RECENTLY ATTENDED the Consultation on Recommendations for HIV Prevention with Persons Living with HIV in Atlanta, GA. AAHIVM was a co-sponsor with the Centers for Disease Control and Prevention (CDC) and the Health Resources and Services Administration (HRSA) and we were represented by myself and Dr. David Hardy, chair of the Academy’s education committee.

The meeting’s purpose was to gather guidance for development of recommendations that seek to reduce the risk of transmission from people living with HIV to uninfected individuals. It was important for AAHIVM to co-sponsor this meeting, given the implications for HIV care providers of the new recommendations, which should be released mid-2012. They will replace recommendations published in 2003.

The introduction to the draft recommendations includes the following language:

“Currently coverage and impact of interventions for prevention with PLWH are suboptimal. Only about 80% of PLWH are aware of their HIV infection status. Only about 70% of HIV-diagnosed persons are linked to care in the months following diagnosis, and only about 60% of those who enter care are retained in care over the long term. Of those in care, only about 70-80% are prescribed antiretroviral treatment (ART), and only about 80% of those on ART have a suppressed viral load. When these steps in the cascade from diagnosis to viral load suppression are taken together, the result is that only about 20% of PLWH in the United States are aware of their diagnosis, in care, on ART, and with a suppressed viral load.”


No one should be satisfied with these numbers—and certainly, our Membership, our Credentialed Providers and other HIV practitioners have a significant role in improving these results.

The 20 percent of those unaware of their infection are responsible for 60 percent of the new infections in the U.S. Reducing the percentage of the unaware not only reduces the number of newly infected, it will also have a positive impact on the percentage linked to care, retained in care, on ART, and viral load suppressed.

Since the CDC’s routine HIV testing recommendations were released in 2006, AAHIVM has focused efforts on increasing linkage to care for newly-diagnosed patients.

Recently, AAHIVM nationally expanded its Referral Link database to assure more quality referrals for general practitioners across the country by including all Academy Members, Credentialed Providers and other HIV practitioners into the searchable database system. Through Referral Link, a general practitioner can provide a quality referral by matching an HIV care provider to the newly-diagnosed patient’s specific situation, taking into account the patient’s location, financial and medical needs.

If you are a current AAHIVM Member or Credentialed Provider, you are automatically included in the database. Please review your Profile to enhance and update your information. If you are a former Member or past Credentialed Provider with AAHIVM, we have created a listing for you, but ask that you opt-in to the database after reviewing your Profile on the AAHIVM site. To do this, login using your email address as your username.

AAHIVM encourages all qualified HIV practitioners to add their profile to the Referral Link database. Adding a listing is free and you do not have to be a Member of the Academy to have a Profile and to be listed in Referral Link. To visit the Referral Link database, please visit the AAHIVM website at www.aahivm.org.
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“HIV Pharmacist™” (AAHIVP) Certification Now Available

THIS MONTH, the Academy officially launches its new HIV Pharmacist™ (AAHIVP) certification program.

Structured similarly to other AAHIVM certifications, the program offers a two-year renewable credential to HIV-focused clinical pharmacists who meet strict experience and continuing education requirements, and who pass a comprehensive exam on all aspects of HIV-related pharmaceutical care.

Providers who complete the new Pharmacist program and then remain current will now be identified by the “AAHIVP” designation in their professional degrees, and will also be identified as Credentialed on the Academy’s online “Referral Link” national care resource directory.

The program began development in 2008 with a three-year pilot testing period, followed by a number of key Pharmacist test development processes. These included establishment and validation of a new “HIV Pharmacist Role Delineation” (also known as an RD or “job analysis”), which details the scope of practice in this profession. From the RD, a content classification system and an exam template were crafted, followed by authoring, classification and assembly of actual exam items.

All of these steps were completed by multiple teams of 10-12 working pharmacist subject matter experts from a variety of professional environments, with only procedural guidance from AAHIVM and its certification vendor. The rigorous methods employed above are in keeping with known test development standards, and assure a highly defensible and reliable measurement instrument. The Academy’s qualifications and reliability as an HIV-specific certifying body are well known, and date back to the original HIV provider certifications developed in 2001.

The entry requirements to become AAHIVP-certified include licensure as a Pharmacist, active patient contact, and documentable continuing education over the past two years. The exam itself consists of 125 multiple-choice items. It is designed as a “knowledge management” type instrument, meaning certifying providers are permitted to access clinical or other informational resources during the completion of the exam, much as they might do in the actual care of complex patient cases. The exam is offered as a written booklet or may be taken online (suggested for security and other reasons).

The Academy’s goals in the establishment of the HIV Pharmacist™ (AAHIVP) testing program are to:

- Present a meaningful and defensible professional development opportunity in HIV pharmacy.
- Increase coordination and linkage to quality care services by incorporating greater numbers of HIV Pharmacists™ into the existing AAHIVM care resource directory.
- Establish a minimum standard of knowledge in HIV pharmacy.
- Provide a reliable referral or consultation mechanism for practicing HIV Specialists™ and other caregivers, to be sure their patients get high quality, professional pharmacy services by an AAHIVP-certified Pharmacist.
- Protect the healthcare consumer by establishing an easily identifiable mechanism to access high quality HIV pharmacy care. Current “AAHIVE”-certified Pharmacists (pilot program certificants) will automatically be converted to the AAHIVP designation upon their next renewal.

AAHIVE-certified Pharmacists who expire in 2012 are not required to recertify in 2011, although they may opt-in to renew this year, thereby earning the new AAHIVP designation immediately, and extending their valid credentialed period through 2013.

Complete information on AAHIVM Credentialing can be found on our website at www.AAHIVM.org. Renewing and non-credentialed Pharmacists may apply online through July 31 (please note that applications received July 1-31 will incur a late charge).

ABOUT THE AUTHOR:
Peter Fox has been Director of Credentialing at AAHIVM since 2007. He joined the Academy in May 2004.
Serving Homeless Women With HIV

THE FACE OF HIV AND AIDS has undergone dramatic change within the last 20 years. Once a death sentence, the disease has been transformed by new medications into a chronic illness that people live with rather than die from. But for our neighbors who are homeless, HIV drugs that prolong life aren’t enough to ensure good health.

HIV is prevalent among the homeless. Studies indicate that anywhere from 3 percent to 20 percent of the nation’s homeless are HIV+. Homeless women are particularly at risk; they are frequently victims of domestic violence and sexual abuse, both of which have been linked to increased likelihood of HIV infection. Substance-abusing homeless women may exchange sex for drugs or money, increasing their risk.

Threats to homeless women’s health are great, as are the challenges of providing them with effective health care. These women face multiple risk factors: addiction, mental illness, poor physical health, low literacy, trauma histories, and lack of adequate income to secure safe and stable housing. Their limited and inconsistent access to health care significantly restricts effective HIV prevention and risk reduction efforts, and hampers patient adherence to complex treatment regimens. Untreated or poorly managed HIV disease can make it impossible for a woman to maintain steady employment, impacting her ability to maintain housing. Poor physical health can also exacerbate pre-existing mental illness and addiction issues.

Faced with the difficulties of serving a highly challenged and growing homeless population at a time of diminishing resources for nonprofits, we are inspired to evaluate what works well in our current services, and explore opportunities to increase our impact. With the generous support of Kaiser Permanente of the Mid-Atlantic States, N Street Village and Miriam’s House are embarking on a project to increase our collaboration to maximize our resources and enable us to have an even greater impact on health outcomes for the homeless women we serve.

Miriam’s House provides a residential community for up to 18 homeless women living with HIV/AIDS in the District of Columbia. When it was founded in 1992, it was designed to serve as an AIDS hospice—a sanctuary where homeless women could live out their final days in a loving and safe environment. With new drug regimens available, the need for hospice services has decreased. Now, Miriam’s House offers housing for women living with HIV who need support in managing their disease and in addressing other challenges, such as addiction recovery.

N Street Village, founded in 1972, offers comprehensive supportive services and housing to homeless and low-income women in the District of Columbia. Last year, it served nearly half of the city’s adult, single homeless women. One of its largest programs is the Wellness Center, which delivers integrated health care, wellness consultations, primary care and psychiatry services, and an array of classes and activities that promote health education, physical fitness, stress reduction, and general wellbeing.

Based on our experience serving vulnerable women, we believe an effective strategy for ensuring good health outcomes for homeless women must contain four elements: af-
fordable housing, collaboration and partnerships, coordinated health care services, and integrated health care approaches.

