country of origin and culture remains vitally important in understanding their approach to their illness and engagement in care. Born and raised in the U.S., the native Latino will most likely more resemble our other patients in their knowledge and use of the healthcare system and our surrounding culture.

But the "borders" that Diaz and Ayala have explored, both internal and external to their family and cultural systems, will continue to influence their relationship with the medical provider and their engagement in care. In the end, it is beneficial in this patient-provider relationship to understand that, although each are Latino, a Puerto Rican from East Harlem, a young Mexican-American from East L.A. and an undocumented immigrant from El Salvador remain very distinct from each other with unique cultural and family backgrounds that influence their approach to this disease. Our understanding of this improves our relationship with them and ultimately their care outcomes.

There are many other factors which may also influence the Latino individual's approach to their daily life and their need for consistent healthcare with an HIV-positive diagnosis. It is helpful to know which generation of immigrant they are.

If the person is first generation American, what was his or her reason for leaving the homeland? It can often be helpful to know how his or her crossing of the border went, as this can often be a complicated journey filled with emotion, trauma and violence. For some, it may be at this border crossing where his or her initial exposure to HIV occurred, described in stories of rape or sex with impoverished sex workers who are also victims of the border situation.

Similarly, it is important to know how long the individual has lived in the U.S., where he or she lived prior to coming to our region, and what other family members live in the U.S. These questions can often reveal lives filled with isolation, violence, poverty, trauma and persecution, either in their past or current situations. The patient's answers also can help in our eliciting and addressing continued high risk behaviors and may be an entryway into diagnosing mental health disorders such as PTSD or depression and determining the subsequent need to involve behavioral health in the provision of care.

Knowledge of these factors in your patients' lives, a knowledge that can be developed over several clinical visits, facilitates a deeper trust or "confianza" between the patient

Latino Communities

In working with the Latino population, over time one can become more keenly aware that there is not one distinct Latino culture or community, but many. The importance of understanding this is that in this wide variety of "peoples," there exist just as many beliefs and barriers which can affect the individual's ability to care for their HIV disease.

These belief systems can be influenced by a patient's family and their place within it, religion, immigration status, gender, and sexuality among others. These factors help determine in many ways how they perceive and deal with their HIV-positive status and how they receive the healthcare information we provide. Ultimately, by gaining a deeper understanding of the unique qualities present in the variety of Latino cultures, healthcare providers can move beyond seeing each patient simply as another "Latino" and anticipating the resulting need for an interpreter. Our growing understanding allows us to "interpret" the clinical visit, approaching each patient as an individual, with unique cultural beliefs, background and story.

A primary factor driving these differences is the Latino patient's country of origin and its unique culture. One of the first questions Latinos will often ask of each other is "Where are you from" ("De donde es?"). This locating of an individual within a regional setting can provide one with
and provider. This trust, of course, has an indirect impact on the individual’s adherence to care and therapy, which is vital in HIV management. Beyond this constant theme of adherence; however, we must recognize that our ultimate goal must include the empowerment and restoration.

**Practical “Tips” for Providers**

As Latino patients present to us with a unique set of challenges, we as HIV specialty providers can work to acquire a distinct set of tools to provide them with integrated care. These tools of course vary from region to region, but there are some basics:

- **Speak the language.** Although for many of us who are new to Spanish, this can be a daunting thought; it is extremely important. Even if we approach the patient with broken, poorly-accented wording, our effort to speak their language builds respect and removes one of the most significant borders preventing a trusting patient-provider relationship. It is only by holding our clinical visits in their language that we can hope to explore the intricacies and unique complexities of their lives amidst their HIV disease. There are many language immersion programs that can benefit medical providers, but the most useful and most affordable immersion opportunity is the one that walks into your clinic every day. Many may also choose to utilize the variety of translation apps now available.

- **Understand the immigration issue and become involved.** This is the biggest concern facing the majority of our Latino patients today, whether it involves them directly or a family member. For many of our patients, even simply traveling to and from their clinic visits places them at risk of encountering a law enforcement officer and the resulting possibility of deportation. Patients lose family members and loved ones overnight to current immigration policies and the deportation of individuals innocent of committing any crime. It is not essential to know our patients’ immigration status, but it is essential to understand that for many of them, and for many of their family members and partners, this is a vital issue. Remaining up-to-date on both the federal government’s and our own state’s ever-changing immigration policies helps us to understand how these play out in our patients’ lives and allows us, as Diaz and Ayala pointed out, to become agents for social change.

- **Read Rafael Diaz’ and George Ayala’s “Social Discrimination and Health: The Case of Latino Gay Men and HIV Risk,” easily available in PDF-format on-line.** It is an extremely fascinating and helpful study which examines HIV disease in context of its larger social settings and challenges us as HIV medical providers to move beyond providing care in our clinics and becoming advocates for greater social change.

- **Understand the unique qualities of the varying Latino cultures.** Start to seek out the things that make each Latino group distinct. Attend Latino cultural events outside of our work. Learning more about a given country or region, its history and its current socio-political situation can only give us further information about our patients. We are where we come from.

This is where we can begin. As we care for more Latinos in our HIV practice, we can gain a deeper understanding of the unique challenges they present to us in relation to both their HIV disease and their psychosocial needs. In the end, caring for the wide spectrum of Latino patients can only enrich us and further our commitment to providing care amidst this continuing epidemic.

**References**


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Challenges of Care on the Border

BY THEO KATSIVAS, MD, AAHIVS
I have been working at San Ysidro Health Center at the HIV Primary Care Program for about 60 percent of my clinical time under a contract with our University of California San Diego Owen Clinic. As academic faculty doing research and working in a U.S./Mexico Border area clinic in Southern California, I have first-hand experience related to Latino/Hispanic HIV care.

My work involving HIV began in 1999 as an Internal Medicine trainee physician and since 2004 I’ve been on staff as Internist/Infectious Disease specialist at USCD’s Owen Clinic, which offers HIV care services to over 3,000 patients, about 25 percent of whom are Latino/Hispanic. At the San Ysidro Health Center, we have some 700 patients, about 95 percent of whom are Latino/Hispanic. I also offer volunteer work on HIV care, across the border in Tijuana, where conditions are quite different from those in the U.S.

Unfortunately, the virus disproportionately affects Mexican Americans and other Latinos who live in the U.S., and that includes women. Women who come in for prenatal screening are sometimes found to be HIV positive and, at the same time, discovering that their primary partner is bisexual/MSM and has been positive for some time. So, clearly, testing is an issue with our population here.

Stigma is a difficult problem as well. There is sometimes an attitude that a man’s primary sexual relations are at home, but he can do whatever he wants outside the home. Obviously, prevention messages simply do not reach this population.

Once a patient is diagnosed, getting into care is easy, and in Southern California, language is usually not a barrier. At our San Ysidro clinic, most of our providers are bilingual or Spanish speaking, and our clinic seems to have great outcomes. Having providers who speak the language and are culturally sensitive to caring for Latino/Hispanic patients is a key to our success.

Family, Community Support
Caring for Latinos is one of the most rewarding things that has happened in my professional life. I find that my patients are extremely grateful for care and have amazing support within community and family. Once the shock of diagnosis is over, families usually rally around the family member who is affected.

I have witnessed amazing stories of people who support their gay son who just came out and is infected. I have had very interesting discussions with several partners as well as families that came together to support their loved one who is now a patient. That is a very positive thing.

At our program at San Ysidro, we are actively involved in setting up support groups, therapy sessions, group therapy, social support, cooking classes, and social outings. So the community is addressing the problem of HIV infection. But, on the other side of the border, there is much more stigma and there are more issues with access to care, as well as testing services.

Most of our patients in the San Ysidro Clinic are virologically controlled (ie they are undetectable). However, our two main barriers are substance abuse and mental health issues. Access to services for the treatment for those issues are problematic. It is difficult for me to link patients to a psychiatrist, with waits often as long as three or four months. Sometimes I have to treat mental health problems in the primary HIV care clinic with the consulting help of my Psychiatrist colleagues, until they can get an appointment slot to see the patient.

Another treatment barrier involves Mexican immigrants who return to Mexico from the U.S. Although returning immigrants will have access to care, the truth is that this care often is lacking. It is not easy to have a steady supply of ARV treatment available all the time. Sometimes it is discontinued. I have witnessed stories of lack of ARV regimens and the availability of medication for returning migrants and deportees who are sent back or decide to go back to Mexico.

The use of alternative and herbal medications for HIV care occurs often in Latinos, and I have heard horror stories of extreme abuse of those medications, especially across the border. There are clinics that treat HIV with “oxygen treatment” or “silver salt” intravenous infusions. Sometimes these patients end up in our hospital. I am not opposed to using alternatives treatments as complementary to ARVs, but would like to see solid study results on the efficacy of those treatments. I support my patients having acupuncture, massage and perhaps regular herbal teas of some sort. But some herbs are presented as a miracle cure, and that ends up being a barrier to care. I am very cautious of my patients using such alternatives to care and am not happy when I hear about them using these herbal medications.

