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Patient Care, Practice Management & Professional Development Information for HIV CARE Providers

HIV Specialist

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BY JAMES M. FRIEDMAN, MHA
EXECUTIVE DIRECTOR, AAHIVM

The HIV Credential: 15 Years and Counting… on You

2015 MARKS THE 15TH YEAR OF THE ACADEMY'S EXISTENCE. In the year 2000, Dr. Scott Hitt and a number of forward-looking HIV practitioners founded the Academy. They thought that given the fast changing pace of new HIV interventions, it was essential that an organization focus on the educational needs of the HIV practitioner, and the necessity of validating that expertise to patients seeking HIV care.

Thus the HIV Medicine Self-Directed Study Guide (later to become the *Fundamentals of HIV Medicine*) was created. Also created was the HIV Specialist credential, which was intended for the practitioner who cared for a substantial number of HIV patients and could demonstrate that he/she kept up with the rapidly changing HIV treatment environment.

Over the years, the credential has evolved and has gained stature in the broader medical community. We created the Low Volume Provider option, which laid a pathway to the AAHIVS (Specialist) credential for the provider who cared for only a few HIV patients. We created the AAHIVE (expert) designation for those HIV practitioners who no longer cared for patients (researchers, HIV educators, HIV medical affairs in pharma companies). More recently, the AAHIVP (HIV pharmacists) designation was added. And this past year, we extended the two-year credential to a three–year credential to reflect a slowing change of pace in HIV medicine.


James M. Friedman

While the Academy has broadened its offerings (The *HIV Specialist* magazine, live CME workshops around the country, the preeminent HIV and Aging blog, a HIV/HCVInstitute, advocacy at the national and state level, a website providing up to date information on the ACA and other HIV topics, etc.), the credential remains at the core of who we are. Currently there are over 2000 U.S. HIV practitioners credentialed with the Academy, a number that has grown substantially over the years.

Recently, I had a lengthy conversation about the HIV credential with one of our credentialed physician members. During that conversation, I noted that about one-half of those credentialed are not members of the Academy—and that membership would never be a requirement.

She stopped in her tracks. "Don't they understand that if the Academy disappeared, the credential would disappear as well?" she remarked.

I replied that while membership has not kept pace with the growth in credentialing over the past several years, it has grown about 5% per year—and that the Academy is in better financial shape than at any time in my seven and one-half years as Executive Director. I assured her that we do try to encourage those credentiallees who are not members to join by offering discounts for credentialing and *Fundamentals* that more than cut the cost of membership in half. She scolded me. "Encouragement is not enough" she said. "You need to be more direct."

I told this very persistent physician member that I would try, but I would NOT threaten bodily harm. Thus the genesis of this article. So here goes.

Those of you who are credentialed, but are not members of the Academy, I hope you consider joining. When you take into consideration the discounts, it can cost as little as $80 per year. These new memberships will add to the strength and influence of the Academy, and perhaps as important, protect me from this very tough and yes, dedicated physician. (I'm just kidding about this last part, Michelle.)

I also want to recognize a very special member and credentialed provider, Dr. Bill Short. Dr. Short has been a great supporter, friend and advisor to the Academy and serves as the guest editor for this issue of *HIV Specialist*. An infectious disease specialist at Jefferson University Hospitals in Pennsylvania, Dr. Short focuses primarily on women with HIV. He has done an outstanding job pooling the best authors to address the unique challenges facing HIV positive women and the providers that take care of them. Thank you, Bill, for being an outstanding AAHIVM member, credentialed provider, Board officer and guest editor. HIV

Currently there are over 2000 U.S. HIV practitioners credentialed with the Academy, a number that has grown substantially over the years.

In the NEWS

AAHIVM Applauds Supreme Court ACA Decision

IN A 6-3 DECISION, the United States Supreme Court recently ruled that insurance subsidies created by the Affordable Care Act (ACA) will remain in place in both state and federal marketplaces. AAHIVM heralded the decision, recognizing that thousands of HIV patients will now retain the coverage, access to care and life-saving medications they gained under the ACA.

"Not only do we celebrate this ruling as a victory for HIV patients, we also recognize that this decision will ensure that millions of Americans can continue to access the healthcare they need to live long, healthy lives," said James M. Friedman, executive director of AAHIVM.

The ACA provides coverage to 16 million Americans who did not have health insurance. The case before the court, King v. Burwell, challenged the legality of health insurance subsidies provided to low- and middle-income people in the 34 states where the federal government is operating insurance marketplaces under the ACA. Had the plaintiff prevailed, 6 million people in the 34 states would have lost their much-needed subsidies.

"Offering insurance subsidies to those that need it most, then threatening to take them away kept many Americans in a healthcare purgatory," continued Friedman. "This ruling not only solidified their peace of mind, it also officially established the ACA as the non-negotiable law of the land."

The ruling reinforces the intention of Congress in passing the ACA that all eligible individuals who purchase health insurance through the exchanges, state or federal, should receive premium tax-credit subsidies.

Biosantech Reports HIV Vaccine Safe, Study Results Suggest it's Effective

Researchers from French-based Biosantech Company recently reported that the company's HIV vaccine candidate was not toxic to 48 HIV-positive patients enrolled in a double-blind study taking place in France. The data was presented at the International Conference on Retroviruses and Novel Drugs in suburban Chicago.

Dr. Sonia Escaich, executive director at Biosantech, reported there were no adverse side effects or drug interactions from the patients who were separated into four groups, with one group of 12 receiving a placebo and the other three receiving different amounts of the HIV vaccine.

Biosantech's vaccine uses a mutant form of the transactivor of transcription (Tat) of HIV-1, which, according to Dr. Escaich, is a good target for inhibition of the retrovirus's expression. She said Tat protein expression is a first step of the virus life cycle to activate its own expression.

Data from this arm of the Phase II study that includes these 48 patients will be published later this summer, according to Corinne Treger, chief executive officer of Biosantech. She reported that a preliminary analysis of this data suggested the proof of concept of the vaccine candidate is obtained in HIV positive patients.

This will allow further developments and the study of combinations with booster of the immune system, such as IMMUNOREX, a treatment developed by Dr. Donatien Mavoungou, the company said.

Note: this was based on a company press release. There was no abstract given. The company's website is www.biosantech.org.

THINKSTOCK

Obama's Global AIDS Coordinator Reordering Funding Priorities

Deborah Birx, appointed by President Obama last year as the administration's global AIDS coordinator, is reordering the use of the $6.8 billion in federal funds provided for her programs, cutting off funding to clinics in Africa that are not finding HIV cases.

"If you had a Starbucks that never sold coffee, you wouldn't keep the site open," she told *Bloomberg Business* in a Geneva interview. "It's not that we're abandoning sites, but we're saying, let's go where there's HIV, focus our resources there."

An audit of about 50,000 clinics that receive funds for HIV testing from the President's Emergency Plan for AIDS Relief (Pepfar) found that about half of those clinics in East Africa are not detecting new cases as the clinics are located in areas with low infection rates, Birx said.

Meanwhile, the Voice of America reported that nearly 95% of African children living with AIDS do not have access to treatment. UNAIDS Executive Director Michel Sidibe reported a near 60% decrease in the number of HIV infections among children under 15, but more than 90% of the more than 3 million children living with the disease are in sub-Saharan Africa, where access to treatment has been a major obstacle to stopping the spread.

More Women Than Men Getting HIV Tests

Nineteen percent of people ages 15–44 had recently had been tested for HIV, including 22% of females and 16% of males, according to new CDC data for 2011-2013.

The numbers were higher for blacks than for any other race and ethnicity. They were also higher for men who had sexual contact with other men: 40 percent had been tested in the year before being surveyed, compared with 20 percent of men who had opposite sex contact.

CDC estimates that about 14% of people infected with HIV are unaware of their infection, which is why many of the tens of thousands of new infections each year are transmitted by people who don't know they have HIV.

For more information, please visit http://1.usa.gov/1Kz2LxQ.

SHUTTERSTOCK/ ISTOCK/ DERWOOD WILLHITE

STUDY Marijuana May Lower Insulin Resistance Risk in HIV/HCV Patients

A study in the journal *Clinical Infectious Diseases* showed that in patients who use marijuana, the drug appears to lower insulin resistance, but the reasons remain unclear. The researchers said that the benefits of cannabis-based pharmacotherapies for patients concerned with increased risk of insulin resistance and diabetes need to be evaluated in clinical research and practice.

Read more at http://cid.oxfordjournals.org/content/61/1/40.abstract

STUDY Smoking Cessation in Patients with HIV

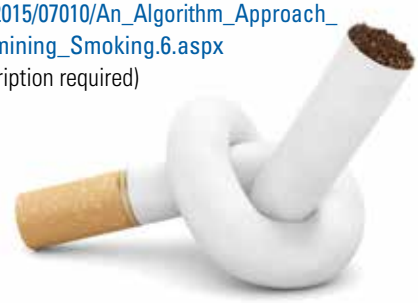
A study in the *Journal of Acquired Immune Deficiency Syndromes* reported that many smokers living with HIV made a greater effort to quit smoking when provided treatment specified by a pharmacotherapy-based algorithm, compared to those given current standard treatment.

The study said that patients given the algorithm-derived treatment reported more quit attempts and experienced a greater reduction in smoking. In addition, measures of "cessation readiness," such as motivation and self-efficacy, also were more favorable for patients who received the algorithm-based treatment.

The study concluded that the algorithm-derived treatment produced positive changes across a number of important clinical markers associated with smoking cessation.

Read more at: http://journals.lww.com/jaids/Abstract/2015/07010/An_Algorithm_Approach_to_Determining_Smoking.6.aspx

(Subscription required)



Giving Back

HILDA ORTIZ-MORALES, NPCS, PHD, AAHIVS
Montefiore Medical Center, Bronx, New York

HILDA ORTIZ-MORALES has spent the majority of three decades as a student; receiving a BSN from Herbert H. Lehman College, a MSN at the College of New Rochelle, an HIV Preceptorship from Johns Hopkins University Medical Center, an HCV Preceptorship at Cabrini Medical Center, and a Doctorate of Healthcare Administration from the University of Phoenix.

Hilda Ortiz-Morales has been providing HIV care since January 1999 and today is a nurse practitioner (NP) at Montefiore Medical Center (MMC), an academic medical center the university hospital for Albert Einstein College of Medicine in The Bronx, NY. Prior to working as a nurse practitioner (NP), Ortiz-Morales was the Clinical Coordinator, Educator and Quality Improvement Coordinator for an AIDS center in New York.

"I was really motivated through these experiences to provide care and manage patients who needed so much education, support, and care," she says. "Especially being brought up under similar circumstances as many of my patients, I felt a great need to give back."

MMC Infectious Diseases Clinic provides services to about 2,500 patients from all over New York City and lower Westchester County. The practice offers a multidisciplinary team approach to patient care, which includes Infectious Disease attendings and fellows, psychiatrists, gynecologists, dermatologists, NPs, physician assistants, social workers, nutritionists, substance abuse counselors, adherence/patient educators, and nursing staff for clinical assessment and monitoring, drug and alcohol support services, psychiatric services, social work, and other social services including peer support and navigation.

Ortiz-Morales has six sessions per week and generally sees between 15 and 20 patients per session.

"My patient population is predominately Hispanic and African American, about 85%, with the remaining 15% being White or West Indian. This demographic has remained rather constant since the start of my

practice. Being fluent in Spanish tends to influence my patient population panel as well," she explains. "Overall, about 55% of my patients are over the age of 50. The population I care for is 90% on either Medicaid or Medicare, and about 10% are still employed with commercial insurance or they utilize ADAP coverage through the Health Insurance Exchanges in New York state through the Affordable Care Act."

Hilda Ortiz-Morales

In her practice, Ortiz-Morales is the HIV-HCV Program Coordinator in which she evaluates and treats patients who are co-infected with HIV and HCV.

A Living Revolution

"The treatment of HCV has been revolutionized in last 18 months with the majority of patients being cured with new therapies. However, to obtain these new agents, the prior authorization process is arduous, with obstacles and requisites put in place by insurance companies in order to deter or delay their availability," Ortiz-Morales says.

In developing the HIV-HCV Co-infection Program, Ortiz-Morales established a mechanism of direct observed therapy (DOT) for HCV therapy. During the interferon era, patients would come weekly for their injections and medications were set up in a pillbox. Even now in the era of directly acting antiviral agents for HCV, patient medications are filled in a pillbox every two to three weeks and patients are seen and monitored for adherence, tolerability, and given support and encouragement, which has led to treatment successes.

When she was asked to run the HIV-HCV Co-Infection Program at MMC, Ortiz-Morales agreed because of the many co-infected patients she referred to Gastroenterology who were rejected due to their HIV co-infection. These providers made incorrect assumptions about patient's ability to adhere that were related to patients' lifestyles, treatment successes, etc., she says.

For many patients, it was imperative that they be afforded the same opportunity for treatment and cure as those who were mono-infected with HCV. "Developing the program from the ground up with the support of the New York State Department of Health was an opportunity that I could never have imagined," says Ortiz-Morales. Today the MMC HIV-HCV Co-Infection Program is well known and has become a model for many programs.

Recalls Ortiz-Morales, "I started treating HIV at a time when regimens were very complex and many patients were unable to maintain the therapies. Now treatment for HIV patients has truly been revolutionized and patients can lead long, healthy lives, and this is truly rewarding. However, I still have patients who refuse needed ART for fear of side effects, or believe in HIV conspiracy theories, and prefer to succumb to the disease of HIV rather than be treated."

Ortiz-Morales motivates her patients to adhere to their treatment regimens using a combination of many factors, including education about HIV disease and the benefits of treatment. She maintains a non-judgmental nature and exhibits care and concern for patients with an earnest investment in their overall well-being. Currently, 88% of her patients on ART have undetectable viral loads.

Ortiz-Morales is also an adjunct professor at Herbert H. Lehman College where she enjoys teaching and mentoring the future generation of Nurse Practitioners and Registered Nurses. She envisions that, in the next 10 years, there will be a transition to ARV medications that can be administered by injection at an office visit and given every three months, thereby increasing treatment rates and rates of undetectability among even the most difficult of populations.

Outside of work, Ms. Ortiz-Morales' interests center around spending time with family. Her son is currently preparing to go to college; a process that she calls "all-consuming." She also enjoys physical fitness.

Asked why she is an AAHIVM Member, Ms. Ortiz-Morales says, "I believe in the strength of membership when it comes to advocacy power for change and growth of the profession. I believe in AAHIVM's organizational mission; to promote excellence in HIV care through advocacy and education." HIV

BY MYRON S. COHEN, MD

Amplification of HIV-1 Transmission by STDs

Where Do We Go from Here?

