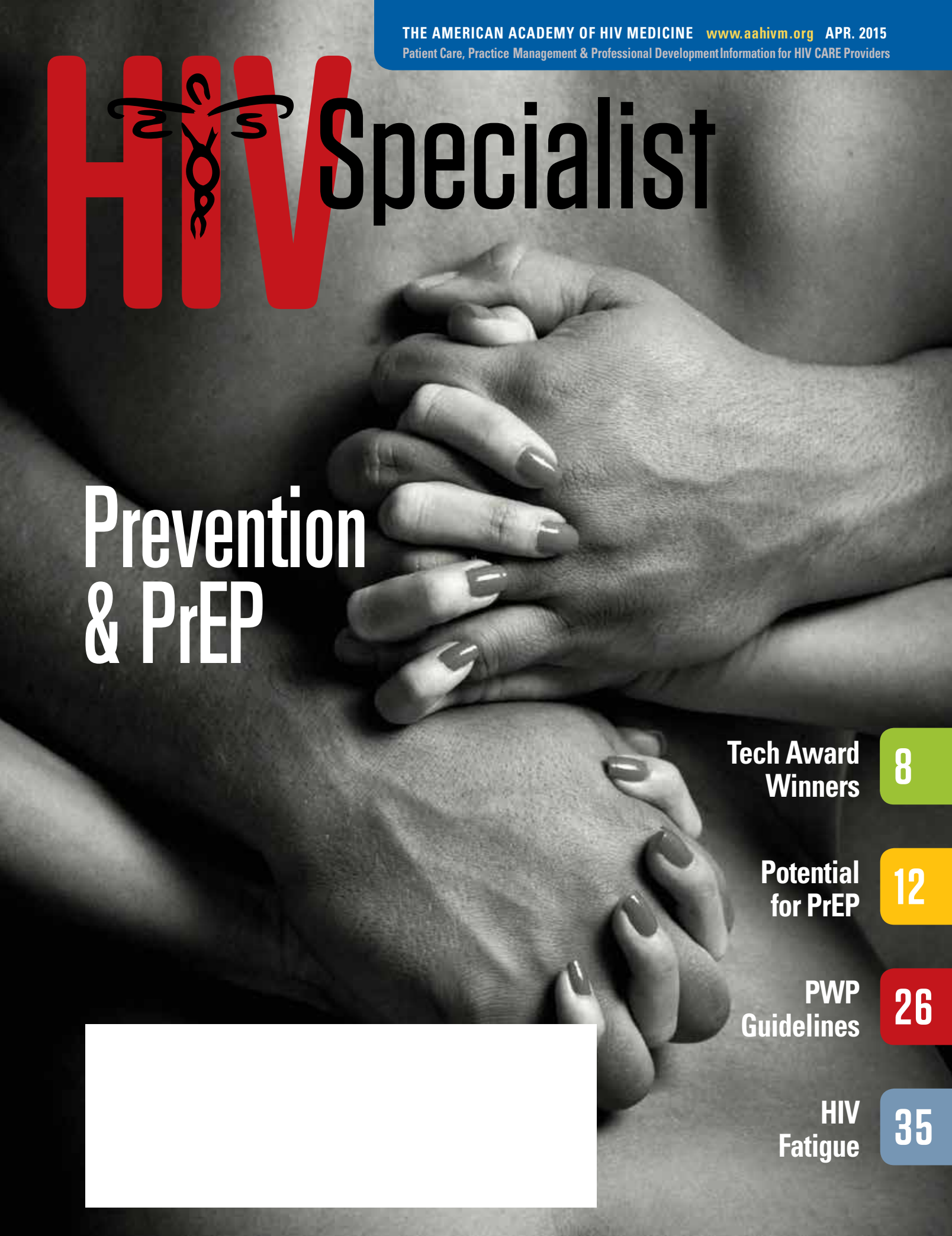
THE AMERICAN ACADEMY OF HIV MEDICINE www.aahivm.org APR. 2015
Patient Care, Practice Management & Professional Development Information for HIV CARE Providers

HIV Specialist



Prevention & PrEP

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FEATURES

DEPARTMENTS

THE AMERICAN ACADEMY OF HIV MEDICINE

HIV Specialist

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

BY JAMES M. FRIEDMAN, MHA
EXECUTIVE DIRECTOR, AAHIVM

Prevention is a Tough Sell

The new cases of HIV in the United States have hovered around 50,000 per year for more than a decade. The real question is why.

THE SIMPLE ANSWER is that prevention is a tough sell—not just with HIV, but with all health issues. For example, this past year we celebrated the 50th anniversary of the Surgeon General's Report on Smoking and Health. And while we have cut the prevalence of smoking in half in the US over the past 50 years, still 20% of our population smoke—and nearly one in five deaths in the US are caused by smoking—nearly ½ million deaths per year.

We spend just a small percentage of the $2.7 trillion annual healthcare expenditures on prevention. The FY 2015 budget for the CDC Division of HIV Prevention was about $750 million, while the Ryan White treatment program was funded at three times as much. Of course, a much higher percentage of HIV expenditures are spent on treatment in other public and private sectors (Medicare, Medicaid and private insurance).

James M. Friedman

For years, the experts at the CDC have diligently worked to develop and refine HIV prevention programs. In fact, in the early days of the epidemic, prevention was the only tool we had. There have been some social and political barriers, but thanks to these early efforts, condoms are widely available and needle exchange programs exist in many jurisdictions.

But prevention efforts continue to face new challenges, especially with regard to at-risk populations. While the number of new infections has remained relatively constant, the makeup of that population is younger, poorer and less educated—a much more difficult group to reach.

Furthermore, the consequences for becoming infected are much less severe than they used to be. For most new infections, the end point is not death or even becoming incapacitated. By taking one tablet a day, the newly infected can expect to enjoy a nearly normal lifespan. To some extent, prevention of transmission is hampered by the successes we have achieved by treatment.

With that as a preamble, this issue of *HIV Specialist* is focused on the prevention of HIV transmission, with an emphasis on PrEP.

Of special interest is the article on providers' perspective on PrEP—the findings from an AAHIVM survey of over 300 providers. In general, providers held favorable attitudes about PrEP, and said they were very likely to prescribe the regimen to most MSM. Despite being identified as optimal candidates for PrEP by CDC guidelines, fewer providers reported that they were very likely to prescribe PrEP to high-risk heterosexuals or people who actively use drugs. Providers noted several primary apprehensions about prescribing PrEP, including concerns about adherence and monitoring.

The key to eradicating HIV and AIDS is prevention. We appreciate all our AAHIVM Members and credentialed providers do every day to educate on the latest advances in HIV prevention. HIV

While the number of new infections has remained relatively constant, the makeup of that population is younger, poorer and less educated—a much more difficult group to reach.

In the NEWS

April is STD Awareness Month

APRIL marks the annual observance of STD Awareness Month. Health departments, health care providers, and community-based organizations should use the momentum gained during this month-long observance to bring a renewed sense of enthusiasm and focus to their STD awareness and prevention efforts, said Gail Bolan, M.D., director of the Division of STD Prevention (STDP) at the National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention.

DSTDP will promote a theme of *Know the Facts! GYT: Get Yourself Tested* during STD Awareness Month this year, Dr. Bolan said, noting that the "many misperceptions and false assumptions about how to prevent STDs, how STD tests are done, and who should be tested."

A *JAMA Pediatrics* article found that one-third of all adolescents didn't talk about sexual health issues with their physicians during annual health visits. Separately, another analysis points out that half of the estimated 20 million STDs that occur in the U.S. each year are among young people. "For all of these reasons, DSTDP wants to make sure young people have access to accurate, helpful information about STD prevention and testing," she said.

This STD Awareness Month, the Division will continue to support the *GYT: Get Yourself Tested* campaign. *GYT* is a youthful, empowering social movement to encourage young people to get tested and treated for STDs and HIV.

Free promotional materials are available from CDC-INFO on Demand, including *GYT* posters, stickers, and postcards that can be displayed in schools, clinics, community organizations, and health departments.

"We also encourage you to promote your own GYT testing event," said Dr. Bolan. For more information on hosting an event or success stories, please visit www.cdc.gov/gyt.

Additional materials that may help STD Awareness Month efforts include fact sheets, brochures, online banners, and STD testing site locators. These materials can be found on the Resource section of CDC's STD Awareness Month website. For those on Twitter and Facebook, please use the hashtag #STDMonth15, or #GYT when promoting STD Awareness Month or *GYT* content.

SHUTTERSTOCK / SHERRY YATES YOUNG

New Compound Raises Hope for HIV Vaccine

A NEW COMPOUND that stimulates muscle cells in monkeys to produce proteins that resemble normal antibodies may eventually result in a vaccine against HIV, according to a study published by the journal *Nature*.

The resulting proteins prevent the virus from attaching itself to a cell, according to study author Michael Farzan, an infectious disease specialist at the Scripps Research Institute in Jupiter, FL. He described the new compound as "the broadest and most potent entry inhibitor described so far."

"It's a twofer," said Dr. Anthony S. Fauci, director of the National Institute of Allergy and Infectious Diseases, which supported the work. "It's very impressive, and the method is quite promising. But it's still just in an animal model, so we'll need to see evidence of whether it works in humans."

Farzan said the compound is simpler and more effective than the current method with which scientists are experimenting: giving monkeys cocktails of several different antibodies that each neutralize only one or two strains of HIV, sometimes imperfectly.

The results demonstrate how the new drug candidate blocked every strain of HIV-1, HIV-2 and simian immunodeficiency virus (SIV), including variants that are the most difficult to block, Farzan said. It was also found to protect against dozes of the virus higher than those that normally occur in human transmission for ar least eight months after injection.

Led by scientists at the Scripps Research Institute, the work involved researchers from Harvard, Princeton, Rockefeller University, the University of Southern California, the Pasteur Institute in France and elsewhere.

Dr. Farzan said the next step will be to test the compound in infected monkeys to determine if it can stop the virus from replicating. Three-stage human trials would be next if those tests are successful.

CROI 2015 HIGHLIGHTS

Inflammation Persists Despite Early ART

A study presented by Netanya Sandler Utay, MD shows that biomarkers of inflammation increase during acute HIV infection and remain high despite early ART therapy.

The study followed 78 acutely HIV-infected patients and 109-negative individuals from Thailand, from diagnosis or enrollment to 96 weeks.

Researchers measured biomarkers of inflammation, including: D-dimer, C-reactive protein, hyaluronic acid, soluble CD14 and intestinal fatty acid binding protein. All were significantly higher in acutely infected patients at time of diagnosis compared to the HIV-negative individuals.

Immune Exhaustion Markers Predict Post-Treatment Control

In a study presented by John Frater, MD, biomarkers of immune exhaustion were associated with how long a patient could control HIV once treatment was interrupted.

The study analyzed a sub-group of patients in the SPARTAC study, a randomized trial of individuals during primary HIV infection, which included a planned treatment interruption after 48 weeks of ART for some study participants.

Dr. Frater said 14% of those who interrupted treatment after 48 weeks still had undetectable viral loads one year later, indicating that early treatment after infection may induce a state of post-treatment control. The study also showed that the amount of HIV DNA present at the time of the treatment interruption predicted how quickly the virus would rebound.

Disappointing Study Results on Vaginal HIV Prevention Gel

A study presented at CROI 2015 appears to have dealt a serious blow to hopes for a vaginal gel to help protect women from HIV infection.

Presented by Helen Rees, MD, MA, MRCGP, Executive Director of the Wits Reproductive Health and HIV Institute of the University of Witwatersrand, the study showed that a gel containing 1% tenofovir (Viread) failed to show any greater efficacy than a placebo gel, largely due to poor adherence.

Key findings from the FACTS 001 study:

- 61 HIV infections occurred with tenofovir compared to 60 in the placebo arm. Both had an infection rate of 4.0 per 100 person-years.
- Participants in both categories only used the gel before 50 to 60% of sexual encounters.
- Only 13% of participants used the gel before sex at least 80% of the time, the threshold for tenofovir gel efficacy.
- The tenofovir gel provided 52% protection against HIV infection among women who had detectable tenofovir levels in vaginal tissue.

FACTS 001 is a Phase 3 study of sexually active HIV-negative women with a mean age of 23 in several South African provinces.

Studies Stress Importance of Early HIV Treatment

Two studies presented at CROI 2015 emphasize the importance of starting HIV treatment within three months of infection and when CD4 count of 350 cells is achieved.

In the Temprano ANRS 12136 study of 2,056 people from the Ivory Coast, participants' health outcomes were assessed for those who received HIV treatment immediately compared to those whose treatment was delayed, based on WHO guidelines, and with out without isoniazid (IPT).

All participants were new to both HIV treatment and IPT and 78% were women with a median age of 35. About 40% had CD4 counts over 500 and all were below 800 cells. Most were followed for more than two years and all took regimens of embricitabine/tenovir (Truvada) with either efavirenz (Sustiva), lopinavir/r (Kaletra) or zidovudine (AZT, Retrovir).

The study showed that immediate treatment and IPT both independently lowered the risk for severe conditions, even when started at CD4 counts above 500. HIV treatment alone lowered the risk by 44% and IPT on its own lowered it by 35%.

SOURCE: C DANEL, ET AL. "EARLY ART AND IPT IN HIV-INFECTED AFRICAN ADULTS WITH HIGH CD4 COUNT (TEMPRANO TRIAL)". 2015 CROI, SEATTLE, WA.

In the Royal Free Hospital Study from London, 142 people who started HIV treatment within three months of infection (37 people) or with chronic infection but above 350 CD4s were studied.

Participants, media age about 33 and mostly MSMs, had maintained continuous treatment for at least five years. Viral loads at study entry were 311,000 for early starters compared to 278,000 for those who started later.

While results indicated that immune system responses to treatment were excellent in both groups, those who started treatment earlier showed better CD4 count outcomes.

SOURCE: S KINLOCH, ET AL. "ENHANCED IMMUNE RECONSTITUTION WITH INITIATION OF ART AT HIV-1 SEROCONVERSION". 2015 CROI, SEATTLE, WA.

HRSA Clarifies Ryan White Allowable Expense Rule

The Health Resources Services Administration (HRSA) HIV/AIDS Bureau's new Policy Clarification Notice (#15-01) revises the agency's interpretation of the Ryan White Program's 10% administrative cap established by Congress.

Such caps are critical to ensure the greatest portion of resources possible goes to program expenses rather than administration expenses. However, the previous interpretation of the policy placed many traditional direct program expenses within the 10% cap, thus creating a hardship on agencies that want to help their communities, but faced unreasonable funding restrictions. The new policy guidance resolves this issue, AIDS United said.

The old policy interpretation treated expenses such as patient management records and rent as administrative costs, where federal-wide regulations recognize these as vital costs required to do this work, and allocable as program and not administrative costs.

The policy clarification is a result of longstanding and widespread HIV community concerns, including those raised by the AIDS United Public Policy Committee, that resulted in a yearlong HRSA review of laws, regulations, and policies that govern the Ryan White Program.

In the NEWS

Study: Fast-replicating HIV Strains Drive Inflammation and Disease Progression

The strain of HIV someone is first infected with, and its capacity to replicate in the body, can have a lasting influence on how the virus disrupts the immune system, according to a study published in *Proceedings of the National Academy of Sciences* (*PNAS*, **http://www.pnas.org**).

"These results reinforce our previous findings (**http://news.emory.edu/stories/2014/07/hiv_fitness_bottleneck_science/**) suggesting that interventions that affect replicative capacity can not only impact disease progression, but also the efficiency of transmission to other people," said senior author Eric Hunter, co-director of the Emory Center for AIDS Research, Georgia Research Alliance Eminent Scholar and a professor of pathology and laboratory medicine at Emory University School of Medicine (**http://emoryhealthsciences.org**). "This informs both vaccine development and eradication strategies."

The study team included the Zambia-Emory HIV Research Project (ZEHRP), African researchers supported by Imperial College London (**http://www.imperial.ac.uk**) and the International AIDS Vaccine Initiative (**IAVI, http://www.iavi.org**), and scientists from the Ragon Institute (**http://www.ragoninstitute.org**).

The researchers obtained HIV samples from 127 newly infected individuals in Zambia and, for each one, derived a measure of the virus' ability to reproduce in culture. Study volunteers were identified before the provision of antiretroviral therapy, an average of 46 days after the estimated date of infection.

The results confirmed the team's previous finding that the replicative capacity of the newly established virus drives how quickly infected individuals' levels of CD4 T-cells declined. CD4 T-cell counts are a measure of immune system health and how quickly infected individuals could progress to AIDS. Those infected with poorly replicating viruses progressed to low CD4 T-cell counts more than two years after those infected with highly replicating viruses.

However, the new, larger study found that the effect of viral replication capacity was very early after infection, and was independent of both initial viral load and whether individuals carried certain protective variants of immune genes called HLA that positively influence immune responses to HIV. People infected with viruses with high replicative capacity had more signs of acute inflammation in the first few months of infection. Their T-cells displayed more signs of "exhaustion" (**https://med.emory.edu/gamechangers/researchers/ahmed/**), which sets the stage for faster disease progression.

"These findings underscore the huge amount that the HIV vaccine field continues to learn from studies of people in the early, acute states of HIV infection in regions where the epidemic is most severe," said author Jill Gilmour, executive director of IAVI's Human Immunology Laboratory (HIL) at Imperial College London. "The study also illustrates increasing African leadership in HIV vaccine research, a pre-requisite for successful long-term collaborative studies on HIV acute infection to inform vaccine design."

The study was funded by the National Institute of Allergy and Infectious Diseases of the National Institutes of Health (R01 AI64060 and R37 AI51231), the Emory Center for AIDS Research (P30 AI050409), the Yerkes National Primate Research Center (OD P51OD11132), USAID through the International AIDS Vaccine Initiative (IAVI) and Action Cycling Atlanta. USAID administers the U.S. foreign assistance program providing economic and humanitarian assistance in more than 120 countries worldwide.

Population Genetics Announces Agreement with Case Western Reserve University to Develop Diagnostics Technology

Population Genetics Technologies Ltd (PGT), a Cambridge, UK-based developer of diagnostic tests based on technology that enhances the sensitivity of Next Generation Sequencing (NGS), has announced a scientific agreement with Case Western Reserve University, Cleveland, OH.

The company will work with Dr. Miguel Quiñones-Mateu, Assistant Professor in the Department of Pathology and Scientific Director of the University Hospitals Translational (CLIA/CAP certified) Laboratory, to further develop diagnostic tests to determine HIV drug resistance for use in clinical management of HIV positive patients.