I am happy to be working with this population and being the main provider who serves our San Diego-Tijuana border area. It is challenging work, but satisfying to see the community rallying around patients and helping to form a close knit, successful program.

About the Author: Theodoros Katsivas, MD, AAHIVS, is Assistant Clinical Professor, specializing in Internal Medicine/Infectious Disease at the UCSD Medical Center, Owen Clinic in San Diego, CA. He can be reached at (619) 543 3995 or tkatsivas@ucsd.edu
INDICATION

ATRIPLA® (efavirenz 600 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate [DF] 300 mg) is indicated for use alone as a complete regimen or in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients at least 12 years of age and weighing ≥40 kg (88 lbs).

SELECTED IMPORTANT SAFETY INFORMATION

WARNING: LACTIC ACIDOSIS/SEVERE HEPATOMEGALY WITH STEATOSIS and POST TREATMENT EXACERBATION OF HEPATITIS B

Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs, including tenofovir DF, a component of ATRIPLA, in combination with other antiretrovirals. ATRIPLA is not approved for the treatment of chronic hepatitis B virus (HBV) infection, and the safety and efficacy of ATRIPLA have not been established in patients coinfected with HBV and HIV-1. Severe acute exacerbations of hepatitis B have been reported in patients who have discontinued EMTRIVA® (emtricitabine) or VIREAD® (tenofovir DF), which are components of ATRIPLA. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who are coinfected with HIV-1 and HBV and discontinue ATRIPLA. If appropriate, initiation of anti-hepatitis B therapy may be warranted.

* Baseline viral load >100,000 copies/mL.
† Baseline viral load ≤100,000 copies/mL.
‡ Study 934: A randomized, open-label, active-controlled, multicenter study comparing tenofovir disoproxil fumarate (TDF) 300 mg + emtricitabine (FTC) 200 mg vs zidovudine (AZT) 300 mg/ lamivudine (3TC) 150 mg, in combination with EFV 600 mg, in 511 antiretroviral-naive patients. From weeks 98 to 144, patients received TDF/FTC fixed-dose combination in place of TDF + FTC. Mean baseline CD4+ cell count was 245 cells/mm³ and median baseline HIV-1 RNA was 5.01 log₁₀ copies/mL. TLOVR analysis (N=487) excluded 22 patients with baseline NNRTI resistance and 2 patients who were treatment experienced.²
§ Other reasons for discontinuation include lost to follow-up, patient withdrawal, noncompliance, protocol violation, and other reasons.
ATRIPLA (efavirenz/emtricitabine/tenofovir disoproxil fumarate): a single-tablet HIV regimen that provides powerful efficacy and demonstrated long-term data through 3 years¹

#1 prescribed HIV regimen for 5 years, with over 5 million prescriptions written²,³

In a 3-Year Clinical Trial in Treatment-Naive Adult Patients¹,⁴...

- Powerful and reliable virologic control through 3 years in patients with high* and low† baseline viral loads¹,⁴
  — In Study 934, 84% of treatment-naive adult patients taking ATRIPLA as its components (n=244) achieved viral load <400 copies/mL vs 73% with Combivir® (zidovudine/lamivudine) + EFV (n=243) through 48 weeks (primary endpoint).¹ The difference in the proportion of patients who achieved and maintained HIV-1 RNA <400 copies/mL through 48 weeks largely resulted from the higher number of discontinuations due to adverse events and other reasons¹ in the Combivir group in this open-label study. Through 144 weeks, 71% of patients taking ATRIPLA (n=227) maintained viral load <400 copies/mL vs 58% with Combivir + EFV (n=229), 73% (88/120) of patients taking ATRIPLA with high baseline viral load* achieved and maintained viral load <400 copies/mL vs 59% (66/112) with Combivir + EFV, and 68% (73/107) of patients taking ATRIPLA with low baseline viral load† achieved and maintained viral load <400 copies/mL vs 57% (67/117) with Combivir + EFV¹,⁴

- Low rate (3%) of virologic failure¹,⁴
  — In Study 934, 3% of treatment-naive adult patients taking ATRIPLA (n=227) experienced virologic failure vs 6% with Combivir + EFV (n=229) through 144 weeks¹,⁴

- Low percentage of patients developed NNRTI (5%) and NRTI (1%) resistance-associated mutations⁴
  — In Study 934, through 144 weeks, resistance to EFV occurred in 5% (n=13) of patients in the ATRIPLA arm and 9% (n=21) of patients in the Combivir + EFV arm, primarily caused by the K103N mutation. The M184V/I mutation, associated with resistance to FTC, was observed in 1% (n=2) of patients in the ATRIPLA arm and 3% (n=6) of patients in the Combivir + EFV arm. No patients developed the K65R mutation, which is associated with reduced susceptibility to tenofovir⁴

- Demonstrated long-term safety and tolerability profile, with a low rate (5%) of discontinuation due to AEs¹,⁴
  — In Study 934, through 144 weeks, the most frequently reported Grade 2-4 adverse reactions reported in ≥5% of subjects receiving ATRIPLA were diarrhea (9%), nausea (9%), fatigue (9%), depression (9%), dizziness (8%), sinusitis (8%), upper respiratory tract infection (8%), rash event (6%), headache (6%), insomnia (5%), anxiety (5%), and nasopharyngitis (5%)¹
  — Through 144 weeks, 5% of patients in the ATRIPLA group discontinued due to adverse events vs 12% in the Combivir + EFV group; discontinuation for other reasons was 20% in the ATRIPLA group and 22% in the Combivir + EFV group⁴
  — The most common adverse reactions that led to discontinuations were: investigator-defined insomnia (n=2; <1%) and rash (n=2; <1%) in the ATRIPLA arm; investigator-defined anemia (n=14; 6%) in the Combivir + EFV arm⁴

Please see Important Safety Information, including Boxed WARNINGS, and Brief Summary of Full Prescribing Information on the following pages.

ATRIPLA®
(efavirenz 600 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) Tablets

AE = adverse event; EFV = efavirenz; FTC = emtricitabine; NNRTI = non-nucleoside reverse transcriptase inhibitor; NRTI = nucleoside reverse transcriptase inhibitor; TLOVR = time to loss of virologic response.
ATRIPLA is not approved for the treatment of chronic hepatitis B virus (HBV) infection, and the safety and efficacy of ATRIPLA have not been established in patients coinfected with HBV and HIV-1. Severe acute exacerbations of hepatitis B have been reported in patients who have discontinued EMTRIVA® (emtricitabine) or TRUVADA® (emtricitabine/tenofovir DF), which are components of ATRIPLA. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who are coinfected with HIV-1 and HBV and discontinue ATRIPLA. If appropriate, initiation of anti-hepatitis B therapy may be warranted.

Contraindications

- ATRIPLA is contraindicated in patients with previously demonstrated clinically significant hypersensitivity (e.g., Stevens-Johnson syndrome, erythema multiforme, or toxic skin eruptions) to efavirenz, a component of ATRIPLA.
- Coadministration of ATRIPLA with bepridil, cisapride, midazolam, pimozide, triazolam, or ergot derivatives is contraindicated, since competition for CYP3A by efavirenz could result in inhibition of metabolism of these drugs and create the potential for serious and/or life-threatening adverse reactions.
- ATRIPLA should not be administered concurrently with voriconazole because of significantly decreased voriconazole plasma concentrations and significantly increased efavirenz plasma concentrations.
- Concomitant use of ATRIPLA with St. John's Wort (Hypericum perforatum) or St. John's Wort-containing products is not recommended since this may lead to loss of virologic response and possible resistance to efavirenz or to non-nucleoside reverse transcriptase inhibitors (NNRTIs).