PERHAPS NO OTHER HIV TRANSMISSION COFACTOR has attracted as much attention as sexually transmitted diseases (STDs). It is now well established that the relationship between HIV and other STDs is intricately bound, causing mutually reinforcing spirals of infection.[1,2]

The latest national surveillance data report nearly 20 million new STDs every year in the United States, with many more likely going undiagnosed and unreported. While anyone can become infected with an STD, certain groups, including sexually active young people and gay, bisexual, and other men who have sex with men (MSM), are at greatest risk. HIV-infected MSM have a greater number of STDs than HIV-noninfected MSM (Figure 1).[3,4]

Incidence of STDs has been stable in previous annual reports, with one significant exception: a rise in syphilis infections among men who have sex with men (MSM). Trend data show that MSM account for 75% of all primary and secondary syphilis cases, the most infectious stages of the disease. About half of MSM with syphilis are also infected with HIV.[4]

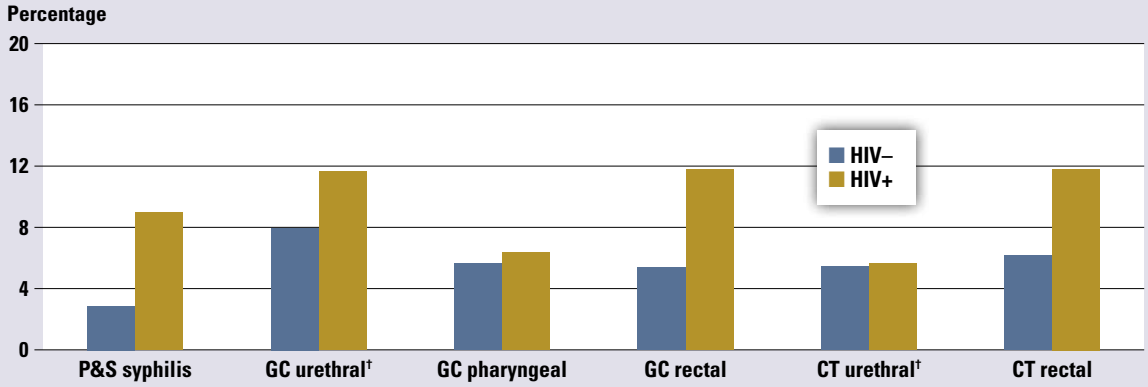
Multiple studies have noted that the annual STD surveillance data correlates with the rate of new HIV infections. Despite the advent of highly active antiretroviral therapy (HAART), the annual incidence of HIV in the United States for the past decade has continued at the same rate (about 50,000 new infections each year), again with one notable current exception: the number of new HIV diagnoses is increasing among young MSM aged 13 to 24.[5]

In 2012, a study of 557 HIV-infected men and women in primary care in four U.S. cities found that 13% had at least one asymptomatic STD at enrollment and 7% had an incidence STD 6 months later; among MSM the STD incidence at 6 months was 20%. Among this cohort, 78% were currently on HAART.[6] The extent to which antiretroviral therapy (ART) can reduce HIV transmission risk provoked by STDs is unclear. However, even in patients receiving ART, treatment of incident STDs remains important.

These data suggest an ongoing "epidemiological synergy" that was first described by Wasserheit more than two decades ago. This synergy was deemed responsible for the explosive growth of HIV in Sub-Saharan Africa and Thailand, areas where classic STDs were common.[2]

In the early 1990s, however, the biological mechanisms responsible for the phenomenon were unclear. My colleagues

FIGURE 1: Proportion of MSM with Syphilis, Gonorrhea, or Chlamydia 2013, by HIV Status*[3]



Note: MSM = men who have sex with men; P&S syphilis = primary and secondary syphilis; GC urethral = Neisseria gonorrhea urethral; GC pharyngeal = Neisseria gonorrhea pharyngeal; GC rectal = Neisseria gonorrhea rectal; CT urethral = Chlamydia trachomatis urethral; CT rectal = Chlamydia trachomatis rectal

*Excludes all persons for whom there was no laboratory documentation or self-report of HIV status.

†GC urethral and CT urethral include results from both urethral and urine specimens.

Source: Centers for Disease Control and Prevention, Atlanta, GA. Used with permission.

and I investigated the hypothesis that STDs increase the likelihood of transmission of HIV-1 through increasing the concentration of the virus in semen.

We found that HIV-1 seropositive men with urethritis had HIV-1 RNA concentrations in seminal plasma eight times higher than in seropositive men without urethritis, despite similar CD4 counts and concentrations of HIV-1. Gonorrhea was associated with the greatest concentration of HIV-1 in semen. After antimicrobial therapy, the concentration of HIV-1 RNA in semen decreased significantly. Blood plasma viral RNA concentrations did not change.[7]

In addition, trichomoniasis in HIV-positive women has been associated with increased vaginal shedding and increased risk of perinatal HIV transmission.[8] Later studies confirmed that HIV could be detected in genital fluids—even when undetectable in the blood[9] and that treating STDs in both men and women who are HIV-positive resulted in reduced HIV shedding in men.[10–12]

PRACTICE TIPS

Combine Screening, Treatment, and Counseling[9]

Five STDs may specifically amplify HIV transmission: syphilis, gonorrhea, chlamydial infection, and HSV-2 in men and women, and trichomoniasis in women.[10]

Because HIV-positive patients in care typically see their physicians two or three times a year, this provides an ideal opportunity to screen for other STDs and provide brief risk-counseling information.

- Screen all HIV patients at least annually for STDs
- Consider screening HIV-positive MSM every 3 to 6 months if they have multiple or anonymous sex partners
- Screen HIV-positive patients for gonorrhea and chlamydial infection in genital and extra-genital sites using nucleic acid amplification tests (NAATs)
- Screen HIV-positive women for trichomoniasis with more sensitive tests, such as NAAT or culture
- Presumptively treat HIV patients who have STD symptoms or report recent sexual contact with partners treated for syphilis, gonorrhea, chlamydia infection, or trichomoniasis, while awaiting STD test results
- Retest patients treated for gonorrhea, chlamydial infection, or trichomoniasis 3 months after treatment
- Emergence of antimicrobial-resistant pathogens may impair the effectiveness of some treatments over time. Use the most recent STD treatment regimens recommended by the CDC: http://www.cdc.gov/std/treatment/2014/2014-std-guidelines-peer-reviewers-08-20-2014.pdf
- Inform patients that reporting cases of STDs, as required by state laws, may prompt health departments to offer Partner Services to your patients. Partner Services can help confidentially inform your patient's sex and/or needle-sharing partners of their potential exposure to HIV and/or STDs and can assist with protecting your patient from STD re-infection. To learn more about how Partner Services works in your area and to obtain information about state and local laws related to Partner Services, contact your local or state health department. To find your local health department, go to www.healthfinder.gov and navigate to the link for "State Health & Human Services."

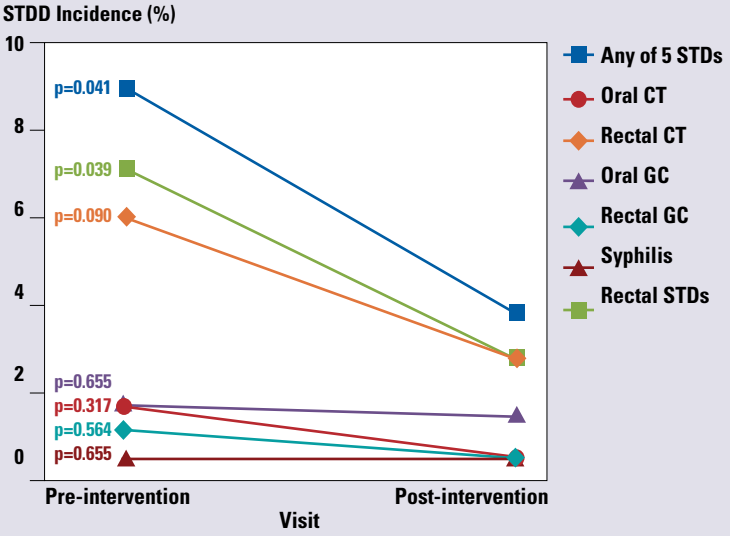
STDs Complicate the Clinical Course of HIV

STDs are known to have a deleterious effect on persons living with HIV, making infections and their consequences worse and more difficult to treat.

In a study of HIV-infected men, those with syphilis (n=77) had an increase in viral load almost five times that of HIV-infected men without syphilis (n=205): MSM with HIV plus syphilis had 54,000 median viral load copies/ml versus MSM with HIV without syphilis had 11,318 median viral load copies/ml.[13]

Several studies have documented the role of herpes simplex virus 2 (HSV-2), the most common cause of genital ulcers worldwide, in increasing genital and plasma HIV-1 viral load.[14,15] A meta-analysis of 11 studies conducted in 2010 showed that HSV-2 co-infection increased plasma HIV

FIGURE 2: Change in Sexually Transmitted Disease Incidence Amongh MSM After Brief Prevention Messages, SUN study, 2005–2007[19]



*Any of five STDs refers to any of the five STDs examined in this analysis: rectal CT, oral CT, oral GC, rectal GC, and syphilis.
CT = chlamydia; GC = gonorrhea; MSM = men who have sex with men
Source: American Sexually Transmitted Diseases Association. Used with permission.

viral load by almost a quarter log (difference in mean VL 0.22 log10 copies/mL, 95% CI: 0.04–0.40).[16]

Amplified Transmission of HIV to HIV-Negative Partners: HIV Acquisition Risk

Additional biological mechanisms that amplify HIV acquisition can vary depending on the STD. Gonorrhea produces inflammation that recruits and activates HIV target cells, making it more likely that HIV will find a cell to infect, whereas syphilis and HSV-2 can produce mucosal breaks and genital ulcers allowing HIV-1 in semen to pass more freely to receptive cells in sexual partners.

MSM and women who engage in receptive anal intercourse remain at disproportionately higher risk for HIV acquisition and transmission because of the unique susceptibility of the rectal mucosa. In many women, gonococcal infections—among the most inflammatory of the classical STDs—produce no vaginal discharge, thus hiding a woman's risk for HIV acquisition.[17]

Safer Sex Counseling: Brief Encounters Make a Big Difference

Many HIV-infected patients never receive safer sex counseling. A recently published Morbidity and *Mortality Weekly Report (MMWR)* from the CDC showed that less than half of all HIV-infected patients received counseling about available HIV and STD prevention strategies, and fewer than 20% were tested annually for STDs. Among HIV-infected MSM, 31.8% engaged in anal intercourse without a condom.[18]

Brief discussions between health care providers and patients during routine clinical care have proven effective in helping patients make informed decisions about sexual behaviors. One study observed a significant reduction in STD incidence after implementing routine twice yearly STD testing coupled with brief safer sex counseling (Figure 2).[19] The findings are consistent with other studies.[20,21]

Conclusions

Observational studies conducted around the world have suggested that treatment of STDs detected through screening could reduce the spread of HIV in populations that have a high STD burden. However, this idea has not been supported by randomized controlled trials.[22]

The failure of such controlled trials for HIV prevention may rest on the fact that we have been unable to treat a specific infection with the right drugs at the right times. The difficulty in interpreting the results of these trials has very recently been reviewed.[23]

Historically, HIV prevention efforts have focused primarily on HIV-noninfected subjects. To respond adequately to "epidemiological synergy" and the threat of amplified HIV transmission, prevention strategies must now use complementary diagnostic, behavioral, and biological tools to recognize and treat classical STDs in both HIV negative and HIV-positive patients in care. HIV

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Myron S. Cohen, MD is the Director of the Institute for Global Health and Infectious Diseases at the University of North Carolina at Chapel Hill. He is widely know for his work on transmission and prevention of HIV. Dr. Cohen helped to develop laboratory methods to measure HIV in genital secretions, as well as methods to determine the best antiviral agents to reduce replication of HIV in these compartments. Dr. Cohen is the architect and Principal Investigator of the multinational HPTN 052 trial, which demonstrated that antiretroviral treatment of people with HIV infection prevents the sexual transmission of the virus; this work was recognized by *Science Magazine* as the "Breakthrough of the Year" in 2011.

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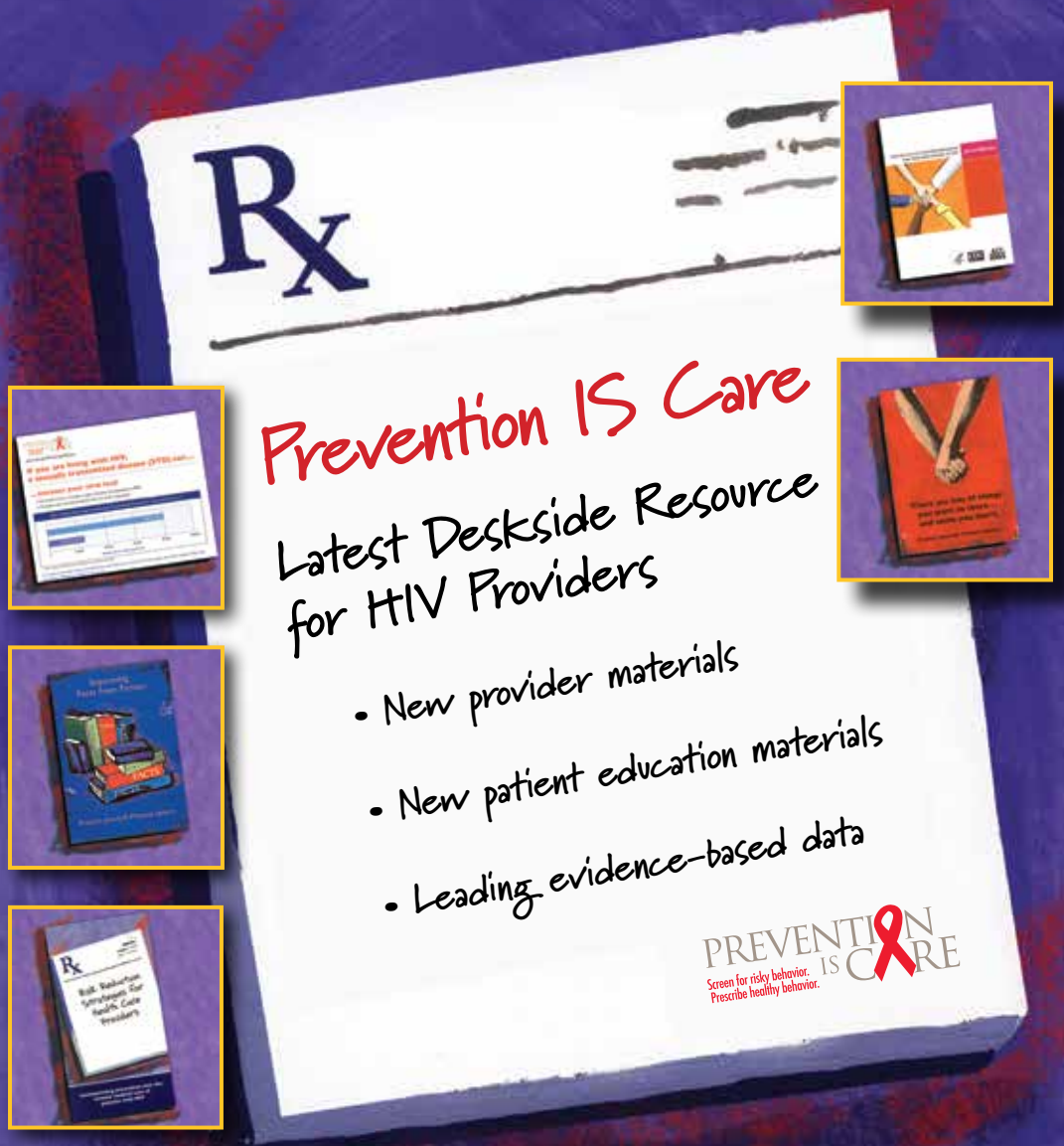
Prevention IS Care

Incorporating Prevention into the Medical Care of Persons Living with HIV



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CENTERS FOR DISEASE CONTROL AND PREVENTION

An Action ALERT

BY WILLIAM R. SHORT, MD, MPH, AAHIVS

Thirty years into the human immunodeficiency virus (HIV) epidemic and our understanding of the unique health needs of women living with this virus continues to evolve every day.