NGS, which enables sensitive detection of mutations, is transforming infectious disease diagnostics and is rapidly moving into routine clinical practice. Standard sequencing tests for HIV drug resistance only detect a mutation that is present in at least 20% of viruses; NGS alone can detect resistance mutations down to the 1–5% level.

However, even this level of detection may be insufficient for clinical use, as mutations at lower levels can lead to development of drug resistance. To overcome this limitation, PGT has developed its VeriTag™ technology, which enhances the power of NGS and enables the confident assessment of mutations in pathogen populations at a 0.1% level, allowing early detection of resistant mutations.

PGT is developing and will market a portfolio of VeriTag™ based NGS diagnostic tests for clinical applications in human infectious disease. The diagnostic tests will be FDA/CE regulatory approved kits with full cloud-based data analysis, data management, and clinical reporting.

The initial diagnostic kits will target the HIV and HCV drug resistance monitoring markets, where the VeX-HIV™ and VeX-HCV™ assays with VeriTag™ technology will confer clear clinical advantages over existing commercial and emerging NGS assays. Subsequent tests will target antimicrobial resistance in healthcare-associated infections to guide therapy more effectively.

Working in Africa, Making a Difference

DAVIDSON H. HAMER, MD, FACP, FIDSA, FASTMH
Zambia Center for Applied Health Research & Development, Lusaka, Zambia

UPON GRADUATION from the University of Vermont College of Medicine, Dr. Hamer did a residency at the Washington Hospital Center in Washington, DC.

Recalled Hamer, "Doing my residency in Washington, DC; in a large urban hospital from 1987 to 1990 during a surging epidemic of HIV in the MSM, IDU, and heterosexual communities stimulated a long term personal interest in HIV. This was a psychologically tough time when many patients came in with multiple opportunistic infections, profoundly low CD4 counts, and the outcome of their illness was often death."

As Hamer's career continued, he did an Infectious Diseases fellowship at Tufts-New England Medical Center. He has provided care in drug and alcohol rehabilitation centers, rehabilitation hospitals, travel clinics, and nursing homes. Hamer is board certified in Internal Medicine and Infectious Diseases, and has Certificates in Travel Health (ISTM) and ClinTropMed (ASTMH).

Hamer had a unique opportunity to work in Dhaka, Bangladesh after his first year in medical school where he spent a few days at a pediatric nutrition-infection clinic.

"Seeing children blinded from vitamin A deficiency, wasted from severe malnutrition, and infected with measles and other vaccine-preventable diseases triggered a lifelong interest in the interaction between nutrition and infection," said Hamer.

For over three years now, Hamer has been on leave from patient care while working as the Director of Research and Evaluation at the Zambia Center for Applied Health Research and Development in Lusaka, Zambia.

While his research activities are focused on maternal, newborn, and child health, HIV has a major influence on outcomes there given the scope of the epidemic in Zambia. In teaching rounds at the provincial hospital in Lusaka, there are many young patients, aged 20 to 40, with HIV, often complicated by tuberculosis or other opportunistic infections.

Said Hamer of his work in Zambia, "Seeing research results translated into national or global policy is very rewarding especially when these lead to population-level benefits. Working in sub-Saharan Africa and Asia, one of the greatest obstacles that I encounter is the health system. Quality of care, communication between different levels of the health system, inadequate transport for referrals, disgruntled, overworked health workers, shortages of supplies, and stockouts of medications combine to make the delivery of high quality care a major challenge."

Hamer feels it is important to really know his patients; their personal life style, usual schedule, work and home situations, in order to understand potential barriers and facilitators to adherence to their ART regimens.

"I also review their most recent medication—using each clinic visit to make sure they are on track. I try to identify new problems such as increased drug or alcohol abuse, or depression that might be interfering with their adherence," said Hamer.

His clinic uses a team approach so that a physician, nurse, and often a psychiatrist and a pharmacist all work with individual patients to help them to cope with the health care system, side effects of their medications, and adherence.

"While this approach may not be unique, if implemented effectively, it can provide major benefits to our patients," he said. Hamer's hope is to make substantial contributions through evidence-based interventions to improve the health of mothers and children in sub-Saharan Africa.

Looking to the future, Hamer's envisions the field of HIV care to utilize personalized approaches to the initiation of ART, faster, more efficient tests for genetic susceptibility to adverse effects of medications, and rapid tests for antiretroviral resistance. Outside of his professional life,

Hamer enjoys tennis, skiing, traveling, cooking, oenology, and learning about different cultures. As for why he is an AAHIVM Member, Hamer said, "I joined AAHIVM due to my longstanding interest in HIV care and to work within a society that helps strengthen the quality of delivery of HIV care while concurrently advocating for providers who practice within this specialized field." HIV

BY GARY BUCHER, MD, FAAFP

ANCHOR's Away!

The Anal Cancer/HSIL Outcomes Research Study

IT'S INDISPUTABLE THAT HAVING A CELEBRITY SPOKESPERSON benefits any cause. Scott Hamilton defeated testicular cancer, Kathy Bates overcame ovarian cancer and is now fighting breast cancer, and two of the original Charlie's Angels, Kate Jackson and Jaclyn Smith, are breast cancer survivors.

But it was the third angel, Farrah Fawcett, who didn't survive her cancer, dying at the age of 62 in 2009 of anal cancer. Fawcett became the one who took this particular cancer from being "unmentionable" to finally grabbing the attention of the public. Now, it even has an awareness day—March 21, 2015 is the second National Anal Cancer Awareness Day—and a foundation, the HPV and Anal Cancer Foundation.

There also is the new International Anal Neoplasia Society, the world's first professional society devoted to the prevention and treatment of AIN and anal cancer. Its mission is "to provide a forum for individuals with a broad spectrum of background, viewpoints and geographic origin, an exchange of ideas and dissemination of knowledge regarding the pathogenesis, diagnosis, treatment and prevention of anal neoplasia." Informational resources are available on the website for both medical providers and patients (http://ians.memberlodge.org).

Stigma again

The stigma surrounding anal cancer is similar to that associated with HIV—both leave those with the disease open to the judgmental assumptions of others about their sexual activity, their self-respect, even their morality. Similar to HIV, the only way to combat such stigma is for those with the disease to refuse to accept ignorance, fear, and judgment as reasonable reactions to conditions caused not by specific behaviors, but by *viruses*.

The most dangerous thing about the stigma associated with any disease is that it often deters people from getting the screening tests that would then lead to treatment. In the case of anal cancer, the human papilomavirus (HPV)—specifically the HPV 16 strain—is responsible for 90% of all anal cancers and there are several screenings that can detect abnormal cells caused by HPV that can lead to cancer.

HPV is the most common sexually transmitted infection (STI), with almost every sexually active person having it at some point. In most cases, the virus will be cleared by the body's immune system within two years and there are currently two FDA-approved vaccines that guard against HPV, Gardasil™ and Cervarix™. They both prevent infection by strains 16 and 18; Gardasil also provided protection against strains 6 and 11.

Despite these advances, anal cancer rates are increasing, with an estimated 7,210 people diagnosed in 2014 with anal cancer in the U.S. Of those, 62% will be women and 38% will be men, with the highest rates occurring among HIV-positive gay men.

Anal Intraepithelial Neoplasia (AIN)

Anal intraepithelial neoplasia (AIN)—abnormal cells in the skin just inside or immediately outside the anus—is classified in three stages:

- AIN 1 (LSIL or low-grade squamous intraepithelial lesions) is least severe, mild dysplasia (proliferation of cells of an abnormal type), and can appear like warts.
- AIN 2 (HSIL, or high-grade squamous intraepithelial lesions) is moderate dysplasia and may progress to anal cancer over time.
- AIN 3 (also HSIL) is severe dysplasia and may progress to cancer.

There is no standard treatment for AIN at this time, as it is difficult to predict which cases will regress if left untreated.

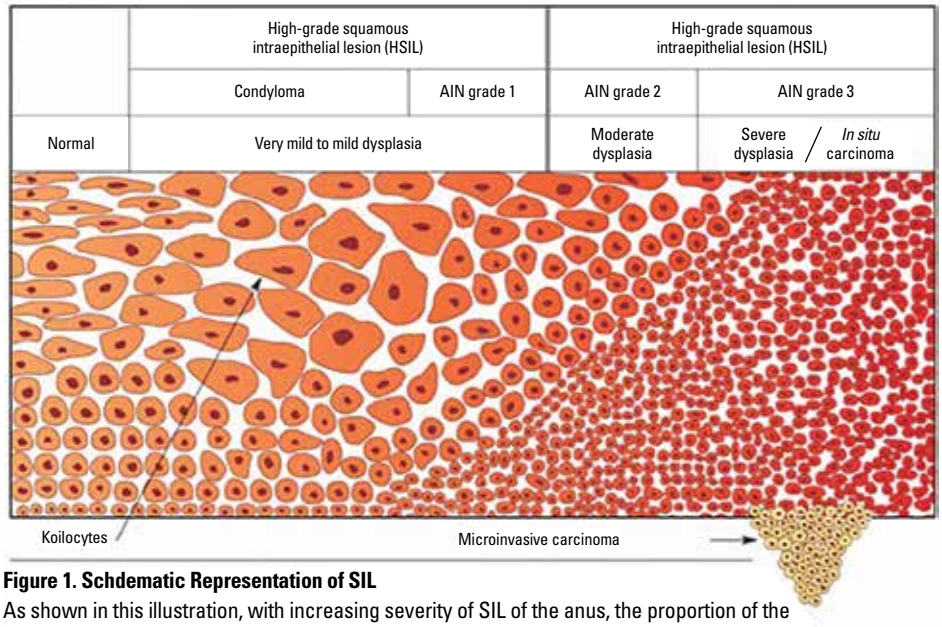


Figure 1. Schdematic Representation of SIL

As shown in this illustration, with increasing severity of SIL of the anus, the proportion of the epithelium replaced by immature cells with large nuclear-cytoplasmic ratios increases. Invasive cancer probably arises from one or more foci of high-grade SIL (HSIL), as depicted in the drawing by epithelial cells crossing the basement membrane below the region of HSIL.

Source: Dr. Joel Palefsky, ANCHOR Study Principal Investigator. Reprinted from The PRN Notebook, Diagnosis and Treatment of HPV-Related Squamous Intraepithelial Neoplasia, by Stephen E. Goldstone, MD, ANCHOR Study clinician.

Screening for Anal Cancer

There are several types of cancers that can involve the anal region: squamous cell carcinoma, which is the most common, cloacogenic carcinoma, adenocarcinoma, basal cell carcinoma, and malignant melanoma. Most have no symptoms in the early stage and symptoms that do appear may be mistakenly thought to be due to other conditions. Thus, attention to patient symptoms and subsequent evaluation for anal cancers is a very important aspect of HIV-patient care.

Screening methods include:

- Visualization of the anal-rectal area for any abnormal skin changes or lesions
- The basic DARE (digital ano-rectal examination), in which the clinician inserts a gloved finger into the anus to detect any abnormalities.
- Anal Pap smears, in which the anus is swabbed to collect cells for examination to detect abnormalities that may be precursors to cancer.

If abnormalities are detected by screening, high-resolution anoscopy (HRA) is recommended, in which an anoscope and a colposcope are used to determine where abnormal anal tissue is located and to guide biopsies. Some clinicians and patients may believe that HRA is an accepted screening tool. However, it must be noted that most health plans will NOT pay for HRA if it is done for screening and not diagnostic purposes. If cancer is confirmed by biopsy, the stage, or the extent of the spread, is determined and treatment options are decided. Generally, the earlier the stage at diagnosis, the easier and more successful treatment will be.

The Anal Cancer/HSIL Outcomes Research (ANCHOR) Study

"If you're HIV-positive, you owe it to your anus to get checked out. It could literally save your butt."

So says the homepage of the ANCHOR Study website (www.anchorstudy.org). Who could resist?

As with any study of this kind, it is challenging to recruit as many qualifying participants as we need. Across the United States, 5,085 men and women will be enrolled in this study. We have tried to give potential subjects the information and motivation they need to sign up, show up, and complete the study.

Committing to five years of monitoring is not easy for many patients. However, the key outcome for the ANCHOR study is to determine if screening and treatment of high-grade SIL is as effective in preventing anal cancer as was found with screening and treatment for cervical cancer in women. Not only will this save lives, but 3rd party payers will be more likely to cover the cost of screening for anal cancer.

To qualify for the study, candidates can be either male or female and must:

- be at least 35 years of age
- be HIV-positive
- never have been vaccinated against HPV
- never have been treated for anal HSIL
- never have had cancer of the anus, vulva, vagina, or cervix.
- have anal HSIL (tests for this will be done)

Participants will be randomly assigned to two groups. Group 1 (Active Monitoring) will not have any anal HSIL treatments. Group 2 (Treatment) will have treatment of anal HSIL chosen by the patient and doctor doing the study.

Active study sites are located in:

- **Boston:**
  Boston Medical Center
  85 E. Concord Street, 6th Floor
  Boston, MA 02118
  Drs. Ami Multani and Lori Panther

  Fenway Health
  The Fenway Institute
  1340 Boylston
  Boston, MA 02215
  617-414-5149
  Dr. Elizabeth Stier

- **Chicago:**
  Anal Dysplasia Clinic MidWest
  2551 North Clark St., Suite # 203
  Chicago, IL 60614
  312-623-2625
  Dr. Gary Bucher

- **New York:**

  Cornell Clinical Trials Unit
  Chelsea Research Clinic
  53 W 23rd St, 6th Fl
  New York, NY 10010
  212-746-7204
  Dr. Timothy Wilkin

  Montefiore Medical Center and Albert Einstein College of Medicine
  1695 Eastchester Road, 5th floor
  Bronx, NY 10461
  212-746-7204
  Drs. Mark Einstein and Rebecca Levine

  Laser Surgery Care
  420 W 23rd St, Suite PB
  New York, NY 10011
  212-242-6500
  Dr. Stephen Goldstone

- **San Francisco:**
  UCSF Mt. Zion Medical Center
  1701 Divisadero St., Suite 480
  San Francisco, CA 94115
  415-353-7443
  Dr. Joel Palefsky

Check the ANCHOR website for future active recruiting sites.

Please help

Medical history is made when people have the courage and dedication to lend their bodies to research. Without clinical trial participants, and the activism of many of them, HIV treatment may never have gotten to single-tablet regimens from AZT monotherapy and hepatitis C treatment might not evolved past interferon. Without effective studies to discover both physical and but social determinants of health, how can those suffering from any illness, including the socially disadvantaged ever have equal access to healthcare?

Hopefully, clinicians will encourage their patients living with HIV who meet all the study's eligibility criteria to consider becoming one of the unsung heroes who will make it possible for us to prevent anal cancer. If you are providing care for patients with or at risk of AIN and anal cancer, encourage them to contact one of the study sites and make a difference in the fight against this disease.

One of the ironies of life is that having an illness that many others have creates a community of sorts. Farrah Fawcett said, "This experience has also humbled me by giving me a true understanding of what millions of others face each day in their own fight against cancer." And it's awe-inspiring to witness an AIDS ride or an MS or breast cancer walk, to see people supporting those they care about as well as perfect strangers they'll never know.

On March 21, honor Anal Cancer Awareness Day by talking to your patients – or your own doctor—about the risk of AIN and having a screening.

How wonderful would it be if instead of coming together in support of those struggling with a disease, we could come together in celebration of the end of it? HIV

ABOUT THE AUTHOR:
Gary Bucher, MD, FAAFP is the Medical Director and founder of Anal Dysplasia Clinic MidWest, a medical practice dedicated to the anal health of men and women with HPV-related anal disease.

High Tech Weapons Against HIV

BY BOB GATTY

TECH

Tech Award Winners Create Innovative Solutions to Improve Patient Care

IN RURAL ALABAMA, where fewer than half of the 12,000 patients diagnosed with HIV have been linked to care and where certified HIV specialists are in short supply, technology is helping to close that gap thanks to the efforts of a creative and dedicated AAHIVM physician member.

In Minnesota, another AAHIVM physician member and his team are using innovative technology to create and manage a quality improvement program centered around the primary care of HIV-positive patients, identifying specific opportunities to improve patient care.

Both of these physicians, Prashanth Bhat, MD, MPH, AAHIVS, assistant director of Medical AIDS Outreach of Alabama, Inc., Montgomery (MAO), and Mark Sannes, MD, MS, director of the Park Nicollet Infectious Disease Clinic, St. Louis Park, MN, are this year's winners of the AAHIVM/Institute for Technology in Health Care HIV Practice Award. They each receive a $10,000 stipend for their work.

Telemedicine in Alabama

In 2012, Dr. Bhat's clinic established a telemedicine network in Alabama to address the increasing lack of access to quality HIV care in the predominantly rural state. Using high definition cameras and video screens that meet privacy requirements of the Health Insurance Portability and Accountability Act, 128-bit encryption, high speed internet and Bluetooth medical technology, clinicians in urban settings can treat patients in rural clinics, providing real-time, direct to patient HIV primary care from a distance.

The technology, Dr. Bhat explained, allows HIV providers to reach underserved populations in rural areas without the need for the doctor or patient to travel, and increasing access to care for HIV positive individuals throughout rural Alabama.