**Affordable Housing**

Studies indicate that access to stable housing correlates with improved health outcomes. For example, an observational study of 676 homeless persons with HIV/AIDS identified through the San Francisco AIDS Registry found over a five-year period that supportive housing was independently associated with an 80 percent reduction in mortality.

Our organizations can house up to 110 women at a time in our residential programs, but the need for affordable housing coupled with supportive services greatly exceeds the supply. Between 2008 and 2010, nearly 4,500 women were served by emergency shelters in D.C.—and over 500 of those women were served for 365 nights or more. Without safe and affordable housing, women living with HIV or AIDS lack the stability they need to focus on improving their health and the consistency required to comply with complex medication regimens.

**Collaboration and Partnerships**

Strong partnerships are key to providing effective client services while maximizing scarce resources.

N Street Village’s Wellness Center relies on collaborations with local public health schools and other nonprofit organizations to deliver many of its health care offerings. Its largest partnership is with Unity Health Care, a medical clinic that provides twice-weekly on-site primary care and psychiatric care to clients.

Other partners offer regular cancer and HIV screenings; seminars on nutrition, medication, and partner violence; and classes on the management of common chronic conditions such as diabetes. Miriam’s House, which does not have the resources to provide these services itself, works with organizations including N Street Village, Whitman-Walker Clinic, and Community Connections to connect its residents to health resources.

**Coordinated Health Care Services**

A homeless woman may have contact with dozens of health care providers at several sites over the course of a year. The lack of communication between providers and contradictory prescriptions and orders can cause confusion at best, and at worst, significant declines in health—particularly for women with HIV.

N Street Village and Miriam’s House each employ a nurse to help homeless women navigate the health care system. Our nurses serve as care coordinators, ensuring that clients are connected to health insurance and primary care providers, that prescriptions are reviewed and refilled, and that clients understand their doctors’ orders and have the knowledge they need to manage their health.

**Integrated Health Care Approaches**

Effective health care for homeless women must address not just physical needs, but also mental, emotional, and spiritual wellness. Health is interconnected; positive change in a woman’s mental health can lead to positive changes in her physical health.

In N Street Village’s Wellness Center, homeless women have access to mental health care through classes, support groups, group therapy, crisis intervention, and psychiatric services. The Wellness Center also offers arts classes, which have a significant impact on improving our clients’ mental health. Addiction recovery is addressed through daily AA/NA meetings held on site, relapse prevention groups, and a spiritual recovery group. Holistic health services provided by volunteers in the Center include yoga nidra, chiropractic care, massage, meditation, and reiki.

By focusing our efforts on these four elements of effective health care for homeless women, we believe that together we can increase our capacity to provide effective services for and improve the health outcomes of homeless women with or at risk of HIV.

**About the Authors:**

**Sam Collins** is Executive Director of Miriam’s House, Washington, D.C.;

**Schroeder Stribling** is Executive Director of N Street Village, Washington, D.C.
HCV-HIV Co-infection 2011: Realization of the Dream

With recent FDA advisory panel recommendations for approval of the first two HCV protease inhibitors, bocepravir and telapravir, Hepatitis C care stands poised at the brink of a radical transformation.

With 10 percent to 90 percent of our HIV patients co-infected with HCV depending on the makeup of our practices, we as HIV providers are positioned to treat them. Our model of detail-driven care, understanding of virology, resistance, combination therapies and drug-drug interactions, multi-disciplinary support teams, and our willingness to spend the time required to understand and care for these complex patients, positions us as the optimal providers of this complex, time consuming and soon to be increasingly rewarding care.

New technology and treatments are changing HCV therapy.

The advent of IL28B testing allows us to look for patients with a CC phenotype, which independently conveys a two-fold increased likelihood of SVR in both genotype 1 and non-genotype 1 patients.

Similar to the revolution wrought by HAART drug therapy, the addition of an HCV protease inhibitor to standard weekly injections of pegylated interferon with twice daily weight-based oral ribavirin is expected to become the new standard of care in co-infection. While past co-infection studies with pegylated interferon with ribavirin in genotype 1 patients showed at best 40 percent cure rates, addition of telapravir and bocepravir in naïve HCV mono-infected patients showed 80 percent and 70 percent cure rates, respectively, with shorter courses of therapy.

Bocepravir was studied in HCV-monoinfected patients in RESPOND-2 and SPRINT-2. These phase three trials involved a four week lead-in with PEG/ribavirin to allow interferon to prime the immune system, optimal ribavirin levels to be reached and decrease the likelihood of development of bocepravir resistance. In the control arm, patients received PEG/ribavirin for 48 weeks. The two test arms added bocepravir at four weeks on top of response guided therapy (RGT) with the duration of PEG/ribavirin therapy based on virologic response at set time points vs. fixed duration therapy with a set 48 weeks of PEG/ribavirin.

In the SPRINT-2 trial of naïve patients, SVR by ITT was achieved by 63 percent in RGT arm, 66 percent in 48-week arm vs. 38 percent in control arm. Even nonresponders and relapers on bocepravir in the RESPOND-2 trial which included 12 percent African Americans and 12 percent cirrhotics—traditionally difficult groups to treat—achieved 59 percent SVR by ITT with RGT and 66 percent with traditional 48 week courses. Forty-six percent in the RGT arm were eligible to stop treatment at 36 weeks. Fatigue, headache, nausea, and anemia occurred in almost half of all patients, with dysgeusia or metallic taste in mouth occurring in about one-third.

The telapravir phase three trials involved 12 weeks of telapravir with PEG/ribavirin followed by 12 vs. 36 weeks of PEG/ribavirin alone. In ADVANCE, 79 percent of naïve patients achieved SVR, while two-thirds of naïve patients required only 24 weeks of therapy, half the duration of our current treatment for GT1 patients. In the REALIZE trial, SVR by ITT was achieved in 85 percent of partial responders, 56 percent of relapers, and 31 percent of non-responders. Fatigue, pruritis, nausea, rash, and anemia were common though only 1 percent of patients discontinued for rash or anemia. Ninety percent of the rashes were mild to moderate and treatable with antihistamines/topical steroids.

While the only coinfection data released to date came from Mark Sulkowski at CROI 2011, it was as impressive and promising as the HCV monoinfected data. This small phase two trial looked at 12 weeks of PEG/ribavirin/telapravir followed by 36 weeks of PEG/ribavirin. Because of the potential for drug-drug interactions with HIV antiretrovirals, only efavirenz and atazanavir/rtv were used with tenofovir/FTC or 3TC. Forty-one of 59 patients had achieved 12 weeks of therapy at time of analysis. Sixty-eight percent on telapravir arm versus 14 percent of those on PEG/ribavirin alone had achieved an undetectable viral load by 12 weeks of therapy. There was no apparent effect on HIV viral loads or telapravir levels, though both efavirenz and atazanavir concentrations were mildly affected.

Getting a patient successfully through a course of therapy is never easy. From rashes to depression to anemia, close monitoring of patient and labs is crucial and requires a team dedicated to a good outcome.

The need to treat has never been more important for many reasons. HCV is not simply a disease of the liver. Decreased quality of life occurs in those with HCV for reasons, ranging from fatigue to depression to arthritis/osteoporosis. The morbidity of cirrhosis with its accompanying ascites and variceal bleeds is horrific.

As survival has extended to decades with HAART, death from end-stage liver disease and/or hepatocellular carcinoma has become the most common cause of death in many HIV practices across the country. The advent of new agents will change the face of HCV by decreasing time on treatment and dramatically improving outcomes. If there was ever a time to start treating HCV in HIV, the moment is now.

About the Author: Margaret Hoffman-Terry, MD, FACP, AAHIVS, practices infectious disease medicine and internal medicine at the Lehigh Valley Physicians Group in Allentown, Pennsylvania.
For this issue of HIV Specialist, we asked clinicians working in differing settings across the nation to tell their stories. We asked them to respond to some basic questions: What is your work life like? What are your key challenges? What are your points of satisfaction? What are your hopes for the future?

They may be working behind razor wire-topped prison walls, in clinics in big cities or small towns, in hospitals, universities, or research facilities, but all have one fact in common: they feel great satisfaction helping millions of men and women across America who have been infected with HIV.

When you talk to them, they will tell you about their challenges, and if you press, about their successes. But as in one voice, they will tell you how different it is today as they help their patients successfully manage their disease and cope with the vagaries of advancing age—rather than, as in the past, delivering a fatal diagnosis.

For all, that is the thought that keeps them going. It is what gives them a sense of accomplishment and contribution. It makes their professional lives complete.

“I have held the hands both of young men who died before their time and now old friends who just wear out. I have seen pill boxes so full you could barely close them, and now we have come to one pill, once a day,” wrote Debra Adams, ACRN. She runs a clinic in Washington that serves mostly the poor, many of whom are migrant farm workers.