Unlike the early years of the epidemic, the management of HIV in the United States today is not just about preventing death and treating opportunistic infections, but it's also about selecting and implementing long term treatment strategies that will enable patients to live long, healthy, and productive lives—and about ways to prevent the occurrence of new HIV infections. For women, realistically this goal can only be achieved through careful attention to gender specific issues and the impact that these issues have on the diagnosis, management, and treatment of HIV infection.

In the U.S., HIV was first reported in women in 1983 and was found among those who had been steady sexual partners of males with acquired immune deficiency syndrome (AIDS).[1] Although men still represent the majority of people living with HIV, the number of women has increased rapidly, and at the end of 2011 an estimated one-in-four individuals living with HIV in the U.S. was female.[2] Minority women bear a disproportionate burden of the disease.

At the end of 2010, women accounted for an estimated 9,500 or 20% of the approximate 45,000 new infections occurring in the U.S. Of these new infections among women, 64% were among black/African Americans compared to 18% for white and 15% for Hispanic/Latinas. Meanwhile, their share of the entire U.S. population is 12%, 68%, and 14% respectively, indicating the disproportionate impact of the HIV epidemic on black women. Regardless of race or ethnicity, unprotected heterosexual contact is the most common mode of transmission.[2]

Focus on Hot Spots

The HIV epidemic in the U.S. has been described as one of low prevalence; however, in certain geographic areas, also known as microepidemics or "hot spots," HIV prevalence is in line with some countries in Sub-Saharan Africa, where the majority of HIV infected individuals reside.[3]

The HIV Prevention Trials Network (HPTN) conducted a study to evaluate the incidence of HIV among U.S. women living in these hotspots with high rates of poverty and HIV prevalence. This study involved 10 urban and periurban communities and a longitudinal cohort of women who had HIV rapid testing at baseline and participated in audio computer-assisted self-interviews at baseline and every six months for up to 12 months.

Among 2,099 high-risk women, 32 (1.5%) were diagnosed with HIV infection at enrollment. The overall annual incidence rate was 0.32%, which is substantially higher than the 2009 national estimates from the Centers for Disease Control and Prevention (CDC) on HIV incidence in the general population of U.S. black women of similar age (0.05%), suggesting that the recruitment strategies were successful in identifying women considered to be at high risk for HIV acquisition. These estimates are comparable to adult incidence rates in Sub-Saharan Africa (0.28% for Congo and 0.53% for Kenya).[4]

To better understand the epidemiology of HIV infection in women and concentrate our prevention efforts, we need to focus on these "hotspots". Misinformation can be spread within these epidemics, as well as disease.

In a survey of residents of the South Side Chicago Housing Authority facilities, a questionnaire that was designed to assess knowledge concerning HIV transmission, the disease, and treatment revealed that many were aware there was effective antiretroviral therapy, However, a quarter thought there was an effective HIV vaccine while 13% thought there was a cure available.[5]

Life Expectancy Improvements

In the early years, an HIV diagnosis was essentially a death sentence. In a recent analysis from the North American AIDS Cohort Collaboration on Research and Design (NA-ACCORD), Hogg and colleagues estimated the change in life expectancy from 2000 to 2007 among individuals who were prescribed antiretrovirals (ART) in the U.S. and Canada. In their analysis, life expectancy increased from 36.1 to 51.4 years from 2000-2002 to 2006-2007, with the greatest increases seen in those who started with a baseline CD4 count above 350 cells/mm3; in this situation a 20 year old HIV positive person with a CD4 count >350 cells/mm3 can expect to live into the early 70s.[6] Of course, these benefits may not be achieved by all individuals for numerous reasons.

In 2009, despite all the major advances in diagnosis and treatment, HIV was the fourth leading cause of death among African American women aged 25 to 44 years, causing about 800 deaths, or 9% of all deaths in this group.[7]

The Women's Interagency HIV Study (WIHS), a representative cohort, studied deaths over a 10-year period among its participants. From 1995 through 2004, deaths from non-AIDs causes increased and accounted for a majority of the deaths by 2001-2004. The most common non-AIDs causes of death were trauma or overdose, liver disease, cardiovascular disease and malignancy. Independent predictors of mortality besides HIV-associated variables were depressive symptoms and active Hepatitis B or C.[8]

Perinatal Transmission

The reduction in perinatal transmission of HIV is one of the most important achievements in HIV medicine, although they continue to occur. In a landmark study, AIDS Clinical Trial Group 076 demonstrated that zidovudine monotherapy administered during pregnancy, labor and delivery and to the newborn, reduced the risk of HIV transmission to the infant from 25% to 8%.[9] Additional studies have demonstrated the effectiveness of combination therapy, further decreasing the risk of HIV transmission to 1–2%.[10]

The Department of Health and Human Services (DHHS) Perinatal guidelines recommend that all HIV-positive women who are pregnant receive effective combination ART regardless of CD4 count to minimize the risk of mother-to-child transmission.[10]

In 2010, an estimated 217 children younger than 13 were diagnosed with HIV in the 46 states with long-term, confidential name-based HIV infection reporting since at least 2007; 162 (75%) of those children were perinatally infected. Missed opportunities included primary prevention strategies for women and girls, lack of prenatal testing, failure to prescribe antiretroviral medication during pregnancy, lack of cesarean section for women with viral loads above 1000 copies/ml, and breastfeeding.[11]

In summary, treating women with HIV provides unique opportunities and challenges for providers. Understanding the epidemiologic trends in HIV-infected women in the US is crucial because these trends are not only complex, but the are also dynamic. **HIV**

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SHUTTERSTOCK/ ANDREYARKUSHA

HIV Prevention Among Women

Current and Future Challenges

ANANDI N. SHETH, MD, MSC AND MONICA GANDHI, MD, MPH

EVERY HOUR, 50 YOUNG WOMEN are newly infected with HIV worldwide.[1] Women and girls now make up nearly half of the over 35 million people living with HIV/AIDS globally.

Despite tremendous advances in HIV treatment, HIV infection is still the leading cause of death among women of childbearing age worldwide.[2,3] In sub-Saharan Africa, where women make up nearly 60% of people living with HIV/AIDS, young women aged 15-24 years are up to eight times more likely to acquire HIV than similarly aged men,[4,5] and even younger girls are disproportionally infected,[6] highlighting women and girls' vulnerability to infection.

These global trends also impact women in the United States. One in four HIV infected persons in the United States are women, a striking shift from the 1980s, when women represented fewer than 8% of all cases.[7] Women also comprise a quarter of persons diagnosed with AIDS, and a quarter of those who die with HIV/AIDS in this country.

Racial and ethnic disparities in the burden of HIV are magnified in women, with 80% of new cases occurring among black and Hispanic women. Additionally, geographic inequalities exist with an increasing burden of both new HIV infections and later-stage diagnoses among women in the southern United States.

Why are women at risk?

Women are particularly vulnerable to HIV infection due to a complex array of social, behavioral, and biological factors.

Over 80% of new HIV infections in women are from heterosexual sex with someone known to have, or be at high risk for, HIV infection.[7] A major barrier to HIV prevention is that many women are not aware of their partner's risk of HIV infection, and therefore do not see themselves at risk.

Indeed, important prevention reports published by the *HIV Prevention Trials Network Women at Risk Committee*[8,9] highlight this vulnerability with the following quote: "Women at risk for HIV acquisition frequently do not appreciate [their] risk. The HIV epidemic among US women is, in many ways, hidden from effective dialogue, both among the populations at risk and within the broader scientific community."

As an additional challenge, health care providers may not adequately assess for HIV risk in women. Moreover, women may not be able to utilize or control many available HIV prevention options, such as mutual monogamy, consistent use of male condoms, and male circumcision.

Women may face intimate partner violence, discrimination, stigma, substance abuse, mental health disorders, poverty, and lack of access to education and/or health care, all of which increase the risk of HIV acquisition. Finally, women are twice as susceptible to HIV during unprotected vaginal sex then men, and this risk further increases during unprotected anal sex or when one member of the couple has a sexually transmitted infection.[10]

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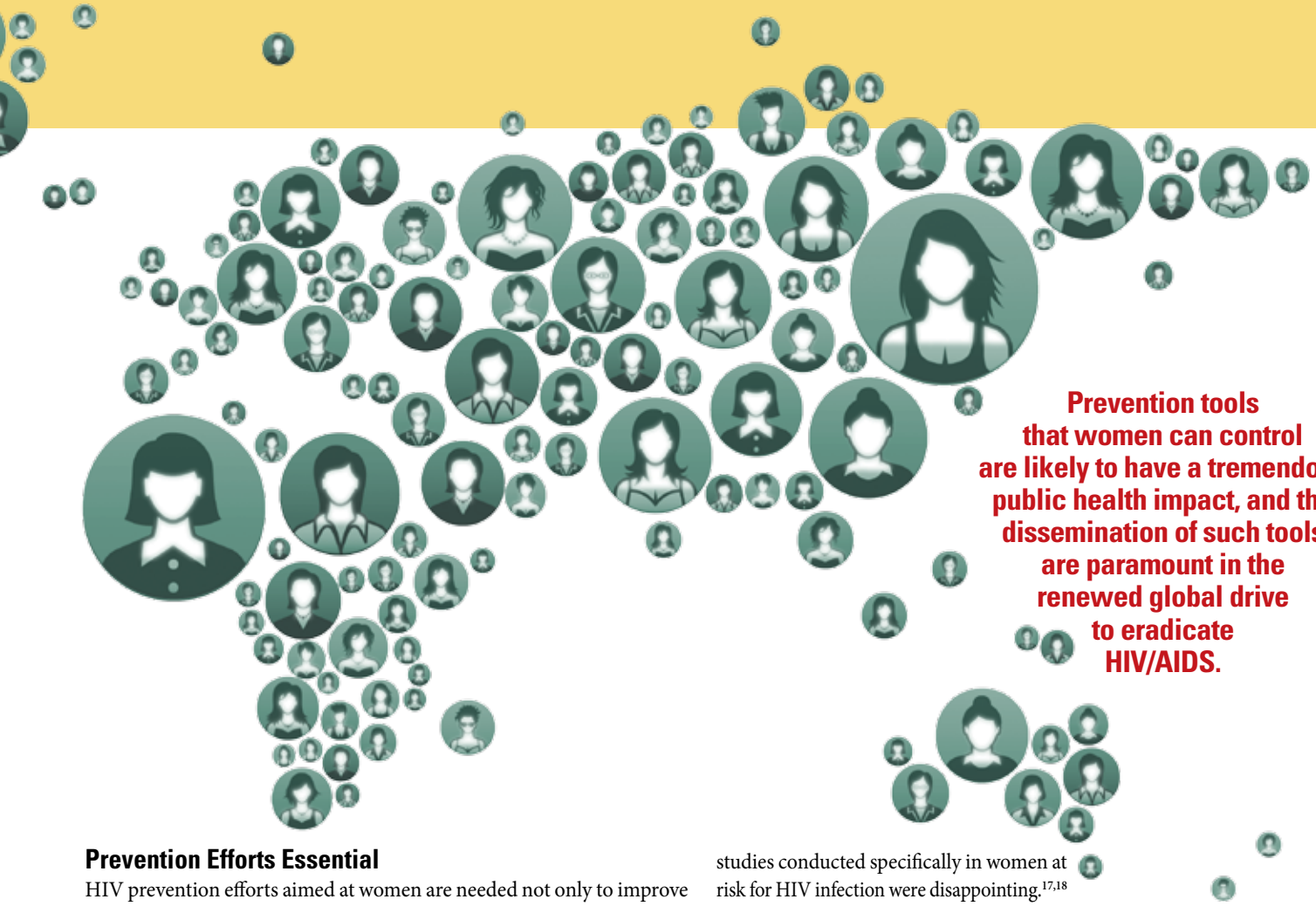

Prevention tools that women can control are likely to have a tremendous public health impact, and the dissemination of such tools are paramount in the renewed global drive to eradicate HIV/AIDS.

Prevention Efforts Essential

HIV prevention efforts aimed at women are needed not only to improve the health of women and their partners, but also to protect their infants from acquiring infection during pregnancy.

Behavioral interventions and promoting condom use are effective in reducing risk, but they are not easily implemented or universally effective, and have reduced, but certainly not eliminated, HIV transmission. Prevention tools that women can control are likely to have a tremendous public health impact, and the dissemination of such tools are paramount in the renewed global drive to eradicate HIV/AIDS.

What about PrEP?

HIV pre-exposure prophylaxis (PrEP) has received increasing attention in the last few years and may help to fill this urgent need for a female-controlled HIV prevention method.