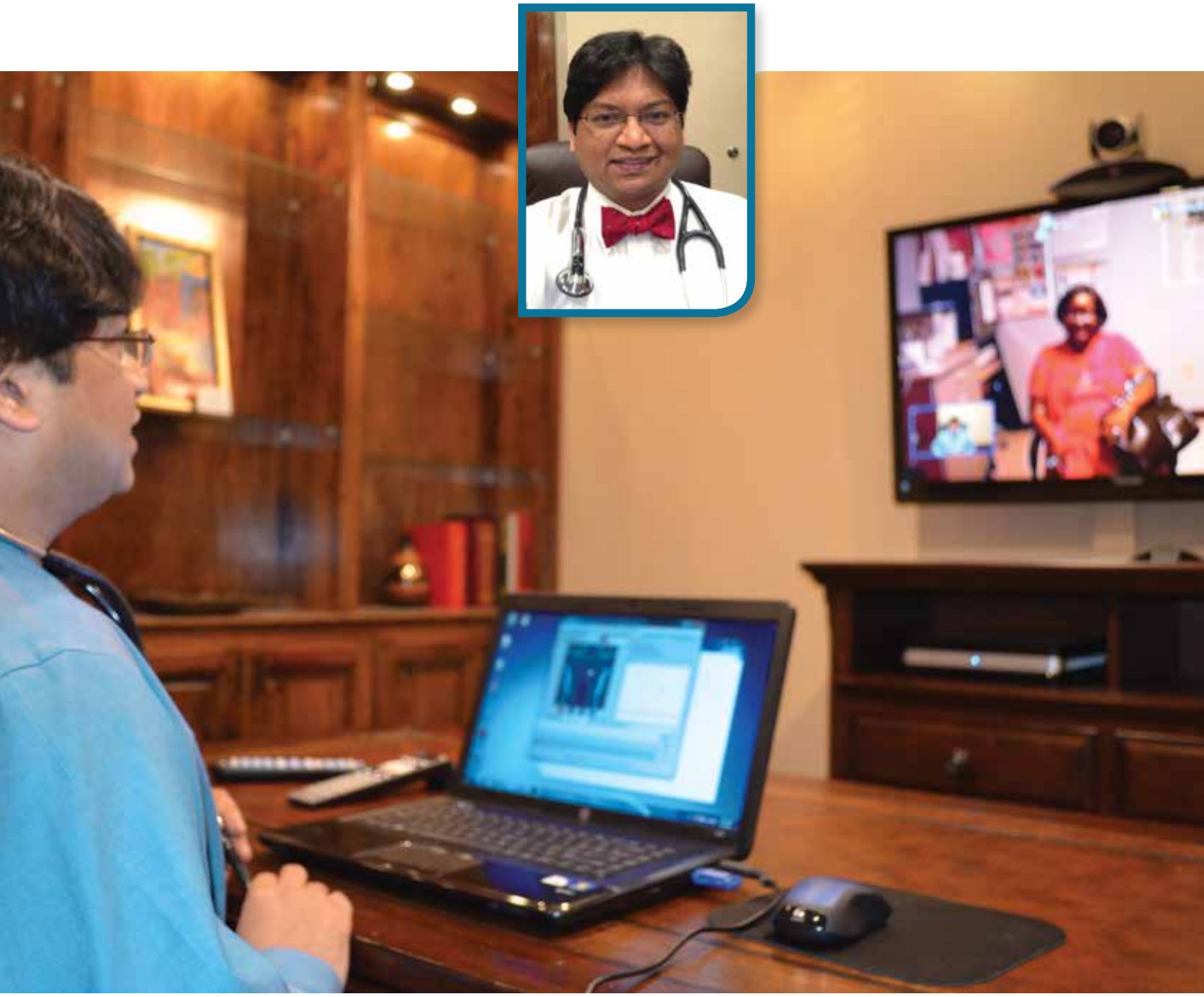
"Today, MAO provides not only primary care, but pharmacy consultations, mental health counseling, and social work support services via telemedicine to seven locations and is planning three more locations by Spring 2015," Dr. Bhat said.

MAO serves about 1,400 patients in 26 of Alabama's 67 counties and is the second largest clinic in the state.

"Alabama has a lack of HIV health care providers," Dr. Bhat explained. "In fact, 61 of the 67 counties have been federally designated as health care provider shortage areas. That is a big problem because there is a high burden of HIV in Alabama."

Stigma is prevalent, exacerbating the problem. "We see children not disclosing their status to parents for fear of being thrown out," he said. "It all points to a general lack of awareness about HIV in the state."

AWARDS



The remote telemedicine system has been created with those issues in mind. "We provide HIV care and treat other primary care issues. A lot of research went into this," Dr. Bhat stressed, noting that HIV clinics have been incorporated into primary care centers, thus helping to reduce the opportunity for stigma.

Today, surveys show that patients treated remotely are overwhelmingly satisfied and have excellent clinical outcomes. Dr. Bhat's team is helping other centers implement a similar system.

Dr. Bhat notes that this program was possible due to the grant support from AIDS United, CDC, Alabama Department of Public Health, and numerous other donors. MAO has partnered with two other agencies in the state to create Alabama eHealth, which could serve as a model for telemedicine collaboration efforts.

"I'm really proud of this," he said. "We are evolving and have expanded to over 11 clinics throughout rural Alabama. This system could be established anywhere where there is a need for HIV primary care. It is a very cost effective and productive model for rural health care."

By targeting locations with high incidence rates and HIV provider shortages, telemedicine can bridge the healthcare gaps for many patients, he said. "By placing telemedicine units in federally qualified health centers, public health clinics, and residency programs, MAO is striving to eliminate stigma for their clients in rural Alabama, allowing them to receive HIV care in a neutral location."

Dr. Bhat said the initial start-up cost was about $68,000, including consulting needs and the cost of establishing the host site. The cost of establishing additional telemedicine clinic sites is about $25,000, with operating costs averaging about $2,500 per month. Without telemedicine, options for providing care in rural locations would be through either client transportation assistance, about $329 per visit, or travel clinics provided by the agency's staff, about $370 per visit.

"Undoubtedly, telemedicine is much more cost effective as a long term solution to providing rural clients access to HIV care. At the end of the day, it is a social justice effort which increases health equity by decreasing health disparity."

Quality Improvement in Minnesota

Meanwhile, Dr. Sannes and his team at the Infectious Disease Department at Park Nicollet Clinic in Minnesota were convinced that a quality improvement program centered around primary care of HIV-positive individuals was needed. The clinic serves as the primary care physician for about 75 percent of the more than 800 HIV-positive patients that it sees each year.

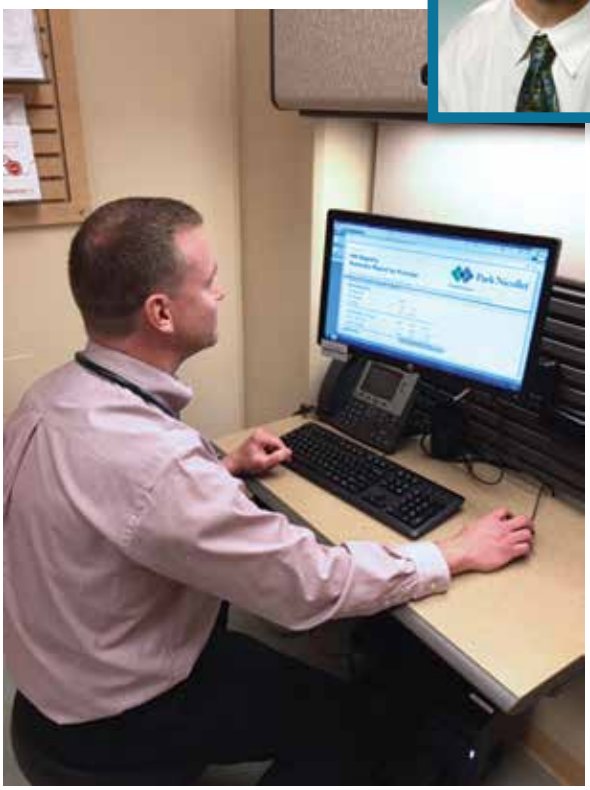
The technology established to accomplish this involved building an HIV registry within the clinic's Epic electronic medical record system that tracks current federal performance measures as well as HIV-specific health maintenance measures.

"If the future of HIV/AIDS care is increasingly around cardiovascular disease risk modification and cancer prevention, registries like this one are going to be absolutely necessary to standardize the screening and management of our patients."

"This technology fills an unmet need in continuous HIV quality improvement for non-academic institutions, and those who are not required to report for Ryan White funding purposes," Dr. Sannes explained. "Our newly minted registry provides that reporting capability for the first time at our clinic, and also provides us future opportunities to create an informal clinical research network with other institutions in our state that use Epic."

The HIV registry went live in November 2014. "We are already able to drill down to the level of individual clinician in real-time, and provide those individuals with immediate quality improvement opportunities, individualizing those interventions to where needs exist in their patient panels, as opposed to clinic-wide initiatives that may help individual providers who are lacking in some area of primary care, but not others," he said.

"We do a lot of quality improvement work in our organization," Dr. Sannes pointed out, explaining the impetus for the program. "We have all of these measures that everyone agrees upon as constituting quality care, so why can't this be a standing order that everybody just runs with? That will lead to better care and will be a more cost effective way of doing this."



The impact of this work is felt in two primary ways in Minnesota.

First, unnecessary variations in HIV-positive patient care are removed by focusing on validated core measures for all clinicians, providing them real-time data regarding how well they are achieving those measures with their patients.

"If the future of HIV/AIDS care is increasingly around cardiovascular disease risk modification and cancer prevention, registries like this one are going to be absolutely necessary to standardize the screening and management of our patients," he said. "We hope to achieve this seamlessly without adding more physician documentation time, by utilizing standing health maintenance order sets in Epic, and letting many of these tasks get completed outside of normal clinic visits."

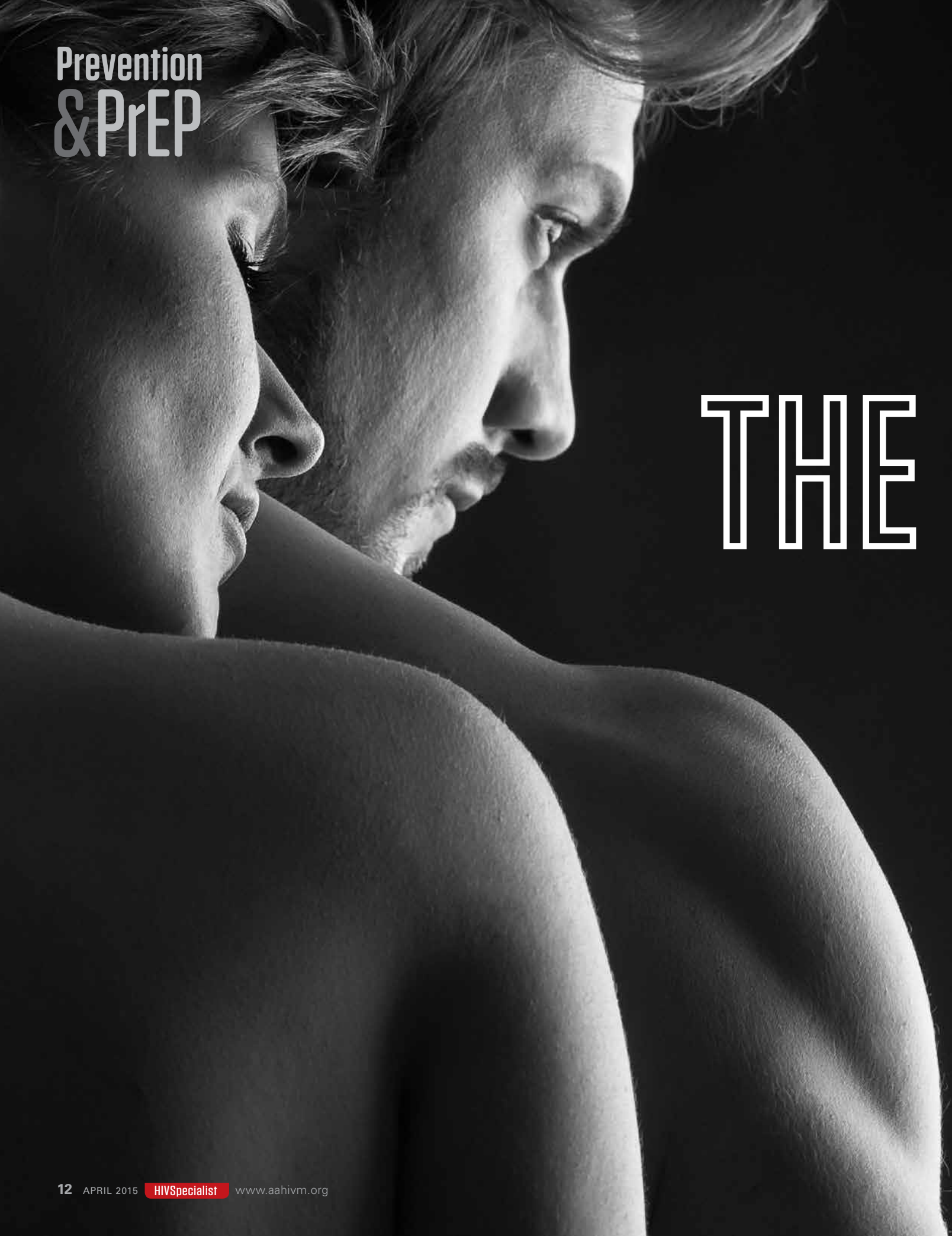
Second, by systematically tracking patients at the clinic, Dr. Sannes said problem points in the HIV treatment cascade can be attacked, focusing on retaining patients in care through lists provided to case managers. This means ultimately getting all patients connected to care, on ART, and achieving undetectable virus, which is now happening with 89% of the clinic's patients.

"That degree of viral suppression ultimately fulfills our goals for treatment as prevention, and avoids new and unnecessary infections from our known HIV-positive patients," he said.

Dr. Sannes described as "extensive" the information technology costs involved in getting the HIV registry to automatically pull data from Epic. But once the registry was built, "it runs itself at this point, and we are just developing monthly reports to track."

The next step, he said, is to share the Epic "code" for the HIV registry with the infectious disease clinic within the organization, bringing another 800 patients into the registry and resulting in tracking about 20 percent of the state's HIV-positive individuals. He pointed out that two other large organizations also use Epic, potentially creating a scenario where a "Minnesota cohort" could be developed to track nearly 75% of HIV-positive individuals in the state.

"We are more than willing to share this with the Epic community," Dr. Sannes said. "The future of HIV is not patients dying from AIDS complications. It's patients dying from cardiovascular disease and cancer disproportionately. We know this patient population is at higher risk. Our future is managing the heart attacks, the strokes and the cancers related to HIV disease." **HIV**



THE

POTENTIAL for PrEP

BY GARY F. SPINNER, PA, MPH, AAHIVS

ALTHOUGH THE FDA APPROVED the use of tenofovir/emtricitabine (Truvada™) for PrEP in July 2012, clinicians have been slow to implement its use in clinical practice. After considering data demonstrating the efficacy of PrEP for HIV prevention in the United States and in many other countries, the Centers for Disease Control (CDC) and the U.S. Public Health Service (USPHS) released the first official clinical practice guidelines on the use of PrEP in May, 2014.[1]

This new guideline recommends that clinicians evaluate their male and female HIV negative patients who are sexually active or who are injecting illicit drugs. They should subsequently consider offering PrEP as a prevention option to those whose behaviors and epidemiologic context place them at substantial risk of acquiring HIV infection.

With a relatively unchanging annual incidence of 50,000 new HIV infections in the U.S., prevention efforts must be expanded. This includes extending the use of ART by all HIV-infected patients which has been proven to significantly reduce the risk of transmission to others. CDC Director Dr. Tom Frieden stated "*HIV infection is preventable, yet every year we see 50,000 new HIV infections in the United States. "PrEP, used along with other prevention strategies, has the potential to help at-risk individuals protect themselves and reduce new HIV infections in the US.*"[2]

The CDC/USPHS recommends that daily oral PrEP should be considered for HIV-uninfected patients with any of the following indications:[3]

- Anyone who is in an ongoing sexual relationship with an HIV-infected partner.
- A gay or bisexual man who has had sex without a condom or has been diagnosed with a sexually transmitted infection within the past six months, and is not in a mutually monogamous relationship with a partner who recently tested HIV-negative.
- A heterosexual man or woman who does not always use condoms when having sex with partners known to be at risk for HIV (for example, injecting drug users or bisexual male partners of unknown HIV status), and is not in a mutually-monogamous relationship with a partner who recently tested HIV-negative.
- Anyone who has, within the past six months, injected illicit drugs and shared equipment or been in a treatment program for injection drug use.

SHUTTERSTOCK

The cost of PrEP ($8,000 to $14,000 annually)—and whether insurers will pay for it—may deter some providers from prescribing it. However, there are patient assistance programs that may cover the costs and, based on my clinical experience thus far, cost has not been a barrier for patients who have requested tenofovir/emtricitabine for PrEP.

The Latest on PrEP from CROI

At the recent Conference on Retroviruses and Opportunistic Infections (CROI), the IPERGAY[4] study showed that "on demand" PrEP in MSM who took two tablets of Truvada (tenofovir/emtricitabine) from 2-24 hours before condomless sex, followed by one tablet the day of sexual contact, and one more the day after, for a total of four tablets, showed an 86% relative reduction in HIV infection. Also at CROI, the PROUD [5] study looked at the use of PrEP in a "real world setting" in which half the study participants were randomized to begin daily PrEP while the other half would defer PrEP for 12 months. The deferred arm was halted when the Truvada arm showed an 86% reduction in HIV transmission.

Another tenofovir gel study, FACTS 001[6] failed to show any prevention benefit in women, but again, adherence was low, as in several previous vaginal gel studies of PrEP. Many have since questioned the utility of on-going studies with this prevention method based on the consistent failure rates. Lastly, the Partners PrEP Demonstration Project[7] in Uganda and Kenya used PrEP as a six-month bridge before the HIV infected partner achieved virologic suppression. Among 1,013 sero-discordant couples, there were only two HIV infections whereas pre-study modeling predicted number of expected infections was 40. This is a 96% reduction in the rate of infection.

On the horizon, PrEP may include long-term antivirals that can be administered every two or three months. At last year's CROI in Boston, there was an impressive study showing the efficacy of a long acting injectable integrase inhibitor,(GSK744)[8] in preventing SIV in macaques. At this year's meeting, the drug, (now called cabotegravir), Lowry and colleagues presented a follow-up study of in-vivo data on the dosing effectiveness of this agent.[9]

With demonstrated efficacy, why has adoption of PrEP been low?

The lack of a clinical practice guideline before May 2014 is one reason for the slow adoption of PrEP by providers. In addition, data from HPTN 052[10] and other studies showing a 96% reduction in HIV transmission in serodiscordant couples when the infected partner was taking antiviral medications suggest that PrEP in serodiscordant couples is unnecessary.

Many HIV clinicians believe with such a low risk of HIV transmission when the infected person is virologically suppressed[3-4], using a costly and potentially toxic regimen in someone without HIV is unnecessary. Other providers may feel that prescribing PrEP to an HIV uninfected person who does not use condoms is granting permission to have condomless sex. In addition, many HIV specialists only treat HIV-infected patients in their practices and are not in the best position to see new patients who are uninfected.

The use of PrEP ideally could be utilized by other health care providers who are more likely to see patients at high risk of contracting HIV. This will require education on their part to gain comfort and knowledge using this prevention intervention. Historically many primary care providers have been slow to adopt the CDC/USFPST HIV screening guidelines so it is not surprising that there is a lack of interest in prescribing antiviral medications to prevent HIV.