Dr. Neal Rzepkowski, a primary care physician used these words: “I’m so blessed to be able to tell people that I’m HIV positive and I’m going to live until I’m 87, so you can too. It is so satisfying to see people be reassured. To get a life.”

There are thousands of these physicians, dentists, researchers, physician assistants, certified nurse practitioners and pharmacists whose calling it is to serve those with HIV. Some may be HIV+ themselves, like Dr. Rzepkowski, and so have a special, personal reason to engage this deadly disease. Others do it because of the challenge; because they realize they have the skill and the knowledge, and so, they are needed. It is because they care.

Here, in the following pages, they tell their stories.
I T ALL STARTED in the mid-to-late 1980s when many of us decided that just doing clinical care wasn’t enough. There were more problems than solutions and we wanted to help find solutions for problems that we saw in our patients—not just wait for someone else to do it.

So we decided we had to get involved in clinical research, a decision that led to the establishment of the Community Research Initiative (CRI) of New England. By creating this separate independent, nonprofit facility, we could be nimble and autonomous and have a place for research separate from where we see patients.

Initially CRI New England was supported with a grant from the American Foundation for AIDS Research (AmFAR), which recognized that more research was needed, that more needed to be done. AmFAR was one of the first organizations to provide support.

Since then, my work week has been split in half—seeing patients with a focus on HIV at Harvard Vanguard Medical Associates and working at CRI. As well, I continue my dedication to clinician education, which I’ve been doing since the beginning.

I see both HIV-positive and HIV-negative patients. This may be an increasingly important aspect of HIV oriented practices. About a year ago it was shown that tenofovir/emtricitabine (aka Truvada), when given to HIV-negative men, helped protect them from contracting HIV. Now we have a new incentive to provide “HIV-informed” care for people without HIV. As a physician, my focus is both on HIV and people at risk of HIV.

Right now our biggest challenge is reduced funding for HIV treatment and research. Much has been done in our field, and the difference between 1985 and now is dramatic. So many of us are extremely proud of how much we have accomplished, but we don’t feel we are done because there are still some problems with treatments and with our patients, despite our treatments.

Our local research has been supported by a combination of funding: NIH, the pharmaceutical industry, state resources, private foundations, and some private donors who support us because they think we are doing something valuable.

Unfortunately, fewer pharmaceutical companies are interested in HIV. The National Institutes of Health budget for HIV research is declining and that is expected to continue, reducing the number of people who will be supported to do research.

Research Initiatives: the variations
With NIH support, CRI is one of 70 study sites across 21 countries answering the question “When should patients start taking HIV medication?” The international START (Strategic Timing of AntiRetroviral Treatment) study, is intended to determine the benefits and risks of beginning medication when a person’s CD4 count is above 500 instead of waiting to start treatment at about 350 cells, the current standard of care.

While every trial wasn’t a success, we have seen many successes, and that has accelerated progress without waiting for somebody else to do it.

Working with the pharmaceutical industry, our site is enrolling multiple trials. For example, in collaboration with Gilead we are a site for a study in which we are comparing their new single tablet regimen based on rilpivirine with the only other single tablet that is currently approved, Atripla.

An example of an independent research project was our FOTO study, supported by foundations, private donors and the state. We compared 60 people on Atripla whose viral load was less than 50 and compared staying on Atripla every day (as is the case now) vs. taking the drug five days a week and 2 days off—thus, FOTO (Five On Two Off.) We showed there was no difference in maintaining suppression using the FOTO regime, which also reduces drug cost by about 28 percent, an issue of ongoing concern in many locations.

We presented our research and thought it would lead to more enthusiasm—both for economic reasons as well as patient “friendliness”. If nothing else, we certainly demonstrated the pharmacologic forgiveness of these three widely used antivirals. If there was another step, the next step would be a larger study to confirm our findings. We still
feel it was sufficiently important to warrant a larger follow-up study, as the factors making Atripla distinct may be worth demonstrating.

For the Future
Research is essential to my work. Research has always focused on making whatever we had even better, and that continues. We have gone from a situation of patients dying a miserable death from AIDS-related illnesses to patients having a close to normal and healthy lifestyle. All of that happened as a result of treatment research, so being part of that progress has been every bit as rewarding as clinical care.

It has allowed us to see the results and be a part of making it happen. While every trial wasn’t a success, we have seen many successes, and that has accelerated progress without waiting for somebody else to do it.

For the future, I’m hoping to be a part of identifying and answering the remaining questions for people with HIV, to control this virus with the safest possible medicines, make treatment as convenient and easy as possible, and see how we can contribute to the work of eradicating HIV as well as preventing it.

That’s what we’re trying to do. We may not get there, but that’s what we hope to do.

About the Author: Calvin J. Cohen, MD, MSC, AAHIVS, is director of research at Community Research Initiative of New England and research director at Harvard Vanguard Medical Association, where he sees patients. He has served as co-chair of the Scientific Advisory Committee of the AmFAR Community-Based Clinical Trial Network and is co-principal investigator of the New England AIDS Education and Training Center.
I am medical director of the Bay Area Perinatal AIDS Center (BAPAC) in San Francisco, CA. As part of a multidisciplinary team, I provide prenatal and preconception care for HIV-infected women, as well as HIV-uninfected women in serodiscordant relationships. I also provide gynecologic care for HIV-positive women.

I do most of my work at San Francisco General Hospital, where we see primarily uninsured patients. I am proud to work there, the site of the first HIV clinic in the world. I also am assistant director of the UCSF fellowship in reproductive infectious diseases, one of three such fellowships in the country. In addition, I am associate director of the National Perinatal HIV Hotline and Clinicians Network at UCSF/San Francisco General Hospital.

Much of my work at BAPAC involves preconception counseling for HIV serodiscordant couples and I am increasingly providing prenatal care for HIV-negative women who have HIV positive partners.

Today I saw a woman in that situation, 20 weeks pregnant, who is just now initiating prenatal care. She is HIV negative, but never uses condoms with her HIV positive partner. He is in care, but not on ARVs, contending he doesn’t need them because he has a high CD4 count. Both are methamphetamine users, as well.

This is the woman’s fourth pregnancy, but the first planned. It is also the first time she has had prenatal care. Her previous three children have been taken away by Child Protective Services, presumably because of drug use. She is in a very chaotic social situation.

Today, we did an ultrasound and tried to get them excited, hoping to use her pregnancy as a teachable moment. We got in touch with his HIV care provider to discuss initiating ARVs for him. We engage such patients about the importance of decreasing sexual transmission, informing them that pregnancy may increase the risk of acquiring HIV.

We want to see the positive partner on medication because that is associated with over 90 percent decrease in sexual transmission. Also, every single time we see them, we encourage condom use. We expect to see this woman weekly. Still, they were clear: they do not realistically will not start using condoms.

I had two prior HIV negative patients this year who took preexposure prophylaxis (PrEP), Truvada, during pregnancy. iPrEX showed us that PrEP can work for men who have sex with men (MSM), but the FEM-PrEP study reported in April raises questions regarding its efficacy in women.

I explained this to the patient today, but she still wants to take Truvada. She says she doesn’t want her baby to get HIV, but she says she realistically will not start using condoms.

To this couple’s credit, they came to their appointment; she underwent HIV testing and was reasonably engaged in the visit. Her partner took photos during the ultrasound and seemed happy about the pregnancy. That is leaps and bounds beyond what she has done in her prior pregnancies. We will see where it leads. That will be the adventure.

Fortunately, not all of our cases are as challenging as this one. At the other end of the spectrum, we have women who are diagnosed and on ARVs. The HIV component of prenatal care is straightforward and they have a completely beautiful and normal pregnancy, with their HIV diagnosis just one minor point of their pregnancy. I see a huge range of realities.

**Sperm Washing**

The ideal is when a serodiscordant couple comes to us for preconception counseling, wanting to know how to reduce the risk of HIV transmission while trying to conceive. Those with HIV have fertility desires the same as the general population.

But how can they do that safely?

If the woman is the positive partner, there are some low tech ways of getting her pregnant without risking transmission of HIV to her partner. By using an ovulation predictor kit and having the male partner ejaculate into a cup or a spermicidal-free condom, they can do home insemination and he is at zero risk of acquiring HIV.

The tricky situation is when he’s positive and she’s negative. HIV does not live in sperm, but it can in semen. One option is sperm washing—separating the sperm from the other components of the semen. Then the woman is inseminated via intrauterine insemination (IUI), in-vitro fertilization (IVF) or intracytoplasmic sperm injection (ICSI).