PrEP is an HIV prevention strategy in which antiretroviral drugs are used by HIV-uninfected persons before a potential HIV exposure to reduce the likelihood of infection. This strategy has been shown to work to reduce HIV infection by 44-86% in large-scale studies, including two conducted among men who have sex with men (MSM),[11,12] one conducted among people who inject drugs,[13] and two conducted in HIV-negative men and women for whom heterosexual sex was the main reported risk factor.[14,15]

Based on these studies, once daily use of an oral fixed-dose combination tablet containing tenofovir disoproxil fumarate and emtricitabine (TDF/FTC, Truvada®) was approved by the U.S. Food and Drug Administration for HIV-negative individuals as a prevention modality in 2012.

Despite the efficacy of PrEP in the trials summarized above, as well as in a trial examining intermittent PrEP in MSM,[16] results from other PrEP studies conducted specifically in women at risk for HIV infection were disappointing.[17,18]

The first study, known as FEM-PrEP, was conducted among over 2000 African women who were randomized to either TDF/FTC or placebo. This study was stopped early when similar numbers of HIV infections were noted in the treatment and placebo groups. The second study, known as VOICE, included over 5000 African women, and similarly demonstrated a lack of efficacy for both daily TDF alone and daily TDF/FTC as prevention strategies.

In both studies, poor adherence to study drug was thought to explain the negative findings. Adherence rates to the active drug were below 40% among women in FEM-PrEP and approximately 30% among women in VOICE, based on levels of tenofovir found in the bloodstream. Furthermore, over half of the women in VOICE had no tenofovir detected in the blood during any study visit, suggesting that most women in this trial were not taking the provided PrEP drug at all.

To date, findings from studies using topical application of antiretroviral agents also have been discouraging for women.

After the CAPRISA 004 trial showed promising results of a 39% reduction in HIV acquisition among women in South Africa with a use of vaginal microbicide containing 1% tenofovir gel before and after sex,[19] two subsequent studies failed to demonstrate any prevention efficacy with the use of either daily[18] or coitally-driven[20] intravaginal tenofovir gel.

Not surprisingly, in the CAPRISA 004 trial, tenofovir gel worked best among women who used it the most. However, in the above mentioned VOICE trial, women who used the same microbicide daily did not demonstrate reduced rates of HIV acquisition, although they also likely had limited adherence to the gel.[18]

Most recently, tenofovir gel used before and after sex was not effective

Female-Controlled HIV Prevention Methods

Female condom	Effective in reducing HIV transmission, but limitations include its expense, the fact that the female condom is not covert, and the potential noise that the latex can make during intercourse.
Diaphragms	No evidence of efficacy in reducing infection rates to women
Microbicides	Multiple failures from trials of older microbicides; 39% reduction in HIV acquisition with vaginal 1% tenofovir gel before and after sex in one study, but no protection found with daily or pericoital use in two other studies where adherence was poor. Alternative drugs and delivery systems, such as vaginal films and rings, are in development and in early trials.
Oral pre-exposure prophylaxis	Effective in reducing HIV transmission in heterosexual women and men in two studies, but not effective in two studies in women at risk for HIV infection where adherence was poor.
Injectable pre-exposure prophylaxis	Several drugs in early trials, including long acting rilpivirine and cabotegravir
Partner antiretroviral treatment	Reduces risk of transmission to uninfected partners

in preventing HIV in over 2000 young South African women (ages 18 to 30) participating in the FACTS 001 study.[20] Despite extensive adherence support and counseling providing during this study, only 13% of women consistently used the product (during less than 80% of sex acts).

In the group of women who had tenofovir detected in the vaginal fluid, indicating appropriate use, the gel was effective in preventing HIV. These oral and topical PrEP studies reinforce that PrEP generally works when used perfectly, even in women. However, these studies highlight the challenge of developing prevention methods that are acceptable and easy to use for young women at risk for HIV—and the urgent need to expand prevention options for this population.

Other reasons besides the need for daily adherence to oral PrEP likely contribute to the reduced uptake of or reduced efficacy of PrEP in some women.

First of all, women may not always be aware of their own risk or the risk of their partners. This may explain why PrEP worked so well in heterosexual women in the Partners PrEP trial, where HIV-negative individuals with known HIV-positive partners were enrolled.[14]

Women in relationships with HIV-positive males (in "serodiscordant" relationships) may better understand their risk and be more likely to take PrEP. Furthermore, some studies have suggested that adequate adherence to PrEP may be more critical for women than for men.

Concentrations of the active form of tenofovir are higher in rectal tissue than vaginal tissue,[21,22] suggesting that the effect of poor adherence may be amplified in women compared to men.

Based on the successful studies for PrEP summarized above, the Centers for Disease Control (CDC) recommends PrEP as an HIV prevention option for sexually active women and men at substantial risk for HIV infection.[26]

Screening and follow-up for patients prescribed PrEP is generally the same for women and men and involves performing regular HIV tests, kidney function tests, and screening

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for sexually transmitted infections, while providing regular medication adherence counseling and side effect assessments. In addition, women should be tested for pregnancy every three months while on PrEP.

PrEP and conception

PrEP is one of several strategies that can protect women from HIV acquisition who are trying to conceive a child with an HIV-infected male partner. The CDC/USPHS guidelines recommend the daily use of oral TDF/FTC as PrEP for one month before and one month after the conception attempt in HIV negative women planning pregnancy with an HIV positive male partner.[26] TDF/FTC is widely used among pregnant and breastfeeding women worldwide for the treatment of HIV, and neither agent has been associated with significant short-term health risks for the fetus or infant. However, longer-term studies of the impact on TDF/FTC use during pregnancy on exposed children's health are in progress, as are studies to examine the use of PrEP during conception.

A path forward

The only currently-approved method of PrEP requires the daily consumption of an oral medication. This strategy is difficult to translate into real-world practice in which decreased adherence will reduce the efficacy of PrEP, particularly for women.

To advance our understanding of how to best tailor PrEP strategies for women, we need to understand how PrEP candidates work in women across a range of dosing strategies and delivery systems. For example, if we demonstrated that a lower dose or an extended dosing interval of an oral medication, a long-acting injectable agent, or a microbide provided via the monthly insertion of a vaginal ring can reduce the risk of HIV acquisition in women, barriers to use might be reduced, adherence could be improved, and the strategy will have better success in preventing HIV infection.

Combining the HIV prevention method of PrEP with another benefit such as contraception (e.g. via a vaginal ring that provides both microbicide and hormonal contraception or by injecting a long-acting PrEP agent with a long-acting hormonal contraceptive) may offer an additional motivation for adherence.[27]

Preclinical or early clinical studies of several alternative dosing or delivery strategies are already underway. These include intermittent oral PrEP dosing in women, long-acting injectable drugs, and drugs applied through vaginal rings, some co-administered with contraceptives.

Prevention of HIV in women should stem from an increased awareness of HIV risk factors, through routine screening for HIV infection, and through providing women with effective and safe HIV prevention methods that they can control.

Maintaining consistent and sustainable adherence to PrEP has been a significant challenge in clinical trials that include women and may be especially important in women due to the tissue disposition of the drugs.

Long-term safety of PrEP in women should be considered and studied further, especially the potential impact on bone mineral density. PrEP is generally safe during conception, pregnancy, breastfeeding, and for use with contraceptives, but additional studies in these areas are needed.

Finally, much like the experience with contraception, women need a mix of options for PrEP to facilitate its use. Thus, research into development of new drugs and delivery systems are needed, as is research on attitudes and acceptability of various products in diverse populations of women. **HIV**

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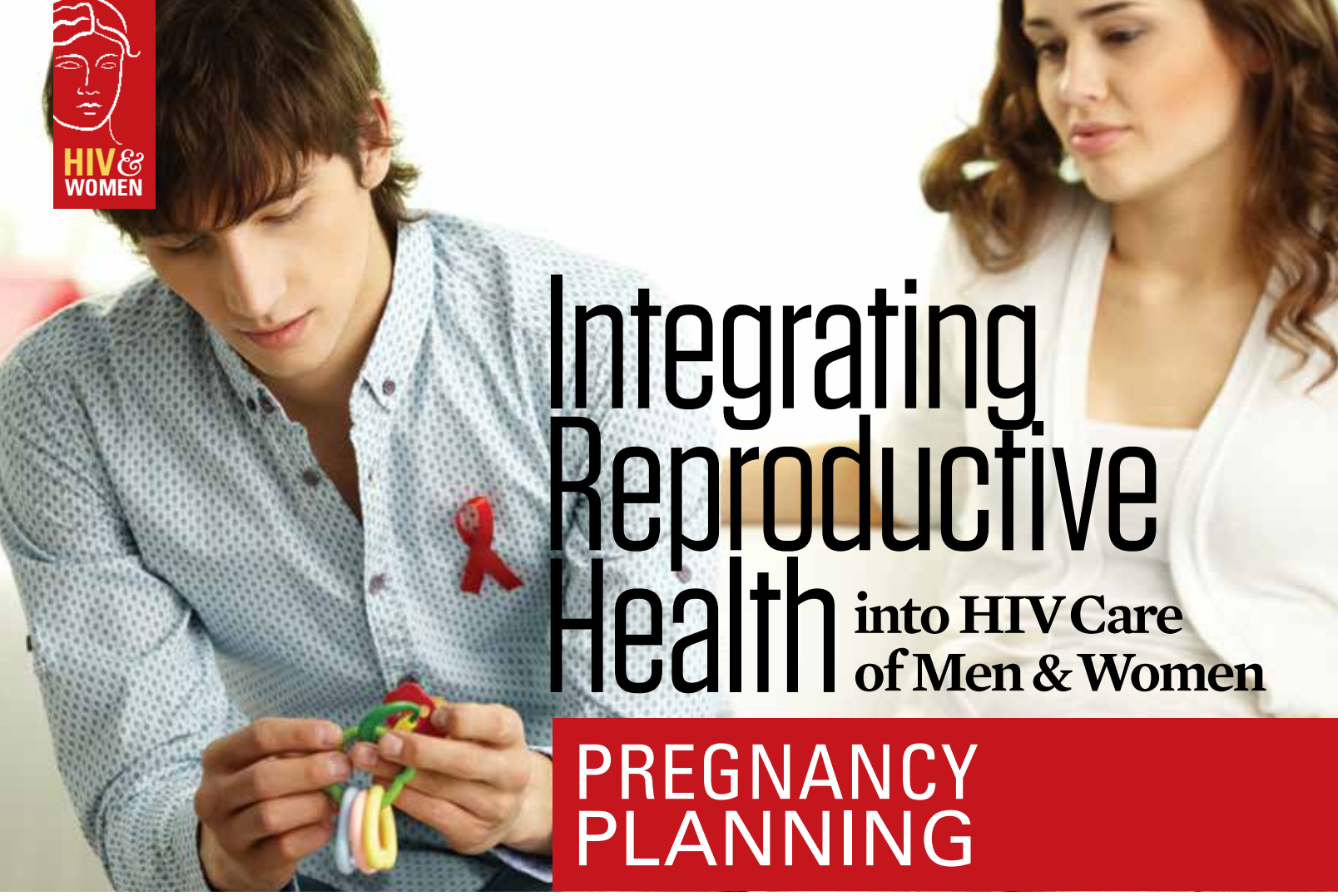

HIV & WOMEN

Integrating Reproductive Health into HIV Care of Men & Women

PREGNANCY PLANNING

BY MARY JO HOYT, MSN AND JOANNE PHILLIPS, MS, RN, C-PNP

HIV CARE PROVIDERS ARE accustomed to taking a detailed sexual history, assessing risk for acquisition of STIs, and working with patients to prevent HIV transmission to partners. But there is another question about a patient's sexual life that is integral to providing comprehensive HIV services for people living with HIV: "Do you want to have (more) children?"

Why?

Roughly three-quarters of people living with HIV in the United States are of reproductive age.[1] Research suggests that men and women living with HIV have fertility desires and intentions that are similar to those of persons who are HIV-uninfected.[2,3,4] However, provider-initiated conversations with people living with HIV about reproductive plans are lacking.[5,6,7]

Data also indicate that the majority of pregnancies among women living with HIV are unintended and that contraception is underutilized.[8,9,10] Furthermore, it has been estimated that there are approximately 140,000 HIV serodiscordant male/female couples in the United States, about half of whom report the desire to have children.[11]

In addition, community stigma regarding childbearing in the context of HIV remains high and patients may fear initiating conversations with their care providers about their reproductive intentions.[12,13] Such data underscore the importance of providing or coordinating care to ensure access to quality contraceptive, preconception and/or safer conception services.

Comprehensive reproductive planning and preconception counseling and care for persons of reproductive age are recommended as a component of routine primary medical care by the Centers for Disease Control and Prevention (CDC) and other national organizations.[14,15] With reproductive planning and preconception care, maternal and fetal outcomes are improved by identifying and modifying risks prior to pregnancy, preventing unintended pregnancies, and improving the health of women and men.[16,17] In the context of persons living with HIV, the additional goals of reproductive planning and preconception care are to minimize the risk of HIV transmission to partners and children.[18]

SHUTTERSTOCK

How?

Routine health promotion activities for all women and men of reproductive age should begin with screening women and men for their intentions to have or not have a child in the short and long term and their risk of conceiving (whether intended or not).

Asking every patient about his or her parenting intentions—at regular intervals throughout the course of care—can open the door to important conversations that are integral to HIV prevention and to providing comprehensive HIV care and treatment. By asking, "Do you want to have (more) children?", the need for additional services like contraceptive counseling can be determined and providers can either offer or coordinate those services.

Resources

Guidelines for reproductive counseling and preconception care—including detailed information about the use of hormonal contraception and antiretroviral drugs—are included in the Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States (Available at: https://aidsinfo.nih.gov/guidelines/html/3/perinatal-guidelines/0). See Table 1 for a list of additional resources, including provider tools and consumer education materials.

