

HIV SPECIALIST

PATIENT CARE, PRACTICE MANAGEMENT & PROFESSIONAL
DEVELOPMENT INFORMATION for HIV CARE PROVIDERS



TREATING
HIV/AIDS
IN OUR

Communities of COLOR

6

CVD & HIV
Initiative

4

“A Dream
Revisited”

5

ACTHIV
Update

30

Implementing
EMR

31



TARGET AUDIENCE:

**Cardiologists
Endocrinologists
Infectious Disease
Practitioners
HIV Treaters
Internal Medicine
Practitioners
Family Practitioners
Other Primary Care
Physicians**

Initiative to Decrease
Cardiovascular Risk
and Increase Quality of Care for Patients Living with
HIV/AIDS

Please join us at a complimentary half-day conference to learn more about the association between cardiovascular disease and human immunodeficiency virus.

Continuing medical educational activity certified for physicians.



October 8, 2009 • Miami, FL

October 22, 2009 • Atlanta, GA

November 5, 2009 • Los Angeles, CA

November 10, 2009 • New York, NY

Learn more and register at learn.heart.org/hiv

HIV SPECIALIST

PATIENT CARE, PRACTICE MANAGEMENT & PROFESSIONAL DEVELOPMENT INFORMATION for HIV CARE PROVIDERS

VOLUME 1 / NUMBER 3 • FALL 2009

CHAIR/BOARD OF DIRECTORS

DONNA ELAINE SWEET MD, MACP, AAHIVS

**EXECUTIVE DIRECTOR
JAMES FRIEDMAN, MHA**

DIRECTOR OF COMMUNICATIONS

ROBERT BANASZAK

EDITOR

ROBERT GATTY

G-NET STRATEGIC COMMUNICATIONS
E: BOB@GATTYEDITS.COM

PUBLICATION DESIGN & ART DIRECTION

BONOTOM STUDIO, INC.

E: INFO@BONOTOM.COM

ROGER O. SELVAGE JR., ART DIRECTOR

ADVERTISING

JANE DEES RICHARDSON, PRESIDENT
AD MARKETING GROUP, INC.
P: 703-243-9046 EXT. 102

E: JRRICHARDSON@ADMARKETINGGROUP.COM

PUBLISHER

**THE AMERICAN ACADEMY
OF HIV MEDICINE**

1705 DeSales St., NW, SUITE 700
WASHINGTON, D.C. 20036

P: 202-659-0699 • F: 202-659-0976

E: INFO@AAHIVM.ORG • W: WWW.AAHIVM.ORG

EDITORIAL ADVISORY GROUP

CHAIR

JEFFREY T. KIRCHNER, DO, AAHIVS
MEDICAL DIRECTOR

COMPREHENSIVE CARE CENTER FOR HIV
LANCASTER GENERAL HOSPITAL, LANCASTER, PA

JEFF BERRY, EDITOR

POSITIVELY AWARE MAGAZINE, CHICAGO, IL

JOSEPH S. CERVIA, MD, MBA, FACP, FAAP, AAHIVS

CLINICAL PROFESSOR OF MEDICINE & PEDIATRICS
ALBERT EINSTEIN COLLEGE OF MEDICINE
ROSLYN, NY 11576

ANITA KAY KALOUSEK, DO, AAHIVS

RENAISSANCE MEDICAL GROUP, WEST HOLLYWOOD, CA

TONIA POTEAT, PA-C, AAHIVS

CHASE BREXTON HEALTH SERVICES, BALTIMORE, MD

RICHARD C. PROKESCH, MD, FACP,

INFECTIOUS DISEASES ASSOCIATES, RIVERDALE, GA

JEFFREY T. SCHOUTEN, MD, AAHIVS,
ATTORNEY AT LAW

DIRECTOR HIV/AIDS NETWORK
COORDINATION (HANC) PROJECT

FRED HUTCHINSON CANCER RESEARCH CENTER
SEATTLE, WA

SHARON VALENTI, NP, AAHIVS

ST. JOHN HOSPITAL AND MEDICAL CENTER
GROSSE POINT WOODS, MI

Fall 2009

www.aahivm.org

CONTENTS

FEATURES

Communities COLOR^{of}

6 Treating HIV/AIDS in Our Communities of Color

The cold statistics tell a stark story about HIV/AIDS in America – a story about Communities of Color, and about how they are disproportionately affected by this deadly disease.

BY BOB GATTY, EDITOR
HIV SPECIALIST



15 Living With, Caring For...

The story of how one HIV patient kicked both alcohol and drugs and now works in a clinic testing and counseling patients, hoping to help stop the spread of the disease.

23

The Bronx Knows

How a New York City program is working to increase testing in communities of color.

BY ROB BANASAK, DIRECTOR
OF COMMUNICATIONS AAHIVM

COVER STORY

Breaching the Barriers, Overcoming the Challenges

As the HIV/AIDS epidemic extends its reach, HIV specialists face the everyday challenge of finding the right approach that will gain trust and allow them to effectively treat their patients and help them survive.

BY BOB GATTY, EDITOR, HIV SPECIALIST



12

26 Health Disparities Wake-Up Call

The federal government's response to the disparities of disease among Communities of Color.

29 Research Study Focuses on Black Gay Men & HIV

A new six-city study is underway designed to help determine the most effective strategies for HIV prevention within the black gay community.

DEPARTMENTS

2 LETTER FROM THE CHAIR

In Focus: Challenge of Racial Disparities

BY JEFFREY T. KIRCHNER, DO, AAHIVS,
CHAIR, EDITORIAL ADVISORY GROUP

5 ON THE FRONTLINES

Understanding & Addressing Racial Disparities: A Dream Revisited

BY JOSEPH S. CERVIA, MD, MBA,
FACP, AAHIVS

31 BEST PRACTICES

Third in a Series: EMR & the HIV Practice

BY RICHARD PROKESCH, MD, FACP

4 AT THE ACADEMY

AAHIVM and AHA Host Free CME Events Addressing CVD and HIV

BY JEFFREY T. KIRCHNER, DO, AAHIVS

30 AT THE FOREFRONT

Risk Factors: Black MSM

BY TONIA POTEAT, MMSC, PA-C,
MPH, AAHIVS

32 QUIKPICS

Incorporating Prevention Messages Into Regular Office Visits

BY J. KEVIN CARMICHAEL, MD,
AAHIVS



In Focus: Challenge of Racial Disparities

WELCOME TO THE THIRD ISSUE OF *HIV SPECIALIST*! We have been receiving great feedback from readers following our first two issues, and hope that you find this issue just as interesting, informative, and relevant to your clinical work.

For many of us who have been HIV care providers in the United States since the epidemic's earliest days, the disease has always presented a host of collateral issues that have made treating it especially challenging—**clinically as well as culturally**. Often these clinical challenges—including medication adherence, drug resistance and treatment failure—have been exacerbated by the cultural challenges of fear, ignorance and stigma. We as HIV clinicians are no strangers to the powerful connection between the disease and the cultural response, and how this connection can affect our capacity to treat those who are infected and to prevent new infections.

This has never been more apparent in our country than it is right now. **We have known since the early 1990's that HIV has disproportionately affected communities of color.**

Now we have the latest surveillance statistics from the Centers for Disease Control and Prevention (CDC) confirming the increasing racial disparities of HIV infection in the United States. For some providers, these statistics reiterate what we have known from our own experience. These data are reflected in the shifting patient populations within our practices. The minority populations that include African-Americans and Hispanic/Latinos **now represent the majority of people we currently serve or will be serving** as the epidemic ages and grows.

How does HIV's disproportionate impact on our nation's communities of color affect how we treat our patients from those communities? This is what we explore in the third issue of *HIV Specialist*. Our authors examine the challenges that HIV care providers are facing in **treating a shifting patient population**. We profile providers who have always treated HIV in communities of color and see how they have addressed racial and cultural barriers. We provide in-

formation regarding research into **HIV's progressive stronghold on some communities of color, and look at how the Federal government plans to address these trends**. We offer a glimpse into the lives of a several patients and their doctors, and **see how they have managed clinical HIV treatment issues with cultural realities**.



Jeffrey T. Kirchner

Also in this issue of *HIV Specialist*, we look at the early success of the three-year "Bronx Knows" testing campaign, the largest of its kind in New York City. This initiative has managed to increase HIV testing by 28% after just one year in a borough whose residents are primarily people of color. You will learn about a series of workshops that are a result of a **collaboration between the Academy and the American Heart Association**. These workshops will be presented at several locations this fall with a goal to **educate providers about issues related to HIV and cardiovascular disease**. Lastly, we include clinical highlights from this past May's **ACTHIV conference in Denver**, and **Dr. Richard Prokesch takes us through the next step in discussing the transition from paper to an electronic medical record system**.

It continues to be a privilege and challenge to serve on the Editorial Advisory Group of *HIV Specialist*. We again encourage you to let us know your thoughts or comments on anything that is happening with *HIV Specialist* by emailing me directly at jtkirchn@lancastergeneral.org or our D.C. staff at communications@aahivm.org. **HIV**

Sincerely,

Jeffrey T. Kirchner, DO, AAHIVS
Chair, Editorial Advisory Group

Recognizing 'Other/Unknown'

Beginning my HIV practice in California I thought of AIDS denialists as fringe elements complicating my work. I gave no credence to the idea that the CIA was involved in creating HIV as a way to kill Africans or African Americans as some of my patients believe.

Working in Africa I think of magical healers as complicating my work, but now I am the fringe practitioner who talks of invisible germs and diseases that cannot be cured.

"Treat" and "Cure" are the same word in most languages, and a doctor that cannot cure is not much of a doctor. Some patients only come to my clinic as their last hope, counting on "traditional healers" and "Marabouts".

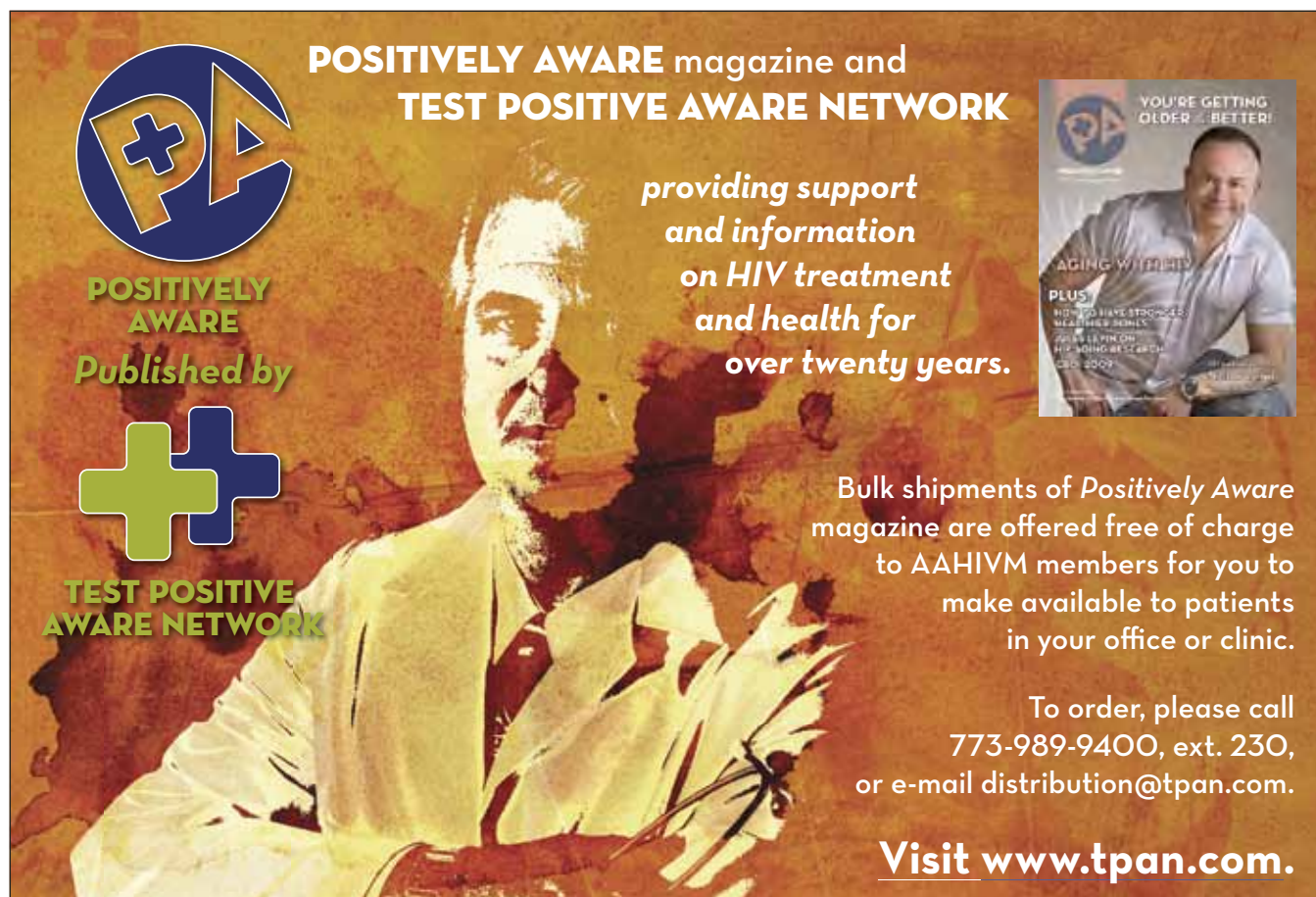
When I talk about HIV being spread by the most intimate of contacts – sex, birth, breastfeeding – and encourage condom use, I am not encouraging their esteem. A white man suggesting condoms appears to some of my patients as a proponent

of genocide, and isn't that why "the CIA made" this disease? Others merely see it as a sign of my idiot-savant status – how can someone know so much and be so ignorant?