Until Jan. 2008, it was illegal for us to offer sperm washing in California because of a 1989 law that prohibited the use of sperm from an HIV positive individual for artificial insemination, even if that person was the partner or spouse.

I served as medical advisor to the California state senator who sponsored legislation to make sperm washing possible. It was supported by our survey of fertility clinics which found that a high proportion of California fertility clinics would be willing to offer services to serodiscordant couples if the law were to change. California reversed the ban and now there are several clinics in California offering sperm washing with assisted reproduction.

Sperm washing also is an option in several other states nationwide for serodiscordant couples, but it can be expensive and not
logistically possible for some. One possible intervention for them is periconceptional PrEP, or “PrEP-ception” as I like to call it—the uninfected woman would take PrEP during ovulation and following unprotected, timed intercourse.

There is a lot of interest in this, but the FEM-PrEP study was prematurely halted because Truvada was not found to be protective against HIV among female participants. There is no obvious biologic reason why PrEP would be effective among MSM but not women. I suspect adherence to the study drug may have played a role in FEM-PrEP, as a high proportion of participants, particularly those taking oral contraception, became pregnant and came off study drug. Last year, CAPRISA found a significant reduction in HIV acquisition among women using peri-coital tenofovir gel. Perhaps gel is better than oral PrEP for women. There are many unanswered questions and we anxiously await final FEM-PrEP results, as well as those from other trials such as VOICE. But it has made us pause as to whether PrEP-ception can be used for these couples.

**Challenges, Some Deadly**

A lot of the women we see have phenomenal psychosocial challenges. That’s the complicated part of helping them with adherence in midst of a chaotic life.

There is another, sometimes deadly, challenge. Many women, once the baby is born, stop caring for their own health, including HIV. Unfortunately, adherence commonly drops off dramatically postpartum. During pregnancy, they have a tangible goal of staying on their meds and not transmitting HIV, but once the baby is born their motivation drops dramatically.

We have had several women who died of HIV-related complications because they were just unable to take their ARVs postpartum. Many of these women have not disclosed their HIV status to people around them. Some are homeless, so taking meds is not a top priority. For some, it’s drug use.

I just went to the funeral of one such patient who was perinatally-infected herself. Her baby was negative, but she could not continue her ARV adherence after delivery. There were also cognitive issues; she struggled despite us trying to optimize all of the social services for her.

Her funeral offered a sense of what we are up against. Some people there were actively using drugs. She had a broken social network and did not disclose her status to most of her relatives. Once I saw her community, it was easier to understand why we were unable to meet her needs after her baby was born. Her baby is now 16 months old and being cared for by her HIV-negative sister.

Today during BAPAC conference we talked about the most difficult patients first and ended on a positive note. There is a lot of burnout for people who do this work. I also attend on Labor and Delivery and get to participate in loads of normal, beautiful, healthy births—that is a nice reprieve.

Despite the challenges confronted by many of my patients, they are the face of resilience. Most are also exceptionally committed to trying their best to have a healthy pregnancy. For many, pregnancy is the first time in their lives they are able to adhere to their antiretroviral medication, minimize drug use, and engage with a healthcare provider.

The key challenge is capitalizing on these successes and helping women continue with these healthy behaviors after delivery, helping them prevent HIV transmission to their babies and live healthy, productive lives. We encourage our women to not only envision having an HIV-uninfected baby, but attending their grandchildren’s high school graduation.

**About the Author:** Deborah Cohan, MD, MPH, AAHIVS is associate professor in the Department of Obstetrics, Gynecology and Reproductive Sciences at University of California, San Francisco. She is medical director of the National HIV Perinatal Hotline and Clinician’s Network and assistant director of the UCSF Fellowship in Reproductive Infectious Diseases. She is a member of the DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents.
To say that I have been HIV positive since the early 1980s is also only touching the surface, although that fact, of course, has played a major role in my life and certainly affects my work.

To say that I am a medium, that I do psychic readings and Native American sweat lodge ceremonies is also true, and it tells you a little more about my life—as well as the direction I want to go someday. I’m 60 now, and in two years or so, I hope to work full time on Indian reservations and try to make a difference there, bringing to bear all of the talents and skills that I possess.

My practice involves work at the HIV clinic at the Erie County (NY) Medical Center and at rural health clinics in Olean, Jamestown, and Dunkirk, NY. At the Medical Center, I am the main doc there, and we have a nurse practitioner. We have about 170 patients all together.

I also go to Buffalo once a week to treat drug addicts who are on suboxone, a drug like methadone that helps patients on “street” opiates who want to get clean. The government limits you to 100 patients on suboxone; some are HIV positives, and this actually is helpful because it encourages adherence to their HIV medication because when we are treating one, we treat the other. They have an incentive to stay on suboxone, and if they don’t come in they know they will go into withdrawal.

It’s been an unusual week. I had a medicine man from South Dakota at my house who came to do healing ceremonies, so we had a lot of people coming in and out. That was a little different.

Usually, on Monday morning and part of the afternoon I’m at one of the rural clinics, and on some Tuesdays I see patients in my private office in Dunkirk or, if not, I go out and...
Wednesday is a tiring day that goes from 8:30 a.m. until eight or later at night, seeing patients at Erie County Medical Center, the main AIDS center in western New York. On Thursday I see patients in satellite clinics in Jamestown or Olean, and every other Friday morning in Dunkirk.

Often on weekends, I work as a speaker, providing training for pharmaceutical companies and speaking on HIV care. I also do some speaking for continuing education for a local AIDS nurses group and patient support groups. I do a lot of speaking on behalf of HIV. People like to hear from a health care provider, an HIV patient, and somebody who's aging because people are living longer with HIV. I cover all three. I'm 60 years old and I've been living with this stuff for 30 years.

We are greatly blessed in New York state because our AIDS Drug Assistance Program is one of best in the country. There are a few HIV positive patients who don't adhere and get sick and then reform. I lost a couple because they couldn't stop using cocaine. That's a frustration and a challenge.

This drug problem is all over the country. I had no idea there was such a drug problem in rural America until I started prescribing suboxone. People from the little town of Frewsburg will go to Buffalo to get drugs, but the dealers also come down there because they get more money for their drugs there. Some of the HIV patients who have legitimate pain end up selling their meds. So I do a lot of drug testing on these people. They're on oxycodone and when I test them and nothing is there but cocaine, obviously they're selling oxycodone for cocaine.

I've been caring for patients since 1983, when my friends began coming in as my patients. Back then, sadly, it was a "good news bad news" type of bad joke. The good news was I could diagnose what was wrong with their health (AIDS) and tell them. The bad news was there was nothing I could do about it to help them so they could live longer.

It's such a different world now. Since 1996 and particularly in the last couple years, I am so blessed to be able to tell the people that I'm HIV positive and I'm going to live until I'm 87. You can too. It's not that bad any more. It is so satisfying to see people be reassured, to get a life. Medicines are simplified now. It is just a different world, and it is so satisfying. 

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Experience and eligibility requirements apply. Visit www.AAHIVM.org for complete information or to apply online. Frontline providers seeing fewer than 20 patients may be eligible to credential in the Clinical Consultant program; see website for details.

About the Author: Neal Rzepkowski, MD, AAHIVS is an HIV primary care physician in Chautauqua and Cattaraugus counties in New York, working at HIV Clinics affiliated with Erie County Medical Center, Buffalo, NY. He began his practice in 1997 and is also a nationally known speaker on HIV topics related to both medical and lay audiences. He is certified by the American Board of Family Practice, the American Association of Medical Review Officers, and the American Academy of HIV Medicine.
Coping WITH ADAP Cuts

Clinic organizes new service to help patients

BY ELIZABETH SHERMAN, PHARMD, AAHIVE

Recently my role has evolved at Memorial Primary Care Center, a clinic serving a predominately Ryan White population in South Florida. Florida has one of the nation’s largest HIV/AIDS case loads.

The recent downturn in the economy has led to increases in the number of patients seeking services through the federal Ryan White program’s AIDS Drug Assistance Program (ADAP), which provides life-saving, costly medications needed by uninsured HIV/AIDS patients.

In June 2010, Florida became the 11th state in the nation to implement a waiting list for ADAP. Two months later, Florida ADAP reduced its drug formulary, cutting out much needed medications for common disease states often aggravated by HIV medications such as diabetes and cholesterol.

Currently, Florida has over 3,900 HIV/AIDS patients on its ADAP waiting list, the highest number of any state in the nation and more than half of the 7,700 people on ADAP waiting lists nationwide.