Lastly, the cost of PrEP ($8,000 to $14,000 annually)—and whether insurers will pay for it—may deter some providers from prescribing it. However, there are patient assistance programs that may cover the costs and based on my clinical experience thus far, cost has not been a barrier for patients who have requested tenofovir/emtricitabine for PrEP.

With extensive data from clinical trials demonstrating that PrEP is highly effective in preventing HIV infections, its use should be encouraged, along with other prevention measures, to help further decrease the incidence of new infections in the United States and globally. **HIV**

Endnotes

1 .cdc.gov/hiv/pdf/PrEPguidelines2014.pdf

2 **http://www.cdc.gov/nchhstp/** Wednesday, May 14, 2014

3 **http://www.cdc.gov/hiv/pdf/PrEPguidelines2014.pdf** iPrEx] "Preexposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men", *NEJM* 2010; 363:2587-2599

4 On Demand PrEP With Oral TDF-FTC in MSM: Results of the ANRS Ipergay Trial, Jean-Michel Molina CROI 2/25/2015

5 Pragmatic Open-Label Randomised Trial of Preexposure Prophylaxis: The PROUD Study, Sheena McCormack; 22LB CROI 2015

6 FACTS 001 Phase III Trial of Pericoital Tenofovir 1% Gel for HIV Prevention in Women Helen Rees, 26LB CROI 2015

7 Near Elimination of HIV Transmission in a Demonstration Project of PrEP and ART Jared Baeten 24 CROI 2015

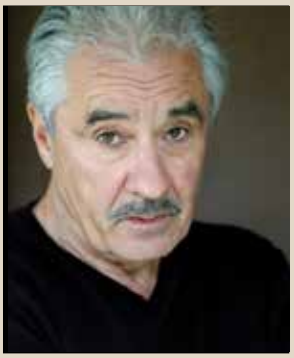
8 MonthlyGSK744Long-ActingInjectionsProtectMacaques Against Repeated Vaginal SHIV Exposures Jessica Radzio 40LB CROI 2014

9 Correlation of In Vivo Cabotegravir Concentration and Prevention of SIV in Macaques Anabel Lowry[1]; 966 LB CROI 2015

10 Grinsztejn B et al, Effects of early versus delayed initiation of antiretroviral treatment on clinical outcomes of HIV-1 infection: results from the phase 3 HPTN 052 randomised controlled trial. Lancet Infect Dis. 2014 Apr;14(4):281-90. doi: 10.1016/S1473-3099(13)70692-3. Epub 2014 Mar 4

Prevention &PrEP

TALES FROM THE CLINIC

VECTORSTOCK / SHUTTERSTOCK / ISTOCK

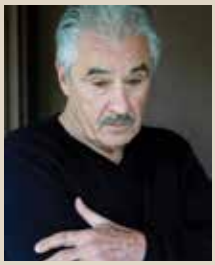
BY TRAVIS SHERER, PA-C, AAHIVS,
GARY F. SPINNER, PA, MPH, AAHIVS
AND SUSAN LELACHEUR, PA-C,

CASE #1

Maurice is a 25-year-old man who was referred to me to by an outreach worker to discuss PrEP. He is a gay black man who uses condoms "sometimes." We had a discussion about the risk of HIV and other STIs, including the benefit of condoms as the best protection from STIs, but this did not seem terribly concerning to Maurice. After a discussion about the risks and benefits of taking tenofovir/emtricitabine co-formulation (Truvada™) daily, and obtaining labs that documented a negative 4th generation HIV test, negative HBV antigen, negative RPR, HCV antibody, and normal renal functions, I gave Maurice a prescription for a month of medication with one refill. Maurice returned for a follow up six weeks later complaining of a urethral discharge over the past week. He acknowledged having had sexual relations with three partners since his last visit. I treated him for gonorrhea and chlamydia and discussed how PrEP will not protect him from other STIs. I sent him for repeat HIV testing and other STI screening, creatinine, and an appointment to see me in two months. Some clinicians might say I have given Maurice permission to have condomless sex by prescribing tenofovir/emtricitabine. To me, Maurice neither needs nor wants my permission to do what he chooses in his private life. I have done my best to educate him about HIV and STI prevention, but the fact that he is taking daily PrEP means that there is hopefully one less young gay man who gets infected with HIV and thereafter infects others. Treating him for gonorrhea only reinforced for me that prescribing PrEP for Maurice is an important intervention for HIV prevention.

The U.S. Public Health Service recommends PrEP [Preexposure Prophylaxis for the Prevention of HIV Infection in the United States–2014 Clinical Practice Guideline, **http://www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf**] for sexual exposure in anyone at high risk for contracting HIV. This case highlights the substantial risk of contracting HIV for gay or bisexual men who have a history of unprotected anal sex. As noted above, some have expressed a fear that a prescription of PrEP will condone or even engender risky sexual behavior. However, data from the iPrEX study found no excessive risk taking behavior in MSMs on PrEP [iPrEx Trial, 20th CROI; Atlanta. 2013. #27 Study Team]. By prescribing PrEP to someone like Maurice, the clinician acknowledges his behavior, meeting the patient where he is, and reduces the risk to himself and to his community.

CASE #2



Alphonso is a 50 year-old-man in a serodiscordant relationship with his HIV-infected wife Carmen. I always encouraged my patients to bring their partners to the clinic if they are willing. I met Alphonso 4 years ago when he accompanied Carmen to her clinic appointment. She had been engaged with mental health services and treated with antipsychotic medications, until she decided that she "did not like how she felt while one them." Subsequently, she had lapses in taking her antiviral medications and I encouraged Alphonso to consider tenofovir/emtricitabine for HIV prevention, since they did not use condoms. Trying to get Carmen to consistently take her ART was unsuccessful, and explaining Alphonso's risk did little to change her behavior. About a year and a half ago, I started Alphonso on PrEP. Carmen subsequently dropped out of care for the past six months, but I continue to see Alphonso every two to three months for HIV and other lab testing, and to provide him with his medication. He remains HIV negative as of his most recent visit.

CASE #3

Marlene is a 45-year-old woman who is married to my HIV infected patient, George. When I first met George five years ago, he had been going to another practice and his HIV had never been virologically suppressed. When I performed genotyping, he had significant HIV mutations. Eventually, he began to take a rather complex ART regimen and his viral load became undetectable. However, about once a year, George would feel pressured by the stresses in his life and discontinue his medications. Last year, when his wife Marlene came to a clinic visit, I brought up the subject of PrEP, and she subsequently made an appointment to see me. She has been on tenofovir/emtricitabine for the past eight or nine months. About six weeks ago when George had his viral load checked (after he assured me that he was adherent with ART) his HIV-RNA level came back at 18,000 copies/ml. It was only after I brought George back to clinic that he admitted being stressed and was not taking his medications. He agreed to go back on them, and within two weeks he was undetectable. Marlene continues to take PrEP and remains free of HIV.

Alphonso and Marlene demonstrate the utility of PrEP among other high-risk groups - heterosexual or homosexual individuals in relationships with a partner who is HIV positive [TDF2: Thigpen MC, et al; TDF2 Study Group. Antiretroviral pre-exposure prophylaxis for heterosexual HIV transmission in Botswana. N Engl J Med 2012;367(5):423-34.; Partners PrEP: Baeten JM, et al; Partners PrEP Study Team. Antiretroviral prophylaxis for HIV prevention in heterosexual men and women [N Engl J Med 2012;367(5):399-410]. In sero-discordant couples, condoms and strict anti-retroviral adherence provide excellent protection, but adherence to either is seldom perfect. PrEP provides both partners an extra level of protection and the peace of mind that comes with it. While data has been convincing that treatment with tenofovir and emtricitabine antivirals offers substantial protection from transmitting HIV, (96% reduction of transmission in HPTN 052) the cases above are examples of the potential benefit of PrEP for couples in which the HIV-infected partner is less than fully adherent with their antiviral regimen. It can be argued that a fully adherent HIV-infected partner in a sero-discordant relationship reduces the risk of HIV transmission to an extremely low level, however studies have shown that the risk of transmission is cumulative over time, and therefore there is never a truly zero risk for the HIV uninfected partner [Clin Infect Dis. 2014 Jul 1;59(1):115-22. doi: 10.1093/cid/ciu223. Epub 2014 Apr 9. Heterosexual risk of HIV transmission per sexual act under combined antiretroviral therapy: systematic review and Bayesian modeling. Supervie V1, Viard JP2, Costagliola D1, Breban R3].

Recent data indicate that PrEP for the uninfected partner and antiviral therapy for the infected partner can provide nearly perfect protection from HIV transmission [Baeten J, et al. Near elimination of HIV transmission in a demonstration project of PrEP and ART. CROI 2015. February 2015. Seattle, Washington. Abstract # 24].

CASE #4

PrEP for Transgender Persons

As a transgender woman, Maria came to my office desperately seeking hormones and a supportive clinician. Despite making her living as a commercial sex worker, HIV and sexual health were not priorities in Maria's life. She had some bad experiences with health care providers before, was not receiving regular medical care. Her hormones were bought on the street or online. Her friend, who is a patient of mine, had encouraged her to come in and see me. I put Maria on hormone replacement therapy, engaged her in regular care, and over a period of time was able to build trust. After realizing that she was not always in a position to demand condom use from her clients, she and I discussed PrEP. Although substance abuse and her source of income resulted in a complicated life that had me concerned about potential adherence issues, I knew she never missed her

SHUTTERSTOCK / ISTOCK

It should be noted that the CDC guidelines recommend PrEP as fixed dose tenofovir/emtricitabine taken daily, but these new data may change how PrEP is used in certain individuals.

hormones. Maria now takes tenofovir/emtricitabine concurrently with her daily hormonal therapy resulting in excellent adherence. Together with her hormones, she now feels a greater sense of empowerment and confidence and is regularly engaged in her overall health-something that would have been unimaginable to her one year ago.

Transgender communities in the United States are among the groups at highest risk for HIV infection, according to the Centers for Disease Control and Prevention. Maria brings to light one additional recommendation for the use of PrEP, use of injection drugs. Substance use, which may include injectable estrogen, and the inherent risks of sex work, puts Maria in an extremely high risk situation [Operario D, et al. Sex work and HIV status among transgender women: Systematic review and meta-analysis. J Acquired Immune Def Syndrome. 2008;48:97–103]. Persons who use drugs should be counselled on both safer drug use and addiction treatment options, however the use of PrEP can keep them HIV negative as they struggle through the complexities of often chaotic lives. Among Injection drug users, the Bangkok study that looked at Tenofovir only, showed a substantial reduction in HIV transmission among this high-risk group. [Choopanya K. et al. Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand [Bangkok Tenofovir Study): a randomized, double-blind, placebo-controlled phase 3 trial. Lancet 2013;381:2083-90].

At the most recent Conference on Retroviruses and Opportunistic Infections in Seattle, there was additional very encouraging data on PrEP. The Proud Study out of London was the first "real world" study to demonstrate the efficacy of PrEP [McCormack et al CROI 2015; abstract # 22LB].

It was considered "real world" because participants knew that they were receiving tenofovir/emtricitabine. This case-control study was stopped early because of the substantial efficacy in the PrEP arm. The use PrEP resulted in an 86% reduction in HIV transmission in MSM. At the same CROI session, follow-up data from the Ipergay study from France was presented which demonstrated that "on demand" PrEP can be highly effective [Molina JM et al.CROI # 23LB]. In this study of MSM compared "on demand" PrEP versus placebo. It found that taking two tablets of tenofovir/emtricitabine 2 to 24 hours before having high risk sexual contact and one tablet daily for two days following the sexual exposure reduced HIV transmission by 86%.

The iPrEx OLE (Open Label Extension) study which was presented at the International AIDS Conference in Melbourne in 2014 also had showed that four doses of Truvada per week was enough to reduce HIV transmission by at least 86% in this study of men who have sex with men. [Grant RM et al. Results of the iPrEx open-label extension (iPrEx OLE) in men and transgender women who have sex with men: PrEP uptake, sexual practices, and HIV incidence. 20th International AIDS Conference, Melbourne, abstract TUAC0105LB, 2014].

It should be noted that the CDC guidelines recommend PrEP as fixed dose tenofovir/emtricitabine taken daily, but these new data may change how PrEP is used in certain individuals.

As noted in all the clinical vignettes and studies above, good adherence to PrEP is necessary to achieve the desired results. Per the recent CDC/USPHS PrEP guidelines, all patients should be screened for HIV and chronic Hepatitis B at baseline, as well as the presence of other sexually transmitted infections prior to initiating PrEP. They should be followed closely with repeat HIV testing at least every three months. Counselling regarding the prevention of sexually transmitted infections and pregnancy is also critical. Condoms and the effective treatment of those already infected with HIV along with the appropriate prescribing of PrEP benefits our patients, their partners, as well as to the community at large. Pre-exposure prophylaxis can offer HIV uninfected persons who have substantial risk of becoming infected significant protection from HIV acquisition. We already have embraced the concept of taking medication to prevent unwanted health consequences such as malaria prophylaxis, contraception to prevent pregnancy and routine immunizations against many viral and bacterial-related illnesses. The prevention of HIV infection with antiretroviral therapy should not carry any more stigma than these other preventive measures. As HIV Specialists, we can make a difference in preventing new infections if we embrace PrEP and teach our medical colleagues to do so as well. **HIV**

ABOUT THE AUTHORS:
Travis Sherer, PA-C, AAHIVS is the program manager of the Lenox Hill Retroviral Disease Center. He recently was appointed to NY Governor Cuomo's Task Force on Ending AIDS and is a former board member of GLMA.

Gary F. Spinner, PA,MPH,AAHIVS works at Southwest Community Health Center in Bridgeport, Connecticut. He provides care to about 300 patients with HIV and also treats mono and co-infected patients with HCV. He has been prescribing PrEP to patients at high risk of contracting HIV for the past two years.

Susan LeLacheur, PA-C, is Associate Professor of PA Studies at The George Washington University School of Medicine and Health Sciences in Washington, DC.

Providers'

ABSTRACT:

The antiretroviral treatment regimen for high-risk HIV-negative people to prevent acquisition of HIV is known as pre-exposure prophylaxis (PrEP). With its demonstrated efficacy in placebo-controlled clinical trials with men who have sex with men (MSM), high-risk heterosexuals, and serodiscordant couples, PrEP has received increasing attention for its potential to significantly curb the rate of new HIV infections.

In May 2014, the Centers for Disease Control and Prevention (CDC) released detailed guidelines to aid providers in prescribing PrEP for their high-risk patients. In light of these new guidelines, we used a web-based survey to examine the current perceptions, attitudes and habits of front-line HIV care providers (n=363) about the use PrEP across the U.S.

In general, providers held favorable attitudes about PrEP, and endorsed that they were very likely to prescribe the regimen to most MSM. Despite being identified as optimal candidates for PrEP by CDC guidelines, fewer providers reported that they were very likely to prescribe PrEP to high-risk heterosexuals or people who actively use drugs.

Providers noted several primary apprehensions about prescribing PrEP, including concerns about adherence and monitoring. Few regional differences emerged with regard to providers' attitudes about PrEP. Findings from this survey highlight issues that may hinder providers from implementing PrEP with their patients, and emphasize the need for ongoing education and guidance for providers about practical issues associated with prescribing PrEP.

ISTOCK

BY
LEAH M. ADAMS, PhD,
BENJAMIN BALDERSON, PhD,
BRUCE J. PACKETT, II,
KATHY BROWN, MD, FACP, AAHIVS,
SHERYL L. CATZ, PhDD

Perspectives on Prescribing Pre-exposure Prophylaxis (PrEP) for HIV Prevention

ALTHOUGH antiretroviral therapy taken by HIV-positive people can reduce transmission risk to people who are HIV-negative, there remains a need for large-scale effective primary prevention approaches targeting HIV-negative persons directly (Cohen et al., 2013).

Despite an abundance of information available about HIV and public health programs targeted towards its prevention, there are an estimated 50,000 new HIV infections in the U.S. each year (Centers for Disease Control and Prevention [CDC], 2012). Antiretroviral therapy has been shown to be a safe and effective tool for preventing initial HIV infection both by reducing the potential for transmission from a person who is HIV-positive with an undetectable viral load and by reducing the ability to be infected for those who are HIV-negative. In the context of proactively using antiretroviral treatment among high-risk HIV-negative adults, the regimen is known as pre-exposure prophylaxis (PrEP).

In July 2012, the U.S. Food and Drug Administration approved the use of once-daily Truvada (tenofovir + emtricitabine; Gilead) for PrEP. Subsequently, the CDC in 2014 recommended that PrEP be considered for patients who are first tested as HIV-negative and present at "substantial risk" for HIV infection, such as HIV-negative partners in serodiscordant couples, men who have sex with men (MSM) without using a condom, or injection drug users with high risk injection behaviors including sharing injection equipment.

In the midst of growing evidence for the *efficacy* of PrEP in clinical trials (Baeten et al., 2012, Grant et al., 2010, Grant et al., 2014, Thigpen et al., 2012) medical providers have been polled to assess their perspectives on the possible *effectiveness* of using PrEP in the "real world." The small literature on providers' opinions about PrEP suggested that although the majority were in favor of PrEP, few had prescribed it, and many physicians had concerns about determining patients' levels of risk, identifying the correct target populations, financing the cost of medication and infrastructure needed to monitor the patients, and were apprehensive about the required daily regimen for high-risk patients who may be unable to adequately adhere (Arnold et al., 2012; Karris, et al., 2013; Krakower et al., 2014; Tellalian et al., 2013).

The survey studies all were conducted prior to the delivery of the U.S. Public Health Service's first comprehensive clinical practice guideline for PrEP use, released on May 15, 2014 (CDC, 2014). This guideline was created to address some of the concerns about prescribing PrEP raised among providers.

Specifically, the guideline offers information about determining patients' appropriateness for PrEP, providing ongoing counseling for HIV risk and monitoring patients who are on PrEP. In addition, there is a 43-page supplement for providers that includes various fact sheets, checklists, and additional counseling information about risk reduction and medication adherence.

Given the release of these detailed guidelines and additional research findings about the use of PrEP (e.g., Murnane et al., 2014), we sought to examine the current perceptions, attitudes and habits of front-line

HIV care providers across the U.S. regarding the use of Pre-exposure Prophylaxis (PrEP). Most prior survey findings have been limited to specific locations (see Arnold et al., 2012; Krakower et al., 2014; Shaeer, Sherman, Shafiqu, & Hardigan, 2014), and given the potential for regional differences in prescribing PrEP (Bush, Rawlings, Ng, Mera, 2014, Karris et al, 2013), we conducted a cross-region survey to explore how provider perspectives may vary based on region-specific concerns.