Conclusion

Through effective communication about reproductive desires and intentions, HIV care providers can identify men and women living with HIV who desire children or who wish to avoid or delay having children with the goal of providing or coordinating appropriate reproductive health services. Reproductive planning and preconception care is a critical component of HIV primary care in order to optimize the health of patients, improve pregnancy outcomes, and to prevent HIV transmission to partners and children. HIV

REPRODUCTIVE PLANNING AND PRECONCEPTION CARE RESOURCES

The HIV and Preconception Care Toolkit

CDC's Expert Panel for Preconception and Reproductive Health of HIV-Infected Persons. Available at: http://www.womenandhiv.org/francois-xavier

United States Medical Eligibility Criteria (US MEC) for Contraceptive Use, 2010

Guidelines and summary charts. Available at: http://www.cdc.gov/reproductivehealth/unintendedpregnancy/usmec.htm

Reproductive health and preconception care consumer resources for HIV-positive men and women HIVE—University of California at San Francisco. Available at: http://www.hiveonline.org/for-you/

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HIV & WOMEN

All Pregnant HIV-infected Women Should Receive ARVs

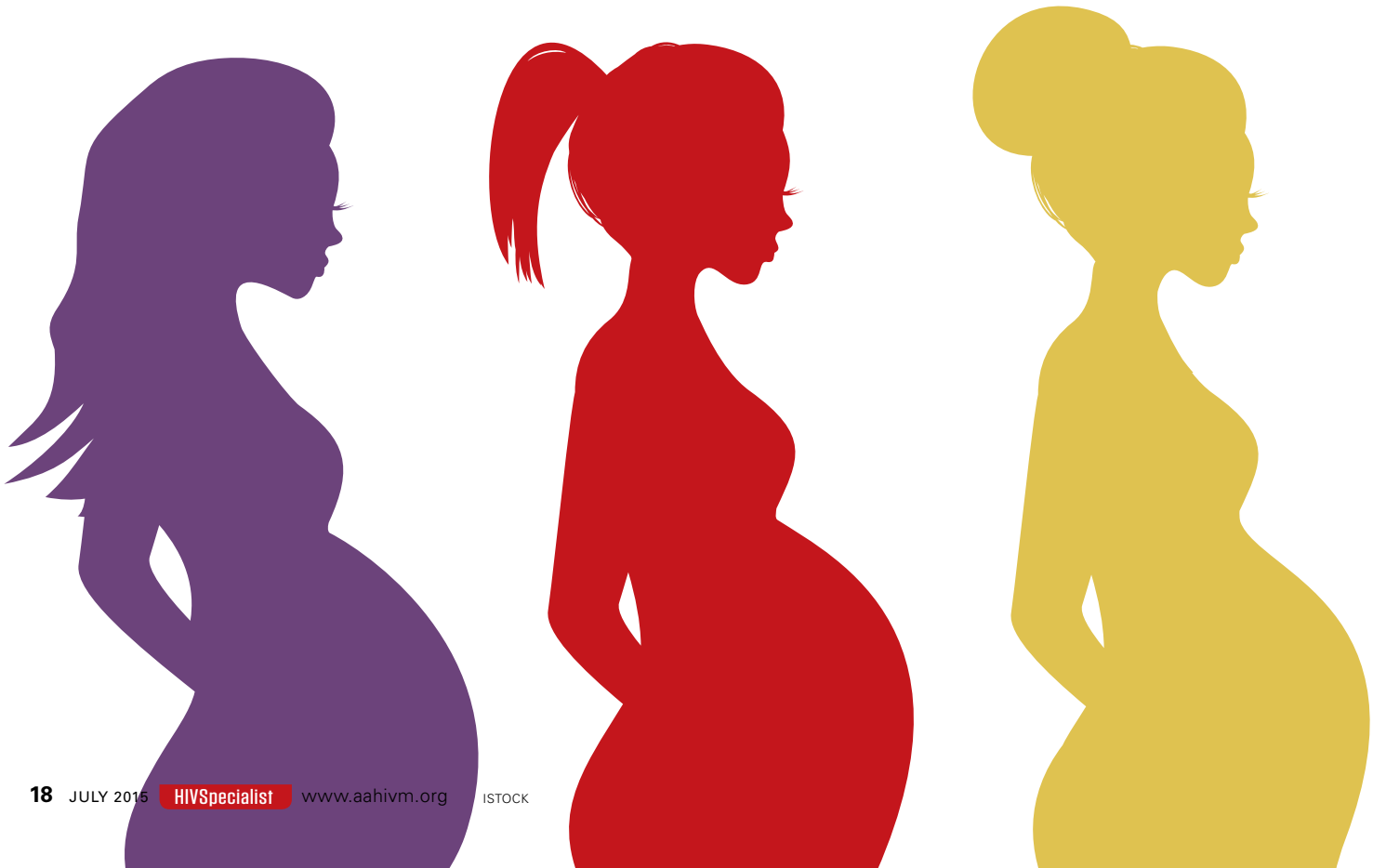
Antiretroviral Therapy in Pregnancy

BY PUJA H. NAMBIAR, MD, JASON J. SCHAFER, PHARMD, MPH, BCPS, AAHIVP, and WILLIAM R. SHORT, MD, MPH, AAHIVS

THE RATE OF PERINATAL TRANSMISSION OF HIV has drastically diminished to less than 2% in the United States[1,2] with the implementation of prenatal HIV screening, antiretrovirals (ARVs), scheduled cesarean delivery when necessary, and the avoidance of breast feeding.

In 1994, the Pediatric AIDS Clinical Trials Group (PACTG 076) demonstrated that the use of zidovudine (ZDV/AZT) monotherapy during pregnancy, intrapartum intravenous ZDV, and the administration of ZDV prophylaxis to the newborn for six weeks reduced the risk of HIV transmission to infants by 67%.[3] Research and literature has proven over time, the benefits of ARVs, not just in the treatment of maternal HIV infection, but also as chemoprophylaxis to reduce the risk of perinatal transmission of HIV.

The physiologic changes during pregnancy may alter the pharmacokinetics of ARVs. In general, the nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs) and non-nucleoside



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Recommendations for use of antiretroviral drugs in pregnant women

Adapted from Panel on Treatment of HIV-Infected Pregnant Women and Prevention of Perinatal Transmission. Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States. March 28, 2014. Available at: http://aidsinfo.nih.gov/contentfiles/PerinatalGL.pdf.

DRUG	COMMENT
PREFERRED TWO-NRTI BACKBONE	
ABC/3TC	Available as FDC, can be administered once daily, but potential HSR. ABC should not be used in patients who test positive for HLA-B*5701.
TDF/FTC or 3TC	TDF/FTC available as FDC. Either TDF/FTC or TDF and 3TC can be administered once daily. TDF has potential renal toxicity, thus TDF-based dual NRTI combinations should be used with caution in patients with renal insufficiency.
ZDV/3TC	Available as FDC. NRTI combination with most experience for use in pregnancy but has disadvantages of requirement for twice-daily administration and increased potential for hematologic toxicity.
PI REGIMENS	
ATV/r + a Preferred Two-NRTI Backbone	Once-daily administration
LPV/r a Preferred Two-NRTI Backbone	Twice-daily administration. Once-daily LPV/r is not recommended for use in pregnant women.
NNRTI REGIMEN	
EFV + a Preferred Two-NRTI Backbone *Note: May be initiated after the first 8 weeks of pregnancy*	Concern because of birth defects seen in primate study; risk in humans is unclear. Postpartum contraception must be ensured. Preferred regimen in women requiring co-administration of drugs with significant interactions with PIs.
ALTERNATE REGIMENS	
DRV/r + a Preferred Two-NRTI Backbone	Less experience with use in pregnancy than ATV/r and LPV/r.
SQV/r + a Preferred Two-NRTI Backbone	Baseline ECG is recommended before initiation of SQV/r because of potential PR and QT prolongation; contraindicated with pre-existing cardiac conduction system disease. Large pill burden.
NNRTI REGIMEN	
NVP + a Preferred Two-NRTI Backbone	NVP should be used with caution when initiating ART in women with CD4 T-lymphocyte (CD4) cell count >250 cells/mm3. Use NVP and ABC together with caution; both can cause HSRs within the first few weeks after initiation.
INTEGRASE INHIBITOR REGIMEN	
RAL + a Preferred Two-NRTI Backbone	Limited data on RAL use in pregnancy, but may be considered when drug interactions with PI regimens are a concern.
INSUFFICIENT DATA IN PREGNANCY TO RECOMMEND ROUTINE USE IN ART-NAIVE WOMEN Drugs that are approved for use in adults but lack adequate pregnancy-specific PK or safety data	
DTG	No data on use of DTG in pregnancy
EVG/COBI/TDF/FTC Fixed Drug Combination	No data on use of EVG/COBI component in pregnancy
FPV/r	Limited data on use in pregnancy
MVC	MVC requires tropism testing before use. Few case reports of use in pregnancy
RPV	RPV not recommended with pretreatment HIV RNA >100,000 copies/mL or CD4 cell count <200 cells/mm3. Do not use with proton pump inhibitor. Limited data on use in pregnancy.
NOT RECOMMENDED Drugs whose use is not recommended because of toxicity, lower rate of viral suppression or because not recommended in ART-naive populations	
ABC/3TC/ZDV	Generally not recommended due to inferior virologic efficacy
d4T	Not recommended due to toxicity.
ddI	Not recommended due to toxicity.
IDV/r	Concerns re: kidney stones, hyperbilirubinemia.
NFV	Lower rate of viral suppression with NFV compared to LPV/r or EFV in adult trials.
RTV	RTV as a single PI is not recommended because of inferior efficacy and increased toxicity
ETR	Not recommended in ART-naive populations
T20	Not recommended in ART-naive populations
TPV	Not recommended in ART-naive populations

Key to Acronyms: 3TC = lamivudine; ABC = abacavir; ART = antiretroviral therapy; ARV = antiretroviral; ATV/r = atazanavir/ritonavir; CD4= CD4 T lymphocyte; COBI = cobicistat; d4T = stavudine; ddI = didanosine; DTG = dolutegravir; DRV/r = darunavir/ritonavir; ECG =electrocardiogram; EFV = efavirenz; ETR = etravirine; EVG = elvitegravir; FDC = fixed drug combination; FPV/r = fosamprenavir/ritonavir; FTC = emtricitabine; HSR = hypersensitivity reaction; IDV/r = indinavir/ritonavir; LPV/r = lopinavir/ritonavir; MVC = maraviroc; NFV=nelfinavir; NRTI = nucleoside reverse transcriptase inhibitor; NNRTI = non-nucleoside reverse transcriptase inhibitor; NVP = nevirapine; PI= protease inhibitor; PK = pharmacokinetic; RAL = raltegravir; RPV = rilpivirine; RTV = ritonavir; SQV/r = saquinavir/ritonavir; T20 = enfuvirtide; TDF = tenofovir disoproxil fumarate; TPV = tipranavir; ZDV = zidovudine

reverse transcriptase inhibitors (NNRTIs) cross the placenta in comparison to the highly protein bound protease inhibitors (PIs).

All pregnant HIV-infected women should receive ART regardless of CD4 cell count or HIV viral load. A combination of antepartum, intrapartum, and infant ARV prophylaxis is known to reduce perinatal transmission by several mechanisms, including lowering maternal viral load and providing pre and post exposure prophylaxis to the infant. The recommendations for using ARVs in pregnant women take into account efficacy data, safety information, and pharmacokinetic studies performed during pregnancy and the post-partum period.

Several other factors such as resistance testing, comorbidities, convenience, adverse effects and drug interactions should be considered when selecting a regimen.

Table 1 lists the current United States Department of Health and Human Services preferred and alternative combination regimens for antiretroviral naive pregnant women as well as agents no longer recommended and those with insufficient data for use in pregnancy.[4]

HIV-infected women who become pregnant while receiving ART should be maintained on their current regimens, assuming the regimen is effective and well tolerated. Discontinuation of ART may lead to increase viral load, immune suppression, disease progression and increased risk of perinatal transmission.

Resistance testing should be performed in pregnant women with detectable viremia (>500 to 1000 copies/ml) while on ART. There have been concerns of neural tube defects with use of efavirenz in the first trimester. The risk of neural tube defects is limited to the first five to six weeks of pregnancy; however a recent meta-analysis showed no overall increased risk of birth defects compared to women on other ARVs.[5] The panel recommends that pregnant women receiving efavirenz-based regimens during the first trimester should continue their regimen, provided it is eight weeks past conception and the patient has achieved viral suppression.

In the past, all HIV-infected women were given intravenous ZDV during labor, regardless of their viral load. The French Perinatal Cohort evaluated transmission in >11,000 HIV-infected pregnant women receiving ART. The overall rate of perinatal transmission was 0.9% with intravenous ZDV and 1.8% without intravenous ZDV. In women with HIV RNA < 1000 copies/ml at delivery, no transmission occurred among 369 women who did not receive intravenous ZDV, compared to 0.6% that received ZDV. Among women with HIV RNA >1000 copies/ml, the risk of transmission was increased without intravenous ZDV (10.2%), compared to 2.5% with ZDV. The panel now recommends the use of intravenous ZDV to HIV-infected pregnant women with HIV RNA >1000 copies/ml or unknown viral load at near delivery.[6]

Established in 1989, The Antiretroviral Pregnancy Registry (APR) is a voluntary, international, prospective exposure registration cohort designed to collect and evaluate data on ARV use and teratogenicity in pregnancy. The success of this registry depends on the participation and support of all heath care providers in enrolling pregnant patients and providing follow up information post-partum. More information can be obtained by visiting the registry website at www.APRegistry.com.

To date, the prevalence of birth effects for first trimester exposure as well as exposure at any time during pregnancy is not higher than those reported in the registry's two population based comparators, the Center for Disease Control (CDC) and Prevention birth defect's surveillance system (MACDP) and the Texas Birth Defects Registry (TBDR).

Due to the success of combination ART, many individuals with access can live a long healthy life. This includes woman who may want to consider having a child. Therapeutic strategies for the management of HIV infection in pregnancy must be planned with a few goals in mind: utilize ARVs that have established efficacy, monitor closely maternal medication adherence, be aware of safety consideration with the available agents with regards to pregnancy, and maximize the prevention of HIV transmission to the newborn. **HIV**

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Soft Issues Hard Trouble

Mental Health, Violence, Addiction Among Factors That Make Adherence Difficult For Women

BY JANET SPINNER, MSN, CNM, AAHIVS

WITH THE ACCUMULATION OF YEARS taking care of women living with HIV, I have become increasingly impressed by a reality that is well known to those of us in the HIV community. The phenomena, I am referring to is how the "soft issues" of mental health, violence, reproductive rights, poverty and addiction interplay to make adherence to HIV care substantially more difficult for the women in the communities we serve.

Because these issues are so pervasive, we lose an appreciation of how profoundly they impede our efforts to improve the well being of the women we care for. In a recent *HIV Specialist* article titled "HIV Fatigue," there was a discussion regarding how time and increasing exposure to the HIV epidemic and the complexities of caring for those affected by it, wears away at our sensitivities to the vulnerabilities of those to whom we are providing services.[1]

Foremost of the life events that have astounded me in their prevalence, is that of personal histories of violent abuse. This may include childhood abuse (sexual, physical and emotional), domestic violence and intimate partner violence. For some of our refugees from war zones, rape/sodomy as a weapon of war may be a part of their personal histories.