I am beginning to be thankful for that slice of pie charts labeled Other/Unknown.

It is a reminder that we all struggle to understand the world as we experience it. There are unknowns and this is the emblem of our need to understand them. My patient often is very Other/Unknown to me, as I am to him. My view on his HIV infection and its management may be extremely "alternative" to his own; how well we bridge that difference is often what determines the success of our treatment.

Kevin Peterson, MD, MPH
HIV Specialist Physician
Medical Research Council Laboratories
Fajara, The Gambia



POSITIVELY AWARE magazine and
TEST POSITIVE AWARE NETWORK

providing support
and information
on HIV treatment
and health for
over twenty years.

Bulk shipments of *Positively Aware* magazine are offered free of charge to AAHIVM members for you to make available to patients in your office or clinic.

To order, please call
773-989-9400, ext. 230,
or e-mail distribution@tpan.com.
Visit www.tpan.com.



At the **BY JEFFREY T. KIRCHNER, DO, FAAFP, AAHIVS**

ACADEMY

AAHIVM and AHA Host Free CME Events Addressing CVD and HIV

THE AMERICAN HEART ASSOCIATION (AHA) and the American Academy of HIV Medicine (AAHIVM) want to enhance HIV patient care and treatment by lowering CVD risk and improving links between multiple providers through the Initiative to Decrease Cardiovascular Risk and Increase Quality of Care for Patients Living with HIV/AIDS.

The AHA and the AAHIVM will offer complimentary Continuing Medical Education (CME) conferences in Miami (Oct. 8), Atlanta (Oct. 22), and Los Angeles (Nov. 5), and New York City (Nov. 12). The CME conferences are certified for physicians. Target audiences include cardiologists, endocrinologists, infectious disease practitioners, internal medicine practitioners, family practitioners, and other physicians who care for HIV-infected adults. Local experts will present the following topics as part of these half-day conferences:

- **Overview of Cardiovascular Disease and HIV Infection** – discusses the HIV-infected patient's potential for mechanisms for increased incidence of CVD, modifiable CV risk factors, and possible ART and chronic inflammation contribution to incident CVD.
- **Cardiovascular Disease Risk Assessment in the HIV-infected Individual** – discusses CVD risk assessment and diagnosis in the HIV patient including the interpretation of lipid abnormalities commonly seen in HIV-infected adults.
- **Cardiovascular Risk Management in the HIV-infected Individual** – identifies key principles in managing CVD risk (including smoking cessation), defines appropriate evidence-based therapeutic interventions to reduce CVD risk, and describes significant drug-drug interactions with statins and antiretroviral therapy to guide clinicians in successful decision making.

The Initiative to Decrease Cardiovascular Risk and Increase Quality of Care for Patients Living with HIV/AIDS supports the dialog between HIV specialists, ID physicians, internists, family physicians, cardiologists, endocrinologists, and other clinicians who treat HIV-infected patients. The goal is to establish a solid position statement and foundation for all physicians who manage HIV patients at risk for cardiovascular disease.

Scientists and healthcare providers convened in June 2007 for the State of the Science Conference: Initiative to Decrease Cardiovascular Risk and Increase Quality of Care for Patients Living with HIV/AIDS, where they assessed the association among HIV, antiretroviral therapy, and cardiovascular disease. According to the group, antiretroviral medications have dramatically reduced the overall death rate among patients with HIV, but emerging data suggests an increased risk for cardiovascular disease.

The conference proceedings titled Initiative to Decrease Cardiovascular Risk and Increase Quality of Care for Patients Living with HIV/AIDS were published online in *Circulation: Journal of the American Heart Association* and in the *Journal of Acquired Immune Deficiency Syndrome* in June 2008.

Updated information and new data will be presented as part of this upcoming CME program. This important clinical information will later be available as an enduring activity through the American Heart Association's Professional Education Center.

As patients continue to live longer with HIV/AIDS, assessment and management of cardiovascular risk factors can no longer be ignored by physicians caring for these patients. **HIV**

To learn more about the initiative and register for a conference, visit the American Heart Association's Professional Education Center at <http://learn.heart.org/hiv>. This AHA and AAHIVM joint initiative is funded by an educational grant from Bristol-Myers Squibb.



On the

BY JOSEPH CERVIA, MD, MBA,
FACP, FAAP, AAHIVS

FRONTLINES

Understanding & Addressing Racial Disparities: A Dream Revisited

BUILDING A LIFE FOR HERSELF despite the burdens of AIDS had been a struggle for Georgette; yet, adherence to therapy during a second pregnancy was rewarded by Ricky's birth, free of HIV. Her dream now is simply to live to watch him grow. Georgette's battle reflects that of communities of color everywhere. Can we as a larger community unite to understand and reduce racial and ethnic disparities in HIV infection and its devastating effects?

With a satisfied smile, Georgette reacted to the good news regarding her latest viral load and CD4+ lymphocyte count, "You see ma', I have been taking care of myself." Good-natured and assertive, Georgette's mother has been her bedrock in a 15 year battle with AIDS, a battle that has exacted a devastating toll...an infant son, several brushes with death, and most recently Georgette's renal function. Nevertheless, with her mother and Ricky, her seven-year old son by her side, this was a moment to celebrate.

Infected by a man who moved into and out of her life much too soon, Georgette first learned of her HIV infection back home in Jamaica while hospitalized with PCP, which soon claimed the life of her infant son. Since returning to New York to stay with her mother, Georgette has been my patient.

Over the years Georgette's treatment adherence has been challenged, with long periods of absence from care punctuated by serious illnesses and renewed efforts to resume the fight. Most recently, she appeared to be on the right track. "You'll see doc, I'm going to beat this thing. I have a dream of being here to watch Ricky grow up," Georgette reassured me as she walked arm in arm with her mother and son out of the room on our latest visit. It occurred to me that this was a dream we all could share.

Nevertheless, the fulfillment of the dream of such a life unfettered by HIV is not equally enjoyed by all. Populations of color continue to be disproportionately affected by this virus, in terms of incidence, prevalence and outcomes. According to CDC data, although blacks constituted only approximately 13% of the populations of 33 states reporting HIV/AIDS cases between 2001-2004, they accounted for

51% of such diagnoses. Though racial disparities were observed in all transmission categories, they were particularly pronounced among women like Georgette and their children. Blacks accounted for the highest percentages of cases due to high risk heterosexual contact for both men and women, and for the majority (nearly 70%) of perinatal transmission.

Even more disturbing are data from the Veterans Aging Cohort 3-Site Study (VACS 3), which indicate that HIV-infected minority veterans experience poorer survival than do white veterans. In VACS 3, minority veterans had poorer prognosis, greater comorbidities, and lower CD4+ counts at enrollment compared to whites. Minority veterans were more likely to have been diagnosed with HIV as inpatients, later in the course of their disease, and in general, sicker at the time of diagnosis. Interestingly, this study found no evidence of significant racial differences in clinical management or adherence to antiretroviral therapy.

Walking Georgette and her loved ones down the hallway, I was reminded of the importance of close therapeutic alliances in fulfilling the dream of a better life with HIV. Likewise, reducing racial disparities in HIV diagnosis and outcomes will require community-wide alliances in support for new and improved prevention strategies, including expanded HIV testing, and culturally appropriate communication. In addition, infected individuals must be recruited into care earlier. Only then can we realize a dream of reducing the disproportionately devastating impact of HIV upon communities of color. **HIV**



About the Author: Dr. Joseph S. Cervia is Clinical Professor of Medicine and Pediatrics, Albert Einstein College of Medicine. He is Attending Physician, The Center for AIDS Research and Treatment, The North

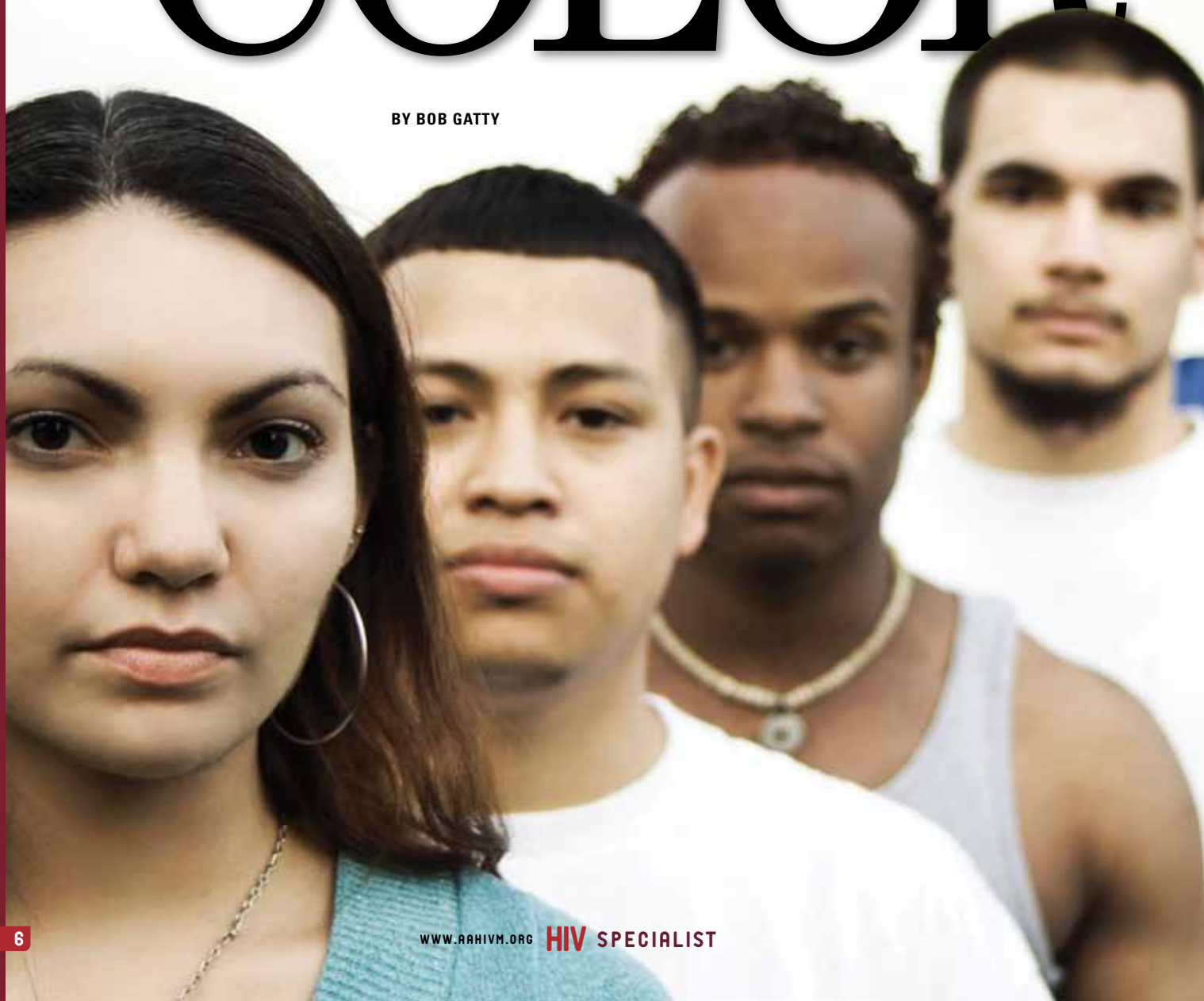
Shore/Long Island Jewish Health System, and Medical Director and Senior Vice-President, Pall Medical, East Hills, NY 11548

Contact: cervia@lij.edu, joe_cervia@pall.com. The author has no conflicts. Patient names and identifying information have been altered to protect confidentiality.