Survey Method

Based on prior research and the current PrEP prescribing guidelines, the authors constructed a web-based survey to assess providers' views on PrEP. The survey consisted of 53 questions, including demographic information, practice type, patient panel information, HIV testing practices, recent PrEP prescribing behaviors, and attitudes and beliefs that influence PrEP prescribing behaviors. A unique link to the web-based survey tool (Survey Monkey [www.surveymonkey.com] was sent via email to 3,484 providers of HIV care across the U.S. in June 2014. Providers were asked to complete the 10-minute survey online on a volunteer/"opt-in" basis. No incentive for participation or completion of the survey was offered.

Participants

The sample pool was comprised of members of the American Academy of HIV Medicine (AAHIVM)—a professional association consisting of predominately front-line HIV care providers in the United States. Those providers include current, dues-paying constituent members of AAHIVM, as well as AAHIVM-credentialed (member or non-member) HIV Specialist providers. Practice types of those approached were varied and representative of the entire association, including Infectious Disease, Internal Medicine, Family Medicine and other providers actively caring for patients. Providers were asked to complete the survey if they were licensed to prescribe treatments (e.g., MD, DO, NP, PA) and to disregard the email if they were not eligible to prescribe (e.g., PhD, PharmD).

Demographics

Three-hundred sixty-three providers completed the online survey. Of those providers, 10 were excluded from analyses because they were not authorized to prescribe medication (e.g., pharmacists, psychologists). Given our interest in exploring regional differences (as defined by the CDC (2014a): Northeast, South, Midwest, West) in attitudes about PrEP among U.S. providers, we excluded an additional 29 respondents who were based internationally (n=18), in Puerto Rico (n=3), or who did not provide details regarding their location (n=8).

The final analytic sample included 324 providers distributed throughout the Northeast (n=85), South (n=119), Midwest (n=36), and West (n=84). Table 1 displays demographic information about the sample, separated by region of practice.

The sample was primarily male (53%), non-Hispanic (93%), and white (76%). Providers ranged in age and in years of medical practice (0-20+ years). Most respondents identified themselves as primary care providers (78 %), and held a mixed caseload of HIV-positive and HIV-negative patients. Their medical specialties included Family Medicine (29%), Infectious Disease (36%), Internal Medicine (25%), and a broad range of other (11%) specialties. There was variation in medical specialty by region ($x^2(9) = 26.28$, $p<.01$), with providers in Infectious Disease more represented in the South and Midwest, and fewer providers in Internal Medicine in these regions compared to the Northeast and West.

HIV and STI Testing Practices

Prior to assessing providers' views about PrEP, we asked about their HIV and sexually transmitted infection (STI) testing practices with their patients, as confirmation of a negative HIV test is recommended as a first step in prescribing PrEP (Table 2). In general, providers endorsed asking questions about their patients' sexual safety (e.g., sexual partners' HIV status, condom use) with regularity, as most reported doing so "Often" or "Always."

Regional differences emerged with regard to providers asking about their patients' sexual partners, with those in the Northeast most frequently reporting that they inquire about their patients' sexual partners ($x^2(9) = 18.75$, $p<.01$). However, no regional differences were found with regard to asking about partners' HIV status or condom use (p's >.05).

The vast majority of providers across all regions reported that they "Often" or "Always" offer HIV and STI testing to patients who engage in high-risk behaviors (p's >.05). However, there was more variability in providers' frequency of offering HIV and STI testing to patients who engage in low-risk behaviors. A regional difference emerged with regard to offering HIV testing to patients who engage in low-risk behaviors whereby over half (51%) of providers in the West reported that they "Always" offer HIV testing to these patients, compared to 26%, 33%, and 37% of providers in the Midwest, West, and South, respectively ($x^2(9) = 17.91$, $p<.01$).

Key Factors in Prescribing PrEP

Providers rated how important (Not At All Important, Somewhat Important, Very Important) nine factors would be in their decision to prescribe PrEP, regardless of whether or not they had already prescribed the regimen to any patients (Figure 1). When measured by the proportion of providers who selected the factor as "Very Important," concerns about adherence (95%), regular follow-up care for monitoring and counseling (93%), and the effectiveness of PrEP in preventing HIV (82%) emerged as the top three considerations in providers' decision to prescribe PrEP across all four regions. After these top three reasons, what is considered most important varied a by region.

The fourth most important issue among providers in the South, Midwest, and West regions was cost, while concerns about side effects was the fourth most important in the Northeast. However, the only statistically significant difference by region was concerns about risk compensation (e.g., concern that the patient may engage in more risky sexual behaviors) ($x^2(6) = 12.89$, $p<.05$). Concerns for risk compensation were generally moderate among providers in the Northeast (37%), Midwest (30%), and West (37%), though a larger proportion of providers in the South (56%) rated the possibility of their patients engaging in more risky sexual behaviors as "Very Important" Providers nationwide rated the potential for patients to sue for malpractice, with the lowest frequency (15%) of "Very Important."

TABLE 1

Providers' demographic details, separated by region of practice

	Total Sample (n= 324)	Northeast/ Mid-Atlantic (n = 85)	South (n = 119)	Midwest (n = 36)	West/ Pacific/ Mountain (n = 84)
	% (n)				
Gender					
Female	52.5 (169)	51.2 (43)	58.8 (70)	47.2 (17)	47.0 (39)
Male	47.2 (152)	47.6 (40)	41.2 (49)	52.8 (19)	53.0 (44)
Transgender	0.3 (1)	1.2 (1)	0.0 (0)	0.0 (0)	0.0 (0)
Age (years)					
Under 40	20.8 (67)	21.2 (18)	17.8 (21)	25.7 (9)	22.6 (19)
40-49	23.9 (77)	16.5 (14)	27.1 (32)	28.6 (10)	25.0 (21)
50-59	32.9 (106)	37.6 (32)	33.9 (40)	28.6 (10)	28.6 (24)
60+	22.4 (72)	24.7 (21)	21.2 (25)	17.1 (6)	23.8 (20)
Hispanic/Latino					
No	93.4 (298)	94.0 (79)	92.4 (109)	94.1 (32)	94.0 (78)
Yes	6.6 (21)	6.0 (5)	7.6 (9)	5.9 (2)	6.0 (5)
Race					
Asian	10.0 (32)	4.7 (4)	12.9 (15)	8.6 (3)	11.9 (10)
Black/African-American	9.4 (30)	9.4 (8)	15.5 (18)	2.9 (1)	3.6 (3)
Native Hawaiian/ Pacific Islander	0.3 (1)	0.0 (0)	0.0 (0)	0.0 (0)	1.2 (1)
White	75.9 (243)	82.4 (70)	64.7 (75)	85.7 (30)	81.0 (68)
Biracial/Multiracial	2.8 (9)	0.0 (0)	6.0 (7)	2.9 (1)	1.2 (1)
Other	1.6 (5)	3.5 (3)	0.9 (1)	0.0 (0)	1.2 (1)
Years in Practice					
0-5	14.4 (46)	9.4 (8)	17.8 (21)	20.0 (7)	12.2 (10)
6-10	14.7 (47)	15.3 (13)	13.6 (16)	8.6 (3)	18.3 (15)
11-15	14.7 (47)	12.9 (11)	12.7 (15)	28.6 (10)	13.4 (11)
16-20	11.9 (38)	5.9 (5)	13.6 (16)	14.3 (5)	14.6 (12)
21+	44.4 (142)	56.5 (48)	42.4 (50)	28.6 (10)	41.5 (34)

	Total Sample (n= 324)	Northeast/ Mid-Atlantic (n = 85)	South (n = 119)	Midwest (n = 36)	West/ Pacific/ Mountain (n = 84)
	% (n)				
Practice Type					
Academic medical center	17.3 (56)	22.4 (19)	12.6 (15)	22.2 (8)	16.7 (14)
Community health center/Federally qualified health center	23.8 (77)	30.6 (26)	21.0 (25)	19.4 (7)	22.6 (19)
HIV Clinic	26.9 (87)	21.2 (18)	34.5 (41)	16.7 (6)	26.2 (22)
HMO/Hospital System	4.0 (13)	4.7 (4)	0.8 (1)	8.3 (3)	6.0 (5)
Private Practice	21.3 (69)	16.5 (14)	21.0 (25)	25.0 (9)	25.0 (21)
VA/Other federally funded system	2.2 (7)	1.2 (1)	2.5 (3)	5.6 (2)	1.2 (1)
Other	4.6 (15)	3.5 (3)	7.6 (9)	2.8 (1)	2.4 (2)
Primary Practice Role					
Direct patient care	88.5 (286)	84.5 (71)	89.9 (107)	91.7 (33)	89.3 (75)
Medical education	4.3 (14)	4.8 (4)	5.0 (6)	5.6 (2)	2.4 (2)
Medical research	3.1 (10)	4.8 (4)	1.7 (2)	0.0 (0)	4.8 (4)
Other	4.0 (13)	6.0 (5)	3.4 (4)	2.8 (1)	3.6 (3)
Primary Care Provider					
No	22.2 (71)	20.2 (17)	25.4 (30)	38.9 (14)	12.2 (10)
Yes	77.8 (249)	79.8 (67)	74.6 (88)	61.1 (22)	87.8 (72)
Medical Specialty					
Family Medicine	29.3 (94)	20.5 (17)	31.4 (37)	22.2 (8)	38.1 (32)
Infectious Disease	35.5 (114)	33.7 (28)	40.7 (48)	58.3 (21)	20.2 (17)
Internal Medicine	24.6 (79)	31.3 (26)	17.8 (21)	16.7 (6)	31.0 (26)
Other	10.6 (34)	14.5 (12)	10.2 (12)	2.8 (1)	10.7 (9)
% of Caseload: Seronegative					
0% (no HIV-seronegative patients)	18.2 (58)	13.1 (11)	25.0 (29)	14.3 (5)	15.7 (13)
1-9%	17.6 (56)	14.3 (12)	20.7 (24)	14.3 (5)	18.1 (15)
10-24%	8.5 (27)	13.1 (11)	5.2 (6)	14.3 (5)	6.0 (5)
25-49%	17.0 (54)	21.4 (18)	12.9 (15)	11.4 (4)	20.5 (17)
50-74%	22.3 (71)	20.2 (17)	22.4 (26)	28.6 (10)	21.7 (18)
75-100%	16.4 (52)	17.9 (15)	13.8 (16)	17.1 (6)	18.1 (15)

Likelihood of Prescribing PrEP to Patient Groups

Providers were asked to report their likelihood (Not At All Likely, Somewhat Likely, Very Likely) of prescribing PrEP within the next year to a variety of patient groups. There were no statistically significant regional differences in providers' likelihood of prescribing PrEP across these groups (p's >.05). Across all regions, nearly 79% of providers reported being "Very Likely" to prescribe PrEP to MSM with a positive partner, making this group the most likely to be prescribed PrEP within this sample (Figure 2).

Across all regions, at least half of the providers endorsed being "Very Likely" to prescribe PrEP to MSM with a partner who has risk factors (66%), MSM who sometimes uses condoms (63%), MSM with a partner of unknown status (61%), and MSM with a history of STIs (61%).

In general, fewer than half of the providers endorsed being "Very Likely" to prescribe PrEP to an IV drug user (49%), MSM with a positive partner on highly active anti-retroviral therapy (HAART) (48%), heterosexuals with risk factors (47%), methamphetamine users (44%), and MSM, regardless of risk (44%); these proportions were not significantly different by region (p's >.05). Providers endorsed being "Very Likely" to prescribe PrEP to MSM who always use condoms at the lowest frequency (30%), and this was also true in all regions.

Discussion

This paper represents the first study of providers' opinions about prescribing PrEP that was administered after the May 2014 release of the U.S. Public Health Service's first comprehensive clinical practice guideline for PrEP use. This guideline was meant to clarify how to determine patients' HIV risk and indications for prescribing PrEP, reinforce the importance of ongoing counseling for safe sex and HIV risk reduction, and detail the necessary monitoring of PrEP for safe use (CDC, 2014b). In the present study, we sought to understand the factors that affect providers' likelihood of prescribing PrEP and learn about whom providers believe to be an appropriate target population for PrEP. We aimed to explore these opinions as they varied across U.S. regions.

Consistent with Karris and colleagues (2013), we found limited evidence of variation across region of practice with regard to HIV and STI testing practices and perceptions of PrEP. Our findings regarding providers' attitudes about prescribing PrEP did not mirror those that found regional differences in actual prescriptions of PrEP, with the largest proportion of PrEP recipients living in the South, and the smallest proportion in the Midwest (Bush et al., 2014).

Generally, providers report frequently asking their patients about sexual partners, their partners' HIV status, and offer testing to patients who engage in high-risk behaviors. Of note, providers expressed a wider range of perspectives on providing testing to patients who reported low-risk behaviors. It is unclear whether the providers in this survey were operating within an "opt-in" or an "opt-out" model of HIV testing.

In order to increase patients' awareness of their HIV status, especially among those who may not request testing or those who may not be traditionally identified as at high-risk for HIV, the CDC recommends that providers use an "opt-out" model in which all individuals between the ages of 13 and 64 are tested for HIV, unless they decline (Branson et al., 2006). Implementation of opt-out HIV testing has been found to be feasible and acceptable to patients and providers (Haukoos et al., 2010; White, Scribner, Martin, & Tsai, 2012).

With regard to prescribing PrEP, providers' concerns mirrored previous findings in other published works, and this was the case regardless of region of practice (Arnold et al., 2012; Karris, et al., 2013; Krakower et al., 2014). Providers were most concerned about their patients maintaining adherence and following up for monitoring. Both of these issues have been addressed in the CDC guidelines for PrEP, and emerging findings from PrEP studies suggest that the minimum required adherence for protection against HIV for MSM may be less than originally believed (Grant et al., 2014). Most providers appeared to be in favor of PrEP, noting that an important factor in the decision to prescribe was that it would reduce the risk of HIV infection.

When asked to rate their likelihood of prescribing PrEP to members of certain patient groups, providers generally endorsed being "Very Likely" to prescribe to MSM patients who have been identified as "high risk" by the U.S. Public Health Service's guideline (e.g., MSM with positive partner, MSM with risk factors, MSM with history of STIs, MSM with partner of unknown status). While 79% said they were "Very Likely" to prescribe PrEP to this group, 21% of respondents were not "Very Likely" to prescribe PrEP to high risk MSM.

This suggests that despite clearer guidance on PrEP in practice and positive research findings with this population there is still some skepticism about prescribing PrEP to MSM. This skepticism may have been reflected in concerns about risk compensation, cost of treatment, and other factors that we assessed.

Importantly, across the nation, fewer providers (<50%) were "Very Likely" to prescribe PrEP to heterosexual patients with risk factors or to patients who use drugs, even though the CDC guidelines identify these patients as appropriate for PrEP. Providers' reticence to prescribe to these groups may reflect beliefs about transmission risk behavior or concerns about the efficacy of PrEP for heterosexual patients, especially women, given early null findings for women and emerging information about adequate dosing of Truvada for effective levels in vaginal/cervical tissue (van Damme et al., 2012). Less willingness to prescribe PrEP to active drug users may represent concern for the feasibility of maintaining proper adherence to and commitment to medical monitoring of PrEP among patients who have active substance abuse problems. Before providers are willing to follow guidelines for the provision of PrEP, these concerns will likely need to be further assessed and addressed, along with the delivery of strategies to assist physicians with complexities that may impede proper adherence (e.g., substance abuse, and mental health treatment).

Study Limitations

The present study is not without limitations. Our sample was drawn from providers affiliated with the AAHIVM, and as a result, may not be representative of providers who are less familiar with HIV/AIDS.

Analyses were limited to providers (e.g., physicians, nurse practitioners, and physician assistants) who are able to prescribe PrEP directly, and this exclusion may have contributed to our low response rate (10.4%) as providers were asked to self-exclude from the study after receiving an invitation if they were not licensed to prescribe medication.

Limiting our study to prescribing providers excludes the viewpoints of other providers who have an important role in patients' adherence to PrEP.

TABLE 2

Questionnaire

	Never/Rarely/ Occasionally	Often	Always	Chi-Square
In the past year, how often have you done the following with patients over the age of 18 years:				
Asked about sexual partners:				**18.75***
Northeast	3.7 (3)	31.7 (26)	64.6 (53)	
South	14.9 (17)	38.6 (44)	46.5 (53)	
Midwest	14.3(5)	40.0 (14)	45.7 (16)	
West	3.8 (3)	51.2 (41)	45.0 (36)	
Asked about sexual partners' HIV status:				**7.76**
Northeast	11.1 (9)	46.9 (38)	42.0 (34)	
South	19.3 (22)	37.7 (43)	43.0 (49)	
Midwest	25.7 (9)	42.9 (15)	31.4 (11)	
West	11.3 (9)	48.8 (39)	40.0 (32)	
Asked about condom use:				**11.90**
Northeast	3.7 (3)	38.3 (31)	58.0 (47)	
South	10.5 (12)	43.0 (49)	46.5 (53)	
Midwest	17.6 (6)	41.2 (14)	41.2 (14)	
West	7.5 (6)	53.8 (43)	38.8 (31)	
Offered HIV testing to patients who engage in low-risk behaviors:				**17.91***
Northeast	18.3 (15)	30.5 (25)	51.2 (42)	
South	32.7 (37)	30.1 (34)	37.2 (42)	
Midwest	25.7 (9)	48.6 (17)	25.7 (9)	
West	17.9 (14)	48.7 (38)	33.3 (26)	
Offered HIV testing to patients who engage in high-risk behaviors:				**6.30**
Northeast	7.4 (6)	19.8 (16)	72.8 (59)	
South	12.6 (14)	22.5 (25)	64.9 (72)	
Midwest	14.3 (5)	17.1 (6)	68.6 (24)	
West	3.8 (3)	21.8 (17)	74.4 (58)	
Offered STI testing to patients to who engage in low-risk behaviors:				**9.48**
Northeast	21.0 (17)	32.1 (26)	46.9 (38)	
South	28.9 (33)	34.2 (39)	36.8 (42)	
Midwest	37.1 (13)	37.1 (13)	25.7 (9)	
West	20.0 (16)	45.0 (36)	35.0 (28)	
Offered STI testing to patients to who engage in high-risk behaviors:				**6.45**
Northeast	3.7 (3)	22.0 (18)	74.4 (61)	
South	5.3 (6)	24.6 (28)	70.2 (80)	
Midwest	8.6 (3)	25.7 (9)	65.7 (23)	
West	0.0 (0)	22.8 (18)	77.2 (61)	

For example, a recent Florida survey found that 71% of sampled pharmacists reported having too little information to counsel patients, and the majority endorsed unfavorable opinions about PrEP (Shaeer et al., 2014).