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Mental illness, including severe depression, psychosis, borderline personality disorders and schizophrenia are common among our patients and unfortunately frequently under-addressed.

Gender based violence and intimate partner violence affects 55% of the women living with HIV in the United States—a significantly higher percentage of the population as compared to women not infected by HIV (36%).[2]

Each of these has a profound impact on the ability of the survivor to cope with occurrences of daily living and complete the tasks necessary for a normal life. There is copious data demonstrating the correlation between mental illness, but not the least significant are post-traumatic stress disorder (PTSD), and depression.

Mental illness, including severe depression, psychosis, borderline personality disorders and schizophrenia are common among our patients and unfortunately frequently under-addressed. This is due to limited resources but also the fact that some women are not interested in our services because of cultural reasons, familial demands, economic issues and myriad other personal factors including work hours.

Chronic pain syndromes, including chronic pelvic pain, are not uncommon in those that have been sexually assaulted.[7] The pain syndrome itself amplifies a central sensitization process that makes the pain harder to manage. This may exacerbate tendencies to pursue cigarettes, opioids, alcohol and other drugs of abuse. Central sensitization is a process that involves a hyper excitation of an individual's neurons in response to stimuli, especially noxious stimuli.[8,9]

Poverty within this cluster of women tends to be the norm. Women with a history of violence are more likely to be under-educated and marginally employed, if at all. In order to cope, their chosen lifestyle may include street working and living with an abusive partner to secure a shelter for themselves and their children. They may frequently have little choice about condom use and abstinence. They may not feel safe enough to disclose their HIV status due to the high risk of domestic violence in their lives. They may be afraid of being tested for HIV fearing increased stigma, violence and shame directed from family members friends and significant others, with the accidental discovery of their status. They may not divulge their status as women with histories of battery/abuse/rape and gender-based violence, fearful of the stigma related to those life events. They may believe the event was their fault and feel a certain degree of shame (believing that "I deserve this").[5]

There is a vicious cycle and inter-connectedness between the above attributes that magnifies their impact on an HIV affected woman's ability to adhere to her ART regimen. Perversely, it also acts to escalate the individual aspects of the complex series of events.

Consider Charmaine

Charmaine, was sexually abused by her mother's boyfriend starting at the age of ten.

She was eventually removed from her home by the State Department of Children and Families, as she was not attending school and was sexually active with multiple partners. Charmaine was subsequently diagnosed with PTSD, a major depressive disorder, as well as drug addiction. She had two children by age 25, both of whom were removed from her care due to lack of supervision and neglect. She became a prostitute.

Charmaine was diagnosed with HIV during her second pregnancy, but she failed to return for follow-up appointments in the postpartum period. When she finally re-entered care, she could not comply with her HIV medications. She made several attempts to comply, but found she could not bring herself to take her ARVs as "they make me feel like I'm sick." Attempts to engage her in mental health care were hindered by recurrent cocaine and heroin use. She eventually became involved with a local faith-based recovery group, which convinced her that the medications were of no use and if she would only "give herself up to the spirit," she would be cured.

Then There is Sarai

Sarai, is a 21 year old Congolese refugee who was infected with HIV through maternal-to-child transmission. She has never successfully adhered to an ART regimen.
Her early adolescence was troubled by a mother whose attentiveness was diminished by substance use and abusive boyfriends. Sarai was sexually abused at age 11 by an older cousin. Though she is 21, her cognitive decision-making is characteristic of early adolescence. She is deficient in her ability to see cause-and-effect and employs magical thinking to cope with the stigma of HIV infection. (And the icing on the cake is her inability to/dislike of swallowing pills!).

Sarai is intermittently adherent to her care, frequently missing appointments and doses of her medications. Her viral load has never been undetectable, her last CD4 count was 150. This unfortunate young woman was recently hospitalized for candidal esophagitis.

Her gynecological health has been troubled by high grade cervical dysplasia. She was recently treated for a severe genital herpes outbreak. She has been a bit more compliant as "she never wants to get herpes again."

ISTOCK/ CHRISTOPHE BOURLOTON

A Vicious Never-Ending Cycle

These vignettes are a compilation of experiences presented to me by my patients. I have no doubt that other HIV clinicians recognize many of these same traits in their patients.

And so, these HIV-infected women become sicker with increasing numbers of co-morbidities, more self-blame regarding their illness, increased mental health morbidities, decreased employability, decreased coping skills, adoption of adverse coping strategies, more violence, and increased poverty. It is a vicious cycle that is self-perpetuating.

Central sensitization, psychiatric co-morbidities, substance use, deleterious coping mechanisms, poverty, decreasing self-esteem, HIV-related neurological impairments, poverty, limited access to healthcare and medications are also all part of the same cycle. HIV fatigue is an understandable outcome, as we face the difficult patient with the recurrent failure in adherence. These are often our most difficult and frustrating patients.

The key to intervening in an effective fashion is having the time allotted for, and willingness to learn about the patient's life. Personal histories of battery and violence are not readily shared. Busy clinic schedules often make the important life events of our most difficult patients the last thing we want to discuss, because of the time constraints.

I would suggest, that just as we routinely ask, "do you have sex with men, women or both?" We must also routinely ask, "Have you ever been battered, raped or abused?" Then be prepared to sit down and ask, "What do you mean by that?" You'll probably find out more then you wanted to know.

The systems we practice in will not be effective if they lack a coordination of essential services in an accessible, flexible, efficient model. The concept of a medical home with integration of services offers some hope as segues to much needed services. These may include mental health, psychiatric, infectious disease , dental, dermatologic, obstetric, gynecologic, contraceptive management, nutrition, and translation. This model has not reached its potential in many settings.

Whatever system is developed, if it lacks the flexibility to respond to the frequently changing and multiple challenges in women's lives, it will not work. Homelessness, child care, multiple jobs are demands that will not be erased from our individual women's lives by discussing their need to adhere to our concept of excellent care.

Finally, I believe we have yet to develop necessary interventions to end the cycle of gender based violence and the domino-like cascade of self-reinforcing events that confound our best efforts.

President Obama challenged us in September, 2013 through the report "Addressing the Intersection of HIV/ AIDS, Violence Against Women and Girls, and Gender-Related Health Disparities," to pursue research to develop strategies to confront this sickening cyclical problem in our patients lives. This interagency federal working group report on intimate partner violence is a call to action. Research is ongoing and we need to support it and implement evidence based best practices.[10]

Our best selves demands this. HIV

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HIV & WOMEN

Major Depressive Disorder and HIV Positive Women

How well are we assessing?

BY TRACY HICKS, MSN, FNP-BC

MAJOR DEPRESSIVE DISORDER (MDD) is very prevalent in our society and it is imperative that providers adequately assess for symptoms of this condition. Mental illness and chronic disease such as HIV are common in primary care. A collaborative approach is needed to ameliorate segmented patient care and promote a holistic approach to treatment of these conditions.

Roberts et al (2009) discussed the concept of providing an integrated mental health rotation that educates practitioners on the holistic care model. Additionally, segmented care produces barriers such as linkage to care, accessibility, and deficient provider-patient relationships. While the article did not specifically mention HIV, the concept can be disseminated into the HIV clinical setting addressing those with MDD.

A subpopulation adversely affected by MDD is women with HIV disease. Morrison et al (2014) found the rate of current MDD to be four times higher in HIV-seropositive women at (19.4%) than in HIV-seronegative women at (4.8%). Major Depressive disorder affects medication adherence and has been noted to decreased quality of life (Roberts et al 2009).

The percentage of women with HIV in the United States is increasing, and there is a lack of data on psychiatric diagnoses in this population. It is noted that HIV-seropositive women are at significantly greater risk of major depressive disorder compared with a similar demographic of HIV-seronegative women.

Major depressive disorder in HIV-seropositive women is comparable to those rates in women with cancer and women with cardiovascular disease. Moreover, nearly 20% of HIV-seropositive women have diagnosable major depression. Studies suggest that HIV-infected women should be screened and assessed for depression (Morrison et al 2014).

Barriers and Facilitators

Several issues impact treatment of MDD in HIV positive women, such as initiating and adjusting treatment, insufficient assessment, linkage to care, and comfort level.

In 2009, the Texas Department of State Health Services (DSHS) contracted the University of Texas at Austin School of Social Work to conduct an evaluation study (Capacity Building Project) of the mental health and substance abuse services available across the state of Texas to those living with HIV/AIDS. The primary goal of the Capacity Building research project was to gain insight into the barriers and facilitators to accessing and linking HIV infected individuals in the state of Texas to essential mental health and substance abuse services.

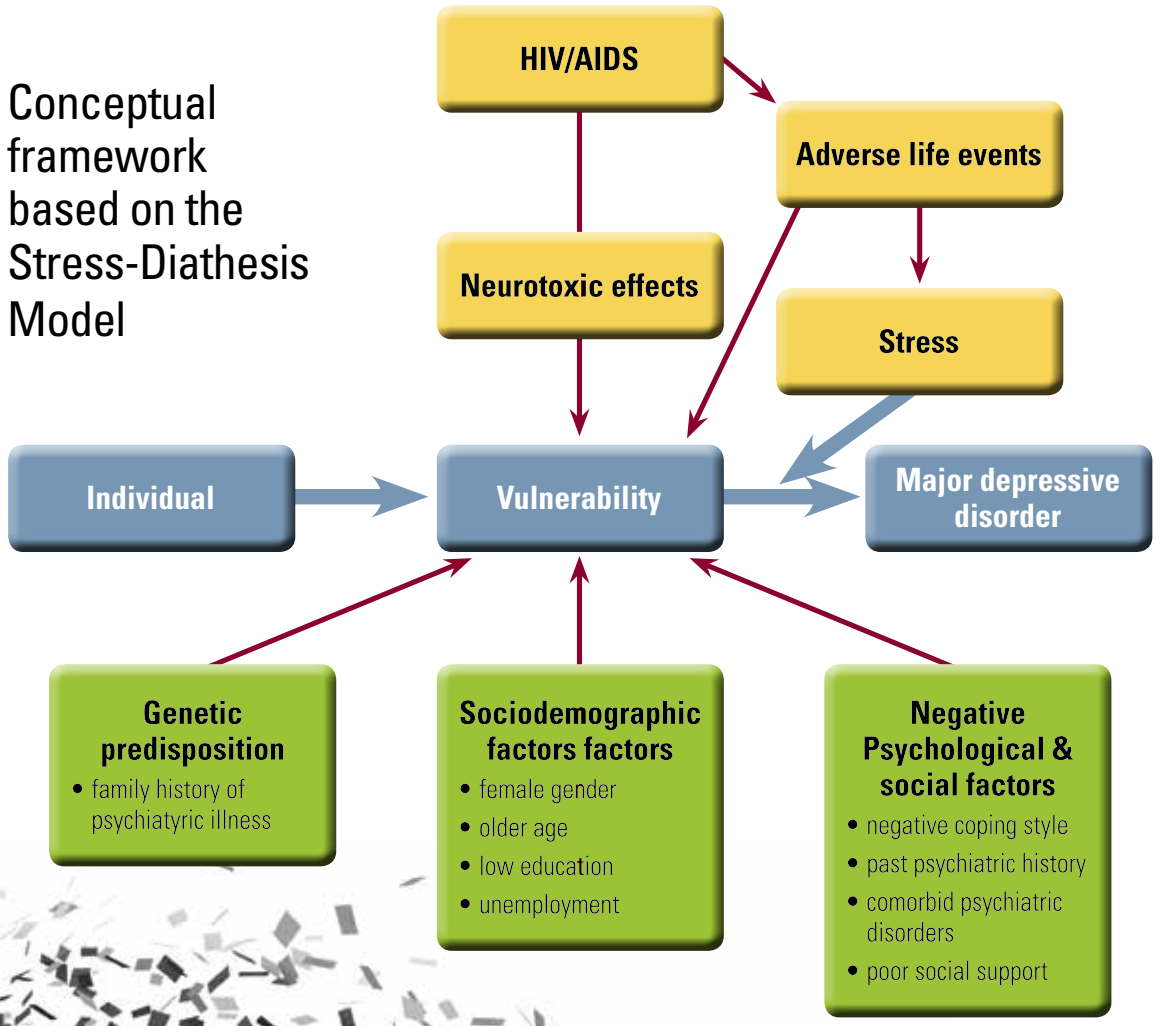
The components of the project included interviews across the state to identify barriers to care for HIV clients. These interviews encompassed those with mental health and substance abuse issues. An analysis of previous jurisdictions' of providers needs assessment, focus groups with regional providers of mental health and substance abuse, an online survey of case management staff directly responsible for the assessment and referral of clients into care, interviews with clients across Texas to ascertain barriers to care, key informant interviews, on line surveys and an analysis of the resource directories across the state for accessibility and availability of services.

The study identified barriers to care including accessibility to mental health treatment, client readiness and motivation, lack of individuality in mental health care, stigma, adequate assessment tools/skills, and lack of specialized training (Texas Department of State Health Services, 2007). Providers had more confidence in initiating the first treatment for depression than in changing and or modifying the treatment regime.

HIV healthcare providers should screen all patients for MDD and other mental health problems at every clinical encounter.

HIV causes significant stress for those affected by the disease. Women often have multiple responsibilities including the care of their children and subsequently often neglect their own care. Figure 1 illustrates the effect of MDD. HIV

Conceptual framework based on the Stress-Diathesis Model



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Breastfeeding with HIV

Yes or No? More Discussion Needed

BY JUDY LEVISON

RECOMMENDATIONS FOR METHODS of infant feeding by women with HIV depend largely on availability of resources within a geographic area.

Studies published in the 1990s, prior to the widespread use of antiretroviral therapy for pregnant and breastfeeding mothers, demonstrated a risk of HIV transmission via breastfeeding as high as 16% (Nduati 2000). However, attempts to introduce artificial feeding (formula) in low resource settings resulted in a higher infant mortality rate from diarrheal disease than from HIV (Natchu 2012; Thior 2006).

In the United States, where formula is acceptable, feasible, affordable, sustainable and safe (AFASS) and where banked breast milk may be an option, the Department of Health and Human Services (DHHS)-sponsored Perinatal Guidelines clearly advise against breastfeeding by HIV-infected women (Perinatal Guidelines 2014).

In contrast, in low resource countries, exclusive breastfeeding combined with maternal combination antiretroviral therapy (cART) or infant antiretroviral prophylaxis until complete weaning is the standard of care (WHO 2010).