Warnings and Precautions

- Efavirenz plasma concentrations may be altered by substrates, inhibitors, or inducers of CYP3A. Efavirenz may alter plasma concentrations of drugs metabolized by CYP3A or CYP2B6.
- Since ATRIPLA contains emtricitabine and tenofovir DF, ATRIPLA should not be coadministered with COMPLERA® (emtricitabine/riplevirine/tenofovir DF), EMTRIVA® (emtricitabine), TRUVADA® (emtricitabine/tenofovir DF), or VIREAD® (tenofovir DF). Since ATRIPLA contains efavirenz, ATRIPLA should not be coadministered with Stivalc® (efavirenz) unless needed for dose-adjustment when coadministered with rifampin. Due to similarities between emtricitabine and lamivudine, ATRIPLA should not be coadministered with drugs containing lamivudine, including Combivir® (lamivudine/zidovudine), Epivir® or Epivir-HBV® (lamivudine), Epzicom® (abacavir sulfate/lamivudine), or Truvada® (abacavir sulfate/lamivudine), or Trizivir® (abacavir sulfate/lamivudine/zidovudine). ATRIPLA should not be administered with Hepsera® (adefovir dipivoxil).
- Serious psychiatric adverse experiences, including severe depression (2.4%, 0.9%), suicidal ideation (0.7%, 0.3%), nonfatal suicide attempts (0.5%, 0%), aggressive behavior (0.4%, 0.3%), paranoid reactions (0.4%, 0.3%), and manic reactions (0.1%, 0%) have been reported in patients receiving efavirenz and placebo regimens, respectively. In addition to efavirenz, factors identified in a clinical trial that were associated with an increase in psychiatric symptoms included a history of injection drug use, psychiatric history, and use of psychiatric medication. There have been occasional reports of suicide, delusions, and psychosis-like behavior, but it could not be determined if efavirenz was the cause. Patients with serious psychiatric adverse experiences should be evaluated immediately to determine whether the risks of continued therapy outweigh the benefits.
- Fifty-three percent of patients reported central nervous system (CNS) symptoms (including dizziness [28.1%], insomnia [16.3%], impaired concentration [8.3%], somnolence [7.0%], abnormal dreams [6.2%], and hallucinations [1.2%]) when taking efavirenz compared to 25% of patients receiving control regimens. These symptoms usually began during Days 1-2 of therapy and generally resolve after the first 2-4 weeks of therapy; they were severe in 2.0% of patients, and 2.1% of patients discontinued therapy. After 4 weeks of therapy, the prevalence of CNS symptoms of at least mild severity had decreased to 4.1% in patients receiving efavirenz compared to 12% in patients receiving control regimens containing efavirenz. Nervous system symptoms are not predictive of the less frequent psychiatric symptoms. Patients receiving ATRIPLA should be alerted to the potential for additive CNS effects when ATRIPLA is used concomitantly with alcohol or psychoactive drugs. Patients with CNS symptoms such as dizziness, impaired concentration, and/or drowsiness should avoid potentially hazardous tasks such as driving or operating machinery.
- It is recommended that creatinine clearance (CrCl) be calculated in all patients prior to initiating therapy and as clinically appropriate during therapy with ATRIPLA, and routine monitoring of CrCl and serum phosphorus be performed for patients at risk for nephrotoxicity and, in particular, patients with a history of renal disease or diabetes, or patients who have experienced renal events while receiving adefovir dipivoxil. ATRIPLA should not be given to patients with CrCl <50 mL/min. Renal impairment, including cases of acute renal failure and Fanconi syndrome (renal tubular injury with severe hyperphosphatemia), has been reported in patients treated with tenofovir DF. ATRIPLA should be avoided in patients with the use of nephrotoxic agents.

ADVERSE REACTIONS

- ATRIPLA (efavirenz/emtricitabine/tenofovir disoproxil fumarate) may cause fatal harm when administered during the first trimester to a pregnant woman. Women should not become pregnant or breastfeed while taking ATRIPLA. Barrier contraception must always be used in combination with ATRIPLA (e.g., oral or other hormonal contraceptives). Because of the long half-life of efavirenz, adequate contraceptive measures are recommended for 12 weeks after discontinuation of ATRIPLA. If the patient becomes pregnant while taking ATRIPLA, she should be apprised of the potential harm to the fetus.
- Mild-to-moderate rash is a common side effect of efavirenz. In controlled clinical trials in adults, 26% of patients treated with efavirenz experienced new-onset skin rash compared with 17% of patients treated in control groups. ATRIPLA should be discontinued in patients developing severe rash associated with blistering, desquamation, mucosal involvement, or fever. Rash was reported in 45% (26/57) of pediatric patients receiving efavirenz. Grade 3 or 4 rash was reported in 5% of pediatric patients compared to 0.9% of adults receiving efavirenz.
- Liver enzymes should be monitored before and during treatment in patients with underlying hepatic disease, including hepatitis B or C infection; in patients with marked transaminase elevations; and when ATRIPLA is administered with (e.g., oral or other medications associated with liver toxicity. A few of the postmarketing reports of hepatic failure, including cases in patients with no pre-existing hepatic disease or other identifiable risk factors, were characterized by a fulminant course, progressing in some cases to transplantation or death. Liver enzyme monitoring should be considered for patients without pre-existing hepatic dysfunction or other risk factors.
- Bone mineral density (BMD) assessment should be considered for patients who have a history of pathologic bone fracture or other risk factors for osteoporosis or bone loss. Decreases in BMD have been seen with tenofovir DF. Cases of osteomalacia (associated with proximal renal tubulopathy and which may contribute to fractures) have been reported in association with the use of tenofovir DF. Use ATRIPLA with caution in patients with a history of seizures. Convulsions have been observed in patients receiving efavirenz, generally in the presence of known medical history of seizures.
- Immune reconstitution syndrome has been reported in patients treated with combination antiretroviral therapy, including the components of ATRIPLA. Autoimmune disorders (e.g., Graves’ disease, polymyositis, and Guillain-Barré syndrome) have also been reported to occur in the setting of immune reconstitution; however, the time to onset is more variable, and can occur many months after initiation of treatment.
- Redistribution/accumulation of body fat has been observed in patients receiving antiretroviral therapy.

Drug Interactions

- Coadministration of ATRIPLA with didanosine should be undertaken with caution. Patients receiving this combination should be monitored closely for didanosine-associated adverse reactions.
- Lopinavir/ritonavir has been shown to increase tenofovir concentrations. Patients on lopinavir/ritonavir plus ATRIPLA should be monitored for tenofovir-associated adverse reactions. ATRIPLA should be discontinued in patients who develop tenofovir-associated adverse reactions.
- Coadministration of ATRIPLA and atazanavir is not recommended. Efavirenz and tenofovir DF have been shown to decrease concentrations of atazanavir. Atazanavir has also been shown to increase tenofovir concentrations.
- Saquinavir should not be used as the only protease inhibitor in combination with ATRIPLA.

See Full Prescribing Information for complete list of drug-drug interactions.

Hepatic Impairment

ATRIPLA is not recommended for patients with moderate or severe hepatic impairment because of insufficient data; use in patients with mild hepatic impairment.

Dosage and Administration

The dose of ATRIPLA for patients at least 12 years of age and weighing ≥40 kg (88 lbs) is 1 tablet (containing 600 mg of efavirenz, 200 mg of emtricitabine, and 300 mg of tenofovir DF) once daily taken orally on an empty stomach. Dosing at bedtime may improve the tolerability of nervous system symptoms. ATRIPLA is not recommended for use in patients ≥12 years of age or in patients with CrCl <50 mL/min. When ATRIPLA is administered with rifampin to patients weighing ≥60 kg, an additional 200 mg/day of efavirenz is recommended.

See Brief Summary of Full Prescribing Information, including Boxed WARNINGS, on the following pages.

References:
1. ATRIPLA [package insert]. Foster City, CA: Bristol-Myers Squibb & Gilead Sciences, LLC; 2012. Source: Bristol Myers Squibb. All other trademarks are owned by third parties.
3. Bristol-Myers Squibb Company. ATRIPLA is a registered trademark of Bristol-Myers Squibb & Gilead Sciences, LLC. SUSTIVA is a registered trademark of Bristol-Myers Squibb Company. All other trademarks are owned by third parties.

Bristol-Myers Squibb
Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with

Nervous System Symptoms: Fifty percent (531/1008) of subjects receiving

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Indications and Usage

ATRIPLA is contraindicated in patients with previously demonstrated clinically significant hypersensitivity (e.g., Stevens-Johnson syndrome, erythema multiforme, or toxic skin eruptions) to efavirenz, a component of ATRIPLA. Clinical Experience with efavirenz in subjects who discontinued other antiretroviral agents

Nausea, headache, dizziness, somnolence, pruritus, telemere and injection site, are the most common events associated with the use of efavirenz in patients treated with efavirenz containing regimen. Efavirenz, in combination with tenofovir DF, is associated with an increased risk of bone effects (osteopenia, osteoporosis) in pediatric subjects. Under normal conditions, the risk of bone effects is similar to adults.

Subjects with baseline creatinine clearance ≥50 mL/min were treated with efavirenz + lamivudine + zidovudine or efavirenz + lamivudine + zidovudine + zalcitabine. Subjects were randomized to receive lamivudine + zidovudine or lamivudine + zidovudine + zalcitabine. In Study 356, mean reductions in BMD of -0.347 for the lumbar spine and -0.458 for total body. Skeletal growth (height) appeared to be unaffected. Markers of bone turnover in tenofovir DF-treated pediatric subjects

In a pediatric clinical trial in adults, 26% (266/1008) of subjects treated with 600 mg efavirenz were reported in 5% (3/57) of pediatric subjects compared to 0.9% of adults

In Study 073, subjects with stable, virologic suppression on antiretroviral therapy who were randomized to receive ATRIPLA or to stay on their current therapy were followed for 12 weeks after discontinuation of ATRIPLA. In both groups, the majority of the reduction in BMD occurred in the first 24-48 weeks of the trial and this reduction was sustained through the end of the trial.