With recent funding cuts to the Ryan White program and ADAP in Florida, HIV-infected patients are faced daily with the challenge of medication access, a significant barrier to effective care and treatment. These challenges extend to both patients on the ADAP waiting list and to patients already covered by ADAP, and create opportunities for significant interventions by clinical pharmacists.

Ryan White patients on Florida’s ADAP waiting list do not have access to prescription drug benefits for antiretroviral medications. In our clinic, the case management and pharmacy teams work together...
Our Team
I have been the Program Director since 1993. We work as a team, with the public health nurses acting as nurse managers for all the patients, and then an infectious disease physician and a family planning physician working with them. The bilingual family planning doctor handles long-term care issues, including women's health and management of other diseases. The infectious disease doctor takes care of HIV management and provides hospital care for AIDS patients.

My philosophy of management is to allow each member of our team to practice in the way she or he was taught, with integrity and respect. I believe this is a direct reflection on our low rate of staff turnover. Most of my staff members have been with the clinic for at least 10 years. We have the pleasure of long-term relationships with our patients, several having been with us since the beginning.

We have really small offices in a very large migrant health center. We are a quiet clinic. We've been around long enough that patients can find us, but the general public isn't usually aware of us. This has been ideal as rural areas tend to seem small and confidentiality is always a concern.

The migrant health center, Yakima Valley Farm Workers Clinic, has always supported us, and we have kept up with rising costs by constant grant writing and always trying to minimize expenses.

I love our model of care. As a public health nurse, we utilize all of our skills to abstract records and succinctly provide an overview of patient history, order routine labs, tests, screenings, and immunizations. We are able to really get to know patients and affect care. We believe that everyone has a contribution to make to care management, and at our weekly patient staffing there is often spirited discussion about patient readiness for antiretroviral therapy or other aspects of care. Our medical director is always available to us and he has grown to trust our assessment skills. We have learned to culture anything that drips and gather all the data before calling. The nurses provide the 24 hour on-call services and can refer to the medical director when necessary.

Then and Now
HIV care has changed a great deal in the last twenty years. I have held the hands both of young men who died before their time and now old friends who just wear out. I have seen pill boxes so full that you could barely close them, and now we have come to one pill, once a day.

Today I see more patients with less money for dental, chemical dependency, and mental health care. We stretch to help patients fill out reams of paperwork for insurance that does not always ensure confidence that we can meet all of their health care needs. I see the ravages of methamphetamine and barebacking sexual practices and the hope of topical microbicides.

I am proud of our clinic and the services we provide. Our team provides exquisite care for challenging patients in a dynamic atmosphere. I know I have been given the opportunity to make a difference, and for that I am very grateful.

to ensure these patients are immediately enrolled in the pharmaceutical industry’s patient assistance programs (PAPS), so those who cannot afford to pay can still obtain their lifesaving medicines.

To accomplish that requires organization and effort. For example, patients initiating HIV therapy with a three-drug regimen require separate applications to each pharmaceutical company.

To address this challenge—and to provide greater medication oversight—we organized a new service: A case manager enrolls patients in the PAP program; the PAP medications are shipped from the pharmaceutical company to our outpatient clinic pharmacy; a PAP-dedicated pharmacy technician ensures all medications in a multi-drug regimen are received before calling patients to pick up the medications.

This integrated approach improves patient adherence and alerts the health care team to lapses in coverage. In my clinic, our effective collaboration between pharmacy and other services allows Ryan White patients on the Florida ADAP waiting list to access much needed care.

Ryan White budget cuts have resulted in a shrunken formulary, particularly with respect to non-HIV medications. Because multiple comorbidities frequently attend HIV infection, impoverished patients now experience a broader assault on their ability to manage care. In Florida, ADAP patients must fill their HIV medications, and other covered medications, at the Health Department pharmacy. Patients with diabetes must then fill their anti-diabetic medications at a different pharmacy. This increases the financial burden and results in lost time for patients while making it difficult for care providers to reconcile medication lists and oversee care. When multiple pharmacies are involved, it may make medication reconciliation more difficult for the provider, and complicate timely refills for the patient. As a clinical pharmacist it is vital, therefore, that I maintain an accurate medication snapshot of patients’ pharmacies and coordinate the appropriate filling and use of medications.

The challenges posed by funding cuts to the Ryan White program in Florida have set a stage where I can apply my skills and expertise to increase adherence, improve patient outcomes, and reduce the economic burden on public health.

About the Author: Debra Adams, ACRN, has worked in underserved communities for her entire 28 year career. She has worked in a very rural hospital, Yakama Indian Nation, as the home health nursing director, and Yakima Valley Farm Workers Clinic for the past 18 years. She is also on the faculty of the University of Washington Northwest AIDS Education and Training Center. She has a masters degree in Nursing Education.

About the Author: Elizabeth Sherman, PharmD, AAhive, is Assistant Professor of Pharmacy Practice at Nova Southeastern University College of Pharmacy in Ft. Lauderdale, FL and provides clinical service as an HIV/AIDS Clinical Pharmacy Specialist at Memorial Primary Care Center at Miramar.
ABOUT 20 YEARS AGO, I started the Oral Health Center within the Grady Health System’s Infectious Disease Program (IDP) in Atlanta. Now, in addition to directing that clinic, I am also Chief of Dental Services at the hospital.

What makes the IDP so successful is that we are a very large one stop shop, with over 5,100 HIV patients, the vast majority of whom have an AIDS diagnosis. The Oral Health Center follows approximately 1,800 patients. The IDP offers comprehensive care, which includes a primary care clinic for men, family centered care for women, children and youth, a center for well-being that offers mental health and substance abuse counseling, a pharmacy, radiology, a laboratory, case management, Emory’s Center for AIDS Research and outpatient infusion therapy. Several AIDS Service Organizations are also housed in our building, including a housing agency and a food pantry service. Literally, we have everything under one roof and are, by far, the largest provider of Ryan White funded services in the Atlanta metropolitan area.

The key challenge the Oral Health Center faces is that the need far outweighs the available resources. If you add in long-term survivors who may not have had access to care in the past, and the people who cannot afford care, and then you add HIV on top of that, which accelerates some of the disease states, you end up with a lot of oral disease to manage. It is no wonder that, in most places around the country, consumer surveys show that the number one unmet need is HIV oral health care.

With my staff of 17, we provide comprehensive oral health care services, including root canals, crowns, dentures, and managing oral pathology in association with HIV and AIDS. We do fillings, cleanings, gum work, extractions—everything except implants.

Special Challenges
In one sense, treating HIV or AIDS patients is no different from treating anyone else. A filling is a filling; a cleaning is a cleaning. But for medically complex individuals, you must have a greater handle on significant lab values. Communication between medical and dental health providers is crucial. Both sides need to know what lab values are important, and be able to communicate when needed.

With advanced HIV disease, we see rapidly advancing periodontal disease and secondary to that we have a problem with dental caries, or cavities. And then there are soft tissue lesions that we very seldom see in healthier patients.

Once oral disease has been managed our goal is to maintain oral health. As a result, we place a priority on prevention and we provide patients with supplies that will help maintain oral health. We also make available prescription fluorides and mouth rinses to treat disease as needed.

We are so busy that I had to start my first waiting list in 20 years, so our most valuable resource is our time. Once we get somebody’s mouth healthy, our goal is to keep it that way.

Provider Fears
Are some providers concerned about treating HIV and AIDS patients? Yes. What got me into this field years ago was that no one would treat patients with HIV. I will never forget my first referral. My mother, who worked in the office answering the phone, told me I had to take the call because the person was rude and threatening. She was right, he was. But when I spoke to him, I learned that he had always had his teeth cleaned every six months, but when he got his diagnosis, no one would touch him.

Ryan White Extension/Reauthorization is Crucial
I am very concerned about what the future might hold in light of health care reform implementation and the upcoming Ryan White reauthorization. There is no dental care component to health reform and it is critical that oral health services for people living with HIV and AIDS be maintained.

Medicaid expansion under health care reform does not include dental care and Medicare does not have an oral health benefit. So there are limited oral health resources for HIV+ patients with limited incomes. Our only hope lies with the continuation of the Ryan White programs. My program, and others around the country, could not survive long without Ryan White funding.
When I started, I basically hired whoever came to be interviewed; whomever God sent. But last year when I had an opening for a dental hygienist, there were over 50 applicants. So the work we’re doing in AIDS education is paying off!

**Satisfaction**

Is my work satisfying? Absolutely! Even in the darkest days of this epidemic, the Oral Health Center was always a place of life. We went through a phase when we didn’t know if people would live to get their dentures, but almost always they found a way to make their appointments. We are now watching each other grow older together. That is a point of great satisfaction.