BACKGROUND

TREATING HIV/AIDS IN OUR Communities COLOR^{of}

BY BOB GATTY



THE COLD STATISTICS TELL A STARK STORY ABOUT HIV/AIDS IN AMERICA. It's a story about the Communities of Color that create the rich diversity of our nation, and about how those same communities are disproportionately affected by this deadly disease.

According to the most recent surveillance data from the Centers for Disease Control and Prevention (CDC), more than 1 million Americans are infected with HIV, with about 300,000 of them unaware they are HIV positive and another 225,000 aware but not receiving appropriate care. More than 500,000 have died of AIDS, to date, and more than 195,000 of them are African Americans.

DISPARITIES OF A DEADLY DISEASE, IN PERSPECTIVE

While they represent only 12.2 percent of the total U.S. population, African Americans account for 40 percent of cumulative AIDS cases, 50 percent of reported AIDS cases, and 46 percent of new HIV infections. The incidence of AIDS is 25 times higher in African American women than in white, about eight times higher in African American men.

Frank J. Oldham, Jr., president and chief executive officer of the National Association of People with AIDS, says that although treatment breakthroughs over the last 15 years have dramatically lowered AIDS deaths in the U.S., black Americans still have double the chance of dying compared to an HIV-positive white person of the same age.

"Even in the era of effective treatment, AIDS is still one of the leading causes of death in the black community," Oldham said in a forward to a new Black AIDS Institute study, *Passing the Test: The Challenges and Opportunities of HIV Testing in Black America*, which focuses on HIV testing in America. The Institute is non-profit organization based in Los Angeles, CA, which is dedicated to reducing HIV/AIDS health disparities by mobilizing black institutions and individuals in efforts to confront the epidemic in their communities. The report is available at www.blackaids.org.

CDC reports that men who have sex with men (MSM) account for the majority of new cases, with about 30,000 becoming HIV-positive each year. Young black men are most vulnerable, the agency says. "Among MSM overall, there were more new HIV infections in young black MSM aged 13-29 than any other age or racial group of MSM," said Kevin Fenton, MD, PhD, director of the National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention at CDC.

However, CDC reports that injection drug use (IDU), also a major form of transmission, is responsible for more HIV/AIDS cases among African Americans and Hispanics than among whites. In 2003, data showed that among IDUs, blacks accounted for 40 percent of HIV infections, com-

Photo by Simon McCance / iStock

Communities COLOR

DISPARITIES OF A DEADLY DISEASE,
IN PERSPECTIVE

Recommendations for Clinicians

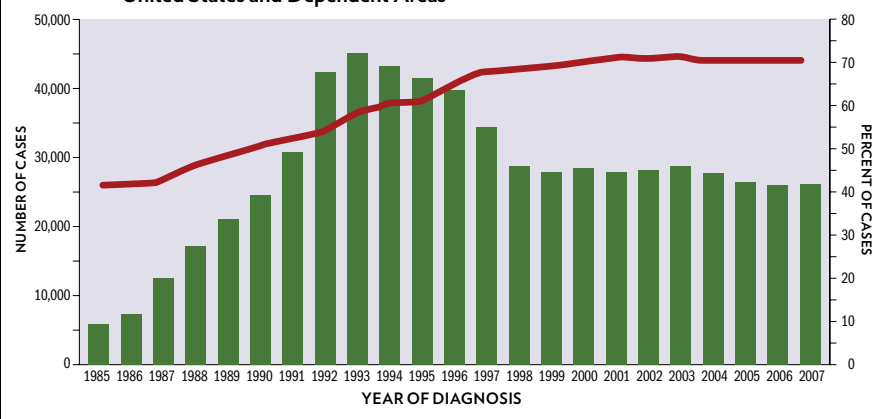
The National Minority AIDS Education and Training Center (NMAETC) has issued these recommendations to help clinicians better serve patients in the various communities of color:

African Americans/Blacks American Indians/Alaska Natives Asian & Pacific Islander Americans

- Recognize that many patients who present in your office may come from a culture that is suspicious of the American health care system.
- Make sure your providers and staff members treat each individual who calls or visits your office with dignity and respect.
- Reflect the populations you serve in the materials displayed in your office.
- Use easy to understand language when discussing health concepts.
- Understand the role of family in patient decision-making and be open to patients bringing family members to the appointments.
- Where possible, make child care available.
- Structure programs to meet all patients' mental, physical, and social service needs.
- Schedule appointments in times and locations suitable for people who work.
- Be open to making community presentations on HIV/AIDS and other health problems in the communities you serve.
- Stress the role of prevention in keeping communities disease-free.

continued on page 10

FIGURE 1 AIDS Cases among Minority Races/Ethnicities 1985–2007—
United States and Dependent Areas



Source: Centers for Disease Control and Prevention

pared with Hispanics, 33 percent and whites, 25 percent.

The National Minority AIDS Education and Training Center (NMAETC) points out that similar numbers are found in other minority populations. Hispanics accounted for 18 percent of HIV/AIDS in 2005; Hispanic males had more than three times the AIDS rate of non-Hispanic white males, and Hispanic females had more than five times the AIDS rate of non-Hispanic white females. Although the Native American population infection rates are not as high as those of African Americans and Hispanics, “studies and treatment data show an alarming increase in infection rates among this population,” NMAETC reported. “Likewise, the Asian American and Native Hawaiian-Pacific Islander populations have experienced a rapid increase in HIV/AIDS cases.”

In 2007, CDC estimated numbers of HIV/AIDS diagnosed in the 34 states with confidential name-based HIV infection reporting, by race or ethnicity:

Race or Ethnicity	Est. # HIV/AIDS Cases in 2007
American Indian/Alaska Native	228
Asian	455
Black/African American	21,549
Hispanic/Latino	7,484
Native Hawaiian/Other Pacific Islander	46
White	12,566

“The impact of HIV/AIDS in these communities of color is exacerbated by an often-alarming disparity in access to comprehensive healthcare between minorities and whites, NMAETC says. “Accessing healthcare can be a daunting challenge for minorities with HIV/AIDS because of economics, lack of health insurance, proximity to healthcare, and stigma concerning HIV/AIDS in families, communities and in the healthcare system itself.”

“To win the battle against HIV it is crucial that African Americans – and indeed, all Americans – get tested for the virus during routine medical care, as the CDC and the American College of Physicians recommend.”



Anthony S. Fauci, M.D.

Treatment Requires Understanding

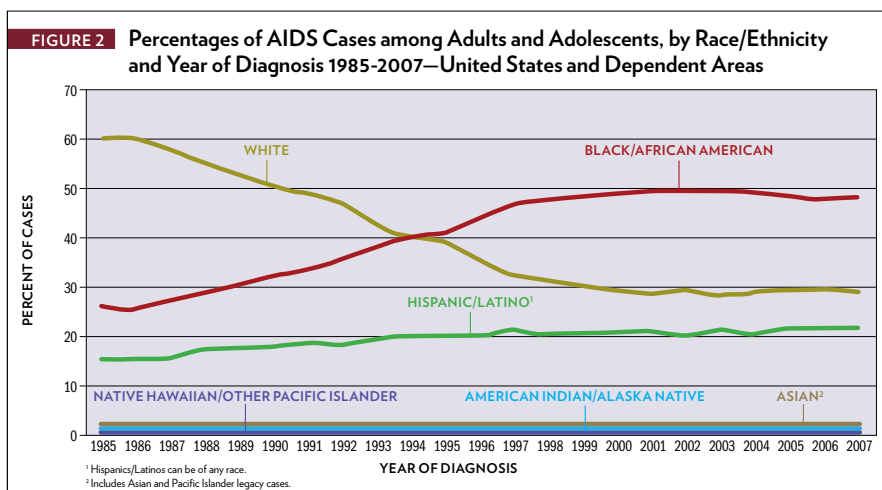
Clinicians need to understand these issues and the disproportionate impact of HIV/AIDS among minorities if they are to effectively apply “culturally competent treatment approaches as well as effective prevention methodologies,” NMAETC advises, pointing out there are many existing “barriers” to effectively caring for patients in the communities of color, including:

- Availability of health services in their communities.
- Economic hardship.
- Stigmatization associated with disease.
- Cultural avoidance of discussing issues related to sexual behavior, alcohol or drug use.
- Privacy and honor.
- Distrust of American healthcare system.
- Language difficulty.
- Citizenship status.

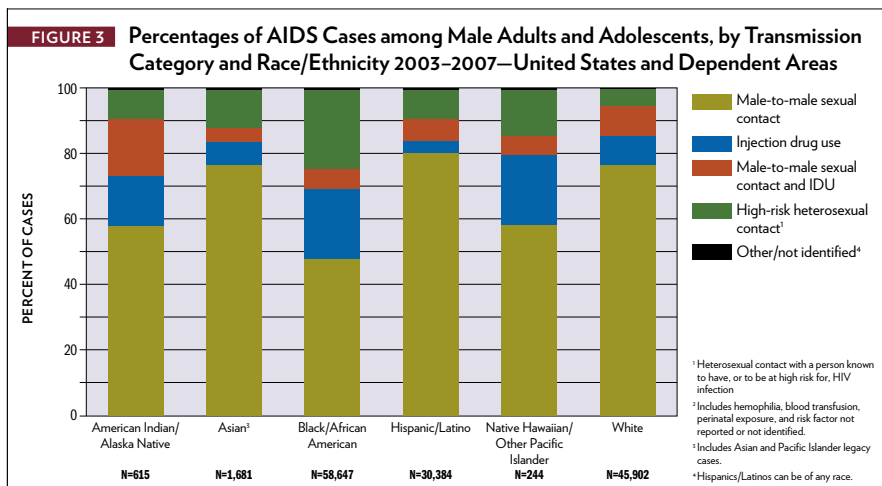
In addition, American Indians/Alaska Natives and Native Hawaiian patients may have a distrust of Western medicine and systems. Native Americans/Alaska Natives may be faced with a lack of providers who share their culture and worldview, and communication issues resulting from more than 200 Native languages. Other concerns for these patients may include a view of sickness and its relationship to disharmony, high illiteracy rate, joblessness, and substandard housing.

Anthony S. Fauci, M.D., director of the National Institute of Allergy and Infectious Diseases at the National Institutes of Health (NIH), is well aware of the special challenges involved with HIV/AIDS in America’s communities of color.

“To win the battle against HIV,” he said, “it is crucial that African Americans – and indeed, all Americans – get tested for the virus during routine medical care, as the CDC and the American College of Physicians recommend.” With so many people not knowing that they are infected, the



Source: Centers for Disease Control and Prevention



Source: Centers for Disease Control and Prevention

Communities *of* COLOR

DISPARITIES OF A DEADLY DISEASE, IN PERSPECTIVE

Recommendations for Clinicians
continued from page 8

Native Hawaiian

Recommendations for these patients were identical to those above, with the addition of:

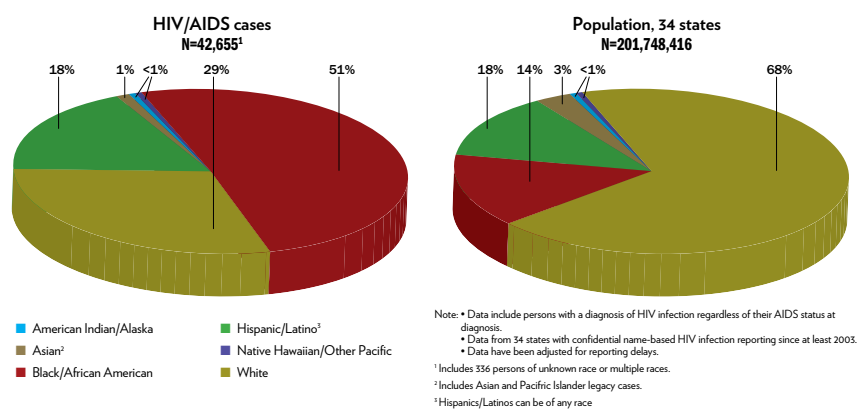
- Enhance coordination and support Native Hawaiians health services with private organizations, including Native Hawaiian trusts and government agencies and facilities.