In January 2015, the American Psychological Association released a statement highlighting the important role that health psychologists will play in improving adherence to PrEP and helping to overcome barriers to PrEP use such as stigma (Lu, 2015). Understanding and addressing the unique perspectives of providers across a range of health professions affiliated with HIV prevention is needed in order to best implement PrEP.

Our study was unable to ascertain which providers, beyond endorsing a willingness to prescribe PrEP, had actually already prescribed PrEP to their patients. As such, we were unable to answer questions about differentiating factors between prescribers and non-prescribers, an important issue in light of clearer guidelines that are now available.

Findings from this survey demonstrate that although more extensive guidelines about PrEP are available to providers, there are remaining issues that may prevent providers from wholeheartedly endorsing and implementing PrEP with their patients. U.S. providers will require more information about the use of PrEP with non-MSM populations, and require additional guidance about practical issues associated with its delivery (e.g., cost, monitoring) to reach the full potential of PrEP as a tool in preventing HIV infection. **HIV**

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ABOUT THE AUTHORS:
Leah M. Adams, PhD, is a post-doctoral research fellow in Women's Health and Aging at Group Health Research Institute in Seattle, WA. Her work focuses on illness prevention and chronic disease management, with an emphasis on HIV.

Ben Balderson PhD, is a research associate and psychologist at Group Health Research Institute in Seattle, WA. Dr. Balderson's work is focused on enhancing self-management and medication adherence in HIV.

Bruce J. Packett, II, is the Director of Professional Development at the American Academy of HIV Medicine.

Kathy Brown, MD, FACP, AAHIVS is with Group Health in Seattle, Washington.

Sheryl L. Catz, Ph.D. is a professor at the Betty Irene Moore School of Nursing at UC Davis, where she teaches courses in research methods, mentors students and conducts research in the areas of HIV, health behavior promotion, chronic disease management and health information technology.

FIGURE 1

How Important Are the Following Factors in Prescribing PrEP?

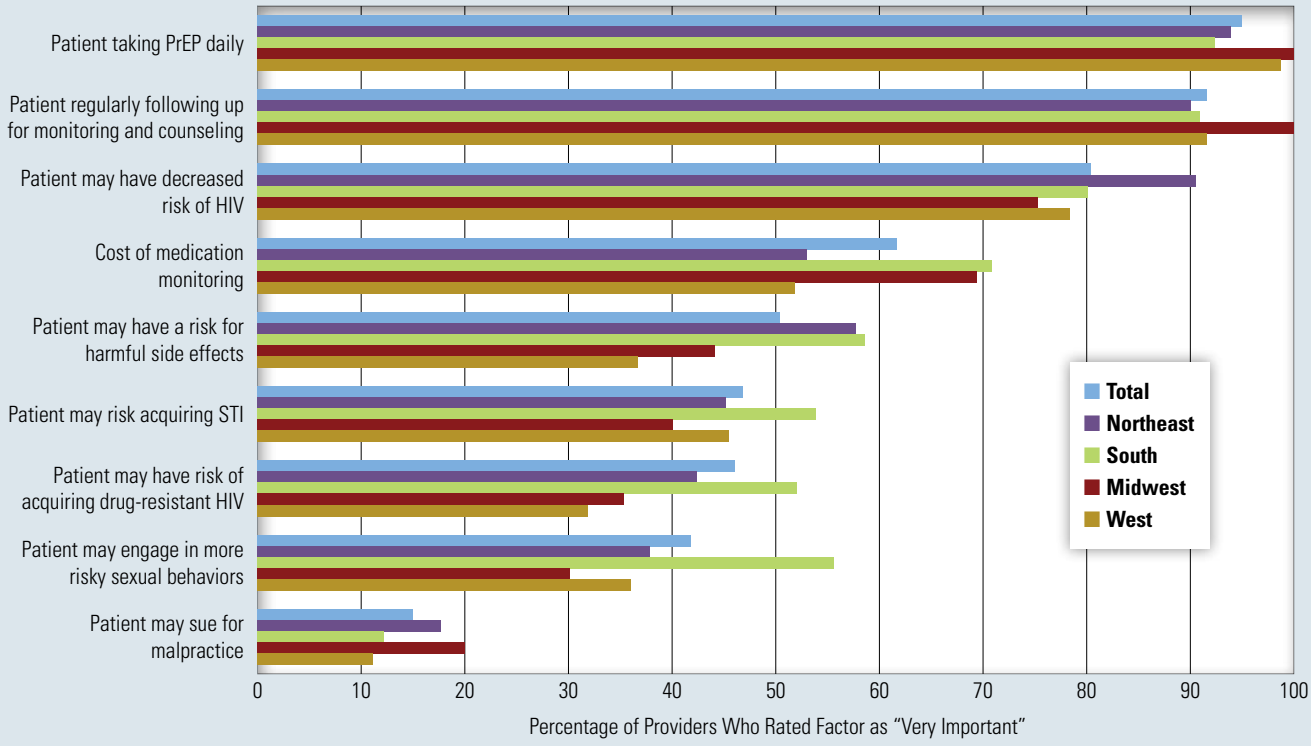
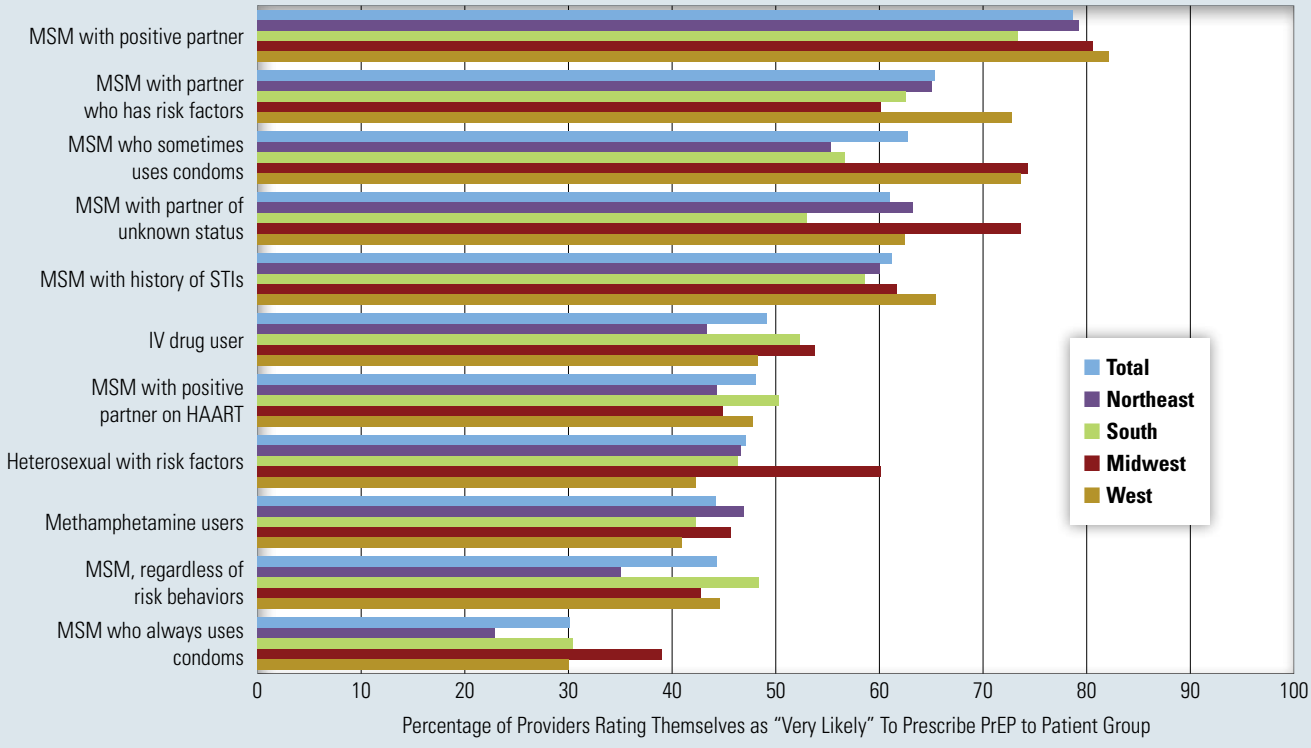


FIGURE 2

Rate the Likelihood That You Would Consider PrEP in the Next Year for Each of the Following Patient Groups



HIV Prevention with Adults and Adolescents with HIV

Highlights of Updated CDC Recommendations for HIV Care Providers

BY AMRITA TAILOR, MPH AND KATHLEEN IRWIN, MD, MPH, FACPM, FIDSA

Highlights for Clinical Providers

The recommendations for clinical providers span several domains. Each includes strategies that are new or warrant more attention. Some of the most important recommendations are summarized here.

General principles
Create a spirit of partnership and shared decision making with patients to promote their personal health and prevention goals.
Linkage to and retention in HIV medical care
Assess barriers to starting HIV care, help patients enroll in health insurance, expedite scheduling of HIV visits, and provide appointment reminders and transportation assistance.
Implement systems to alert providers about patients with suboptimal follow-up.
Initiation of and adherence to ART
Inform all patients with HIV about how early initiation of ART can improve their health, prolong their lives, and reduce HIV transmission to others.
Offer ART to all patients, regardless of CD4 count, who demonstrate readiness to start a long-term regimen that requires high adherence.
Choose regimens that are effective, reduce pill burden and side effects, simplify dosing, and are most affordable.
Provide advice on adherence tools and strategies, such as individually tailored counseling and pill boxes.
Assess self-reported adherence at each visit and use a nonjudgmental manner.
Assess and manage side effects of ART at each visit.
Monitor viral load to identify patients with insufficiently suppressed virus who may benefit from adherence support.
STD preventive services
Screen sexually active patients at least annually for STDs that facilitate HIV transmission, including syphilis, gonorrhea, and chlamydia in men and women, and trichomoniasis in women.
Screen for STDs using CDC-recommended provider- or self-collected specimens from genital and extra genital sites (i.e., rectal and oropharyngeal sites in men who have sex with men) and the most sensitive tests: nucleic acid amplification tests for gonorrhea, chlamydia, and trichomoniasis, or culture for trichomoniasis [13].
Treat patients who have positive screening tests or a clinical diagnosis of these STDs with CDC-recommended regimens [14, 15].
Services for other medical and social factors that influence HIV transmission
Provide or refer patients with HIV to other medical and social services (e.g., substance abuse treatment) that reduce HIV transmission risks and that promote regular HIV care (e.g., transportation and nutritional assistance).

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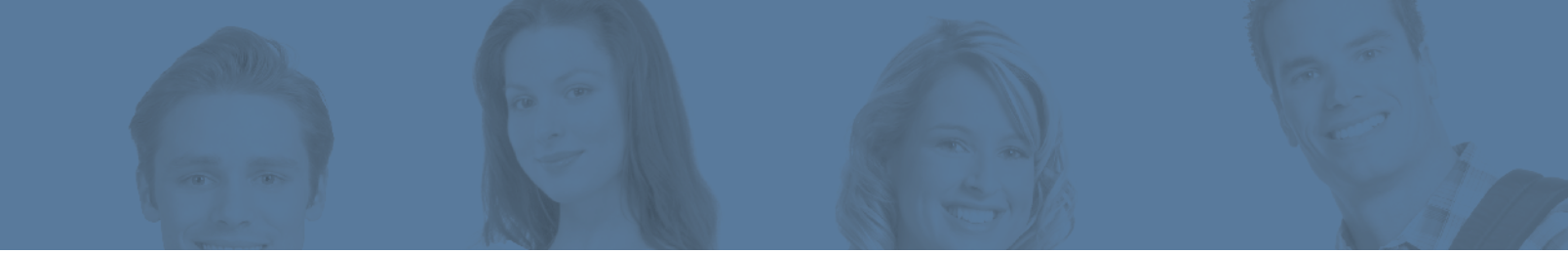

IN DECEMBER 2014, the Centers for Disease Control and Prevention (CDC) published *Recommendations for HIV Prevention with Adults and Adolescents with HIV in the United States*[1] and three companion summaries[2–4] that list subset of recommendations for the primary audiences of the guideline: clinical providers, nonclinical providers, and staff of health departments.

CDC developed these evidence-based recommendations in collaboration with the Health Resources and Services Administration (HRSA), the National Institutes of Health, the American Academy of HIV Medicine, the Association of Nurses in AIDS Care, the International Association of Providers of AIDS Care, the National Minority AIDS Council, and the Urban Coalition for HIV/AIDS Prevention Services.

The guidelines update and expand earlier recommendations from the 2003 publication, *Incorporating HIV Prevention into the Medical Care of Persons Living with HIV*[5] that covered only selected strategies: behavioral risk screening and risk-reduction counseling, screening for sexually transmitted diseases (STD), partner notification, and referral to other medical and social services that might reduce HIV transmission (e.g., substance abuse treatment).

Several factors prompted this update, including advances in behavioral, biomedical, and structural interventions that reduce the risk for HIV transmission from persons with HIV.[6–7]

Reproductive health and pregnancy services
Assess the reproductive plans of female and male patients.
For patients who wish to avoid pregnancy, provide or prescribe effective contraception or refer to another provider for contraception services. Advise patients using medical or surgical contraception to also use condoms to prevent HIV transmission.
Provide postpartum contraceptive services to women with HIV who wish to prevent or delay future pregnancies.
Inform patients of the risk of perinatal transmission should they become pregnant.
Refer patients who wish to become pregnant to clinicians skilled in preconception counseling of HIV-infected women.
Offer prenatal, intrapartum, and postpartum ART to pregnant women with HIV, regardless of CD4 count, to prevent perinatal transmission.
Avoid invasive prenatal and intrapartum procedures in women with HIV who are not virally suppressed.
Inform HIV-uninfected pregnant women about the benefits of consistent condom use and explain that preexposure prophylaxis (PrEP) to prevent HIV acquisition is not contraindicated in pregnancy.
Risk screening and risk-reduction services
Ask patients at least once a year (or more often as needed) about behaviors that can increase risk for transmitting HIV (e.g., sex without condoms or sharing drug-injection equipment).
Offer condoms and inform patients who share drug-injection equipment about sources of legal, sterile syringes in jurisdiction (e.g., pharmacies, syringe service programs).
Provide risk-reduction interventions, such as brief, evidence-based interventions suited to busy clinicians [16] or specialized counseling for HIV-discordant couples seeking joint services [17].
Services for sex and drug-injection partners
Encourage patients to notify their sex and drug-injection partners of possible HIV or STD exposure using methods that minimize the risk of stigma, discrimination, and prosecution.
Refer patients for voluntary, confidential assistance from health department partner services specialists who are trained to handle complex situations (e.g., possible partner abuse) and to identify partners found through the Internet and anonymous venues.
Inform patients with HIV about the availability of PrEP or nonoccupational post-exposure prophylaxis for HIV-uninfected partners when clinically indicated to reduce their risk of HIV acquisition.
When patients with HIV refer their sex and drug-injection partners, offer partners screening for HIV, STDs, and viral hepatitis and prompt linkage to treatment.
Clinical quality improvement
Apply quality improvement methods, including rapid cycle strategies for clinical settings, to improve the effectiveness and efficiency of HIV prevention and care services.

Therefore, the updated guidelines cover many new topics, such as linkage to care, using ART to prevent HIV transmission ("treatment as prevention"), and ART adherence support. The guideline consolidates new and longstanding federal recommendations and advances the goals of the National HIV/AIDS Strategy: prevent new HIV infections, increase the number of persons with HIV who are aware of their infection, prevent HIV-related illness and death, and reduce HIV-related health disparities.[8]

Implementation of the Affordable Care Act (ACA) and the expansion of Medicaid programs in many states have improved access to HIV prevention and care for persons of all income levels.[9, 10] These new opportunities for HIV prevention in the United States are welcome at a time when the number and longevity of persons with HIV is increasing and demand is growing for HIV prevention and care services in primary care settings staffed by clinicians who do not specialize in HIV care.[11]

Expanding Capacity for HIV Prevention Services Through Partnerships

In contrast to the 2003 recommendations for HIV medical care providers, the updated guideline is directed to a broader audience: clinical providers who provide HIV medical care in primary care or specialty practices; nonclinical providers who provide health education, risk-reduction interventions, case management, and social services outside health facilities; and staff of health departments who offer voluntary partner notification or monitor HIV surveillance data for care patterns and health outcomes of persons with HIV.

By engaging a more diverse HIV workforce, the recommendations encourage cross-sector partnerships to serve persons with HIV in clinical and community settings and to expand the number of trained HIV service providers. The updated guidelines also encourages use of multidisciplinary health care teams that engage physicians, nurses, health educators, case managers, pharmacists, and other staff. [12] By using task-sharing and task-shifting, these teams can be particularly effective for patients with complex medical and social issues (e.g., substance abuse, unstable housing, and poverty) that hinder retention in HIV care or ART adherence.

Coverage for HIV Prevention Services

Implementing this comprehensive set of recommendations will depend on longstanding and new sources of coverage and reimbursement.

Most HIV-related screening, diagnosis, treatment, health education, and counseling services are covered by private insurance plans, the Ryan White HIV/AIDS Program, Medicaid, Medicare, the Department of Veterans Affairs (VA), and other government health care and assistance programs.

Expanded access to health care through the ACA and reauthorization of federal HIV care programs, such as HRSA's Ryan White HIV/AIDS program, ensures continued access to comprehensive HIV care for many persons with HIV. Also, CDC and state and local governments fund community-based organizations and health departments to distribute condoms and to provide free or low-cost services for patient navigation, STD screening and treatment, partner notification, risk-reduction interventions, and health education.

Nevertheless, gaps in coverage may delay uptake of some recommendations. For example, some Medicaid and private insurance plans may not cover support services now covered by the Ryan White HIV/AIDS Program, such as

- assistance with linkage to and retention in HIV care
- case management
- some ART adherence support strategies
- transportation, housing, and employment assistance
- some substance use treatment and mental health services
- partner notification

Some antiretroviral medications have prohibitive copays or may not be included in drug formularies of health plans or medical assistance programs. Recent studies indicate that up to 55% of ACA health plans require enrollees to pay an average of 35% of their total ART cost[(18)]. Providers who are aware of the costs of HIV drugs in formularies of local health plans and medical assistance programs are better equipped to help their patients find effective regimens that are most affordable.