I love the people. I have an incredible patient population. It is large, but I have known some of these people for many years now. I have children who are growing up. I have patients who are becoming grandparents. No longer do I hear the stories that “My partner died and I got thrown out of the house.”

The changes that we’ve witnessed are truly remarkable. But what is distressing is seeing young people come in with full-blown AIDS; some with serious oral manifestations of HIV—these are young kids! One of the things I do around the country is set up HIV screening as a part of routine dental care so people can learn their status and get linked to care. We just have to keep fighting.

**ABOUT THE AUTHOR:** David Reznik, DDS, is a graduate of Emory College and Emory University School of Dentistry, and is currently the Director of the Oral Health Center of the Infectious Disease Program of Grady Health System in Atlanta, GA. Dr. Reznik is President of the HIV Dental Alliance (HIVDent.org), an Internet organization designed to facilitate the oral health care of people living with HIV disease and Dental Director of the Southeast AIDS Education and Training Center. His research activities include the metagenomics of periodontal disease in patients living with HIV disease.
After taking a year off during medical school to do international medicine, I dreamed of working abroad in an underserved community with limited resources where good care was often a challenge, but one I was willing to take on. Although far from a tropical setting, I found that underserved community I dreamed of a lot closer to home than I ever imagined. Working for the Washington State Department of Corrections (WA DOC), I still get to travel—I drive to 12 out of the 14 prisons statewide where I see and treat prisoners who are infected with HIV. On any given day there are about 80-90 HIV-infected patients within the WA DOC, but given the turnover rate, I may see up to 150 unique patients in a year.

I also work at the Ryan White funded clinic in Seattle, where many of my prison patients obtain their care after release. With the help of the WA DOC release planner, HIV-infected patients are transitioned back to the community, one of the most important aspects of keeping them engaged in care. When possible, I see my prison patients for their first clinical visit after release, as a bridge to their primary community provider.

**Pros and Cons**

The most difficult as well as the most rewarding part of the job is the patients. Before coming to prison, offenders often have little or no access to medical care in the community. Many offenders have never had prior contact with a medical provider in their entire lives, except maybe an occasional emergency room visit.

Access to healthcare is mandated in corrections, but for offenders to engage in care it is essential to establish a trusting relationship that hope-
fully will transfer to their community provider after release. But that’s not always easy. Most offenders relate to medical providers as they do other authority figures in their lives, so gaining their trust can be difficult to achieve. However, once that trust is established, it can lead to real change. It can improve their attitude regarding their own health, and it may also reduce the likelihood that inmates will return to prison again.

The care of persons living with HIV in prison is complicated by the higher rate of co-morbidities. The prevalence of mental illness is much more common among the offender population, and even more so among those living with HIV. In addition to their HIV infection, most of my patients have chronic viral hepatitis, usually a result of substance abuse, which may not be as much of an issue during incarceration, but is frequently soon after release. Our Prevention for Positives Program attempts to reduce high-risk behaviors upon release and decrease HIV transmission in the community.

However, in some ways caring for patients while they are incarcerated is easier than on the outside.

In prison, housing, food and transportation are provided. Good health often becomes a higher priority. There also is less drug use and a more structured lifestyle, which improve adherence rates. Not surprisingly, the overall adherence rate to HIV medications in prison has been shown to be better than after release. Of patients in WA DOC on HAART, more than 85 percent have complete viral suppression. I have found that offenders are very appreciative of good care, which certainly helps to establish that trust that is so important.

One of the most satisfying aspects of my position as the WA DOC infectious disease physician is the ability to introduce medical students and internal medicine residents to correctional medicine.

Visiting a prison to see patients is an experience that they may otherwise never have. It helps trainees become aware of the incarcerated population that is frequently ignored and forgotten, despite the fact that it encompasses over 1 percent of the U.S. population.

While it may be easy for the community to close their minds to offenders once the prison doors close behind them, it is important to understand that one day, most will return to the community. The extent that they can be influenced and treated while inside is important to how well they adjust upon their release. I continue to strive to improve the prevention services provided inside the walls and the transition back to the community.

Thus, after traveling these roads up and down Washington to prison after prison, it has become clearer to me how offender health actually is public health. I feel satisfied in my work and enjoy the patients with whom I interact. I believe it makes a difference.

**About the Author:** Lara Strick, MD, MSC works as an Infectious Disease physician for the Washington State Department of Corrections. She is also Clinical Faculty at the University of Washington, sees patients at Harborview Medical Center’s HIV Clinic, and is Corrections Program Director at the Northwest AIDS Education Training Center. She is involved in clinical HIV education and offers an HIV preceptorship in the correctional setting.

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in their entire lives, except maybe an occasional emergency room visit.
The State Medicaid Funding Crisis

By Joseph P. McGowan, MD, FACP, AAHIVS and Holly A. Kilness, MA

2011 has unfolded as a daunting year for state budget makers. Following the worst recession the U.S. economy has seen since the 1930s, and record foreclosures and unemployment numbers that have eroded tax bases, many states are facing severe fiscal situations.

According to the Center on Budget Policy and Priorities, some 44 states and the District of Columbia are projecting budget shortfalls for fiscal year 2012, which begins July 1, 2011 in most states. These come on top of the large shortfalls that states closed in fiscal years 2009 through 2011. Some states, such as Illinois and California, are facing budget shortfalls of tens of billions of dollars.

Except for Vermont, every state has some sort of requirement to balance the state budget written into their state laws or constitutions. Even though the economy seems to be slowly trending towards a recovery, the states’ fiscal condition remains perilous.

In addition, the federal government has trimmed back on funding assistance to the states that comes through a variety of programs. News stories out of Washington talk about spending cuts, austerity budgets, and budget caps, serving as a reminder that states should not expect to receive help from their federal partners.

The result has been state lawmakers making deep spending cuts to public programs, including (and in some cases, especially) to public health programs. They are also searching for new ways to stretch every penny spent on these programs to its furthest extent.

In the state of New York, the Medicaid program has fallen subject to just such conditions. Medicaid, which provides health care for the low-income individuals who cannot otherwise afford it, is also the largest funder of HIV infected patients in the U.S. The state of New York had a $10 billion budget deficit to address this year, and the state Medicaid program was a ripe target for budget-slashers in Albany. The program represents the largest single piece of the state’s budget, spending more than either California or Texas. It also represents a major portion of many county budgets.

In his “State of the State” speech earlier this year, Governor Cuomo made clear that he intended to reform the program. He began with formation of a so-called Medicaid Redesign Team (MRT) comprised of healthcare experts, insurance leaders, patient advocates, business professionals and state lawmakers. The panel was charged with reviewing the program and making suggestions for change, and for savings.

The MRT met for about a month and a half, all told. They received public input on such matters as inadequate Medicaid reimbursement rates, long term care costs, and medical liability reform and provisions for encouraging medical homes. The panel’s recommendations, which promised to produce savings of almost $3 billion, came with recommendations for a fundamental realignment for the Medicaid program.

Under the changes, people living with HIV/AIDS, previously an exempt category, will be moved into managed care programs—an attempt to squeeze out savings by allowing insurance companies to cut costs through coverage restrictions.

The concern for persons living with chronic diseases, such as HIV, is that HMOs historically place insurance companies, not doctors or patients, in charge of medical decisions. HMOs may restrict various treatments and medications, or only cover the cost of generic versions of medications. For patients with HIV, this can mean restricted access to life-saving medications, or disruptions in continuity of care. For providers, this could mean limitations on their ability to offer optimal care and treatment regimens to their patients.

The members of AAHIVM’s New York/New Jersey chapter have watched this year as these proposals unfolded to become provisions of the Governor’s Budget Amendment and legislative proposals A.4009 and S.2809.

One provision that caused a great deal of concern for HIV providers was the proposed elimination of the so-called “Provider Prevails” provision, which allows providers to select optimal treatment courses for patients, without need for prior approval.

On March 18, 2011, as the Chapter Chair, I authored a letter on behalf of the New York/New Jersey Chapter of AAHIVM, and our membership, to express concern with some of the provisions of these proposals. The letter was sent directly to the office of Governor Cuomo, with copies to the offices of the Lieutenant Governor, state House Speaker, state Senate President, and the Majority and Minority Leaders of the NY state House and Senate. At the time, all three budget proposals were burning their way through the Assembly like wildfire.

The letter stated:

“Although we generally support initiatives to improve the health system and cost efficiency of public programs, we are concerned about provisions that alter the prescription medication benefits in such a way that they restrict the ability of providers to prescribe optimal drug regimens for patients.