Hispanic/Latino

- Create an environment that is inviting, friendly and respectful.
- Understand patients feel more comfortable when they are able to view artwork and materials that reflect their cultures.
- Use easy to understand language when discussing health concepts.
- Use the population's native language, when possible, and provide translation services for offices where language is not spoken by staff members.
- Do not assume that people with limited English-speaking proficiency cannot understand what you are saying. Many can but are hesitant to acknowledge it.
- Be open to patients bringing family members to the appointments, but use discretion when delivering HIV diagnosis.
- Where possible, make child care available.
- Structure programs to meet all patients' mental, physical, nutrition and social service needs.
- Have flexible office hours and locations, where possible.

For more information on these recommendations, visit the NMAETC's website at www.nmaetc.org. HIV

FIGURE 4 Percentages of HIV/AIDS Cases and Population by Race/Ethnicity, 2007–34 States



Source: Centers for Disease Control and Prevention

chances of further spreading the virus are increased, as is the likelihood of becoming very ill without treatment, he said.

Dr. Fauci pointed out that “a significant number of Latinos with HIV get tested late in the course of their disease, long after proper counseling and treatment should begin, adding that NIAID “strongly endorses” testing during routine medical care for adolescents, adults, and pregnant women, as recommended by CDC.

The Black AIDS Institute, in its *Passing the Test* study, said that while 52 percent of blacks surveyed reported having taken an HIV test, compared to 38 percent of Hispanics and 34 percent of whites, blacks actually should be tested at much higher rates to ensure prompt diagnosis because infection levels are so much higher in the black community.

“The high prevalence of undiagnosed HIV infection is a key reason why the epidemic is so much worse in Black America than in other parts of the U.S.,” the Institute said. “Up to 70 percent of all new infections in Black America are the results of risky behavior among people who do not know they are infected. And because black people are more likely to be diagnosed late in the course of infection, they are also more likely to die.”

CDC cited these additional factors as placing African Americans at increased risk:

- Higher prevalence of sexually transmitted diseases (STDs)
- Socioeconomic factors
- Stigma

About Stigma

Stigma, an ongoing issue for HIV/AIDS patients, is a particularly difficult concern in many communities of color. CDC cites stigma associated with HIV and homosexuality as a factor that helps to spread HIV in African American communities.

“Clinicians need to understand these issues and the disproportionate impact of HIV/AIDS among minorities if they are to effectively apply *culturally competent treatment approaches as well as effective prevention methodologies.*”

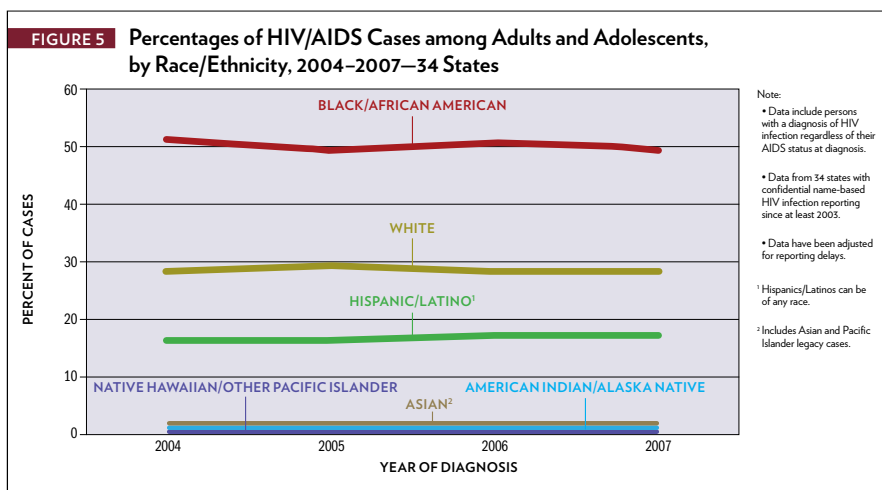
“Fear of disclosing risk behavior or sexual orientation prevents many from seeking testing, treatment and support from friends and family,” CDC reports in its document, *Fighting HIV Among African Americans*. “As a result, too many in African American communities lack critical information about how to prevent infection.”

The Henry J. Kaiser Family Foundation reports in a 2009 study that stigma may be waning in the U.S.—69 percent of adults saying that people they know would not think differently about them if they found out they had been tested for HIV. Nevertheless, Dr. Fauci points to it as a particularly serious problem among many Asians, Pacific Islanders, Alaska Natives, and Native Hawaiians.

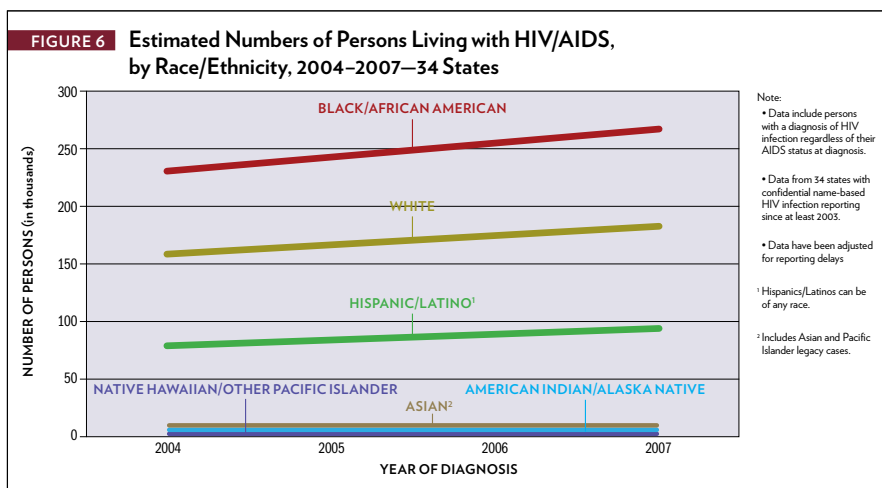
“Stigma associated with men having sex with men and cultural taboos against discussing sexual matters may...create difficulties for Asians and Pacific Islanders around negotiating condom use,” he said. “This has important repercussions, because high-risk sexual contact with a man accounts for at least three quarters of new HIV infections among male Asians and more than half of new HIV infections among female Asians.”

He expressed similar concerns about American Indians, Alaska Natives and Native Hawaiians, noting that the stigma associated with HIV/AIDS and homosexuality may discourage many from getting tested and seeking counseling and treatment.

“As our nation works to broaden access to health care, it is my hope that more native communities will gain access to testing and treatment facilities for HIV as well as other sexually transmitted infections that increase the risk of acquiring and spreading HIV and are highly prevalent among native peoples,” Dr. Fauci said. **HIV**



Source: Centers for Disease Control and Prevention



Source: Centers for Disease Control and Prevention

BY BOB GATTY

Breaching the Overcoming the Barriers, Challenges

AS THE HIV/AIDS EPIDEMIC STEADILY REACHES into America's Communities of Color, HIV specialists face the everyday challenge of finding the right approach that will gain trust and allow them to effectively treat these patients and help them survive and improve their lives.

Often, however, there is resistance born of cultural and lifestyle differences between patient and provider, of traditions and superstitions, and even suspicions that linger from the earliest years of HIV infection in America.

Increasingly, HIV specialists are faced with such challenges as America becomes ever more culturally diversified. A new online survey by the American Academy of HIV Medicine (AAHIVM) completed in July shows that exactly 50 percent of HIV specialists who responded have experienced increased racial and cultural diversity in their practices, with 26 percent reporting that patients of color now account for more than 75 percent of their practice.

To respond to these changes, medical practices have adapted – by adding education and training on cultural issues, hiring culturally competent staff including bilingual or even multilingual providers, and taking other steps to specifically address issues related to changing patient demographics.

Some inner city practices treat increasing numbers of African American and/or Hispanic IV drug users often living in poverty, who may – or may not – be men who have sex with men (MSM). Others serve patients from a variety of African nations or from Central and South America with unique customs and beliefs that directly affect treatment and care.

Often, suspicions that HIV/AIDS is a plot against African Americans, originating from the U.S. Public Health Service Tuskegee syphilis study in which African Americans were denied therapy for syphilis to study the natural history of the disease, persist and challenge HIV providers who treat patients of color.

COVER STORY



Communities of COLOR



Communities COLOR

BREACHING THE BARRIERS,
OVERCOMING THE CHALLENGES

Some clinics see increases in the numbers of women, many of color, who contracted HIV/AIDS from men, or from trading sex for drugs.

Overcoming Differences, Gaining Trust

All of this means there are barriers to breach, suspicions to overcome, languages, attitudes, and traditions to understand.

“The barriers may be age, cultural, education, income, language, generational – but we have to cross those barriers to be able to communicate with our patients,” said Daniel Pearce, DO, AA-HIVS, who has been caring for HIV/AIDS patients since 1988, primarily serving people of color. Today, he is the Medical Director of HIV Services and an Associate Professor of Internal Medicine at Western University of Health Sciences, and is helping to establish a new HIV/AIDS clinic at San Bernardino County’s Arrowhead Regional Medical Center.

Dr. Pearce notes that as a heterosexual white male, his life experiences are far different from many of his patients. But, as

known as “Jonesy” to her patients.

“We have a very high population of those with criminal backgrounds, some of whom are returning to the community after incarceration – people whose lives have been pretty tough.” Some of Jonesy’s patients come from Africa and Central America and speak a variety of languages and dialects. While the “Language Line” (which provides telephone-based translation services) can help, the clinic often uses interpreters provided by John Peter Smith Hospital, which operates the clinic.

“You must try to honor them and their family members and respect and understand their cultures,” said Jonesy. “I even give them my cell phone number so they can call me if they can’t get through [to the office]. I like music, so I try to slide something into our consultations about their music, something to make a connection. Or I try to use one or two words in their language. They laugh. It makes it easier to communicate.”

Dr. Pearce reasons with his patients, explaining that he successfully treats many people with similar issues and that he feels comfortable working with them. His fluency in Spanish makes it easier for him to connect with Hispanic patients without having an interpreter as a go-between.

“I try to gain their respect,” he said. “Doctors may not appreciate the psychological, physical, and social pressures that a drug user goes through. I can acknowledge this, but it’s hard to relate. The more you deal with it, the more you understand that their lives are different; that drugs give them an



Sharon Jones, CFNP, AAHIVS

QUESTION 1 What percentage of your HIV patients are:

		RESPONSE AVERAGE	RESPONSE TOTAL	RESPONSE COUNT
Black/African American		39.30	4,205	107
Hispanic/Latino		21.92	2,324	106
Caucasian/White		36.09	3,753	104
Asian		4.63	296	64
Native Hawaiian/Other Pacific Islander		1.07	49	46
Native American		3.10	152	49
Answered question				108
Skipped question				0

QUESTION 2 For the past 15 years, how has your HIV patient base changed towards a more racially or culturally diverse practice?

		RESPONSE PERCENT	RESPONSE COUNT
Significant change (Minority population patients now account for > 75% of my practice)		26.0%	27
Moderate change (Minority population patients now account for > 50% of my practice)		24.0%	25
Some change (Minority population patients now account for < 25% of my practice)		16.3%	17
No change		33.7%	35
Comment			34
Answered question			104
Skipped question			4

every HIV specialist understands, it is critical to gain the patient’s trust to successfully treat HIV. “Sometimes they tell you what you want to hear; sort of performing when they are with you,” he said. “When you hear them talking to staff, though, you may hear another story. And when you see their lab numbers, that’s the proof about what is going on.”

“You just have to hang in there, keep your promises, do your follow-up,” said Sharon Jones, CFNP, AAHIVS, who works at the Healing Wings Clinic in Fort Worth, TX, where she is

escape, an absence of pain and suffering.”