Evidence supporting exclusive breastfeeding in areas that may not have the affordable and safe water that is needed to mix formula comes from several studies carried out primarily in African nations. Coutsoudis showed that mixed feeding (alternating formula with breast milk) had a higher risk of HIV transmission than exclusive breastfeeding (Coutsoudis 1999).

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The Kesho Bora study (Kenya, Burkina Faso and South Africa) demonstrated that breastfeeding women maintained on triple antiretroviral therapy until weaning had a lower risk of HIV transmission than women whose babies received a single dose of nevirapine followed by a week of zidovudine, 5.4% vs. 9.5% (Kesho Bora study 2011).

The Mma Bana trial (Botswana) concluded that women taking cART until complete cessation of breastfeeding had a 1.1% risk of transmission to their infants (Shapiro 2010).

The Breastfeeding, Antiretrovirals, and Nutrition (BAN) study (Malawi) compared infant prophylaxis that continued beyond weaning to maternal cART; a control group received one week of prophylaxis. Rates of HIV transmission were 1.7%, 2.9%, and 5.7%, respectively (Chasela 2010). Of note, serial maternal viral loads during breastfeeding were done in the Mma Bana study but only at enrollment or enrollment and at delivery in the other two.

The cumulative findings of these studies led to the World Health Organization (WHO) guidelines published in 2010, suggesting Option A (infant antiretroviral prophylaxis for the duration of breastfeeding) or Option B (maternal cART throughout breastfeeding).

Although it makes sense to recommend avoidance of breastfeeding in countries with easy access to alternatives, we live in a global world, where culture and expectations of people from one continent may be transferred to another. Specifically, many women born in Africa, but living in the United States, Canada or Europe may desire to breastfeed because of tradition as well as the fear that their friends and families will suspect they have HIV if they choose not to breastfeed; formula feeding in this context may be a red flag to their communities that they have HIV.

Also, many cities are seeing an influx of African women who are coming to the United States to deliver their babies with the plan of returning to their home countries six weeks postpartum. If these women do not breastfeed, they take the risk of not being able to find affordable and safe formula when they return home.

However, an ethical tension arises between a woman's right to make the personal decision to breastfeed and an infant's right to minimize his/her risk of HIV acquisition via breastfeeding (Kennedy 2015).

Doc-Patient Discussion Needed

If we are to avoid women surreptitiously breastfeeding or alternating breast milk and formula, clinicians need to open the door to a frank discussion of the subject.

A possible introduction of the subject might be, "In the United States we recommend that women with HIV not breastfeed. Is that an issue or problem for you?"

By asking the question we allow women to voice their concerns and wishes and discuss ways they might be able to negotiate formula feeding in their setting. If a woman insists on breastfeeding, then a harm reduction model may be appropriate (Marlatt 2012).

Within a harm reduction model in the context of breastfeeding and HIV, clinicians strongly advise women with HIV to not breastfeed, but understand that some women may feel social, familial, and cultural pressures against that recommendation (Levison 2014).

If a woman opts to breastfeed, then she needs to maintain an undetectable viral load, have frequent viral load testing, exclusively breastfeed, have prenatal consultation with the pediatric specialists who will be following the baby, and possible maintenance of baby on antiretroviral prophylaxis until after cessation of breastfeeding. Collaboration and coordination of care between the obstetric provider and the pediatric team is crucial. We also hope to avoid criminalization of HIV-infected mothers who choose to breastfeed (Stanton 2014).

One other question that has been raised by critics of the harm reduction approach is whether the findings from sub-Saharan Africa can be generalized to the developed world. However, in the U.S., Canada, and Europe serial viral load testing while breastfeeding is available, which was not the case in many of the studies cited above.

One would expect regular, e.g., monthly, viral load testing to add incentive to mothers to continue antiretroviral therapy and to allow clinicians to be alerted early if a breastfed infant is at risk. **HIV**

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CHRISTINE WISNOM, CDA, RN, BSN, LOUIS G. DEPAOLA, DDS, MS, and VALLI I. MEEKS, DDS, MS RDH

Dental Management of the Patient with HIV/AIDS

How to Care for Your Dentures.

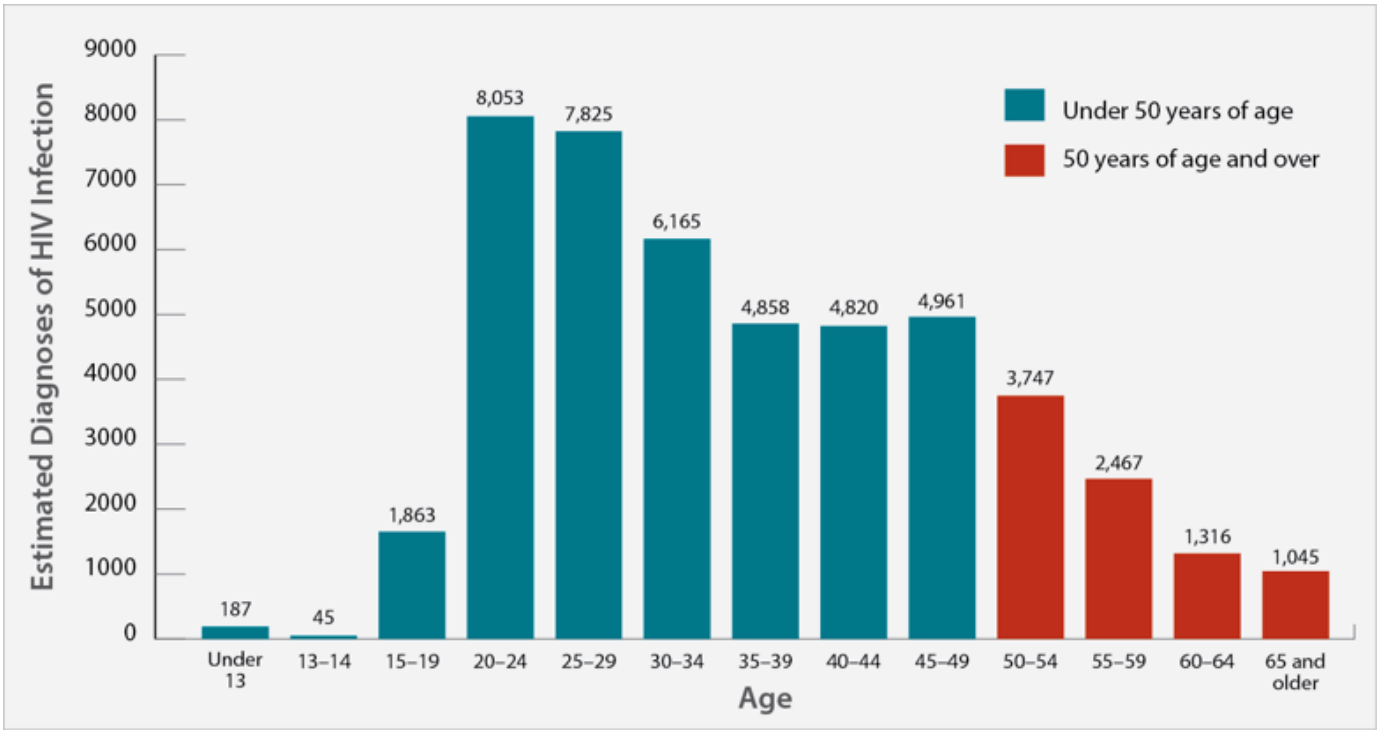
IN THE UNITED STATES, the graying of the HIV population is expanding exponentially due to multiple factors. Baby boomers, born 1946–1966, are one of the fastest expanding demographic groups. Risk factors for HIV infection in this population share many similarities with other groups, including multiple and unprotected sexual contacts as well as limit knowledge regarding disease prevention and transmission.

In the United States in 2011, persons aged 55 and older accounted for approximately 26% (313, 200) of the 1.2 million individuals with HIV infection. In 2013, 27% (7,108) of the 26,688 AIDS cases were diagnosed within this group.

Research indicates that older Americans are often diagnosed with HIV infection later in the course of their disease, because they are less likely to discuss risk behaviors with their health care providers; and many symptoms of HIV infection mimic symptoms of advancing age, including fatigue and weight loss.

This often results in a poor prognosis and more damage to their immune system. Statistics support these actions. In the years 2004-2009, 98% of people aged 25-29 survived more than one year after HIV diagnosis, compared to only 73% of newly HIV-diagnosed people aged 65 and older. The effects of late diagnosis and an advanced decline in

FIGURE 1: Estimated Diagnoses of HIV Infection by Age, 2013, United States



Reference 2: HIV Surveillance Report 2015; vol.25.

the immune system often impact oral health as well as general health.[2]

To address this situation, the White House developed the National HIV/AIDS Strategy (NHAS), designed to maximize the effectiveness of treatment modalities and linkage to care in an effort to reduce HIV infections in Americans. These strategies are impacting the battle against HIV disease in the US.

Maintaining Oral Health is Key

Recent advances in medications and health behaviors are resulting in reduced opportunistic infections and an increased life span in older adults with HIV infection. In terms of dentistry, maintaining optimal oral health is an integral component to maintaining overall optimum health.

For the older population, this may mean replacement of missing teeth with a partial and/or complete denture. Designing oral health care guidelines to meet this need requires the expertise of both HIV oral health care providers as well as HIV specialists.

A review of current literature revealed limited resources to address these challenges. To complement the NHAS, the University of Maryland, School of Dentistry's PLUS Program, with the support of the Pennsylvania Mid-Atlantic AIDS Education and Training Center grant, designed a patient education module titled "Dental Management of the Patient with HIV/AIDS: Current Concepts. How to Care for your Dentures" as a patient resource.

Oral Health Initiative

An overview of this patient education program module is presented to highlight important points to assist health care providers as they discuss overall health treatments with their patients. The complete module may be accessed at the Pennsylvania Mid-Atlantic AIDS Education and Training Web Page, at https://www.pamaaetc.org; click on Services/Resources, Clinical tools and Materials, Dental Guides. Recent and informational updates in prosthodontics and infectious diseases were used in developing the patient education program module.

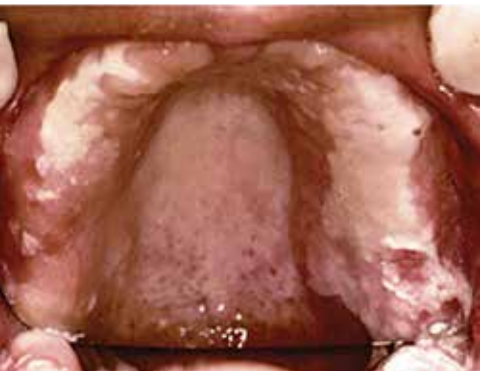
98% of people aged 25-29 survived more than one year after HIV diagnosis, compared to only 73% of newly HIV-diagnosed people aged 65 and older. The effects of late diagnosis and an advanced decline in the immune system often impact oral health.

In the U.S., approximately 26% of people between the ages of 65-74 need dentures. However, younger people may also experience oral health care problems resulting in the need for the removal of teeth and replacement of the missing teeth with dentures.[3]

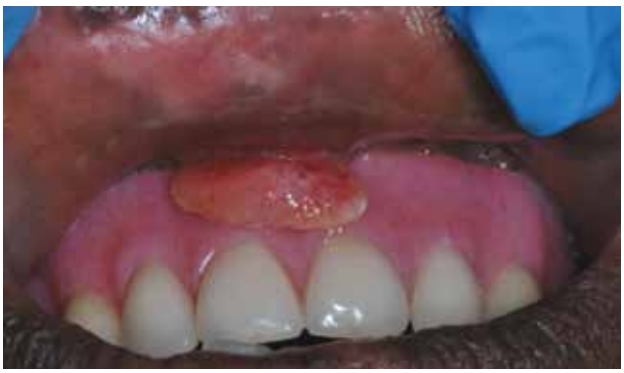
In addition, patients with HIV disease may experience certain oral health problems related to their dentures. Some problems frequently seen in HIV+ patients who wear dentures include:

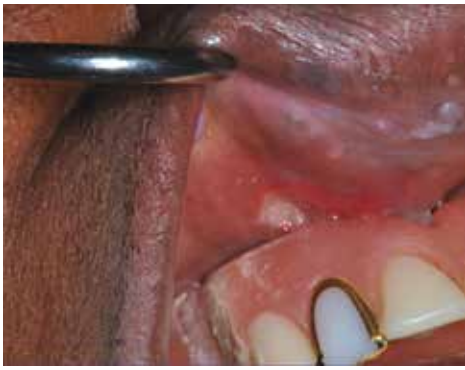
- Loose fitting denture due to weight loss
- Ulcers (Sores) in the mouth resulting from rubbing or irritation of poorly fitting dentures
- Biofilms which can cause Candidiasis (Thrush)

Weight loss is often related to loss of appetite and can be a side effect of medications. Oral candidiasis (Thrush), a lesion commonly seen in people living with HIV disease, can cause pain, edema and discomfort when swallowing and eating.[4]



Picture 1. The white patches or plaques seen on the palate, tongue or throughout the mouth in Thrush (Oral Candidiasis) in a denture patient.[5]





Pictures 2 and 3 (courtesy of Dr. Valli Meeks) illustrate a traumatic ulcer from continued irritation of an ill-fitting denture

Picture 1 illustrates the white patches or plaques seen on the palate, tongue or throughout the mouth in Thrush (Oral Candidiasis) in a denture patient.[5]

Wearing a denture continuously has been identified as a primary cause for Thrush. Therefore dentures should always be removed before going to bed.[6] Thrush can spread from the mouth to the throat as well as systemically to the lungs. In addition, certain medications may also cause Thrush.[7,8]

Weight loss is often related to loss of appetite and can be a side effect of medications. Oral candidiasis (Thrush), a lesion commonly seen in people living with HIV disease, can cause pain, edema and discomfort when swallowing and eating.

Loose fitting dentures can cause pain, difficulty eating and speaking, and oral ulcers. Pictures 2 and 3 (courtesy of Dr. Valli Meeks) illustrate a traumatic ulcer from continued irritation of an ill-fitting denture.[5] Normal age-related changes to the face and jaws, as well as gastrointestinal problem such as nausea and diarrhea resulting in weight loss also can be responsible for loose/poorly fitting dentures.[4]

An epulis, the overgrowth of tissue around the edge of the denture, may also result from poorly fitting dentures, necessitating surgical removal. Following removal, the denture may need to be professionally relined or a new denture may need to be made.[5]

A biofilm is an invisible film that forms on the surface of a denture. Biofilms can cause fungal infections like oral candidiasis or Cheilitis.[8] Research suggests that certain oral bacteria may cause infection in the heart, lungs, and other areas of the body. It may also directly affect the function of the immune system.