Pregnancy should be avoided in women receiving ATRIPLA. Barrier contraception and other measures to avoid pregnancy should be strongly encouraged. In patients with pre-existing hepatic disease or other identifiable risk factors

Clinically relevant fractures (excluding fingers and toes) were reported in 4 subjects

Adverse Reactions from Clinical Trials Experience: Clinical Trials in Adult Subjects - Study 934 was an open-label active-controlled trial in which 57 adults with prior exposure to nevirapine or efavirenz who had experienced virologic failure were randomized to receive ATRIPLA or to stay on their current therapy. The median time to onset of rash in pediatric subjects was 8 days.

Evaluations of bone mineral density (BMD) in children 8-15 years of age demonstrated that the mean percent change from baseline to study end in BMD was -1.1% for LS and -0.8% for total body. There was a significantly greater mean percentage decrease from baseline to BMD in the lumbar spine in subjects receiving tenofovir DF through 24 weeks.

In Study 356, 1% (1/100) of patients reported a serious event related to tenofovir DF treatment, and 0.3% (3/100) of patients reported an adverse event related to tenofovir DF treatment. Of the 12 serious adverse events reported in patients treated with tenofovir DF in Study 356, 4 were treatment-related.

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Indications and Usage

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Atripla Disoproxil Fumarate

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Atripla has been shown in vivo to inhibit CYP3A and CYP2B6, and may increase steady-state serum concentrations of other substances. Therefore, concomitant use of Atripla with other substances that are substrates for CYP3A and CYP2B6 is not recommended. Although no clinical interactions have been reported, recommendations for concomitant use of Atripla with other substances can only be made if similar results are observed in clinical trials. Several studies have shown that concomitant use of Atripla with ritonavir leads to an increase in disoproxil fumarate levels.

Formulations/Dispensing:

Lipiodol: Lipoïdol is to be used in the primary care setting at an initial dose of 20 mg of disoproxil fumarate per day. The dose may be increased to 40 mg per day if needed. The most common side effects associated with Lipiodol use are nausea, vomiting, and diarrhea. Lipoïdol may also cause skin reactions, such as rashes and urticaria.

Additional information:

- Lipoïdol should be taken with food to help prevent these side effects.
- Patients should be monitored for signs of dehydration and electrolyte imbalance.
- Lipiodol is contraindicated in patients with significant kidney or liver disease.

References:


Drug Interactions: A statement to patients and healthcare providers is included on the product’s bottle label: ALERT! Find out about medicines that should NOT be taken with ATRIPLA (efavirenz/emtricitabine/ tenofovir disoproxil fumarate). ATRIPLA may interact with some drugs; therefore, patients should be advised to report to their doctor for use of any other prescription, nonprescription medication, or herbal products, particularly St. John’s wort.

General Information for Patients: Patients should be advised that: ATRIPLA is not a cure for HIV-1 infection and patients may continue to experience illnesses associated with HIV-1 infection, including opportunistic infections; they should remain under the care of a physician when using ATRIPLA. Patients should avoid doing things that can spread HIV-1 to others. Do not share needles or other injection equipment. Do not share personal items that can have body fluids on them, like toothbrushes and razor blades. Patients may have any kind of sex without protection. Always practice safe sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood. Do not breastfeed. We do not know if ATRIPLA can be passed to your baby in your breast milk and whether it could harm your baby. Also, mothers with HIV-1 should not breastfeed because HIV-1 can be passed to the baby in the breast milk. The long-term effects of ATRIPLA are unknown; redistribution or accumulation of body fat may occur in patients receiving antiretroviral therapy and that the cause and long-term health effects of these conditions are not known; ATRIPLA should not be coadministered with COMPLERA, EMTRIVA, or VIREAD; or drugs containing lamivudine, including Combivir, Epivir, Epzicom, or Trizivir. SUSTIVA (efavirenz) should not be coadministered with ATRIPLA unless needed for dose-adjustment (See Warnings and Precautions). ATRIPLA should not be administered with HEPESPA (See Warnings and Precautions).

Patients should also be advised that:

- Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported. Treatment with ATRIPLA will be suspended in any patient who develop clinical symptoms suggestive of lactic acidosis or pronounced hepatotoxicity (See Warnings and Precautions).
- They should be tested for hepatitis B virus (HBV) before initiating antiretroviral therapy. Sever severe acute exacerbations of hepatitis B have been reported in patients who are coinfected with HBV and HIV-1 and have discontinued EMTRIVA or VIREAD, which are components of ATRIPLA (efavirenz/emtricitabine/ tenofovir disoproxil fumarate).
- Renal impairment, including cases of acute renal failure and Fanconi syndrome, has been reported. ATRIPLA should be avoided with concurrent or recent use of a nephrotic agent (See Warnings and Precautions).
- Decreases in BMD have been observed with the use of tenofovir DF. BMD monitoring may be performed in patients who have a history of pathologic bone fracture or other risk factors for osteoporosis or bone loss (See Warnings and Precautions).
- Take ATRIPLA orally on an empty stomach and it is important to take ATRIPLA on a regular dosing schedule to avoid missing doses.
- Central nervous system symptoms (NSS) are commonly reported during the first few weeks of therapy with efavirenz. Dosing at bedtime may improve the tolerability of these symptoms, which are likely to improve with continued therapy. Patients should be alerted to the potential for additive effects when ATRIPLA is used concurrently with alcohol or psychoactive drugs. Patients should be instructed that if they experience NSS they should seek immediate medical evaluation. Patients should be advised to inform their physician of any history of mental illness or substance abuse (See Warnings and Precautions).
- A common side effect is rash. Rashes usually go away without any change in treatment. However, since rash may be serious, patients should be advised to contact their physician promptly if rash occurs.

Reproductive Risk Potential: Women receiving ATRIPLA (efavirenz/emtricitabine/ tenofovir disoproxil fumarate) should be instructed to avoid pregnancy (See Warnings and Precautions). A reliable form of barrier contraception must always be used in combination with other methods of contraception, including oral or other hormonal contraception. Because of the long half-life of efavirenz, use of adequate contraceptive measures for 12 weeks after discontinuation of ATRIPLA is recommended. Women should be advised to notify their physician if they become pregnant or plan to become pregnant while taking ATRIPLA. If this drug is used during the first trimester of pregnancy, or if the patient becomes pregnant while taking this drug, she should be apprised of the potential harm to the fetus.

The Effective Latino Clinic: A Checklist for Success

BY ALISSON SOMBREDERO, MD

AS A LATINO HIV SPECIALIST, I often wonder why Latinos living with HIV face so many barriers to care. In the clinic where I routinely diagnose patients with CD4 counts less than 200 cells/mm3 and opportunistic diseases, I am reminded of the early 1980s. Several studies have shown that Latinos living with HIV are less able to access and remain engaged in HIV care. Our goal as a treatment community should be to address these barriers and turn them into opportunities to help the HIV infected Latino population achieve better health outcomes.

A culturally competent and Spanish speaking Latino HIV clinic can be extremely effective in achieving this, and although we, at the Positive Health Program (PHP), part of the HIV Division at UCSF, are in the early stages of creating this space for our Latino patients, the components of an effective Latino HIV clinic have become clear.

Here is a checklist to consider:

- Hire Spanish speaking staff, familiar with Latino cultural practices and values, including front desk clerks, medical assistants, nurses, laboratory technicians, social workers, case managers, substance abuse counselors, clinical pharmacists, primary care providers and mental health specialists.
- Provide clinicians who treat the patients with warmth and respect of the patient’s traditions, home remedies and practices.
- Have a multidisciplinary team with twice a month meetings to discuss patient briefings and case conferences.
- Create a “one stop shop,” where the patient can access ambulatory outpatient care, as well as supportive services like getting help completing applications and forms for benefits and health insurance, domestic violence and immigration services, housing and transportation benefits, food stamps and vouchers, Spanish language materials (brochures, pictures and videos) with a range of literacy levels need to be provided.
- Establish treatment adherence program using pill boxes, pictures, direct observed therapy, alarms or text messaging, educational Spanish speaking videos.
- Offer home or clinic delivery of HIV medications and referral to a Spanish speaking pharmacy.
- Provide flexible schedules for the working population, as well as child care for patients who are parents.
- Develop networks of referrals to agencies that serve Latinos.
- Create focus groups to identify and understand the Latino clinic population needs.
- Train and hire patient navigators and peer advocates to support new patients in case the patient preference is a one-on-one approach
- Conduct support and educational groups targeted to Latino subgroups, like MSM, heterosexual men, women, transgender, hepatitis C, treatment adherence, substance abuse among others.
- Validate the importance of social groups, arts, crafts, food, in order to decrease social isolation.