“As an organization of front-line HIV care providers, we support the ability of providers to determine the best course of treatment for their patients. We believe that the best determination of appropriate medical treatment occurs in the relationship between provider and patient. The virus responds to particular treatment regimens in different ways due to its inherent ability to develop drug resistance rapidly in...”
HIV care is at risk as budgets are slashed

different patients so that the optimal treatment for one person may not be the same as for another. The only person who can adequately make that decision is the treating physician.

“Requirement of prior authorization for currently protected classes of drugs means more administrative barriers that restrict the ability of providers to prescribe the best course of medication for each individual patient. Individual response to antiretroviral treatment is not always equal. Successful HIV drug therapy involves the prescription of complicated cocktails of drugs therapies, close monitoring for effectiveness, rigid adherence by patients, and evaluation and mitigation of side effects by a medical professional. Basing decisions for drug prescription on cost or inclusion on a formulary list ignores best practices in care, clinical evidence indicating varied outcomes for individual patients in terms of age, gender, race, and ethnicity, and important considerations of safety efficacy and tolerability of particular drugs. Additionally, specific patient indicators of drug resistance heavily inform provider decisions about which treatment course is best for each patient. In short, treating the medical needs of HIV patients with a “one size fits all” approach can actually lead to more medical complications, higher treatments costs, and worse health outcomes. The so-called “Prescriber Prevails” provision must be maintained for this reason.

“We are also concerned with changes that may limit access to prescription medications, such as anti-retrovirals, immunosuppressants, anti depressants and others which were previously protected from managed care preferred drug carve-outs. The proposed law would place New York State Medicaid prescription practices out of compliance with Medicare Part D regulations which are intended to protect vulnerable populations by including all antiretroviral drugs. The reasons for this protection are stated as “(1) restricted access to multiple drugs would have major or life threatening clinical consequences for individuals who have a disease or disorder treated by the drugs, and (2) there is significant clinical need for individuals who have a disease or disorder to have access to multiple drugs within a category.”

“The New York Medicaid program already has a preferred drug list (PDL) provision that allows prescribers to bypass the PDL if indicated by the particular needs of a patient. Changes to the Medicaid system should facilitate the process of individualized medicine, not obstruct it. Disruptions in continuity of care can have life-threatening consequences to individuals living with HIV.”

Governor Cuomo and state legislators passed a state budget on March 31, 2011. In it, the MRT’s recommendations were largely adopted by the legislature.

The budget cut $2.3 billion in funding for the Medicaid program. It also places a 4 percent yearly spending cap on the state Medicaid program, limits future growth in the program, and ends automatic rate increases, and reduces reimbursement rates. The so-called global spending cap holds annual growth in spending for the program to 4 percent beginning next year, and gives the governor broad authority to force cuts if the health care providers don’t do it themselves.

Payments for medications for the elderly were reduced by $36 million in the budget. Home health care benefits were also reduced, along with funding for dental services, some hospitals, nursing homes, and psychiatric facilities in the state will also receive reduced funding, and there is talk of possible closures.

Under Medicaid redesign, patients with Medicaid will be limited to 20 physical therapy visits a year, all personal care services will need to be approved through managed care organizations (MCOs), enteral supplements (other than tube feedings) will no longer be covered by Medicaid and patients and their providers will need to endure the daily bureaucratic burden of seeking approvals and prior authorizations for needed services from MCOs who are often ill-suited and disinclined to understand and appreciate the complex needs of people living with HIV/AIDS. AAHIVM received a letter in response from an Assistant Director at the New York Department of Health’s Division of Financial Planning and Policy on March 30th, 2011 - just one day prior to the passage of the Governor’s $132.5 billion dollar budget.

The letter assured that people with HIV and other chronic diseases will continue to be able to get the drugs they need. However, it indicates that already-existing Medicaid managed care plans will be “responsible for meeting their needs.” The letter claims that the State of New York will provide “strong guidance to plans to ensure that they continue to provide access to medically necessary prescription drugs.” However, the issuance of specific guidance along these lines was not provided for in the legislation, nor has it been announced as pending by the Department as yet.

The letter also stated that prior authorization for antiretrovirals and immunosuppressants has not been proposed by the MRT, and is not “envisioned” by the Department of Health. This murky terminology forces one to wonder, what is the Department’s vision for how treatment recommendations by prescribers that fall outside the approval of the managed care plans will be handled? For example, as older anti-HIV drugs become available in generic form, will providers be asked to use these agents or split fixed-dose combination tablets? According to the letter, “Patient protections, including an escalation and appeal process and the right to a fair hearing, will ensure continued access to needed medications.”

This is not a comforting vision for HIV providers. This policy and others like it are being considered by cash-strapped states around the country as an option to reign in health care costs, trim state budgets, and balance state’s bottom lines. However, the bottom line is that such policies can result in profound health consequences for HIV patients, and the providers that serve them.
The clinical trial, HPTN 052, was slated to end in 2015 but findings were released early because an interim review by an independent data and safety monitoring board (DSMB) concluded it was clear that use of antiretrovirals by HIV-infected individuals with relatively healthier immune systems substantially reduced transmission to their uninfected partners. It was the first time a major randomized clinical trial has reached such a conclusion.

“Previous data about the potential value of antiretrovirals in making HIV-infected individuals less infectious to their sexual partners came largely from observational and epidemiological studies,” said NIAID Director Anthony S. Fauci, MD “This new finding convincingly demonstrates that treating the infected individual—and doing so sooner rather than later—can have a major impact on reducing HIV transmission.”

Led by study chair Myron Cohen, MD, director of the Institute for Global Health and Infectious Diseases at the University of North Carolina at Chapel Hill, HPTN 052 began in April 2005 and enrolled 1,763 couples, all at least 18 years of age. The vast majority of the couples (97 percent) were heterosexual, which precludes any definitive conclusions about effectiveness in men who have sex with men.

**Study Details**

The study was conducted at 13 sites in Botswana, Brazil, India, Kenya, Malawi, South Africa, Thailand, the United States and Zimbabwe. The U.S. site collected only limited data because of difficulties enrolling participants into the study. However, data from one serodiscordant couple at the site was included in the DSMB's analysis.

At the time of enrollment, the HIV-infected partners (890 men, 873 women) had CD4+ T-cell levels between 350 and 550 cells per cubic millimeter (mm³) within 60 days of entering the study. The HIV-uninfected partners had tested negative for the virus within 14 days of entering the study. The HIV-uninfected partners had tested negative for the virus within 14 days of entering the study.

The investigators randomly assigned the couples to either one of two study groups. In the first, the HIV-infected partner took a combination of three antiretroviral drugs. In the second group (the deferred group), the HIV-infected partners began antiretroviral therapy when their CD4 counts fell below 250 cells/mm³ or an AIDS-related event, such as Pneumocystis pneumonia, occurred.

Throughout the study, both groups received the same amount of HIV-related care that included counseling on safe sex practices, free condoms, treatment for sexually transmitted infections, regular HIV testing, and frequent evaluation and treatment for any complications related to HIV infection.

In its review, the DSMB found a total of 39 cases of HIV infection among the previously uninfected partners. Of those, 28 were linked through genetic analysis to the HIV-infected partner as the source of infection. Seven infections were not linked to the HIV-infected partner, and four infections are still undergoing analysis.

Of the 28 linked infections, 27 infections occurred among the 877 couples in which the HIV-infected partner did not begin antiretroviral medicines when their immune systems were relatively healthy, according to findings from a large-scale clinical study sponsored by the National Institute of Allergy and Infectious Diseases (NIAID).

**Findings of a new international study**

MEN AND WOMEN INFECTED WITH HIV reduced the risk of transmitting the virus to their sexual partners by taking oral antiretroviral medicines when their immune systems were relatively healthy, according to findings from a large-scale clinical study sponsored by the National Institute of Allergy and Infectious Diseases (NIAID).

The clinical trial, HPTN 052, was slated to end in 2015 but findings were released early because an interim review by an independent data and safety monitoring board (DSMB) concluded it was clear that use of antiretrovirals by HIV-infected individuals with relatively healthier immune systems substantially reduced transmission to their uninfected partners. It was the first time a major randomized clinical trial has reached such a conclusion.

“Previous data about the potential value of antiretrovirals in making HIV-infected individuals less infectious to their sexual partners came largely from observational and epidemiological studies,” said NIAID Director Anthony S. Fauci, MD “This new finding convincingly demonstrates that treating the infected individual—and doing so sooner rather than later—can have a major impact on reducing HIV transmission.”