Such patients, Dr. Pearce contends, do not think about the future. “They are short term thinkers living day to day or week to week. They say, ‘All my relatives are in prison or dead, so why shouldn’t I be?’ We can’t relate to that.”

“Human behavior is the worst part,” he said. “How do we change human behavior? It’s a very hard nut to crack. It’s much easier for scientists to work with chemicals and medicines than with human behavior.”

Thus, having a multidisciplinary and multicultural staff is essential in working with patients from the many communities of color.

At the U.S.-Mexico border, a Mexican born RN who resides in Mexico has confidentially been given international phone numbers from Mexican and American patients who frequently cross the border. She often uses a Mexican cell phone to call patients and reminds them of appointments, and they call her

on that number regarding their health concerns. She is seen as sort of a Mexican mother figure and is the glue for that clinic. She is an example of how clinic staff from the local community can be critical links to patients.

Amy Sitapati, M.D., AAHIVS, associate director of the University of California San Diego Owen Clinic at Hillcrest, is former medical director for a Ryan White funded HIV practice at Howard University in Washington, D.C., a practice composed almost entirely of non-white patients.

There, a black outreach staffer in her mid-20s was critical to putting patients at ease. “She was interested in music and jazz, and would put on what I called her club face, stand in the front of the clinic, and greet patients. She would say, ‘How you doin’, Mr. so and so?’ Clients felt warmth and protection. We invited patients with any kind of infectious disease, so AIDS/HIV patients were kind of

Living With, Caring For...

IT WAS 1986 AND ALEX TROY BROWN, newly graduated from Morgan State University with a communications degree, had just been commissioned as a 2nd Lieutenant in the U.S. Army. He was happy and proud, a young black man who had overcome obstacles, achieved, and was on his way to success.

But Brown had a dark secret, intravenous drug use, and that same day, after completing a physical for the Army, he was exposed in a terrible way.

“They told me that I had this virus,” Brown said. “It was horrible. The only thing I new about it was what it did to my mother and father. They both died of AIDS. And I got it because I did drugs.”

Then came denial. Heavy-duty drugs. Booze. He refused to recognize the reality of his diagnosis. “For nine years I didn’t say the word HIV,” Brown said, his voice quiet. “It took a lot of pain and suffering for me to work it out. That form of denial is what kept me from committing suicide. But I was probably trying to commit suicide indirectly by IV drug use.”

There was homelessness, living in shelters and sleeping under Baltimore’s bridges. But he always had some sort of a job like waiting tables at waterfront restaurants, always enough to get him his next fix. “I never had trouble getting jobs,” he said. “I just had trouble keeping them.”

It was 1995 and Brown was AIDS defined, down to 95 pounds, his viral load “in the millions.”

“I was praying to die,” he remembered. “I was living in a recovery house, sneaking out and using. I got very sick, and they insisted

I get treatment.”

Sent to Johns Hopkins Bayview Medical Center, he encountered Dr. Michael Fingerhood, who, along with his staff, Brown credits with both saving his life and helping him recover.

“I didn’t relate to Dr. Fingerhood at first,” Brown admitted. But Dr. Fingerhood assigned Jullian Bethea, “a nurse practitioner in dreadlocks,” to work with him and she has been on his case ever since. “Dr. Fingerhood is fabulous,” Brown said, “and so is she. When she gets stuck, they put their heads together and come up with something for me. It’s a total team approach.”

Today, life is much different for Alex Troy Brown.

“My CD4 is up to 500 and my viral load is undetectable. I have a beautiful home and a family, three sons, and I even have a four-month-old grandson, Alex Troy Brown III. I never thought I would see that. I thought HIV would steal that from me.”

Breaking the Barriers

But that is only half of the story.

Not only is Brown still a patient of Dr. Fingerhood’s, he frequently joins him in sessions with medical students and residents, helping to educate them about addiction. Brown also is an outreach coordinator

continued on page 16



Alex T. Brown

Photo by Bob Gatty

Communities COLOR

BREACHING THE BARRIERS, OVERCOMING THE CHALLENGES

hidden in that multi-service practice. We were able to cross the biggest barrier in D.C.—stigma.”

There were times, however, Dr. Sitapati said, when young mothers with AIDS, some of whom were single parents with “extremely limited social resources,” would refuse hospitalization and treatment fearing their children would be taken away. “They just stayed at home until they died,” she said. “They were petrified about losing their kids.”

One of Dr. Sitapati’s areas of expertise is anal dysplasia, she said, emphasizing the need to exercise caution when asking certain questions that might be embarrassing for many – especially so for patients from some communities of color.

“One lady who is half black and half Mexican had visible anal tears. I asked her what happened,” Dr. Sitapati recalled. “She said her boyfriend was too rough. She had never disclosed before that she had anal receptive sex. Until we really stop and pause and ask open-ended questions – ‘Do you have any symptoms in your bottom or when you go to the bathroom?’ If they say, ‘Well, it hurts a little,’ you can find out. But if you get straight to the point and ask, ‘How many people did you have anal receptive sex with?’ they are not going to tell you. It’s private and they are embarrassed.”

For many MSM patients of color, it’s easier to acknowl-

continued on page 21

continued from page 15

for the HIV/AIDS clinic at the University of Maryland’s Institute of Human Virology in Baltimore, headed by Robert C. Gallo, M.D., who co-discovered that the HIV virus causes AIDS two decades ago.

“They use me...to reach these people, to get them to take their medications. I have to break through the barriers and let them know that I was just like them. They need to see people who live well with HIV. You have to have your doctors and nurses, but you also have to have individuals who walked that way of life.”

Brown can see through any stories that he’s told by patients regarding sexual practices or drug use, for example.

“I already know all the games,” he said. “I lived them for many years. I was just fortunate to be able to get through it.”

Also working at the University of Maryland Medical Center’s emergency room in Baltimore, Brown runs HIV tests on patients and provides counseling on HIV prevention.

“He’s really good at building rapport and convincing people to get tested,” Dr. Fingerhood said.

“Just the other day, we had a patient with swollen lymph nodes everywhere. I tested him, and he was positive,” Brown said. “I had to tell him. I was standing there in my scrubs and white lab coat with my credentials on my jacket. But I told him I have been there, too. A lot of our success depends on having individuals living with the virus taking care of people who have the virus. It works. Our passion levels are higher. It is very personal, very emotional.”

Brown says he’s involved with a group that is geared to helping HIV/AIDS patient form health relationships and to cope with such difficult issues as disclosing their HIV status to others.

“There is a lot of resistance (to disclosure) that comes from stigma, shame, guilt, rejection, so it spreads the epidemic because people still have sex and are sharing needles,” Brown said. “Until we get society to look at HIV the same way as other diseases, it won’t go away. People fear rejection from loved ones. Stigma in our society is extremely high and it makes people feel they have to go further underground.”

In addition to his work at the clinic and in the emergency room, Brown spends some 30 hours a week at STAR (Sisters Together &

Reaching), a community-based organization in Baltimore that provides financial assistance and direct services to HIV/AIDS patients.

As STAR’s youth coordinator, Brown’s focus is on prevention – on helping young people avoid the poor decisions that can result in a future controlled by HIV/AIDS. Brown acknowledges the mistakes he made as a young man that undoubtedly contributed to his condition – IV drug use, unprotected, promiscuous sex.

“That’s a key to recovery,” he said, “acknowledging what you did that got you here.”

In an exam room at the clinic, Brown pointed to the results of an OraQuick Advanced HIV test he had just completed. Both the C and T lines were red. It was a positive test.

“That is my test,” he said. “That is me. I tested myself to show you an example.” Ironically, HIV/AIDS has been a blessing for Brown, he says. “It has helped me determine what my purpose and mission in life can be, to help others, to serve my community and my God.”

“Where the police used to chase me,” he said, “Now they call me Sir and Mr. Alex. It’s a nice feeling. You know, I once went almost two years with never laughing. Now, I laugh every day.” **HIV**



Michael Fingerhood, MD

Photo courtesy of Michael Fingerhood

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Due to the need for co-administration of PREZISTA with ritonavir, please refer to ritonavir prescribing information for ritonavir-associated adverse reactions.

Clinical Trials Experience: Treatment-Naïve Adults

The safety assessment is based on all safety data from the Phase 3 trial TMC114-C211 comparing PREZISTA/rtv 800/100 mg once daily versus lopinavir/ritonavir 800/200 mg per day in 689 antiretroviral treatment-naïve HIV-1-infected adult subjects. The total mean exposure for subjects in the PREZISTA/rtv 800/100 mg once daily arm and in the lopinavir/ritonavir 800/200 mg per day arm was 54.8 and 53.3 weeks, respectively.

The majority of the adverse drug reactions (ADRs) reported during treatment with PREZISTA/rtv 800/100 mg once daily were mild in severity. The most common ADRs to PREZISTA/rtv 800/100 mg once daily ($\geq 5\%$) of at least moderate intensity (\geq Grade 2) were diarrhea and headache. 2% of subjects in the PREZISTA/rtv arm discontinued treatment due to ADRs.

ADRs to PREZISTA/rtv 800/100 mg once daily of at least moderate intensity (\geq Grade 2) in antiretroviral treatment naïve HIV-1-infected adult subjects are presented in Table 2.

Table 2: Selected Adverse Drug Reactions to PREZISTA/rtv 800/100 mg Once Daily* of At Least Moderate Intensity (\geq Grade 2) in Antiretroviral Treatment-Naïve HIV-1-Infected Adult Subjects

System Organ Class, Preferred Term, %	Randomized Study TMC114-C211	
	PREZISTA/rtv 800/100 mg once daily + TDF/FTC N = 343	lopinavir/ritonavir 800/200 mg per day + TDF/FTC N = 346
Gastrointestinal Disorders		
Abdominal pain	4%	5%
Acute pancreatitis	< 1%	< 1%
Diarrhea	6%	13%
Dyspepsia	< 1%	0%
Flatulence	< 1%	< 1%
Nausea	3%	3%
Vomiting	2%	3%
General Disorders and Administration Site Conditions		
Asthenia	< 1%	0%
Fatigue	< 1%	2%
Hepatobiliary Disorders		
Acute Hepatitis (e.g., acute hepatitis, cytolytic hepatitis, hepatotoxicity)	< 1%	< 1%
Metabolism and Nutrition Disorders		
Anorexia	1%	< 1%
Diabetes mellitus	< 1%	< 1%
Musculoskeletal and Connective Tissue Disorders		
Myalgia	< 1%	< 1%
Nervous System Disorders		
Headache	5%	4%
Psychiatric Disorders		
Abnormal Dreams	< 1%	< 1%
Skin and Subcutaneous Tissue Disorders		
Pruritus	< 1%	< 1%
Rash	2%	4%
Stevens-Johnson Syndrome	< 1%	0%

N=total number of subjects per treatment group

TDF = tenofovir disoproxil fumarate

FTC = emtricitabine

* Excluding laboratory abnormalities reported as ADRs

Laboratory abnormalities:

The percentages of antiretroviral treatment-naïve HIV-1-infected adult subjects treated with PREZISTA/rtv 800/100 mg once daily with Grade 2 to 4 laboratory abnormalities, considered ADRs, are presented in Table 3.

Table 3: Grade 2 to 4 Laboratory Abnormalities Observed in Antiretroviral Treatment-Naïve HIV-1-Infected Adult Subjects*

Laboratory Parameter Preferred Term, %	Limit	Randomized Study TMC114-C211	
		PREZISTA/rtv 800/100 mg once daily + TDF/FTC N = 343	lopinavir/ritonavir 800/200 mg per day + TDF/FTC N = 346
Biochemistry			
Alanine Aminotransferase			
Grade 2	> 2.5 to \leq 5.0 X ULN	5%	5%
Grade 3	> 5.0 to \leq 10.0 X ULN	3%	2%
Grade 4	> 10.0 X ULN	< 1%	3%
Aspartate Aminotransferase			
Grade 2	> 2.5 to \leq 5.0 X ULN	6%	6%
Grade 3	> 5.0 to \leq 10.0 X ULN	3%	2%
Grade 4	> 10.0 X ULN	< 1%	2%
Alkaline Phosphatase			
Grade 2	> 2.5 to \leq 5.0 X ULN	1%	< 1%
Grade 3	> 5.0 to \leq 10.0 X ULN	0%	< 1%
Grade 4	> 10.0 X ULN	0%	0%
Hyperbilirubinemia			
Grade 2	> 1.5 to \leq 2.5 X ULN	< 1%	3%
Grade 3	> 2.5 to \leq 5.0 X ULN	0%	< 1%
Grade 4	> 5.0 X ULN	0%	0%

Table 3: Grade 2 to 4 Laboratory Abnormalities Observed in Antiretroviral Treatment-Naïve HIV-1-Infected Adult Subjects* (cont.)