The ideal Latino clinic will translate to higher rates of patients engaged and retained in HIV care, adherent to antiretrovirals, with higher rates of HIV viral load suppression, lower number of patients with low CD4 counts and opportunistic infections. Overall, we hope for a healthier HIV Latino population.
FOLLOWING THE RESULTS OF THE 2012 ELECTION, there has been an emphasis to address the problems of our immigration system, primarily because of the growing Latino electorate. Remarks by both President Obama during his State of the Union address and the bipartisan effort in the Senate have created an encouraging environment to address the many problems with the United States immigration system.

According to the Pew Research Center, of the almost 52 million Latinos in the United States, close to 19 million, or about 36 percent, are foreign born. This statistic includes naturalized citizens, green card holders, and undocumented men and women. According to estimates, of these 19 million, 8.4 million are undocumented Latinos, which represents approximately 76 percent of the total undocumented population.

During his speech, President Obama recognized a need for new dialogue concerning HIV and AIDS. While speaking to nation’s role as a global force, the President said the “United States will join our allies to eradicate such extreme poverty in the next
two decades...by realizing the promise of an AIDS-free generation.” President Obama’s commitment to HIV/AIDS has been highlighted particularly by the first-ever National HIV/AIDS Strategy, which he announced in 2009. A significant part of the strategy focuses on the need to target our resources and attention towards the most heavily impacted populations and regions, which include Latinos and Latinas. According to the Kaiser Family Foundation, Latinos accounted for 20 percent of new HIV infections and 19 percent of people living with HIV as of 2009, and 22 percent of new AIDS diagnoses as of 2010.

So what is the relationship between immigration reform and HIV/AIDS? Why is immigration reform critical to improving health outcomes and reducing health disparities?

According to the CDC, for Latinos, 29 percent of HIV diagnoses and 31 percent of AIDS diagnoses were born outside of the United States and U.S. territories. Two of the critical components of the National HIV/AIDS Strategy - “Increasing Access to Care and Improving Health Outcomes for People Living with HIV” and “Reducing HIV-Related Disparities and Health Inequities”—require an in-depth understanding of the populations being affected by HIV and AIDS.

### Immigration and HIV Care

A little over 13 million Latino immigrants are non-citizens, which includes green card holders, undocumented immigrants, and those with different types of visas. These different statuses can often affect many aspects of an immigrant’s life, such as whether or not they are aware of their rights, their knowledge of available services, their level of English proficiency, and their ability to regularly travel to their countries of origin. In other words, different kinds of immigrants are here for different reasons.

There is a different sense of how “being healthy” can be organized into their lives. For example, many immigrants do not access any medical care until they are very ill, and then the hospital emergency room is the go-to place for care.

Additionally, “undocumented,” “immigrant,” and “Latino” are often conflated at a time when being undocumented is heavily stigmatized. States like Arizona and Alabama have been hailed as models with legislation that equates immigrants to criminals. Although there has been a shift to work on fixing our immigration system, President Obama’s policy has resulted in 1.5 million deportations over the last four years, more than any president on record. Many immigrants are fearful that accessing any type of service, including public services that they are entitled to by law, may result in deportation.

A discussion of access to HIV care would be incomplete without talking about the Patient Protection and Affordable Care Act (ACA). The ACA has been hailed as the Lynch-pin for the so-called AIDS free generation, and is even cited multiple times in the National HIV/AIDS Strategy as a key component to ending the epidemic. The cost of treating HIV is high, and having access to quality health insurance is essential to getting high quality care for anyone living with HIV.

In general, health insurance access is a major problem for Latinos in the United States. According to the Pew Research Center, 30 percent of Latinos lack health insurance, and almost half of uninsured Latinos are foreign-born. Approximately 27 percent of foreign-born Latinos are considered to be in poverty. Medicaid expansion, one of the primary mechanisms of the ACA, would dramatically increase the amount of Latinos with health insurance, making it much easier to access care.

However, this transition is not seamless. Immigrants have multiple barriers to accessing health insurance under the ACA, ranging from long waiting periods to becoming eligible to not being able to access health insurance completely. Undocumented immigrants have very few options to pay for expensive HIV care if they are uninsured, and other priorities, such as rent or food, often come first. Immigration reform that offers a pathway to citizenship and addresses this problem of access to care would improve the health offerings for millions of Latinos, and move us closer to effectively engaging the AIDS epidemic.

### The Role of the HIV Care Provider

While effective immigration reform could go a long way to helping all foreign-born Latinos have greater access to health care and HIV care services, it cannot solve the problem entirely.

HIV care providers must educate and engage the Latino immigrant community in a culturally appropriate way. Although it is generally the rule that patients are the primary drivers in accessing care (people go to the doctor’s office, not the other way around), community engagement towards people who especially do not access any medical care is essential.

Conversations about “acculturation” and “assimilation” often miss a very basic point about immigration—that not all immigrants are here for the same reasons. Even among native-born Latinos and non-Latinos, different people must be engaged in different ways given how they organize their lives. Latino immigrants are no different. Education and engagement must be tailored to their needs in order to better connect them to health care services.

This, coupled with immigration reform that will better shape the environment in which we all live, will put us in a better position to fully engage the AIDS epidemic and better serve all people living with HIV.}

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**Immigration reform that offers a pathway to citizenship and addresses this problem of access to care would improve the health offerings for millions of Latinos, and move us closer to effectively engaging the AIDS epidemic.**
A middle age Hispanic man from Mexico lived in the U.S. for about ten years. After four weeks in the intensive care unit, he died.

As a native Spanish speaker, I listened to his story. His job was the same as thousands of immigrant day laborers working in the fields, in harsh heat for low pay, and in some cases below the minimum wage (if they lack proper documentation). Alone in the U.S. with all his family in Mexico, he was one of those 11 million undocumented immigrants “sin papeles” (without documents).
My patient’s sole purpose in life was to earn money to send to his family in Mexico. Ironically, he was a medical student in Mexico, but he could no longer afford the expenses and tuition of this education. The oldest of 8 brothers and sisters, his parents could not support him, so he decided to come to the U.S. to work and earn money to help his siblings get the education he could not afford for himself.

A few days before he died he told me: “Todo esta bien, lo sé, ellos tendrán un mejor futuro no como el mío” (“Everything is fine, I know it, they will have a better future different from mine.”).

Living undocumented in the U.S. was a nightmare for this young man, always living in fear and in the “shadows,” something he only did for the sake of his family. He had hoped to return to his native Mexico, but of course, that dream did not materialize. He had bought a one-way bus ticket to Mexico, but he got too sick to travel just a few days before leaving.

My patient, who did not have health insurance, told me he had been feeling sick for several months before coming to the intensive care unit because he no longer could walk. He had developed shortness of breath for weeks and finally was diagnosed with HIV during his admission to the hospital. He told me that he was not sure how he acquired the HIV infection, but he suspected it was from a prostitute whom he frequently visited.

Unfortunately, this story repeats itself almost every day in the U.S. Sadly, in my short career, I have been a witness to many. I know that I am not alone.

Two years ago I lost another Hispanic patient with HIV who needed surgery to have his spleen removed. But, he did not have health insurance because he was undocumented. So, he came to the emergency room every time he was sick and received platelet transfusions. In the end, money was wasted and the patient died.

In such cases, for Hispanic patients with HIV, particularly those who are sin papeles, the tragedy of their disease affects entire families who also become victims—true silent victims who are often ignored.

But today, the power of politics offers hope. With the rapid growth of the Hispanic population and its great voting potential, politicians can no longer ignore their issues. That was apparent in the last Presidential election, and it grows ever more evident by the day. Latinos and Latinas who are documented care deeply about their undocumented brethren, and they are increasingly wielding the political and economic power that is theirs.

But let’s stop and think beyond politics and illnesses. The undocumented Hispanic population with HIV infection is incalculable. How can we accurately calculate this number if these people remain in the shadows, afraid to even go to the hospital for a simple illness or to get tested? Certainly, local community health clinics can see them. But they do not show up because of the fear of deportation. So instead, when it is too late, they are brought in against their will, perhaps even unconscious.

Then, because they do not speak English, they are unable to communicate their symptoms to their doctors.

This illustrates the need for more Spanish-speaking physicians in the U.S. As the Hispanic population continues to increase, do not we need more Hispanic physicians? Should we not accommodate the need of the actual population living in the U.S.? It needs to evolve according to the population trend so that the supply of Spanish-speaking bilingual physicians meets the demand—a move that could actually help reduce healthcare costs.