Patients with dentures should clean their mouth with a soft bristle tooth brush daily before inserting their denture. This also removes plaque and improves circulation to the oral tissues. Rinsing the mouth daily with a non-alcoholic mouthrinse improves comfort and reduces halitosis. Cleaning dentures regularly helps to remove biofilm and therefore reduces bacteria and other disease causing organisms.[8]

Health care providers should be a resource for their patients regarding all aspects of their health. Networking with oral health specialists enhances patients overall health care outcomes. Properly caring for dentures improves oral health, the ability to eat for healthy weight maintenance and reduces the possibility of oral opportunistic infections.

*Therapeutic solutions to loose fitting dentures, oral ulcers, treatments for candidiasis and other oral infections are fully illustrated at the web-address above. HIV

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References for Picture 1. . Pictures 1, 2 & 3, provided courtesy of Dr. Valli Meeks, University of Maryland, School of Dentistry, PLUS program. The PLUS Program is a dedicated HIV oral health care clinic, with a 25 year history. "Oral Thrush Symptoms, Causes and Treatment." *WebMD*. WebMD.com, June 2014. Web. 14 Aug. 2014. http://www.webmd.com/oral-health/guide/dental-health-thrush.

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BY SEJA JACKSON, APRN-BC, AAHIVS

Older Women...Living in the Shadows

AGING WOMEN LIVING WITH HIV face significant challenges. Women over 50 living with HIV remain in the shadows, both in practice and in research; however, as they are an increasing constituent of the epidemic, it is more important to understand the complexity and intersectionality of their needs.

There is a paucity of research that focuses on this population and much of it concentrates on menopause and menopausal symptoms (Jackson, 2015).

According to statistics released in 2015 by the Centers for Disease Control and Prevention, women over the age off 50 make up 23% of new diagnoses, are diagnosed later and progress to AIDS more rapidly than younger women.

Aging women, who no longer need to worry about pregnancy, use condoms less frequently and are at more risk for HIV transmission due to the physiologic changes of aging, such as increased vaginal mucosal thinning and dryness.

HIV stigma plays a role in preventing women over 50 from using prevention measures for HIV and sexual disease, seeking HIV testing, and participating in HIV care (Centers for Disease Control and Prevention [CDC], 2015).

Menopause initiates women into a new phase of their lives, which intensifies and compounds the effects of HIV infection. This can be a difficult time, with unexpected physical and mental changes, and for those living with HIV infection it can be particularly problematic (Cejtin, 2012; Womack, Brandt, & Justice, 2015).

Additionally, symptoms of menopause can be difficult to distinguish from symptoms of HIV and opportunistic infections. Issues such as the increased risk of osteoporosis, cardiovascular health concerns, metabolic changes with aging, and the use of hormone replacement therapy and antidepressants to treat hot flashes become increasingly important in decisions about HIV care (Kanapathipillai, Hickey, & Giles, 2013; Martin, Fain, & Klotz, 2008; Kojic, Wang, & Cu-Uvin, 2007; Miller et al., 2005).

Routine primary care needs for women over 50 living with HIV include hepatitis C diagnosis and treatment, cervical and anal cancer screenings, and risks of polypharmacy in addition to standard primary care (Womack et al., 2015).

Just as critical, though less researched and infrequently addressed, are issues such as cognitive changes, substance use, depression and other psychosocial issues, economic concerns and cultural issues of aging.

In a comprehensive review of the literature, Durvasula (2014), addresses these issues and also suggests research agendas and policy advocacy. Psaros et al., (2012, 2015), conducted two qualitative studies; the first focused on intimate partner relationships and women aging with HIV infection and the second examined the experience of being a woman over 50 living with HIV infection.

The impact of stigma on intimate partner relationships, body image concerns as a barrier to relationships, and the disclosure dilemma were themes identified in the first study (Psaros et al., 2012). The themes that emerged in the second study were: uncertainty of disease course, the process of acceptance over time and strategies for living successfully each day (Psaros et al., 2015). These studies were particularly important as they expressed the feelings and experiences of women over 50 living with HIV in their own words.

Psychosocial concerns are prominent and critical for women aging with HIV infection.

Women living and aging with HIV have significantly higher stress levels than the national average of HIV uninfected women (Webel et al., 2014). The higher stress is due to many factors including physical, emotional, and financial concerns impacted by living with HIV infection. Women have identified that they could not differentiate physical or emotional symptoms as belonging to the aging process or to HIV infection and that health providers often lacked answers to their questions.

Additionally, "health providers, especially if the provider was a man, rarely asked about their emotional health. Most believed that their providers did not understand or have the time to deal with the emotional needs of women living with HIV…" (Enriquez, Lackey, & Witt, et al., 2008, p. 42).

Women over 50 living with HIV have unique situations and challenges. Those of us working in the field of HIV need to listen carefully, be sensitive to needs, find answers, and be creative with the solutions for women living and aging with HIV infection. Destigmatizing the HIV diagnosis is particularly important for older women living with HIV in order for them to comfortably live full lives. We must be allies and advocates for this group that is often living in the shadows. HIV

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SHUTTERSTOCK

National Study Finds Life-Threatening Barriers In Access To Breakthrough Hepatitis C Drugs

A TEAM OF RESEARCHERS FROM THE BROWN UNIVERSITY DEPARTMENT OF MEDICINE, Rhode Island's Miriam Hospital, Harvard Law School's Center for Health Law and Policy Innovation, Treatment Action Group, and Kirby Institute of Australia, has released findings from a nationwide study of Medicaid policies for the treatment of hepatitis C virus (HCV), which affects over 3 million Americans. The study examined reimbursement criteria for sofosbuvir (Sovaldi), a highly effective medication to cure HCV in the overwhelming majority of patients. The article, which was published today in the *Annals of Internal Medicine*, details the coverage restrictions put in place by most Medicaid programs, and calls for policy change to improve access to new life-saving HCV treatment.

"Federal Medicaid law requires coverage of sofosbuvir, yet reimbursement criteria for Medicaid programs effectively cut off access to treatment. Intentional or not, the denial of treatment by the overwhelming majority of states goes against the spirit of the federal law," said Dr. Lynn E. Taylor of Brown University Department of Medicine, lead author of the study.

The most frequently found restrictions fall into three main categories: how much fibrosis (scarring of the liver) a patient has (limiting treatment to individuals with more advanced fibrosis); substance use (mandating a period of abstinence from alcohol/drug use and/or demanding toxicology screening); and provider limitations (allowing only certain specialist physicians to prescribe sofosbuvir or requiring consultation with a specialist).

"Ultimately, we found that access restrictions are not based on scientific evidence, current treatment guidelines or clinical data," said co-author and Harvard Law School's Center for Health Law and Policy Innovation Director Robert Greenwald. Greenwald adds, "Notably, 74% of the 42 state Medicaid programs for which information is available limit treatment to individuals with advanced fibrosis or cirrhosis."

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Such restrictions contradict the American Association for the Study of Liver Disease and the Infectious Disease Society of America treatment guidelines which support treatment for all HCV-infected persons, except those with limited life expectancy (less than 12 months) due to non-liver-related diseases.

"Rates of advanced liver disease complications and associated healthcare costs are rising in the United States." said Dr. Taylor. "Although there is a high risk of progression to decompensated cirrhosis and liver cancer among patients with advanced fibrosis, limiting access to people who have already progressed to late-stage disease as compared to treating earlier to prevent these liver-related complications seems counter-intuitive as a public health strategy."

Restrictions based on drug and/or alcohol use also were common. Among the state Medicaid programs for which information was available, 88% of states include drug and/or alcohol use or abuse in their eligibility criteria, with 50% requiring a period of abstinence of 3 to 12 months and 64% requiring negative urine drug screening. "This is particularly concerning because the majority of new and existing cases of HCV in the United States exist among people who inject, or have injected drugs," said Dr. Taylor. "Rather than excluding people who use alcohol or drugs from treatment, even those with cirrhosis, they should be a priority group due to both improved individual heal th outcomes and potential HCV cure as prevention benefit."

Since 2002, National Institutes of Health HCV guidelines have supported HCV treatment regardless of injecting drug use. International guidelines from the American Association for the Study of Liver Disease/Infectious Diseases Society of America, the European Study for the Association of the Liver, the International Network for Hepatitis in Substance Users and the World Health Organization, now all recommend treatment for HCV infection among people who use drugs. "There is compelling evidence that HCV treatment is safe and effective among people who inject drugs," said Dr. Taylor.

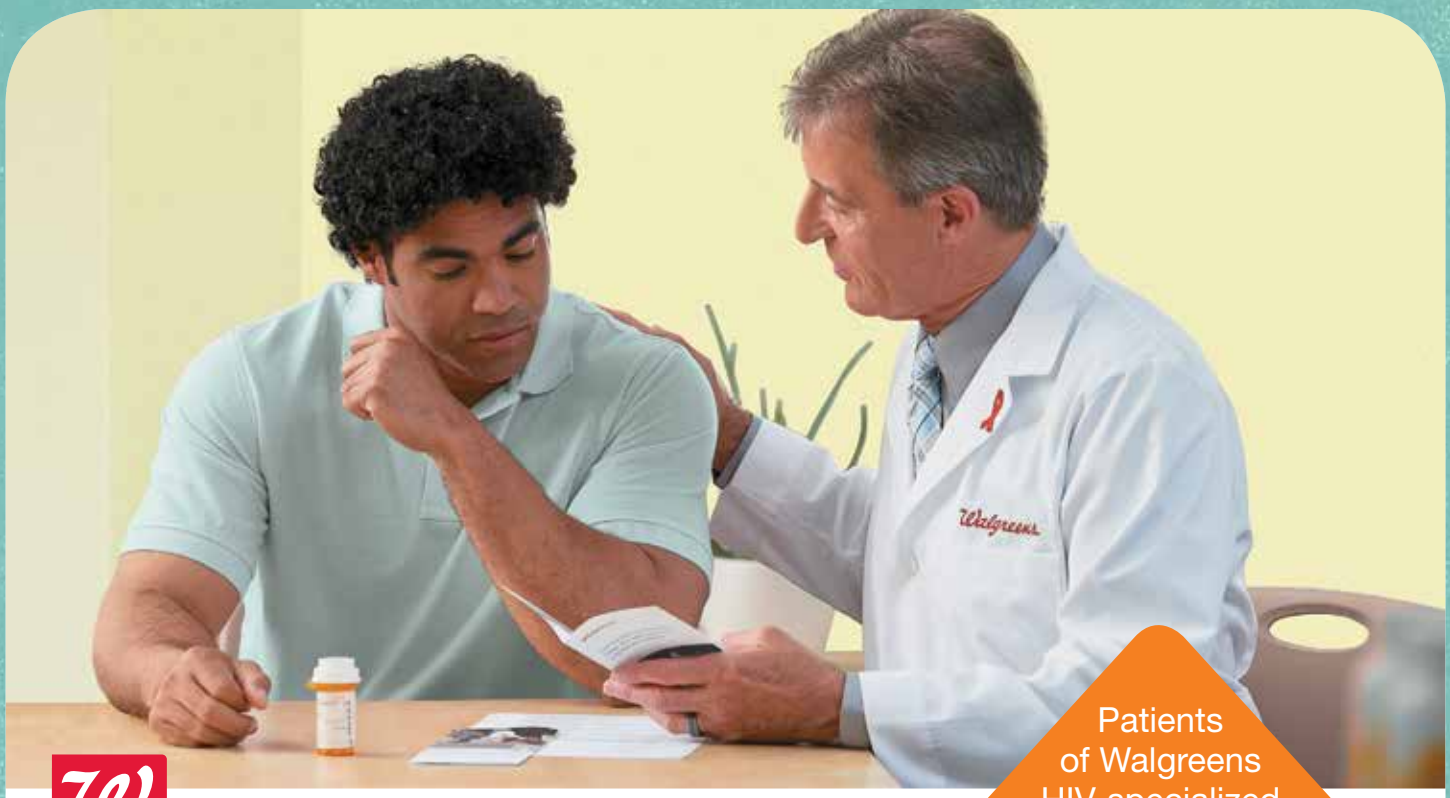
"The Medicaid restrictions generally apply to the poorest and most underserved patients with HCV infection, are highly stigmatizing, and not evidence-based," said Associate Professor Jason Grebely, co-author of the paper from the Kirby Institute at UNSW Australia. "The data suggest that state Medicaid policies for access to new HCV therapies should be reviewed and revised in line with national and international clinical recommendations."

"It is unacceptable for treatment to be held hostage by state Medicaid programs," added Tracy Swan, co-author and Hepatitis/HIV Project Director at Treatment Action Group. "Medicaid programs have never forced people to wait for treatment until they are so sick that they are left with a higher risk for liver cancer—even if they are cured. We would never refuse treatment for cancer or other infectious diseases until people developed severe organ damage, nor do we withhold treatment for these illnesses from people who drink alcohol or use drugs."

"Ultimately, we found that access restrictions are not based on scientific evidence, current treatment guidelines or clinical data," said co-author and Harvard Law School's Center for Health Law and Policy Innovation Director Robert Greenwald. Greenwald adds, "Notably, 74% of the 42 state Medicaid programs for which information is available limit treatment to individuals with advanced fibrosis or cirrhosis."

In distinct contrast to the situation in the United States, Australia's Pharmaceutical Benefits Advisory Committee (PBAC) has recently recommended two highly effective sofosbuvir-based regimens for Pharmaceutical Benefits Scheme (PBS) listing, without drug use or disease stage-related restrictions. Assuming that price negotiations are completed and Federal Cabinet approval gained, Australia should have the broadest access to interferon-free therapy internationally, with PBS listing expected in December 2015 or April 2016," said Professor Greg Dore from the Kirby Institute.

Based on its findings the study recommends that states review their access criteria and revise them as needed to align with national clinical recommendations. The study concludes that treatment access for people living with HCV should be based solely on clinical criteria and medical evidence. Since the current restrictions do not make clinical, public health, or long-term economic sense, these restrictions should be removed. HIV



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1. Cocohoba J, Murphy P, Pietrandoni G, Guglielmo BJ. Antiretroviral refill adherence in community HIV-specialized pharmacies (HIV-SP) vs. non-specialized pharmacies (NSP). Poster presented at: 16th International Meeting of the International Society for Pharmacoeconomics and Outcomes Research, May 21-25, 2011; Baltimore, MD.
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