Laboratory Parameter Preferred Term, %	Limit	Randomized Study TMC114-C211	
		PREZISTA/rtv 800/100 mg once daily + TDF/FTC N = 343	lopinavir/ritonavir 800/200 mg per day + TDF/FTC N = 346
Biochemistry			
Triglycerides			
Grade 2	500-750 mg/dL	2%	6%
Grade 3	751-1200 mg/dL	1%	4%
Grade 4	> 1200 mg/dL	< 1%	< 1%
Total Cholesterol			
Grade 2	240-300 mg/dL	12%	19%
Grade 3	> 300 mg/dL	1%	4%
Low-Density Lipoprotein Cholesterol			
Grade 2	160-190 mg/dL	11%	6%
Grade 3	\geq 191 mg/dL	2%	4%
Elevated Glucose Levels			
Grade 2	126-250 mg/dL	6%	7%
Grade 3	251-500 mg/dL	< 1%	0%
Grade 4	> 500 mg/dL	0%	0%
Pancreatic Lipase			
Grade 2	> 1.5 to \leq 3.0 X ULN	2%	< 1%
Grade 3	> 3.0 to \leq 5.0 X ULN	< 1%	< 1%
Grade 4	> 5.0 X ULN	0%	< 1%
Pancreatic Amylase			
Grade 2	> 1.5 to \leq 2.0 X ULN	4%	2%
Grade 3	> 2.0 to \leq 5.0 X ULN	3%	3%
Grade 4	> 5.0 X ULN	0%	< 1%

N=total number of subjects per treatment group

TDF = tenofovir disoproxil fumarate

FTC = emtricitabine

* Grade 4 data not applicable in Division of AIDS grading scale.

Clinical Trials Experience: Treatment-Experienced Adults

The safety assessment is based on all safety data from the Phase 3 trial TMC114-C214 comparing PREZISTA/rtv 600/100 mg twice daily versus lopinavir/ritonavir 400/100 mg twice daily in 595 antiretroviral treatment-experienced HIV-1-infected adult subjects. The total mean exposure for subjects in the PREZISTA/rtv 600/100 mg twice daily arm and in the lopinavir/ritonavir 400/100 mg twice daily arm was 53.5 and 51.5 weeks, respectively.

The majority of the ADRs reported during treatment with PREZISTA/rtv 600/100 mg twice daily were mild in severity. The most common ADRs to PREZISTA/rtv 600/100 mg twice daily ($\geq 5\%$) of at least moderate intensity (\geq Grade 2) were diarrhea, nausea, rash, and abdominal pain. 3.7% of subjects in the PREZISTA/rtv arm discontinued treatment due to ADRs.

ADRs to PREZISTA/rtv 600/100 mg twice daily of at least moderate intensity (\geq Grade 2) in antiretroviral treatment-experienced HIV-1-infected adult subjects are presented in Table 4.

Table 4: Selected Adverse Drug Reactions to PREZISTA/rtv 600/100 mg Twice Daily* of At Least Moderate Intensity (\geq Grade 2) in Antiretroviral Treatment-Experienced HIV-1-Infected Adult Subjects

System Organ Class, Preferred Term, %	Randomized Study TMC114-C214	
	PREZISTA/rtv 600/100 mg twice daily + OBR N = 298	lopinavir/ritonavir 400/100 mg twice daily + OBR N = 297
Gastrointestinal Disorders		
Abdominal distension	2%	< 1%
Abdominal pain	5%	2%
Diarrhea	12%	18%
Dyspepsia	2%	< 1%
Flatulence	< 1%	1%
Nausea	7%	6%
Vomiting	4%	3%
General Disorders and Administration Site Conditions		
Asthenia	3%	1%
Fatigue	1%	1%
Metabolism and Nutrition Disorders		
Anorexia	1%	2%
Diabetes mellitus	< 1%	0%
Musculoskeletal and Connective Tissue Disorders		
Myalgia	1%	< 1%
Nervous System Disorders		
Headache	2%	3%
Psychiatric Disorders		
Abnormal dreams	< 1%	0%
Skin and Subcutaneous Tissue Disorders		
Pruritus	< 1%	1%
Rash	6%	3%

N=total number of subjects per treatment group

OBR = optimized background regimen

* Excluding laboratory abnormalities reported as ADRs

Laboratory abnormalities:

The percentages of antiretroviral treatment-experienced HIV-1-infected adult subjects treated with PREZISTA/rtv 600/100 mg twice daily with Grade 2 to 4 laboratory abnormalities, considered ADRs, are presented in Table 5.

Table 5: Grade 2 to 4 Laboratory Abnormalities Observed in Antiretroviral Treatment-Experienced HIV-1-Infected Adult Subjects*

		Randomized Study TMC114-C214	
Laboratory Parameter Preferred Term, %	Limit	PREZISTA/rtv 600/100 mg twice daily + OBR N = 298	lopinavir/ritonavir 400/100 mg twice daily + OBR N = 297
Biochemistry			
Alanine Aminotransferase			
Grade 2	> 2.5 to ≤ 5.0 X ULN	6%	5%
Grade 3	> 5.0 to ≤ 10.0 X ULN	2%	2%
Grade 4	> 10.0 X ULN	1%	2%
Aspartate Aminotransferase			
Grade 2	> 2.5 to ≤ 5.0 X ULN	4%	6%
Grade 3	> 5.0 to ≤ 10.0 X ULN	2%	2%
Grade 4	> 10.0 X ULN	< 1%	2%
Alkaline Phosphatase			
Grade 2	> 2.5 to ≤ 5.0 X ULN	< 1%	0%
Grade 3	> 5.0 to ≤ 10.0 X ULN	< 1%	< 1%
Grade 4	> 10.0 X ULN	0%	0%
Hyperbilirubinemia			
Grade 2	> 1.5 to ≤ 2.5 X ULN	0%	1%
Grade 3	> 2.5 to ≤ 5.0 X ULN	< 1%	0%
Grade 4	> 5.0 X ULN	< 1%	0%
Triglycerides			
Grade 2	500-750 mg/dL	11%	11%
Grade 3	751-1200 mg/dL	7%	9%
Grade 4	> 1200 mg/dL	2%	5%
Total Cholesterol			
Grade 2	240-300 mg/dL	24%	19%
Grade 3	> 300 mg/dL	8%	11%
Low-Density Lipoprotein Cholesterol			
Grade 2	160-190 mg/dL	13%	11%
Grade 3	≥ 191 mg/dL	7%	8%
Elevated Glucose Levels			
Grade 2	126-250 mg/dL	8%	9%
Grade 3	251-500 mg/dL	< 1%	< 1%
Grade 4	> 500 mg/dL	< 1%	0%
Pancreatic Lipase			
Grade 2	> 1.5 to ≤ 3.0 X ULN	2%	4%
Grade 3	> 3.0 to ≤ 5.0 X ULN	2%	< 1%
Grade 4	> 5.0 X ULN	< 1%	0%
Pancreatic Amylase			
Grade 2	> 1.5 to ≤ 2.0 X ULN	6%	6%
Grade 3	> 2.0 to ≤ 5.0 X ULN	6%	3%
Grade 4	> 5.0 X ULN	0%	0%

N=total number of subjects per treatment group

OBR = optimized background regimen

* Grade 4 data not applicable in Division of AIDS grading scale.

Serious ADRs

The following serious ADRs of at least moderate intensity (≥ Grade 2) occurred in the Phase 2b studies (Studies TMC114-C213, TMC114-C202, TMC114-C215, and TMC114-C208) and Phase 3 studies (TMC114-C211, TMC114-C214, TMC114-C209, DUET-1 (TMC125-C206), and DUET-2 (TMC125-C216)) with PREZISTA/rtv: abdominal pain, acute hepatitis, acute pancreatitis, anorexia, asthenia, diabetes mellitus, diarrhea, fatigue, headache, hepatic enzyme increased, hypercholesterolemia, hyperglycemia, hypertriglyceridemia, immune reconstitution syndrome, low density lipoprotein increased, nausea, pancreatic enzyme increased, rash, Stevens-Johnson Syndrome, and vomiting.

Additional ADRs to PREZISTA/rtv identified in adult subjects in other clinical trials

In Studies TMC114-C213, TMC114-C202, TMC114-C215, TMC114-C208, TMC114-C209, DUET-1, and DUET-2, the only additional ADR of interest identified was lipodystrophy.

Patients co-infected with hepatitis B and/or hepatitis C virus

In subjects co-infected with hepatitis B or C virus receiving PREZISTA/rtv, the incidence of adverse events and clinical chemistry abnormalities was not higher than in subjects receiving PREZISTA/rtv who were not co-infected, except for increased hepatic enzymes [see *Warnings and Precautions*]. The pharmacokinetic exposure in co-infected subjects was comparable to that in subjects without co-infection.

Postmarketing Experience

The following events have been identified during postmarketing use of PREZISTA. Because these events are reported voluntarily from a population of unknown size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Rarely, events of hypersensitivity (including facial edema), and rhabdomyolysis (associated with co-administration with HMG-CoA reductase inhibitors and PREZISTA) have been reported.

DRUG INTERACTIONS

See also *Contraindications* and *Clinical Pharmacology* (12.3) in Full Prescribing Information.

Potential for PREZISTA/rtv to Affect Other Drugs

PREZISTA co-administered with ritonavir is an inhibitor of CYP3A and CYP2D6. Co-administration of PREZISTA and ritonavir with drugs that are primarily metabolized by CYP3A and CYP2D6 may result in increased plasma concentrations of such drugs, which could increase or prolong their therapeutic effect and adverse events (see Table 6).

Potential for Other Drugs to Affect Darunavir

Darunavir and ritonavir are metabolized by CYP3A. Drugs that induce CYP3A activity would be expected to increase the clearance of darunavir and ritonavir, resulting in lowered plasma concentrations of darunavir and ritonavir. Co-administration of darunavir and ritonavir and other drugs that inhibit CYP3A may decrease the clearance of darunavir and ritonavir and may result in increased plasma concentrations of darunavir and ritonavir (see Table 6).

Established and Other Potentially Significant Drug Interactions

Table 6 provides dosing recommendations as a result of drug interactions with PREZISTA/rtv. These recommendations are based on either drug interaction studies or predicted interactions due to the expected magnitude of interaction and potential for serious adverse events or loss of efficacy.

Table 6: Established and Other Potentially Significant Drug Interactions: Alterations in Dose or Regimen May Be Recommended Based on Drug Interaction Studies or Predicted Interaction [See *Clinical Pharmacology* (12.3) in Full Prescribing Information for Magnitude of Interaction, Tables 8 and 9]

Concomitant Drug Class: Drug Name	Effect on Concentration of Darunavir or Concomitant Drug	Clinical Comment
HIV-Antiviral Agents: Nucleoside Reverse Transcriptase Inhibitors (NRTIs)		
didanosine	↔ darunavir ↔ didanosine	Didanosine should be administered one hour before or two hours after PREZISTA/rtv (which are administered with food).
HIV-Antiviral Agents: HIV-Protease Inhibitors (PIs)		
indinavir (The reference regimen for indinavir was indinavir/ritonavir 800/100 mg twice daily.)	↑ darunavir ↑ indinavir	The appropriate dose of indinavir in combination with PREZISTA/rtv has not been established.
lopinavir/ritonavir	↓ darunavir ↔ lopinavir	Appropriate doses of the combination have not been established. Hence, it is not recommended to co-administer lopinavir/ritonavir and PREZISTA, with or without ritonavir.
saquinavir	↓ darunavir ↔ saquinavir	Appropriate doses of the combination have not been established. Hence, it is not recommended to co-administer saquinavir and PREZISTA, with or without ritonavir.
Other Agents		
Antiarrhythmics: bepridil, lidocaine (systemic), quinidine, amiodarone, flecainide, propafenone	↑ antiarrhythmics	Concentrations of these drugs may be increased when co-administered with PREZISTA/rtv. Caution is warranted and therapeutic concentration monitoring, if available, is recommended for antiarrhythmics when co-administered with PREZISTA/rtv.
digoxin	↑ digoxin	The lowest dose of digoxin should initially be prescribed. The serum digoxin concentrations should be monitored and used for titration of digoxin dose to obtain the desired clinical effect.
Anticoagulant: warfarin	↓ warfarin ↔ darunavir	Warfarin concentrations are decreased when co-administered with PREZISTA/rtv. It is recommended that the international normalized ratio (INR) be monitored when warfarin is combined with PREZISTA/rtv.
Anticonvulsant: carbamazepine	↔ darunavir ↑ carbamazepine	The dose of either darunavir/ritonavir or carbamazepine does not need to be adjusted when initiating co-administration with darunavir/ritonavir and carbamazepine. Clinical monitoring of carbamazepine concentrations and its dose titration is recommended to achieve the desired clinical response.
Anticonvulsant: phenobarbital, phenytoin	↔ darunavir ↓ phenytoin ↓ phenobarbital	Co-administration of PREZISTA/rtv may cause decrease in the steady-state concentrations of phenytoin and phenobarbital. Phenytoin and phenobarbital levels should be monitored when co-administering with PREZISTA/rtv.