Do I care more or less if a person has a stamp in their passport? As health care providers, we do not ask the migratory status of any human being who comes into our care. This is not part of our “history and physical.” We have taken an oath and committed our careers to save lives without prejudice. We fight against diseases, infections, heart attacks, strokes, etc., not politics.

I told my patient, “It is not worth it. You should be able to live in your country and enjoy your life along with your brothers and sisters.”

He said, “The problem is that they won’t have a good life if I don’t help them, so I need to live.” At the end of his hospitalization, he could not walk; he was disoriented and bothered by the noise of the antibiotic pump alarms every single day. He was intubated for weeks and thus, could not talk during the last week of his life. We did everything possible to save his life. But after one month in the intensive care unit, he died.

Every day, after I would see him, I would ask myself the same question: How often does this happen in the U.S.? The government has been trying to make changes in immigration laws for a long time. If it is not addressed soon, more people will continue to die and the healthcare system will continue assuming the costs of this neglected situation. Here in the U.S., this is not an illegal immigration problem, or a Hispanic problem; it is an American problem and affects us ALL.

HIV

Latinos and Latinas who are documented care deeply about their undocumented brethren, and they are increasingly wielding the political and economic power that is theirs.

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There are many behavioral, social, cultural, and health care risk factors and barriers that place migrants at increased risk for HIV infection in and out of the United States. Below is a brief summary of the major points from published studies and also from personal and professional observations that support the growing concern for HIV disease in the migrant community.

Both migrant men and women are likely to engage in high-risk sexual behavior, especially when being so far from home. Migrant men often enter into sexual relationships with commercial sex workers and infrequently use condoms. Moreover, male migrant workers, who are often isolated from their families, are more likely to accept sexual solicitations from other men in the United States when work is hard to find.

Migrant women are not immune to high risk sexual behavior. When field work is scarce, female workers may turn to unprotected sex for money or drugs.

In addition, it is common practice for migrants to use and share non-sterile syringes to inject illicit drugs, vitamins, and antibiotics in the United States. Alcohol abuse is also prevalent.

As in many other segments of society, stigma and homophobia in the Latino culture leads to stronger misperceptions about HIV and can prevent or discourage migrants from pursuing education, testing, and treatment of the disease. Because of their lack of education, most workers believe they are at low risk for HIV infection.

Exact prevalence rate of HIV in the migrant community is unknown, but estimates range from 2.6-13 percent. Testing and diagnosis are difficult to obtain because of the constant mobility of migrants for work and the barriers to testing that are commonplace.

Although largely unknown, most migrant workers contract HIV while working and living in the United States. In effect, this has contributed to rising HIV infection rates, particularly among women in high-migrating cities and states of Mexico. The most common risk factor for these women in contracting HIV is through a male sexual partner who has traveled to the United States for work.

Medical care is restricted to many migrant workers due to their limited language abilities, income, lack of medical insurance, and United States citizenship. Rural specialty clinics who serve HIV patients are limited in the United States. It is even more difficult to find such clinics that are also equipped with the cultural and linguistic resources to better serve our migrant worker population.
**Recommendations, Solutions**

The promotion and development of migrant worker unions are necessary so stronger labor contracts can be negotiated. These contracts will ensure that workers are paid higher wages and equipped with employer-based medical insurance coverage.

Continued lobbying to convince Congress to help sustain and financially support the Ryan White Care Act is needed to provide financial support to the organizations involved in the education, prevention, testing, and treatment of HIV. This increased funding can also help to support the AIDS Drug Assistance Program (ADAP), which is crucial for the treatment of HIV for undocumented migrant workers. This action would allow migrant workers to access costly medications that would otherwise be unattainable, given their exclusion from attaining full-scale Medicaid and Medicare prescription drug benefits in the United States. With appropriate funding from the Ryan White Care Act and federal/state governmental incentives, more rural migrant community health centers can be at the forefront of HIV education, testing, counseling, and treatment services for migrant and seasonal workers.

HIV-positive migrant workers also should have access to specialists properly trained in HIV disease and care in the United States. Access to such specialty care can be problematic in rural areas. With governmental incentive programs such as the National Health Service Corp, in the form of loan repayment and scholarships, and the HIV credentialing program from the American Academy of HIV Medicine, primary care clinicians may be more amenable and qualified to practicing HIV medicine in rural communities.

Given the constant mobility of their work, which moves according to the seasons, and resulting discontinuity of care, infected migrant workers must receive ongoing HIV medical care by the establishments and communications of local, regional and international networks of treatment facilities both within and outside of the United States.

To control the emerging HIV epidemic on both sides of the U.S. and Mexico border, the President’s Emergency Plan for AIDS Relief (PEP-FAR) should provide funds to Mexico and other Latin American countries to support the collaborative efforts in the education, prevention, and treatment of HIV disease of those affected. Priority should be placed on distributing funds to the border and rural areas with high infection rates.

Further research is needed to examine the social and cultural factors that influence sex and drug-related decision-making amongst Latino male and female migrant workers.

**The Bottom Line**

Migrant workers are traveling to the U.S. in search of work and to pursue the American dream. Unfortunately, for many this dream is too often negatively impacted secondary to infection with HIV.

These workers deserve a safer passage into, within, and out of the United States. Since Latino migrant workers are vital for the economic development of our agricultural industry, additional resources are needed to address the behavioral, social, cultural, and health care risk factors and barriers that place migrant workers at increased risk for HIV infection.


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FOR US LATINOS, FAMILY ALWAYS COMES FIRST.

When growing up, my mother taught me that, though every person is unique, Hispanic people are more special than anyone else. I embraced this simple yet strong concept while aspiring to become a healthcare provider among the Hispanic population. The term “Hispanic” acknowledges a cultural group with a common heritage stemming from Spain’s colonization of the Americas. Although sharing the same historical background—and a common language—Hispanics can be categorized both as a single ethnic group and subcategorized for their diverse idiosyncrasies (like Mexicans, Puerto Ricans, Cubans, and so forth).

According to 2010 Census figures, the Hispanic population in the United States reached 50.5 million, outnumbering the population of Canada.
TREATMENT: Uniqueness

BY IVÁN MELÉNDEZ-RIVERA, MD, FAAFP, AAHIVS
Unfortunately, this Hispanic growth also reflects the alarming increase of HIV infections. Although representing the 16 percent of the total population of the United States, Latinos are still considered an ethnic minority, and as a result, they face very specific needs, including late access to medical care, and misperceptions and lack of knowledge about the U.S. healthcare system.

To face this inevitable statement, several challenges should be addressed when providing healthcare to the Latino population. Patient-Provider communication, if not the biggest of them all, is the most important when managing HIV infection, specifically due to language and health-literacy barriers.

Generally speaking, an average 40 to 80 percent of medical information exchanged with patients is immediately forgotten after a regular checkup; this amount proportionally increases during consultation time. Only half of the retained information is remembered (though not in a correct manner); spoken information approximately remains on a 17 percent basis, in comparison to an 84 percent that is reinforced by the use of words and illustrations (pictograms).

In Puerto Rico, where I practice, a language barrier does not represent a problem for local providers, but engaging patients into a culture of healthcare consistency still is considered a dilemma. Puerto Ricans are diagnosed with HIV at a late stage in their lives and they only access healthcare when they feel very sick. Most people do not see the need to engage in medical care if they do not present any symptoms.

**Latinos and the U.S. Health Care System**

Developing a healthy relationship with a medical provider, as well as becoming a proactive part of the healthcare care team, is still a foreign concept for most Latino patients diagnosed with HIV. Considering the special uniqueness of this population, this fact may change with some important adjustments.

It is necessary to encourage patients to educate themselves about all his/her options, how to express his or her opinions, concerns, doubts and disagreements. Perhaps due to sociocultural reasons, most of Hispanic patients typically adopt a submissive attitude when consulting a healthcare provider. Latinos tend to reserve their complaints and assume an auto-discriminatory pattern. Whatever a doctor may say is taken as irrefutable, like a biblical truth of sorts, and as a result, patients do not even attempt to express any opinions or concerns.

Latinos do appreciate mutual respect in social relationships, especially with figures of authority. They strive to preserve personal integrity when interacting with others. Thus, as patients, when receiving any medical attention or drug treatment from an authority, they need to feel they are being “treated with respect” and valued as a person or else any medical advice will be discarded.

Also, Latinos have a different perception of time, with a more flexible understanding of punctuality. When establishing contact with a patient, saving time must be considered a less important factor than a warm, satisfactory social relationship. A Latino patient may perceive a hurried pace or fo-
Although representing the 16 percent of the total population of the United States, Latinos are still considered an ethnic minority, and as a result, they face very specific needs, including late access to medical care, and misperceptions and lack of knowledge about the U.S. healthcare system.

cus on saving time on the part of a caregiver as plain rudeness. Sometimes, treatment is limited by the patient itself. They tend to avoid any contact with a medical provider concerned about their privacy, particularly afraid that someone might reveal their diagnosis. In Puerto Rico, this situation has been surpassed: patients can visit any Medicaid office for qualifications instead of referring them to a specific location—usually in their own community. That improves their concern for privacy.