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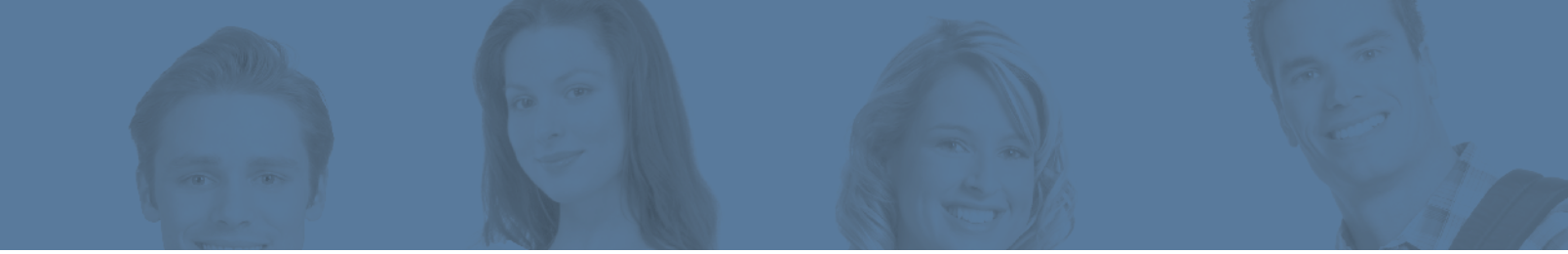

Resources to Help Implement the Recommendations

Several resources can help HIV care providers implement these recommendations.

- Decision support tools, flow diagrams, checklists, provider and patient fact sheets, and packages for implementing evidence-based interventions, such as:
  - CDC Resource Library: **http://www.cdc.gov/hiv/prevention/programs/pwp/resources.html**
  - Resource Center for Prevention with Persons Living with HIV: **www.hivpwp.org**
  - CDC's Effective Interventions: **www.effectiveinterventions.org**
- Training and technical assistance, such as:
  - AIDS Education and Training Centers (AETCs): **http://www.aidsetc.org/resources**
  - National Network of STD/HIV Prevention Training Centers: **http://nnptc.org/**
  - Technical Assistance Resources, Guidance, Education, & Training (The TARGET) Center: **https://careacttarget.org/**
- Summaries of experience in implementing these recommendations in clinical demonstration projects, such as:
  - Enhanced Comprehensive HIV Prevention Planning: **http://www.cdc.gov/hiv/prevention/demonstration/echpp**
  - Care and Prevention in the United States: **http://www.cdc.gov/hiv/prevention/demonstration/capus**
  - Partnerships for Care: **http://www.cdc.gov/hiv/prevention/demonstration/p4c**

Initial Steps HIV Care Providers Can Take to Implement the Updated Recommendations

- Review the recommendations and assess current HIV prevention interventions in your practice
- Identify areas where you could close gaps between current practices and recommended practices suited to your patients
- Identify resources to bridge these gaps, such as:
  - Resources listed above
  - New staffing models, such as multidisciplinary teams, task-shifting, task-sharing, or collaborating with health departments and community-based AIDS service organizations that offer free or low-cost services
  - Information on coding and billing for prevention services
- Apply rapid-cycle quality improvement methods to better align your practices with the recommendations

Conclusion

These updated recommendations are numerous and ambitious. Clinicians must focus on interventions that are most feasible given their professional authority, skills, and resources and the priorities of their patients and communities. Equipped with this blueprint for action, clinical providers can collaborate with other providers in their practices, as well as with nonclinical providers and public health organizations providing HIV prevention and care services. Together, this skilled HIV workforce can advance our nation's goals of improving the health of individuals with HIV and preventing further HIV transmission. [8]

HIV

ABOUT THE AUTHORS:

Amrita Tailor, MPH, is a health scientist and guideline development expert in the Division of HIV/AIDS Prevention at the U.S. Centers for Disease Control and Prevention, Atlanta, Georgia.

Kathleen Irwin, MD, MPH, FACPM, FIDSA directs HIV guideline development in the Division of HIV/AIDS Prevention at the U.S. Centers for Disease Control and Prevention, Atlanta, Georgia.

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REINVENTING THE CON

DOM

A Global Crisis of Marketing Myths

BY DANNY RESNIC

FOR SUCCESS

MY JOURNEY is an intriguing 21st century David & Goliath story, relevant to the daily lives of people around the globe. I will explain how and why I challenged the condom industry. It's my story of change worth fighting for.

Jack Selig was the love of my life in the early 1980's. He was among the first diagnosed with AIDS and he died of pneumonia in November 1982. I was condom-vigilant after I lost Jack until one day in 1995, a condom I used broke and I tested positive for HIV. My future looked very bleak, but fortunately this coincided with the new drug cocktails and I am here today as a victor, not a victim.

Condoms hold a unique position among consumer products that sustains a long history of complaints and dissatisfaction. Condom design has remained unchallenged for over 100 years, as the idea for the old rolled condom developed around 1902—before the Wright Brothers' first powered airplane flight. Aviation has since evolved into rocket science, and we have been to the moon and landed on Mars. But the old rolled condom has stayed essentially the same, except for distractions like colors and flavors.

In the '60s and '70s, condoms provided protection from STDs, although they were primarily sold for contraception. The condom industry was rocked to its foundation with the invention of the first birth control pills in the early 1960's which became the preferred form of contraception. Condom sales took a financial hit overnight. Smaller brands shut down or became swept up in corporate acquisitions.

So how did the rolled condom re-emerge like a phoenix rising from the ashes to become a leading form of protection again after the Pill? It was the 80's, which brought AIDS, one of the most devastating diseases ever to affect humanity.

By 1995, after my HIV diagnosis, I discovered there was something inherently wrong with the condom narrative. Male consumers had been sold a twisted condom story that worked only because the industry offered no alternative. The truth is consumers have been duped by the condom industry oligarchs and subsequently by well-meaning global healthcare agencies.

Outdated Flawed Design

The CDC evaluates rolled latex male condoms for contraceptive efficacy at a failure rate of 18%, and 21% for a female condom, called FC2. These devices are approved by the FDA and recommended by agencies like Planned Parenthood and the World Health Organization (WHO), among others.

Think about that for a minute. Imagine the probability or practicality of other devices that could be considered acceptable at an 18 to 21% failure rate. How about traffic lights? Imagine if traffic lights were reliable only 80% of the time. None of us would tolerate failing traffic lights. What about pacemakers or railroad crossing gates? Of course not.

Regulatory agencies like the FDA, WHO, and the CE-Mark have accepted the industry's 80% threshold for contraceptive effectiveness of condoms. As the spread of HIV and unplanned pregnancies are analyzed exponentially with these metrics, epidemiologists could forecast an alarmingly unmanageable future.

The larger problem with circa 1902 condoms has not been their clinical failure rates. The bigger issue is that they make no sense in terms of their functionality, and here's why. In 1995, I recognized the 'lollipop lie', the reason why rolled condom design is flawed, dysfunctional and categorically wrong.

The Lollipop Lie

The challenge: taste a lollipop through the wrapper and determine what flavor it is. It will not matter how micro-thin the cellophane wrapper is, you will never taste the flavor through the wrapper. This is the flawed concept behind old rolled condoms that manufacturers spend millions of dollars to perpetuate: the myth that consumers should be able to taste a lollipop through the wrapper; 'transferred sensation'. Consumers don't need condoms that are colorful or flavorful. They need condoms that feel good.

Roll-on, immovable, static latex condoms defeat the natural order of human sexual anatomy by overlooking what I call the 'fluid factor'. Sexual anatomy normally operates with direct fluid contact in a wet, slippery, warm, primordial environment that stimulates an electrifying, orgasmic response between partners. It's like explosive atomic energy. In 1902 the old rolled condom, unfortunately, circumvented the 'fluid factor'. It never occurred to anyone how significant that missing component could be for consumer acceptability. Society wasn't even discussing sex openly in the 1900s, and the condom industry got a free pass to perpetuate the lollipop myth.

The old rolled condom disrupts intimacy; it can pinch and snag the skin, desensitize the sexual experience and generally interfere with the overall pleasure associated with sex. Male consumers have been stuck with this single option for more than a century. It is unreasonable to expect consistent consumer uptake with the outdated old rolled condom design.

A snapshot of the condom industry shows the market dominated by three major brands; Trojan, Lifestyles, and DUREX. Collectively they hold a 95% market share of the $5 billion global condom market. These brands inherently defy innovation because of their co-dependent relationship with the old rolled condom design outsourced to manufacturing facilities. Potential innovation is considered by marketing committees and becomes counter intuitive to the creative process of product design.

These brands have become trapped by their self-limiting manufacturing infrastructure resistant to innovation. Also, these publicly traded companies are responsive only to stockholders, not to consumers, and collectively they have limited the market to one type of device that is over 100 years old. Recently a fourth company, the Female Health Co., has joined their ranks with 25 years of failed innovation.

So given universal dissatisfaction with rolled latex condoms, the high contraception failure mode, an oligopoly controlled industry that self-limits innovation, and my own HIV diagnosis from a broken condom, I decided it was time to create a condom revolution. My idea was simple: a movable, folding condom that created reciprocating motion with a lubricated, internal fluid surface.

This would replicate the 'fluid factor' that rolled condoms could never provide, creating sensation from inside, not from outside. The outcome of this new technology has been astonishing. ORIGAMI has developed a technology that will change the future landscape of the condom industry with consumer driven products that emphasize pleasure.

The new ORIGAMI condoms have switched from silicone to a non-toxic form of latex that has no odor or sour taste. The newly developed material is free of a class of a cancer causing chemical called nitrosamines, common to most latex condoms that have levels exceeding European Union (Eu) leaching standards for nitrosamine carcinogens.

Innovation, Sex & Pleasure

The first NIH study for my movable slip-on male condom was a success and I decided to challenge the existing female condom with a better idea. Most retail consumers are unfamiliar with FC2 because the company primarily sells to donor agencies that provide product to low economic regions such as Sub-Saharan Africa. The company that owns the FC2 brand produces only one product and banks its revenue stream on its singular donor market position.

I proposed a new foldable female condom idea to the NIH and the clinical research was funded immediately. I was cautioned by researchers to lower my expectations with preliminary prototypes because it would likely take several revisions to get it right.

After several meetings with our OB/GYN project consultant, my first design was tested in a clinical trial conducted by the Women's Global Health Imperative at RTI International in San Francisco. In July 2013, they reported a 67% consumer preference for ORIGAMI Female Condom (OFC) over the existing FC2, which only received a 16% consumer acceptability rating by women and men in the study. It's easier to use than FC2 and it's a design-centric approach provides pleasure for both partners.

It's ironic to realize that it took a gay man like myself to reinvent the female condom. I had nothing. No perspective. I used common sense, consultants, and anatomical research found on-line.

After several of my NIH clinical trials, I was made aware of a stunning revelation that most condom users and even HIV prevention agencies were never told. It was a secret swept under the rug for decades; condom makers are not required to provide safety data for anal sex use, a primary means of HIV transmission.

Anal sex is considered by the FDA to be 'off-label' use of condoms, so they don't require such clinical testing data from manufacturers. Condoms are tested and sold exclusively for vaginal use as contraception. Because anal sex is a more rigorous activity than vaginal sex, condom breakage can be higher. The condom industry conveniently avoids this commercial regulatory conundrum as long as their rolled condom is sold only for contraception. That places consumers at risk every day by failing to provide safety data specific to anal sex.

In May 2014, I received the Bill & Melinda Gates Foundation Grand Challenges Award. It was pivotal in the evolution of ORIGAMI condoms. The foundation recognized the urgent need for a 'next generation condom' and facilitated the development of the OIC (ORIGAMI Internal Condom). A clinical trial of this product will be completed by September 2015. It is the first condom suitable for either vaginal or anal sex as a gender-neutral MPT strategy.

The condom has typically been promoted as admonishment for 'protection'. My task is relevant to prevention, although my mission is to change the decades-old narrative from admonishment and obligation to one of pleasure and consumer uptake. ORIGAMI's goal is to restore sex to a more user-friendly and pleasurable experience once again. ORIGAMI plans to launch its product line at the end of 2015. Consumers are demanding the change they deserve with a voice in the condom revolution. **HIV**

ABOUT THE AUTHOR:
Danny Resnic is the CEO and founder of ORIGAMI Healthcare Products, Inc. based in Los Angeles, CA. He studied at the Art Center College of Design, Pasadena, CA.

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WHAT DO WE MEAN BY 'HIV Fatigue'?

BY W. DAVID HARDY, MD , AAHIVS

IN THE CONTEXT OF HIV HEALTHCARE, it can generally be defined as intentional or unintentional "behavioral drift" or movement away from time-tested principles of optimal adherence to antiretroviral medications used for treatment or prevention of HIV infection, from safer sex practices and from the sense of personal responsibility to stop the transmission of HIV. Why does this occur? That's simple. Long-term maintenance of human behavioral change requires ongoing and innovative approaches to re-prioritize and re-inforce those behavioral changes. What are its consequences? Reversion to previous (or new) behaviors of medication nonadherence, high risk sexual or drug use behavior and loss of a sense of personal responsibility to halt HIV transmission resulting in virologic failure, viral resistance to medication, increased probability of HIV transmission and growing numbers of new HIV infections.

So, let's look at some examples of HIV Fatigue in the HIV healthcare setting and some innovative approaches to addressing and preventing or reversing it.

Perhaps the best place for HIV healthcare providers to start is to examine the behavior over which we have the most control… our own. For those of us who have been caring for HIV+ persons for time measured in decades, it is uniquely important for us to consistently check our own thinking, attitudes and behavior when providing HIV care. We must remember that most of our current patients do not share our past experiences with the ravages of HIV disease. Therefore, to assume that they inherently harbor a similar sense of the potential mortality from the infection, as we knew it, is frequently a misplaced assumption. Further, to recount tales of the "bad old days" is often viewed as being irrelevant and out-of-touch with current HIV care. We must regularly examine and update, if necessary, our attitudes and behavior in regard to the ever-changing landscape of the HIV epidemic.

It's important for us to remember that although we have counselled and cared for hundreds of newly diagnosed HIV+ patients, the newly diagnosed patient sitting in front of us today has never heard our highly polished and well-rehearsed soliloquy on what to expect as a newly diagnosed patient. Even though it is our 1001st time to deliver this news and initiate care, we must remember that it is the first time for that newly diagnosed patient in front of us. This is truly one of those "art of medicine" opportunities to deliver the news with the same degree of patience and compassion as we did with our first diagnosed patient.

Conversely, downplaying the seriousness of the current state of HIV infection too much may undermine the important new messages of self-care, prevention and adherence, which we want to deliver to our patients. Again, this is an area where we must guard against expressing our own feelings of HIV Fatigue and deliver consistent messages of the importance of antiretroviral therapy, safer sex practices and personal responsibility to not transmit the virus.

Even though it is our 1001st time to deliver this news and initiate the first time for that newly diagnosed patient in front of us.

Next, let's focus on a far more challenging area of identifying and managing HIV Fatigue, stemming from behavior over which we often have limited or no control – the behavior of our HIV+ patients.

HIV Veterans

First, let's consider our long-time treated patients, sometimes called "HIV veterans" or "legacy patients". Often, these are the persons for whom we may have the least concern. They are often viewed as the "lucky survivors" and first beneficiaries of antiretroviral therapy. Some may have experienced and survived an opportunistic infection or cancer. Surely, these individuals will always be ardent adherers to the medications which saved their lives. Further, isn't it reasonable to assume that they will forever conscientiously practice safer sex and drug use so as not to transmit the virus that has caused harm in their lives to any of their partners? These are misassumptions for which we must consistently check. Just because a patient has reported perfect adherence for 10 or more years manifest by persistently undetectable HIV RNA levels, these persons are also "at risk" of falling prey to HIV Fatigue, perhaps even more than others. Many of my patients, after taking antiretrovirals diligently for many years, often ask, "How long do I have to take these pills?" Did they forget that they may have almost died due to this virus...maybe so. We must never forget that probably all of our patients dream of one day not having HIV and not having to take daily medications. This is hope that we never want to lightly dismiss or take away from our patients.

How can we identify and address HIV Fatigue with our HIV veterans? Several useful and, for some, innovative techniques include:

1. Discuss medication adherence at EVERY visit. Never make the assumption that past adherence ensures future adherence. These discussions can sometimes uncover lapses in insurance coverage or pharmacy benefits which patients may have been embarrassed to divulge voluntarily.
2. Discuss sexual and drug using behavior with ALL patients. Never assume that elderly (>50 years), divorced, widowed, religious patients don't have sex. Remember that living a full and "normal" life with HIV commonly includes sexual activity.
3. Discuss the positive aspects of living longer with HIV infection. While this can sometimes be a slippery slope, attempt to focus on significant life events (births, marriages, job promotions, travel) which patients would not have experienced if they had not lived.
4. Discuss opportunities for and potential benefits of disclosure of HIV diagnosis. Many long-surviving patients commonly carry the psychological burden of well-suppressed, but undisclosed infection which can weigh heavily on them. Remember, one is only as sick as their secrets.
5. Re-inforce a sense of personal responsibility, as long-term survivors, to be ambassadors of stopping the HIV epidemic by preventing new HIV infections. Re-iterate their critical role in being a part of "the End of AIDS", by maintaining their own good health, keeping their virus suppressed and recognizing and championing safer sex and drug use practices.

Recently Diagnosed

Let's now turn to identifying and addressing HIV Fatigue in the patient diagnosed in the past 3-5 years.

It is critical to remember that these persons are navigating very different communities than the ones that many of us knew early in our practice of HIV medicine. As HIV infection has become a "chronic, treatable medical condition", not unlike hypertension or diabetes, some of the previous sense of 'benevolent compassion" has waned for those infected. In addition, many of the once well-funded, community-based, AIDS service organizations which provided a wide range of basic necessities of life have gone out-of-business or have reduced capacity…at the same time when the proportion of newly HIV-diagnosed persons living in poverty is increasing. Further, prevailing attitudes among some HIV-affected communities, particularly the MSM community, have changed from ones of compassion and assistance to shame and avoidance. Traditional religious beliefs among some in the African-American community may not always be accepting of persons with HIV infection.

A young, recently HIV-diagnosed MSM may find himself to be the only member of his social circle infected and consequently fearful of sharing his diagnosis with close friends for fear of ridicule and shame. Similarly, the older, recently infected MSM, who "should have known better", may be hesitant to seek assistance due to similar fears. These situations can lead to isolation, not seeking or dropping out of care and of course poor medication and safer sex behavior adherence. In the case of African-American MSM, the sense of isolation may be heightened due to a sense of not being a part of either community with nowhere to turn. Thankfully, a growing number of community programs directly addressing this rapidly growing patient group are becoming available.