Table 6: Established and Other Potentially Significant Drug Interactions: Alterations in Dose or Regimen May Be Recommended Based on Drug Interaction Studies or Predicted Interaction (cont.) [See *Clinical Pharmacology (12.3)* in Full Prescribing Information for Magnitude of Interaction, Tables 8 and 9]

Concomitant Drug Class: Drug Name	Effect on Concentration of Darunavir or Concomitant Drug	Clinical Comment
Other Agents		
Antidepressant: trazodone, desipramine	↑ trazodone ↑ desipramine	Concomitant use of trazodone or desipramine and PREZISTA/rtv may increase plasma concentrations of trazodone or desipramine which may lead to adverse events such as nausea, dizziness, hypotension and syncope. If trazodone or desipramine is used with PREZISTA/rtv, the combination should be used with caution and a lower dose of trazodone or desipramine should be considered.
Anti-infective: clarithromycin	↔ darunavir ↑ clarithromycin	No dose adjustment of the combination is required for patients with normal renal function. For patients with renal impairment, the following dose adjustments should be considered: <ul style="list-style-type: none"> For subjects with CLcr of 30-60 mL/min, the dose of clarithromycin should be reduced by 50%. For subjects with CLcr of < 30 mL/min, the dose of clarithromycin should be reduced by 75%.
Antifungals: ketoconazole, itraconazole, voriconazole	↑ ketoconazole ↑ darunavir ↑ itraconazole (not studied) ↓ voriconazole (not studied)	Ketoconazole and itraconazole are potent inhibitors as well as substrates of CYP3A. Concomitant systemic use of ketoconazole, itraconazole, and darunavir/ritonavir may increase plasma concentration of darunavir. Plasma concentrations of ketoconazole or itraconazole may be increased in the presence of darunavir/ritonavir. When co-administration is required, the daily dose of ketoconazole or itraconazole should not exceed 200 mg. Plasma concentrations of voriconazole may be decreased in the presence of darunavir/ritonavir. Voriconazole should not be administered to patients receiving darunavir/ritonavir unless an assessment of the benefit/risk ratio justifies the use of voriconazole.
Antimycobacterial: rifabutin The reference regimen for rifabutin was 300 mg once daily	↑ darunavir ↑ rifabutin ↑ 25- <i>O</i> -desacetyl-rifabutin	Dose reduction of rifabutin by at least 75% of the usual dose (300 mg once daily) is recommended (i.e., a maximum dose of 150 mg every other day). Increased monitoring for adverse events is warranted in patients receiving this combination and further dose reduction of rifabutin may be necessary.
β-Blockers: metoprolol, timolol	↑ beta-blockers	Caution is warranted and clinical monitoring of patients is recommended. A dose decrease may be needed for these drugs when co-administered with PREZISTA/rtv.
Benzo-diazepines: parenterally administered midazolam	↑ midazolam	Concomitant use of parenteral midazolam with PREZISTA/rtv may increase plasma concentrations of midazolam. Co-administration should be done in a setting which ensures close clinical monitoring and appropriate medical management in case of respiratory depression and/or prolonged sedation. Dosage reduction for midazolam should be considered, especially if more than a single dose of midazolam is administered. Co-administration of oral midazolam with PREZISTA/rtv is CONTRAINDICATED.
Calcium Channel Blockers: felodipine, nifedipine, nicardipine	↑ calcium channel blockers	Plasma concentrations of calcium channel blockers (e.g., felodipine, nifedipine, nicardipine) may increase when PREZISTA/rtv are co-administered. Caution is warranted and clinical monitoring of patients is recommended.
Corticosteroid: Systemic: dexamethasone	↓ darunavir	Systemic dexamethasone induces CYP3A and can thereby decrease darunavir plasma concentrations. This may result in loss of therapeutic effect to PREZISTA.
Corticosteroid: Inhaled/Nasal: fluticasone propionate	↑ fluticasone propionate	Concomitant use of inhaled fluticasone propionate and PREZISTA/rtv may increase plasma concentrations of fluticasone propionate. Alternatives should be considered, particularly for long term use.

Table 6: Established and Other Potentially Significant Drug Interactions: Alterations in Dose or Regimen May Be Recommended Based on Drug Interaction Studies or Predicted Interaction (cont.) [See *Clinical Pharmacology (12.3)* in Full Prescribing Information for Magnitude of Interaction, Tables 8 and 9]

Concomitant Drug Class: Drug Name	Effect on Concentration of Darunavir or Concomitant Drug	Clinical Comment
Other Agents		
HMG-CoA Reductase Inhibitors: pravastatin, atorvastatin, rosuvastatin	↑ pravastatin ↑ atorvastatin ↑ rosuvastatin	Use the lowest possible dose of atorvastatin, pravastatin or rosuvastatin with careful monitoring, or consider other HMG-CoA reductase inhibitors such as fluvastatin in combination with PREZISTA/rtv.
Immuno-suppressants: cyclosporine, tacrolimus, sirolimus	↑ immuno-suppressants	Plasma concentrations of cyclosporine, tacrolimus or sirolimus may be increased when co-administered with PREZISTA/rtv. Therapeutic concentration monitoring of the immunosuppressive agent is recommended when co-administered with PREZISTA/rtv.
Narcotic Analgesic/ Treatment of Opioid Dependence: methadone, buprenorphine, buprenorphine/naloxone	↓ methadone ↔ buprenorphine, naloxone ↑ norbuprenorphine (metabolite)	No adjustment of methadone dosage is required when initiating co-administration of PREZISTA/rtv. However, clinical monitoring is recommended as the dose of methadone during maintenance therapy may need to be adjusted in some patients. No dose adjustment for buprenorphine or buprenorphine/naloxone is required with concurrent administration of PREZISTA/rtv. Clinical monitoring is recommended if PREZISTA/rtv and buprenorphine or buprenorphine/naloxone are coadministered.
Neuroleptics: risperidone, thioridazine	↑ neuroleptics	A dose decrease may be needed for these drugs when co-administered with PREZISTA/rtv.
Oral Contraceptives/estrogen: ethinyl estradiol, norethindrone	↓ ethinyl estradiol ↓ norethindrone	Plasma concentrations of ethinyl estradiol are decreased due to induction of its metabolism by ritonavir. Alternative methods of nonhormonal contraception are recommended.
PDE-5 inhibitors: sildenafil, vardenafil, tadalafil	↑ PDE-5 inhibitors	Sildenafil at a single dose not exceeding 25 mg in 48 hours, vardenafil at a single dose not exceeding 2.5 mg dose in 72 hours, or tadalafil at a single dose not exceeding 10 mg dose in 72 hours can be used with increased monitoring for PDE-5 inhibitor-associated adverse events.
Selective Serotonin Reuptake Inhibitors (SSRIs): sertraline, paroxetine	↔ darunavir ↓ sertraline ↓ paroxetine	If sertraline or paroxetine is co-administered with PREZISTA/rtv, the recommended approach is a careful dose titration of the SSRI based on a clinical assessment of antidepressant response. In addition, patients on a stable dose of sertraline or paroxetine who start treatment with PREZISTA/rtv should be monitored for antidepressant response.

In addition to the drugs included in Table 6, the interaction between PREZISTA/rtv and the following drugs were evaluated in clinical studies and no dose adjustments are needed for either drug [see *Clinical Pharmacology (12.3)*]: atazanavir, efavirenz, etravirine, nevirapine, omeprazole, ranitidine, and tenofovir disoproxil fumarate.

Other nucleoside reverse transcriptase inhibitors (NRTIs):

Based on the different elimination pathways of the other NRTIs (zidovudine, zalcitabine, emtricitabine, stavudine, lamivudine and abacavir) that are primarily renally excreted, no drug interactions are expected for these drugs and PREZISTA/rtv.

Other PIs:

The co-administration of PREZISTA/rtv and PIs other than lopinavir/ritonavir, saquinavir, atazanavir, and indinavir has not been studied. Therefore, such co-administration is not recommended.

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category C: PREZISTA should be used during pregnancy only if the potential benefit justifies the potential risk.

No adequate and well-controlled studies have been conducted in pregnant women. Reproduction studies conducted with darunavir showed no embryotoxicity or teratogenicity in mice, rats and rabbits. However, due to limited bioavailability and/or dosing limitations, animal exposures (based on AUC) were only 50% (mice and rats) and 5% (rabbit) of those obtained in humans at the recommended clinical dose boosted with ritonavir.

In the rat pre- and postnatal development study, a reduction in pup body weight gain was observed with darunavir alone or in combination with ritonavir during lactation. This was due to exposure of pups to drug substances via the milk. Sexual development, fertility and mating performance of offspring were not affected by maternal treatment with darunavir alone or in combination with ritonavir. The maximal plasma exposures achieved in rats were approximately 50% of those obtained in humans at the recommended clinical dose boosted with ritonavir.

In the juvenile toxicity study where rats were directly dosed with darunavir, deaths occurred from post-natal day 5 through 11 at plasma exposure levels ranging from 0.1 to 1.0 of the human exposure levels. In a 4-week rat toxicology study, when dosing was initiated on post-natal day 23 (the human equivalent of 2 to 3 years of age), no deaths were observed with a plasma exposure (in combination with ritonavir) of 0.1 of the human plasma exposure levels.

Antiretroviral Pregnancy Registry: To monitor maternal-fetal outcomes of pregnant women exposed to PREZISTA, an Antiretroviral Pregnancy Registry has been established. Physicians are encouraged to register patients by calling 1-800-258-4263.

Nursing Mothers

The Centers for Disease Control and Prevention recommend that HIV-infected mothers in the United States not breastfeed their infants to avoid risking postnatal transmission of HIV. Although it is not known whether darunavir is secreted in human milk, darunavir is secreted into the milk of lactating rats. Because of both the potential for HIV transmission and the potential for serious adverse reactions in nursing infants, **mothers should be instructed not to breastfeed if they are receiving PREZISTA.**

Geriatric Use

Clinical studies of PREZISTA did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger patients. In general, caution should be exercised in the administration and monitoring of PREZISTA in elderly patients reflecting the greater frequency of decreased hepatic function, and of concomitant disease or other drug therapy [see *Clinical Pharmacology* (12.3) in Full Prescribing Information].

Hepatic Impairment

No dose adjustment of PREZISTA/rtv is necessary for patients with either mild or moderate hepatic impairment. No pharmacokinetic or safety data are available regarding the use of PREZISTA/rtv in subjects with severe hepatic impairment, therefore, PREZISTA/rtv is not recommended for use in patients with severe hepatic impairment [see *Dosage and Administration* (2.3) and *Clinical Pharmacology* (12.3) in Full Prescribing Information].

Renal Impairment

Population pharmacokinetic analysis showed that the pharmacokinetics of darunavir were not significantly affected in HIV-infected subjects with moderate renal impairment (CrCL between 30-60 mL/min, n=20). No pharmacokinetic data are available in HIV-1-infected patients with severe renal impairment or end stage renal disease; however, because the renal clearance of darunavir is limited, a decrease in total body clearance is not expected in patients with renal impairment. As darunavir and ritonavir are highly bound to plasma proteins, it is unlikely that they will be significantly removed by hemodialysis or peritoneal dialysis [see *Clinical Pharmacology* (12.3) in Full Prescribing Information].