Considering all aforementioned factors that affect the Hispanic/Latino population, treatment services must take into account:

• **Familiarity**—Be familiar with the patients life, especially his or her family situation. Understand that the family is the primary social unit and source of support. Ask about his or her family and remember to keep them as part of the conversation.

• **Pleasantness**—A polite, cordial social relation is truly valued; it is a central cultural value and a social expectation for this community. A friendly attitude shuns assertiveness, direct negative responses and criticism.

• **Personal approach**—It is a strong Latino preference to establish and maintain relationships with others that reflect a certain familiarity and warmth. Latinos may be more likely to trust and collaborate with someone with whom they had pleasant conversations.

• **Fatalism/determinism**—This constitutes the classic belief that fate determines life outcomes, including HIV/AIDS. For Latinos, this fate is basically unbeatable. This is a common ethos within Hispanic communities, which is often exacerbated by the marginalization that comes when dealing with social problems such as migration, poverty and racism. The perceptions of powerlessness coupled with fatalism can negatively impact any effort towards preventive HIV care.

• **Hierarchism**—An attitude of absolute respect for hierarchy and authority figures is strongly preserved in Latino cultures; the incorporation of this value into clinical consultation is critical.

• **Presentism**—An emphasis on the present, not the past or the future, poses enormous positive implications for HIV/AIDS outreach, screening and treatment. It is often difficult for providers to appreciate this cultural value since it conflicts with the biomedical concept of time, which is future-oriented.

**The “Sex Talk”: Unique on its own**

Having the “Sex Talk” with our Hispanic community can be extremely challenging to any healthcare provider. This important conversation, which may be revealing of certain sex habits that may put the Latino patient at risk for HIV/AIDS, may be impaired by very unique qualities associated with Hispanic culture.

As a socio-cultural tradition, sex and sexuality are not openly discussed, producing a very peculiar “sexual silence.” Especially for some Hispanic women, this sexual silence dictates a claim of decency—they should not know or talk to men about sex because it may suggest promiscuity. Sex behavior is commonly equated with discomfort and even considered as immoral or dangerous.

Both Hispanic men and women report high levels of discomfort about engaging in sex, which in turn, makes it difficult to successfully discuss the use of condoms as a safe practice during intercourse. One survey among Hispanic, unmarried adults found that 44 percent felt uncomfortable having sex with the lights on. This for sure raises a predicament: How can you enforce the use of condoms when people are literally “in the dark?”

When assessing tactics to establish a healthy conversation regarding preventing habits towards a safe sexual contact that prevents HIV infection, a caregiver must validate his/her patient’s feelings (shame, guilt, for example), and avoid any prejudice or judgment. Identifying a staff member that has the skills to make this particular approach with patients will be very helpful to assure a comfortable environment.

**Gender Roles and Machismo**

The strong, powerful force of machismo among Hispanics radiates in every direction. Both Latino men and women feel their impact in various instances. For example, due to their machismo attitudes, male patients may experience serious discomfort when discussing his sexual habits to a female healthcare provider. Gender-discordance will also af-
fect women patients: They would not be particularly open to speak about their intimacy with male doctors, especially when issues like domestic violence or sexual abuse—both strongly linked with raising the risk of HIV infection due to male-dominant roles assumed during sexual intercourse.

Homosexuality brings this situation to another level: Most homosexual patients will not label themselves as gay (“maricón” or “pato”, among other demeaning names used to reference homosexuals). Heterosexual men who have sex with other men usually say these acts are performed only to “relieve sexual tension, without acknowledging either physical attraction or emotional linkage to another man. Healthcare providers should be careful when addressing these issues, particularly avoiding any stereotyped wording that may sound offensive or derogatory.

Other Cultural Issues
To establish a respectful, long-lasting relationship that may enhance both trust and recurrence during prevention and/or follow-up to Hispanic patients infected with HIV, it is important to keep in mind other cultural influences that may alter the course of health care:

- Alcohol consumption: Consuming alcohol is culturally ingrained in Latino culture; it is part of every important festivity.
- “Alternative” medicine: It may not be perceived as the integration of recognized practices such as naturopathic medicine. A patient may seek help from a local pharmacy, a “botica” or whatever home remedies his “vecino” (neighbor) recommends.
- Gossip: This is one of the most destructive patterns in Latino cultures. Afraid of being recognized and gossiped around their neighbors (and even their relatives), most patients miss their medical appointments or the chance to receive any other professional help.
- Religious Beliefs: This may work either as a positive or a negative influence, depending on how much religiousness might alter any decision-making process.
- Family: There are strong familial bonds that may affect the possibility of receiving preventive advice or treatment. Family may interfere with such possibilities when ignoring or covering the situation just as a protective measure. It can also become a source of conflict, isolation and abandonment when dealing with HIV/AIDS, especially when sexual or religious values are strongly enforced within the family.

A Final Word of Advice
Hispanic/Latino communities are culturally rich and provide a wonderful opportunity to understand the measurement of diversity in our own world. As unique as Hispanics may be—and as challenging as they may appear—we should remember one basic principle that will always rule our practice: We are dealing with human beings. They may not share your cultural background or speak your language, but when they feel the connection, a strong bond can be established. This is particularly important in order to enhance prevention skills and raise awareness for protection in order to significantly reduce the risk of HIV infection within the Latino population.

When the moment arrives, just keep in mind these “pearls of wisdom,” as unique as we Latinos are:

- Make the patient feel welcomed. A good handshake, reinforced with eye-to-eye connection establishes a bond of trust.
- Always ask about their family, pets, or how are things at home.
- Keep your posture as a form of parental guidance, but not as a person of punishment.

Making a positive effort will benefit our patients and will result in a decreased possibility of a new infection. Keep in mind uniqueness, and embrace it as a possibility to assess your own capacity to become a better caregiver.

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If you are working with a Puerto Rican community and want to advance a health prevention effort, it is important to realize that their greatest risk of contracting the HIV virus is through injection drug use, and that risk is greatest among the male population. But in treating Mexican-Americans and Cuban-American men, the most likely form of transmission is through unprotected MSM sexual activity. Dominican men also have a high likelihood of having acquired HIV through unprotected sex. So, it does not make much sense to go before a group of Cubans in Miami and talk about the dangers of injection drug use, because that is not the main problem in that community.

Poverty plays a huge role among Latinos in my community in Bridgeport, CT. Unlike many areas of the country, we are not regularly confronted with immigration issues. However, socio-economic status is directly related to greater health disparities and chronic health conditions in addition to HIV, such as diabetes, hypertension, depression, and drug and alcohol abuse.

Some 41 percent of my 630 HIV-positive patients have both HIV and Hepatitis C, as well as a number of other behavioral health conditions. Type 2 diabetes is also common with one in four Puerto Ricans having diabetes by the time they reach 50. Many also suffer from obesity and other conditions that are consequences of low socio-economic status.

I work at a federally qualified center in Connecticut, where 95 percent of my patients are either uninsured or underinsured. We access Ryan White funding here, which helps to provide coverage. We are always managing our patients under conditions where we do not have all of the resources that we need. Fortunately our Connecticut ADAP is a big help to us.
About Stigma

In my population, I do not see stigma as a notable issue, perhaps because our patients are mostly second or third generation and have become acculturated. One-third of our patients are heterosexual, one-third are injection drug users, and one-third are MSM. Most of our female patients acquired the virus through heterosexual activity, which means their male partners are not coming clean with them about their sexual activities—a common issue with Latinas. Our patients come from Peru, Cuba, Dominican Republic, Equador, Mexico, Costa Rica, and Puerto Rico.

However, with HIV-positive patients who are immigrants to this country, many will never discuss the topic because of privacy and cultural beliefs. Patients who are not native born are more likely to hold back information, so it is important for the provider to ask the necessary questions, not avoid them.

Often, Latino patients do not have good relations with their health care provider. Language and cultural differences play a big role, especially if the provider is not Latino. When I speak to them, I understand what they are saying and how they are saying it. When I speak to patient groups, many are completely unaware of their own status and why they are on medication. Many do not understand the history of HIV and do not realize they can live a normal life if they stay on treatment. Many of my patients don’t have Internet because they are poor.

The language barrier between provider and patient often is huge, and there is a need for cross-cultural education so providers understand the differences between the Latino subgroups.

You can transcend the language barrier if you show empathy and even learn just a few phrases so people will understand that you care.