As far as adherence to or ability to negotiate safer sex practices, the insistence on regular condom use may be interpreted by a partner as de facto silent disclosure of HIV infection of the condom user. The potential for resulting destructive rumors can lead to a greater degree of isolation. While managing potentially life-threatening AIDS-defining opportunistic infections or malignancies has markedly decreased, managing potentially life-threatening HIV-related stigma has not, and has in some communities has increased.

care, we must remember that it is

Identifying and addressing HIV Fatigue in this patient population presents unique challenges requiring truly innovative approaches. Some of these can be.

1. Devote additional time and clinic visits to build a solid educational and interpersonal foundation prior to initiating antiretroviral therapy. The time and efforts to provide HIV education and build relationships with recently diagnosed patients prior to introducing antiretrovirals can produced much better long-term results. Allowing time for these patients to traverse the psychological challenges of a recent diagnosis has many benefits. Remember, initiating antiretrovirals is rarely an urgent medical intervention—only for PEP, PMTCT in high-risk situations and with seroconversion or acutely diagnosed infection. Don't allow our enthusiasm as HIV care providers to immediate initiate antiretrovirals in all diagnosed patients overwhelm those patients who are not ready to start.
2. Link recently diagnosed patients to experienced, trusted, high-quality community support organizations. Work with the counselors at these ASOs (AIDS Service Organizations) to find the most appropriate support group for patients.
3. Link recently diagnosed patients to an experienced, trusted, long-term HIV+ person in your clinic. Establishing a relationship with a fellow patient, as a navigator or mentor, who has successfully lived with HIV for many years may provide the non-medical assistance which only another HIV+ person can supply.
4. Discuss patient's knowledge of and comfort with safer sex and drug use practices. Don't assume that this knowledge is common to all at-risk persons. If patients have a good understanding of safer sex/drug use practices, but have trouble negotiating them with partners, arrange time to role play with patients to demonstrate how negotiating these practices can still result in satisfying, healthy sexual experiences.
5. Begin to instill a sense of "healthy respect" for the patients' HIV—not to be feared, not to be forgotten, but to be actively suppressed with simple, modern antiretroviral medications and a positive attitude of self-worth and self-care.
6. Once antiretroviral therapy is initiated, discuss adherence at EVERY visit—in more detail at first, less later on, but never, not at all. Identify real or potential "adherence holes" which resulted in or may result in missed medication doses. Probe for these with open-ended, nonjudgmental questions. When identified, have patients expand on the factors which led to the missed dose(s). Troubleshoot with patients to close the "adherence holes". Use these solutions as opportunities for "check-up" discussions at subsequent clinic visits.
7. Begin to instill a sense of personal responsibility for actively participating as a part of "the END of HIV/AIDS" by keeping their virus suppressed with high medication adherence and halting HIV transmission by using safer sex and drug use practices.

In closing, HIV Fatigue is a very real and potentially harmful intentional or unintentional "behavioral drift" or movement away from time-tested principles of optimal adherence to antiretroviral medications used for treatment or prevention of HIV infection, from safer sex practices and from the sense of personal responsibility to stop the transmission of HIV. It is manifest by medication nonadherence, high risk sexual or drug use behavior and loss of a sense of personal responsibility to halt HIV transmission. It can result in virologic failure, viral resistance to medication, increased probability of HIV transmission and growing numbers of new HIV infections. Long-term maintenance of human behavioral change requires ongoing and innovative approaches to re-prioritize and re-inforce those behavioral changes.

The recommendations above are derived from my 30+ years of experience caring for and treating HIV + patients. They have served me well in identifying and addressing HIV Fatigue in my patients.

I hope that you find some of these techniques helpful as well. **HIV**

ABOUT THE AUTHOR:
Dr. W. David Hardy serves as Clinical Professor of Medicine at the David Geffen School of Medicine at UCLA. From 2002 to 2013 he oversaw, as Director, the academic, research and administrative activities of the Division of Infectious Diseases at Cedars-Sinai Medical Center. Dr. Hardy currently serves as medical officer for Calimmune, a small, California-based and funded, translational science, biotechnical company, providing medical oversight of the first phase I human study investigating gene-modified CD4+ T cells and hematopoietic stem cells as a potential cure for HIV infection.

SHUTTERSTOCK / ALEXANDER RATHS

BY JOSEPH S. CERVIA, M.D., M.B.A., FACP, FAAP, FIDSA, AAHIVS

Fight to Win

How HIV Care and Research May Inform Our Approach to Mental Illness

SINCE THE DAWN OF MY 30-YEAR-OLD MEDICAL CAREER, I have been involved in HIV care and research. Like many of my colleagues, I am heartened by the scientific and clinical advances to which we have been privileged to contribute. Collectively, these developments have resulted in vastly improved outcomes for our patients.

The heartrending funerals that we once attended have given way to luminous birthdays, graduations and weddings. Incredibly, we have come so far, so rapidly, racing an epidemic barely recognized three decades ago.

Reflecting upon the unspeakable suffering experienced by our HIV-infected patients, their loved ones and caregivers in the early years of that epidemic, it is difficult to miss a striking parallel to the anguish borne by those battling serious mental illness today.

Although this latter epidemic has likely been present since the genesis of humanity, its origins remain incompletely understood and effective treatment elusive. Those afflicted largely suffer in silence; many remaining undiagnosed and undertreated, frequently shrouded in denial woven and worn in often futile defense against the indignities imposed by societal ignorance. In the shadow of such profound suffering, can our experiences with HIV enlighten an approach to more effective treatment for serious mental illness in our lifetimes?

In response, I would offer the following five lessons learned from our response to HIV that may shed light in navigating the journey to enhanced outcomes for patients, caregivers and clinicians battling serious mental illness.

1. Silence = Death, So Fight the Stigma

As observed in society's early response to HIV, inadequate understanding of pathophysiology contributes to stigma, which in turn, precludes many from seeking diagnosis and appropriate care. Community support and activism by groups such as GMHC and ACT UP have demonstrated the critical role of advocacy.

Affected individuals and those who care for them must lend their voices to rally continuing support for better understanding and scientifically sound, effective treatment for serious mental illness. This may take the form of public advocacy by means of financial and/or volunteer support for organizations such as the National Alliance on Mental Illness (NAMI)[1], political activism (e.g. lobbying efforts, legislative "white coat" days), research involvement (e.g. volunteering as collaborators, subjects or community advisory board members for clinical trials), and active participation in community-wide educational efforts in the press, schools and houses of worship.

2. *T*ogether *E*veryone *A*chieves *M*ore, So Team Up

An optimal model of multidisciplinary primary care with integrated HIV subspecialty services has been offered for decades by teams optimally consisting of physicians, nurse practitioners, nurses, pharmacists, social workers, case managers, mental health professionals, nutritionists, clergy, and other dedicated caregivers.

ISTOCK

These team members have often developed long-standing and intimate bonds with patients and family members. The very strength of these bonds, forged by shared struggle against such demons as poverty and its associated calamities, social stigmatization, substance use, and all too often, the concurrent illness and death of multiple family members, has made it possible to compassionately and systematically address the needs of individuals and families battling HIV.[2]

In contrast, many individuals grappling with serious mental illness and their loved ones often face schisms wrought by the nature of the affliction, which are only exacerbated by fragmented care delivery. Treatment adherence and quality both would benefit from tighter cooperation with and among care providers.

The value of team effort extends to clinical research infrastructure. The pace of developments in the fight against HIV/AIDS could never have been attained without strong industry, academic, community and government collaboration. Multi-centered clinical trials networks, such as the ACTG[3] and IMPAACT,[4] have learned and demonstrated the synergies accruing to organizing themselves into research agenda committees and working groups, comprised of physicians, basic scientists, pharmacologists, biostatisticians, nurses, mental health professionals, and community advisory board members infected with and/or affected by HIV.

I cannot help but believe that mental health research could benefit from a parallel *S*erious *M*ental illness *A*lliance for *R*esearch and *T*reatment. Brain research needs to get SMART!

3. You Can't Treat What You Can't See

Shortly after the viral etiology of AIDS was identified, reliable screening tests became available in 1985. Nevertheless, their widespread implementation lagged despairingly. There was little enthusiasm for identifying individuals afflicted by a stigmatizing illness for which effective treatment was truly lacking. With attention to fighting stigma, establishing operational care and research networks, and very effective treatments, HIV screening has continued to become much more widely accepted. In addition, non-invasive rapid HIV tests and the availability of more efficacious and better tolerated ART has further bolstered support for widespread screening.

Reliable screening and diagnosis of mental illness is critical in early identification of those at risk and those affected. Efforts to fight stigma and enhance teamwork in mental health care and research will facilitate this effort. However, improved screening cannot await optimal therapeutic options. As we learned in battling HIV, research improvements toward safer, more effective treatments requires the participation of those at risk and affected. If solutions are to be uncovered in the lifetimes of those affected by mental illness, they and those who care for them must be part of that effort.

4. Share the Wealth

Translating promising basic and clinical research findings into standards of care requires attention to regular communication among experts, and between those experts and front line providers, patients and caregivers. For many years, comprehensive HIV clinical practice guidelines such as those from the DHHS have been widely available and regularly updated with each version prominently marked with a 'last updated' date.[5] This frequent updating of practice guidelines becomes all the more relevant as the pace of research progress accelerates.

Novel basic science and clinical research advances in the diagnosis and treatment of serious mental illness must be regularly vetted by experts, and best practices disseminated in the form of comprehensive and current clinical practice guidelines. The integral collaboration of government, industry, and the community as part of the larger research team will facilitate this ongoing process of communication.

5. Fight to Win

In what might arguably have been the darkest days of the HIV epidemic, I shared a vision with my pediatric HIV team of a time in the not too distant future that we would be able to hang a 'Gone Fishing' sign on the clinic door. It seemed laughable at the time, but we kept smiling, and worked to bring reality to that vision. All who would venture to undertake the goal of better outcomes for those battling serious mental illness must share a steadfast belief that it can and will be achieved. With ardent advocacy, relentless research, compassionate care and limitless love, we must fight to win. **HIV**

ABOUT THE AUTHOR: Joseph S. Cervia, M.D., M.B.A., FACP, FAAP, FIDSA, AAHIVS is Clinical Professor of Medicine and Pediatrics, Hofstra-North Shore LIJ School of Medicine, Manhasset, NY 11030. He can be reached at **jcervia@nshs.edu**.

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BY STEPHEN E KARPIAK PhD

HIV Prevention in Older Women

WHILE NEW HIV INFECTION RATES for men have remained the same from 2008 to 2012, rates of new HIV infections in women have declined. In 2012, women accounted for just over 20% (n=9,500), of all new HIV infections in the U.S. However, women accounted for 25% of all new AIDS diagnoses (Stage 3). About 85% were infected by heterosexual transmission, and 14% due to injection drug use. Of these, 64% were African American, 15% were Hispanic and 16% were White.[1]

Sustained prevention efforts are needed for women at increased risk for HIV so their incidence can continue to decline. While many efforts have used CDC approved prevention interventions - it is not clear what primary characteristics of women place them at greater risk for infection. The complexity of these variables is seen in two recently studied Socioculturally based interventions: "Coping with Work and Family Stress" and "Hip Hop 2 Prevent Substance Abuse and HIV." [2]

Additional research has examined whether women trading sex for money, drugs, goods, services, or a place to stay is associated with their risk of HIV acquisition.[3] Structural issues such as poverty, education, domestic violence and a history of sexual trauma during their teen years have been associated with HIV acquisition.[4,5] These factors underlie the high rates of mental health disorders and concomitant substance use behaviors seen in women at risk.[6] Another recent study found that food insecurity and depression were characteristics that place women at elevated risk for HIV infection.[7] It was thought that younger women with older sex partners were at increased risk (similar to younger African American males who seek older males as partners). However, a recent study from South Africa found that variable not to be operative for African women living in that country.[8]

Studies in the U.S. Southern tier find that African-American women do not seek health information and HIV prevention information that could help prepare them to protect themselves from HIV and other STIs.[9] Another study found that safe sex practices by women are dependent on the type and level of commitment they perceive in a relationship.[10] In addition, HIV risk factors may vary based on a woman's age. Postmenopausal women who are not concerned about pregnancy see condom use as having less urgency. They will often engage in risky behavior in order to achieve intimacy that was lost following the death of a spouse. Women of color may compromise their health and safety as they age, knowing there are fewer males as potential partners due to their high HIV infection rate and associated deaths, as well as deaths due to violence, or absence due to high rates of incarceration.[4,11]

As the CDC and other groups launch efforts to promote the use of pre-exposure prophylaxis (PrEP) for HIV prevention, there is little data to guide how best to identify and engage women who would most benefit from this new intervention. We have very limited data on the prevailing beliefs and attitudes of black women regarding PrEP. One recent study[12] found that black women were "open" to PrEP especially since they reported experiencing many "failures" with condoms.[12] The women in this study said they preferred 'taking a pill" as opposed to using an intravaginal gel due to the heightened privacy PrEP would provide. Women in the study did however express concerns regards adherence to PrEP and side effects

As HIV rates hopefully continue to decline in women, it is increasingly imperative that health care providers encourage testing as minority women may perceive themselves at reduced risk. Additional research regarding acceptance and efficacy of PrEP in women, especially in the US, is greatly needed. **HIV**

ABOUT THE AUTHOR:
Stephen E Karpiak PhD is Senior Director for Research and Evaluation at ACRIA Center on HIV & Aging and New York University College of Nursing.

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BY GARY F. SPINNER, P.A., MPH, AAHIVS

AAHIVM Institute for HepatitisC

Fighting for HCV Care and Treatment in Connecticut

IN NOVEMBER 2014, the Connecticut Department of Social Services Medicaid program released a two page policy announcing limitations on the use of sofosbuvir (Sovaldi™), prompted by the previous fiscal quarter's 30 million dollar cost overrun for this drug. Even though most of us treating Hepatitis C (HCV)-infected individuals had begun prescribing the newly available, but very costly, co-formulated medication ledipasvir/sofosbuvir (Harvoni™) for HCV Genotype 1 patients, it was clear that this policy transmittal on sofosbuvir could be the harbinger of more restrictions to come.

As part of the new policy, only physicians board certified in Infectious Diseases and Gastroenterology could prescribe sofosbuvir, and even more restrictive, only for those patients with a Metavir Stage F4, i.e. liver cirrhosis. Several other restrictions in the use of this agent were also put in place, but as clinicians, we felt we needed to immediately address the most concerning barriers to patient access and treatment: the limitations on who can prescribe and who can be treated.

As clinicians representing three different disciplines, Joseph Lim, a hepatologist and Director of the Yale Viral Hepatitis Program, Marwan Haddad, a Family Practice physician and HIV Specialist and Medical Director of HIV, HCV, and Buprenorphine Services at Community Health Center, Inc., and myself, an HIV Specialist at Southwest Community Health Center who treats co-infected and mono-infected patients with HCV, we came together to advocate for a State policy change.

We sent a letter to the Medical Director of the Connecticut Medicaid Program requesting a meeting to discuss this new policy but we were not expecting significant changes to come quickly from our advocacy. After a meeting with officials at the Medicaid program, we recommended that HIV Specialists be added to the list of approved providers who can prescribe sofosbuvir, along with an acknowledgement that there may be other providers who need to be considered as well. More significantly, while we emphasized that all patients with HCV should have access to treatment, until such time when the Medicaid program would be willing to do so, we proposed an interim measure expanding treatment to all patients with Stage F3 and F4, as well as to all patients with HIV or other co-morbid conditions with liver fibrosis staging below F3.

As a result of our advocacy, and the willingness of the Medicaid Medical Director to consider our proposals, and internal meetings at the Department of Social Services to discuss our recommendations, a policy change is being implemented that now allows HIV Specialists, as part of the mix of approved providers, to treat patients with Stage F3 and F4 and all HIV co-infected patients, along with other patients with fibrosis scores less than F3 who have co-morbid conditions.

Of significant help in the process was a letter from Jim Friedman, AAHIVM Executive Director, to the Commissioner of the Connecticut Department of Social Services advocating for treatment of all patients with HCV regardless of liver fibrosis, as well as for expanding the list of approved providers who can treat HCV beyond two particular specialties which serves only to greatly restrict patient access to treatment. I would encourage other AAHIVM members who are facing such barriers in their respective States to consider following our example from Connecticut.

We wish to thank the American Academy of HIV Medicine for its involvement and commend its role in advocating for the needs of patients with HCV in Connecticut. We also think that such future advocacy with other Medicaid Programs and Payers is an important and essential role for AAHIVM to play in the future. **HIV**

I would encourage other AAHIVM members who are facing such barriers in their respective States to consider following our example from Connecticut.

ABOUT THE AUTHOR:
Gary F. Spanner, PA., MPH, AAHIVS works at Southwest Community Health Center in Bridgeport, Connecticut. He provides care to about 300 patients with HIV and also treats mono and co-infected patients with HCV. He has been prescribing PrEP to patients at high risk of contracting HIV for the past two years.

SHUTTERSTOCK

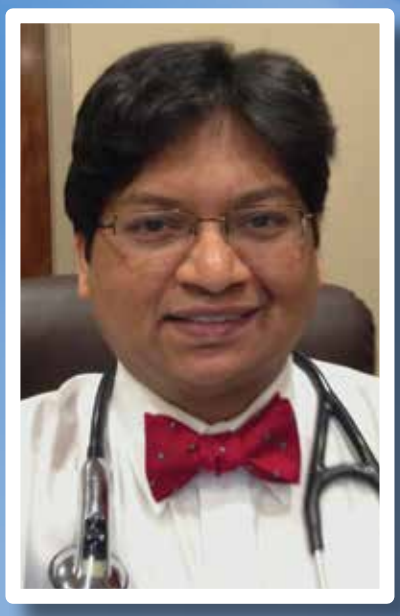
Join the 2015 AAHIVM/Institute for Technology in Health Care HIV Practice Award Winners at one of the breakfast sessions at ACTHIV on May 1 as they discuss their award-winning technologies.

SESSION HIGHLIGHT

Friday, May 1st , 7:50 am–8:50 am

"Paperless Records & HIV Clinical Care With a Laptop!"

SPEAKERS:



Prashanth Bhat, MD, MPH, AAHIVS
Medical AIDS Outreach of Alabama, Inc.

Mark Sannes, MD, MS, AAHIVS
Park Nicollet Clinic-ID