Led by study chair Myron Cohen, MD, director of the Institute for Global Health and Infectious Diseases at the University of North Carolina at Chapel Hill, HPTN 052 began in April 2005 and enrolled 1,763 couples, all at least 18 years of age. The vast majority of the couples (97 percent) were heterosexual, which precludes any definitive conclusions about effectiveness in men who have sex with men.

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Pre-Exposure Prophylaxis (PrEP)

Background, Current Controversies, and Its Role in the Prevention of HIV Infection

Over the last several years, there has been increasing discussion about biomedical strategies to prevent the acquisition and transmission of HIV infection. Several preventative measures have been proposed, including expanded HIV testing, increased condom use, behavioral interventions to reduce high-risk behaviors, mental health counseling, and screening and treatment of sexually transmitted infections.

Recently, investigators for the Pre-Exposure Prophylaxis Initiative (iPrEX) study found that a daily oral dose of two antiretrovirals had a 44 percent efficacy in preventing HIV infection among high-risk HIV-negative individuals compared to placebo. In this multinational, randomized, double-blind, placebo-controlled clinical trial, daily co-formulated emtricitabine/tenofovir (Truvada®), in conjunction with other methods of risk reduction, was shown to significantly reduce HIV infection risk among men and transgender women who have sex with men.

Additionally, 17 cases of extrapulmonary tuberculosis occurred in the HIV-infected partners in the deferred treatment arm compared with three cases in the immediate treatment arm. There were also 23 deaths during the study. Ten occurred in the immediate treatment group and 13 in the deferred treatment group.

The study was designed to evaluate whether antiretroviral use by the HIV-infected individual reduced HIV transmission to the uninfected partner and potentially benefited the HIV-infected individual as well. It also was designed to evaluate the optimal time for a person infected with HIV to initiate antiretrovirals in order to reduce HIV-related sickness and death. Based on their analysis, the DSMB recommended that the deferred study arm be discontinued and that the study participants be informed of the trial’s outcome.

“We think these results will be important to help improve both HIV treatment and prevention,” said Dr. Cohen.

The study was conducted by the HIV Prevention Trials Network, largely funded by NIAID with additional funding from the National Institute on Drug Abuse and the National Institute of Mental Health.

Additional support was provided by the NIAID-funded AIDS Clinical Trials Group. The antiretroviral drugs used in the study were made available by Abbott Laboratories, Boehringer Ingelheim Pharmaceuticals, Inc., Bristol-Myers Squibb, Gilead Sciences, GlaxoSmithKline/Viiv Healthcare and Merck & Co., Inc.

The 11 HIV drugs used in various combinations included the following:

- atazanavir (300 mg once daily)
- didanosine (400 mg once daily)
- efavirenz (600 mg once daily)
- emtricitabine/tenofovir disoproxil fumarate (200 mg emtricitabine/300 mg tenofovir disoproxil fumarate once daily)
- lamivudine (300 mg once daily)
- lopinavir/ritonavir 800/200 mg once daily (QD) or lopinavir/ritonavir 400/100 mg twice daily (BID)
- nevirapine (200 mg taken once daily for 14 days followed by 200 mg taken twice daily)
- ritonavir (100 mg once daily, used only to boost atazanavir)
- stavudine (weight-dependent dosage)
- tenofovir disoproxil fumarate (300 mg once daily)
- zidovudine/lamivudine (150 mg lamivudine/300 mg zidovudine taken orally twice daily)

In an ongoing international clinical study called Strategic Timing of Antiretroviral Therapy, NIAID is examining the optimal time for asymptomatic HIV-infected individuals to begin antiretrovirals.
infection prior to initiating PrEP, and the lack of other HIV preventative measures used in conjunction with prophylactic medications.

In the CDC’s “interim guidance,” a stepwise process of evaluating patients and prescribing PrEP was proposed. It is recommended that potential candidates for PrEP first be screened to meet certain eligibility criteria prior to starting preventive medication, including the assessment of whether other risk-reduction measures were being used consistently, and whether patients were at ongoing high risk for HIV acquisition. Further, it is recommended that PrEP recipients have close follow-up, including HIV antibody tests and risk-reduction counseling every 2-3 months. Additionally, following discontinuation of treatment, certain measures such as HIV testing and further risk-reduction referrals were advised. Through this highly structured use of PrEP, it was deemed that antiretroviral prophylaxis had the potential to “contribute to effective and safe HIV prevention for MSM.” However, the CDC noted that HIV prevention was not a labeled indication for FTC/TDF (Truvada®), and that the long-term safety of this medication in uninfected patients has yet to be fully elucidated.

In the months following the iPrEX study and the CDC “interim guidance,” there has been much debate regarding the role of PrEP as part of a comprehensive HIV prevention strategy. This was highlighted in a recent statement issued by the AIDS Healthcare Foundation (AHF), the largest community-based HIV/AIDS medical provider in the nation, titled, “Open Letter to Gilead Sciences on PrEP: One Pill a Day Will Not Keep the Doctor Away.” Reviewing the results of the iPrEX study, the AHF authors noted that adherence to PrEP in the trial was poor, even with “intensive monthly medical visits accompanied by full STD and HIV screening and extensive counseling.” The use of PrEP in actual experience, they argued, without the close healthcare supervision and support present in the study, could only lead to even lower adherence. Furthermore, the inconsistent use of prophylactic FTC/TDF (Truvada®) would lead patients to “become infected, develop drug resistance, and then spread the drug-resistant virus to others.” Additionally, the AHF warned, “if patients are taking a drug that they believe will prevent them from becoming HIV positive, they will be more lax in their use of condoms.”

Given the results of the iPrEX study, the CDC’s “interim guidance,” and the concerns regarding prophylactic antiretroviral therapy, the role of PrEP in HIV prevention is still far from clear. Yet, these medications are currently available, and physicians can provide them on an off-label basis. Little is known about the actual prescribing habits of healthcare providers regarding PrEP, however, and whether these medications have already been given to patients in the community.

We are currently conducting an anonymous study of HIV specialists and other healthcare providers using a 21 question survey to evaluate the knowledge about and use of PrEP in the prevention of HIV acquisition. We will also assess the general opinion of health-care providers regarding prophylactic antiretroviral therapy, and how this preventative treatment is thought to compare to other proven methods of HIV risk-reduction. The survey will be sent to Members of the American Academy of HIV Medicine (AAHIVM), with the understanding that these individuals already have some knowledge of antiretrovirals and the specific risk factors that lead to increased HIV infection.

Through this study, we hope to better gauge the knowledge and attitudes of clinicians regarding PrEP. Furthermore, by learning about the prescribing habits of health-care providers, we will be able to identify the discrepancies between the CDC “interim guidance” and actual clinical practice. Ultimately, we hope to use the results of our survey to further assess the utility of PrEP as part of a comprehensive strategy to prevent the acquisition and transmission of HIV.

Please take the time to share your knowledge and opinions about the use of PrEP as a viable means of HIV prevention when the survey is sent to you. It requires only five to 10 minutes of your time. If you are not a Member of AAHIVM, the survey is available on the Academy’s website for easy access at www.ahivm.org.

We plan to summarize the results of the survey in the HIV Specialist in an upcoming issue.

About the Authors: Dr. Khalid Maznavi, MD practices internal medicine at Torrance Memorial Hospital in Torrance, California. Fritz Bredeek, MD, PhD, is the Medical Director for Metropolis Medical in San Francisco and an active faculty member at the California Pacific Medical Center, San Francisco. He serves as a visiting professor for the Infectious Disease Department at UCLA. W. David Hardy, MD, AAHIVS, is the Director of the Division of Infectious Diseases at Cedars-Sinai Medical Center and Associate Professor of Medicine-in-Residence at the David Geffen School of Medicine at UCLA. Dr. Hardy is also the chair of the AAHIVM education committee.

References
AAHIVM encourages all qualified HIV practitioners to add their Profile to the AAHIVM Referral Link database. Adding a listing is free and you do not have to be a Member of the Academy to add a Profile.

If you are a current AAHIVM Member or Credentialed Provider, you are already included! AAHIVM recently expanded our Referral Link database to assure more quality referrals by including all Academy Members, Credentialed Providers and other HIV practitioners into the searchable database system.

Please take the time to ensure your information is accurate by logging into your online Profile.

AAHIVM developed Referral Link, in partnership with the CDC, to provide general practitioners with a useful referral resource for newly-identified HIV patients following routine testing.

To visit the Referral Link database, please visit the AAHIVM website at www.aahivm.org.
Discussing prevention helps protect your patients and their partners.

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