By Richard Torres, MD, MPH, FACP, FACGS, AAHIVS

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I HAVE WORKED AS A NURSE PRACTITIONER for 32 years and have specialized in HIV for the past 22 years, including 20 years at Presbyterian Hospital in New York and now for the past two-and-one-half years at the Jersey City Medical Center. We treat many undocumented Latino patients, and that is a challenge.

But another challenge is to be working and caring for patients whose culture is much different than my own. You need to listen to their health beliefs, to what is important to them and find a way to explain things in a way that they will understand. But before I can do that, I must understand.

The first Latino population that I worked with was primarily Puerto Rican in East Harlem. Now at the Jersey City Medical Center, our patients come from everywhere south of the border.

We are a Ryan White funded clinic and many of our patients are working and have health insurance. But those who are undocumented must turn to ADAP and charity care, which, of course, is limited.

Family situations pose a challenge as well. Some people are married and might have U.S.-born children, but they, themselves, are never going to be eligible for citizenship. This limits their ability to cope with many of the problems they face.

Recently, I saw a man whose mother was dying in South America, but he could not go to be with her because he could not access HIV treatment there, and he would not have been able to get back into the U.S. The lack of ability to travel for undocumented workers with HIV is a huge problem.

There are some unique medical conditions that appear to be common with many patients with Latin American heritage, such as kidney disease.

I have also found that often people born in the tropics are more likely to be antibody positive for toxoplasmosis, a parasitic disease caused by the protozoan Toxoplasma Gondii. A 2004 study published in *Lancet* said seroprevalence was 75 percent in El Salvador.

Those with a weakened immune system can become seriously ill and the parasite can cause encephalitis and neurologic diseases. It is an opportunistic infection and can be deadly.

It is also essential to recognize and understand the importance of religion in the Latino culture. Some people believe it is God’s will if they get sick and die. This is part of the stigma around HIV because many think that whatever they did was a sin, and this is punishment. I have to explain, “No, this is a virus, not a punishment.”

I have also had many people tell me that it is God’s will whether they get better. I often hear, “Well, I went to church and they prayed over me, and I know He will heal me.” This is painful for me to hear, especially when they reject medication due to this belief. This is where peer educators are so helpful. They will often tell the patients, “Why do you think God made all the scientists and doctors and nurses? He made them so they can help you.” That approach helps people concerned about taking medications for religious reasons accept treatment.

Working with Latinos is the same as anyone working outside of their native population. You must make the effort to get to know the culture. Make the effort to bring out what their health beliefs are and what motivates them so you can relate to them and provide the help and care that they need.


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The Pharmacist: Addressing Barriers to Adherence

As a pharmacist working with the HIV community, my number one job is to address barriers that can prevent HIV patients from adhering to their treatment and medication protocol. These barriers often include untreated mental health, substance use, cost, stigma surrounding HIV, side effects, and the simple burden of taking the required pills.

Working primarily with the Latino community infected with HIV, it is clear to me that those barriers can increase significantly. Then, add in such factors as language barriers, transportation difficulties and scheduling conflicts for shift workers or migrant workers—not to mention, the overall medication experience for a culture unaccustomed to needing prescriptions in the first place.

Clearly, HIV care providers increasingly are turning into chronic disease specialists, and in the Latino community there a higher rates of diabetes and coronary artery disease, without the added risks of HAART. Pharmacists can provide recommendations for the best agents to use while treating these patients and help them achieve their therapeutic goals.

Take advantages of this resource and ask that your pharmacist meet with your patients to discuss their diabetes, insulin titrations, need for preventive cares, and other issues involving medications. Here are some steps to overcoming some of these barriers:

- Utilize your social workers and case managers to ensure that patients stay insured and understand the importance of insurance. In some immigrant populations, the idea of insurance is not understood. In most cases, having no insurance means interruptions in therapy.
- Utilize ADAP and patient assistance offered by most HIV drug companies for those uninsured patients who meet income guidelines. If a patient is privately insured, utilize co-pay cards to help decrease high co-pay requirements. Patient assistance can also be used to fill insurance coverage gaps.
- When meeting with your patients, discuss their other health problems, such as diabetes or hypertension. Pharmacists can provide recommendations for the best agents to use during treatment, and help get patients to meet therapeutic goals.
- Try to overcome language barriers by employing fluent staff or onsite interpreters. There are numerous phone translation services also available. When using an interpreter, direct all discussions to the patient and not the interpreter. Patients appreciate conversing in their own language, but if you are using an interpreter but speak to them directly, they will more easily connect with you and understand what you are saying.
- Offer mail or delivery services for patients who cannot come in to the pharmacy during hours to accommodate shift or migrant workers.
- Utilize your state’s AIDS services organizations to provide transportation for patients.
- Include your pharmacist as part of your health care team. They can provide up-to-date refill histories and an idea of adherence. Pharmacists can let you know what is affordable for the patient, and provide invaluable education regarding medication uses, side effects and drug interactions. Pharmacists can provide clinical insight for your patients, as well.

About the Author: Anna Pedersen graduated with a PharmD from Drake University in Des Moines Iowa in 2008 and completed the University of Minnesota Ambulatory Care Pharmacy Residency in 2009. For the past four years, she has worked as a clinical pharmacist on the HIV team at Westside Community Health Services, an FQHC in St. Paul, MN.
Advances in Symptom Management in Persons with HIV Infection

A s A R E S U L T O F A D V A N C E s in combination antiretroviral therapy (cART), HIV-infected persons are living for decades after the diagnosis, and now have close to a normal life expectancy. Indeed, someone infected in the United States today at the age of 26 has a life expectancy of at least another 40 years. Not only has longevity increased, but so also has the quality of life, as HIV-infected persons are initiating cART earlier, and as medications with fewer side effects have replaced older, more side effect-prone medications as “preferred” therapies. However, side effects from these medications do occur, and it is important for health care providers to be aware of them and to manage them appropriately. Chief among common side effects is non-infectious diarrhea that often is associated with antiretroviral therapy (ART).

The protease inhibitor (PI) class of antiretrovirals is used in combination with, typically, two nucleoside reverse transcriptase inhibitors (NRTIs) for approximately 35% of HIV-infected persons on antiretroviral therapy in the United States. PIs are very effective at rapidly suppressing HIV RNA, and, when combined with the very potent cytochrome p450 inhibitor ritonavir, are seldom limited by the development of drug-limiting mutations.

However, this class is associated with gastrointestinal side effects, including diarrhea, in 10 – 25% of persons taking them. The PIs cause diarrhea by increasing chloride ion secretion into the intestinal lumen, accompanied by an influx of water (secretory diarrhea). The PI-associated diarrhea is rarely life-threatening, but can be substantially life-altering, especially when daily watery bowel movements occur in association with cramping and urgency.

Until recently, there was no specific therapy available for the treatment of antiretroviral-associated diarrhea. Anti-motility agents, like immodium and Lomotil, nonspecifically inhibit gut motility and often are associated with objectionable and potentially dangerous post-diarrhea constipation. Typically, patients were unable to find relief, which resulted in a negative impact on both quality of life and treatment compliance.

On December 31, 2012, the U.S. Food and Drug Administration (FDA) approved crofelemer (Fulyzaq®), the first specific treatment for HIV-infected persons on antiretroviral therapy with noninfectious diarrhea. Unlike Imodium and Lomotil, crofelemer provides an antisecretory effect that doesn’t affect gut motility.

Crofelemer is an intraluminally-active, minimally-absorbed oral anti-diarrheal medication that blocks chloride ion secretion by inhibiting the cystic fibrosis transmembrane conductance regulator (CFTR) protein and the calcium-activated chloride channel (CaCC). In blocking chloride secretion, crofelemer reduces the high volume water loss that may cause other symptoms including dehydration and electrolyte imbalance.

This first-in-class drug has impressive efficacy and a safety profile comparable to placebo. In a randomized, double-blind, placebo-controlled and placebo-free multi-center study, 374 patients on cART with a history of diarrhea for a month or longer were evaluated. The data revealed an impressive clinical response for those receiving crofelemer compared to patients in the placebo group. Additionally, the drug did not influence the efficacy or safety of the patients HIV medications. Crofelemer will be available by prescription in the U.S. by the end of March 2013.

As providers, we are charged with not only providing the best care to treat diseases at hand but also are accountable for looking at the side effects that may be associated with treatment and offering a plan of action for minimizing the impact of symptoms. Newly FDA approved medications, including crofelemer, can help us realize our goal. It is also important to ask early and often about complications our patients may be experiencing. Coupled with recognizing expanding treatment options, open communication can help lead the way for us to continually improve treatment compliance and of quality of life for our patients.

References

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The 2013 enrollment period to apply for the HIV Specialist (AAHIVS), HIV Expert (AAHIVE) or HIV Pharmacist (AAHIVP) exams is from:

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