OVERDOSAGE

Human experience of acute overdose with PREZISTA/rtv is limited. Single doses up to 3200 mg of the oral solution of darunavir alone and up to 1600 mg of the tablet formulation of darunavir in combination with ritonavir have been administered to healthy volunteers without untoward symptomatic effects.

No specific antidote is available for overdose with PREZISTA. Treatment of overdose with PREZISTA consists of general supportive measures including monitoring of vital signs and observation of the clinical status of the patient. If indicated, elimination of unabsorbed active substance is to be achieved by emesis or gastric lavage. Administration of activated charcoal may also be used to aid in removal of unabsorbed active substance. Since PREZISTA is highly protein bound, dialysis is unlikely to be beneficial in significant removal of the active substance.

PATIENT COUNSELING INFORMATION

[See *FDA-Approved Patient Labeling* (17.5) in Full Prescribing Information]

A statement to patients and healthcare providers is included on the product's bottle label: **ALERT: Find out about medicines that should NOT be taken with PREZISTA.** A Patient Package Insert for PREZISTA is available for patient information.

General

Patients should be informed that PREZISTA is not a cure for HIV infection and that they may continue to develop opportunistic infections and other complications associated with HIV disease. The long-term effects of PREZISTA are unknown at this time. Patients should be told that there are currently no data demonstrating that therapy with PREZISTA can reduce the risk of transmitting HIV to others.

Patients should be told that sustained decreases in plasma HIV RNA have been associated with a reduced risk of progression to AIDS and death. Patients should remain under the care of a physician while using PREZISTA.

Instructions for Use

General

Patients should be advised to take PREZISTA and ritonavir (NORVIR®) with food every day as prescribed. Patients should be instructed to swallow whole tablets with a drink such as water or milk. PREZISTA must always be used with ritonavir (NORVIR®) in combination with other antiretroviral drugs. Patients should not alter the dose of either PREZISTA or ritonavir (NORVIR®), discontinue ritonavir (NORVIR®), or discontinue therapy with PREZISTA without consulting their physician.

Patients Taking PREZISTA Once Daily

If a patient misses a dose of PREZISTA or ritonavir (NORVIR®) by more than 12 hours, the patient should be told to wait and then take the next dose of PREZISTA and ritonavir (NORVIR®) at the regularly scheduled time. If the patient misses a dose of PREZISTA or ritonavir (NORVIR®) by less than 12 hours, the patient should be told to take PREZISTA and ritonavir (NORVIR®) immediately, and then take the next dose of PREZISTA and ritonavir (NORVIR®) at the regularly scheduled time. If a dose of PREZISTA or ritonavir (NORVIR®) is skipped, the patient should not double the next dose. Inform the patient that he or she should not take more or less than the prescribed dose of PREZISTA or ritonavir (NORVIR®).

Patients Taking PREZISTA Twice Daily

If a patient misses a dose of PREZISTA or ritonavir (NORVIR®) by more than 6 hours, the patient should be told to wait and then take the next dose of PREZISTA and ritonavir (NORVIR®) at the regularly scheduled time. If the patient misses a dose of PREZISTA or ritonavir (NORVIR®) by less than 6 hours, the patient should be told to take PREZISTA and ritonavir (NORVIR®) immediately, and then take the next dose of PREZISTA and ritonavir (NORVIR®) at the regularly scheduled time. If a dose of PREZISTA or ritonavir (NORVIR®) is skipped, the patient should not double the next dose. Inform the patient that he or she should not take more or less than the prescribed dose of PREZISTA or ritonavir (NORVIR®).

Drug Interactions

PREZISTA/rtv may interact with many drugs; therefore, patients should be advised to report to their healthcare provider the use of any other prescription or nonprescription medication or herbal products, including St. John's wort.

Patients receiving estrogen-based contraceptives should be instructed to use alternate contraceptive measures during therapy with PREZISTA/rtv because hormonal levels may decrease.

Fat Redistribution

Patients should be informed that redistribution or accumulation of body fat may occur in patients receiving antiretroviral therapy, including PREZISTA/rtv, and that the cause and long-term health effects of these conditions are not known at this time.



Manufactured for Tibotec, Inc. by:
JOLLC, Gurabo, Puerto Rico

Distributed by:
Tibotec Therapeutics, Division of Centocor Ortho Biotech Products, L.P., Raritan NJ 08869
Patent Numbers: 5,843,946; 6,248,775; 6,335,460 and other US patents pending
NORVIR® is a registered trademark of its respective owner.

PREZISTA® is a registered trademark of Tibotec Pharmaceuticals, Ltd.

© Tibotec, Inc. 2006

Revised: June 2009

1010709B

References: 1. US Department of Health and Human Services. <http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf>. Accessed November 3, 2008. 2. Data on file, Tibotec Therapeutics, Division of Centocor Ortho Biotech Products, L.P.

BREACHING THE BARRIERS, OVERCOMING THE CHALLENGES

Communities COLOR

QUESTION 3 If you answered “significant” or “moderate” or “some” changes to Question 2, please describe changes in this question. What specific changes have you made?

		RESPONSE PERCENT	RESPONSE COUNT
Additional education/training (CME)/Cultural Competence Conferences, etc)		62.9%	39
Addition of culturally competent staff to meet your changing needs		56.5%	35
Use of the Language Line		30.6%	19
Application for additional Federal Funds because of increasing patient demographic without/inadequate health insurance/medication insurance (Ryan White funds/ADAP/increasing need to acquire HMO coverage plans)		30.6%	19
Addition of Case Managers for changing population needs.		43.5%	27
Other (please specify)		14.5%	9
Answered question			62
Skipped question			46

a Seattle, WA clinic that served many African American patients.

“The biggest challenge with many African American and Hispanic men,” she said, “is they won’t admit that they have had sex with other men. I just diagnosed a 79-year-old who will not provide the names of his women partners because he does not want them to know. He probably got HIV from having unprotected male sex, but he will not admit it.”

Having that information is crucial for partner notification and preventing the spread of the virus. “In the black and Hispanic communities, being gay is often looked down upon, and I’ve had patients who have a girl friend just to cover up the fact that they are also having sex with men.”



Betsy Brown, MD, AAHIVS

continued from page 16

edge IV drug use than to disclose their sexual activities, many HIV specialists say. Although they may have sex with men, they do not consider themselves “gay,” Dr. Sitapati stressed. “They may or may not feel comfortable with that label. It’s tough enough to deal with HIV/AIDS, let alone having a label. We don’t want to prevent them from coming in for care because we have offended them in some way.”

“Let the patients tell us who they are and let us ask questions that will help us understand what their barriers are and how we can help to overcome them,” she advised. “Cultural competency is something we should strive for. Just by being open minded we can learn so much.”

Approaching Cultural Sensitivities

Cultural sensitivities are a major concern for Betsy Brown, M.D. AAHIVS, who cares for patients at the Southwest Care Center in Santa Fe, which serves patients from all over New Mexico, about 40 percent of whom are Hispanic and some 5 percent, Native American. Previously, she worked in

patients, there are also important cultural issues, including superstitions, to consider. Indirect questions often work best because some patients believe that talking about something directly “will make it happen,” Dr. Brown explained.

So “you have to say things like ‘If someone doesn’t take their medicine, then this could happen.’”

At her clinic, case managers and nurses team up with physicians to work with patients. “We will each talk to them about responsibility, and about privacy. We offer choice groups they can join to help them make the right choices about disclosure. That seems to help a lot.”

Having rapid testing available helps as well, she said, noting that many patients bring their partners in to be tested. “Reaching people and increasing the number of tests is really important,” she said.

Jonesy’s approach at Healing Wings is to be “very matter of fact” in such discussions. “I simply tell them, ‘these are some of the risk factors that apply to you.’ You have to make



Amy Sitapati, MD, AAHIVS

sure you cover all of the bases, provide advice regarding appropriate risk protection. This is not supposed to be some kind of punishment or confession. If they trust you, they reveal more things about themselves.”

Andrea Jefferson-Saboor, FNP-C, AAHIVS, a nurse practitioner at the AbsoluteCare Medical Center in Atlanta, says she sometimes “shocks” her patients with her direct, frank approach. Approximately 75 percent are African American, and increasing numbers of them women and teenagers.

AIDS medications: the Tuskegee conspiracy theory.

Originating from the U.S. government’s discredited 40-year syphilis study of black men started in 1932, there is still a persistent view among many black Americans that HIV/AIDS was deliberately launched by the government to kill blacks and gays. Among some, that suspicion has now apparently transferred over to a fear of taking their medications, according to some HIV specialists.

“My African American patients are much more worried than others about whether their antiretroviral medications are really good for them,” said Kathleen Clanon, MD, AAHIVS, who manages HIV services at the Alameda County Medical Center in Oakland, CA, where she has worked since 1988.

“They are more likely to know about Tuskegee and are still worried that medical institutions like the county hospital where I work do not have their best interests at heart. Although I assure them that is not the case, some simply think I am a dupe of the conspiracy.”

That belief has had tragic consequences for some patients who have resisted the drug therapy that has been proven to help HIV patients live much longer and relatively normal lives. “I have worried that they would die unnecessarily because of this hesitation,” Dr. Clanon said. “I had to do some

really hard listening to try to figure out what I could do to help people get past that hesitation and take advantage of new treatments. I had to learn that as a white person, there are limits about what impact my words or deeds would have.”

Some patients, no matter what, just could not trust their doctor, especially about medications. “The fear is that the medications will hasten their death, not help them,” she said.

All of this emphasizes the importance of trying to understand what is going on in patients’ lives, regardless of their ethnic background.

“The people I take care of are uninsured, and many have never had a job in the standard economy. They live in violent, scary neighborhoods and are very much on the edge economically,” said Dr. Clanon. “They have all the risk factors that lead to unsafe behaviors. My patients don’t believe they are going to be here a long time anyway. It’s like it’s a community-wide post-traumatic stress disorder, and that affects people’s sexual choices, their medical adherence, and when they decide to come to the doctor.”

Photo courtesy of Kathleen Clanon

QUESTION 4 Do you believe the government is doing enough to address the racial disparities related to HIV/AIDS in this country?

		RESPONSE PERCENT	RESPONSE COUNT
Yes		17.3%	18
No		82.7%	86
Answered question			104
Skipped question			4

“I have fairly decent success with patients meeting them where they are,” she said, “by being very direct and matter-of-fact. I ask the question, ‘Do you sleep with men, women or both?’ It breaks the ice. They can be open and real with me. There is no judgment here. We’re interested in their wellbeing and preventing the further spread of this disease.”

Clinical Pharmacist Jim Scott, PharmD, AAHIVE, who provides drug therapy management at the Jeffrey Goodman Clinic at the Los Angeles Gay & Lesbian Center in Hollywood, says many of the Hispanic patients, about half the clinic’s patient base are uncomfortable discussing their sexual orientation and practices, which can pose a barrier for providers.

“I’ve learned to be very straight-forward about this,” he said. “How they got it is not overly relevant, but how they are keeping secrets from loved ones and friends does become relevant when it comes to their medicine-taking behavior.”

Unfortunately, in many instances, patients will not take their meds because they want to keep their condition secret from their partners and friends. “Stigma is perceived to be greater among Latinos and African Americans” he said.

The Conspiracy Theory

There is another significant barrier that still exists, particularly among African Americans, when it comes to HIV/



Kathleen Clanon, MD, AAHIVS

To confront these issues, Dr. Clanon's clinic utilizes staff members who closely identify with the community. An RN and a medical assistant are local African American women and have known many of the patients since childhood. The safe sex counselor is an African American gay man.

"Patients connect with people in my office in different ways about different issues," Dr. Clanon explained. "They want to talk to me about their labs, but not their sex lives. Our RN is more likely to hear about medication adherence. But it's not just race. It's authority, role, class. There are limits to what patients will tell us, so we have to work in partnership with people from their community."

Providers, especially Caucasians working in communities of color, need to be "braver" when it comes to issues of race, Dr. Clanon contends.

"I try to be a braver white person," she said. "I ask my African American patients, when talking about starting ARVs, if they have heard anything about these meds maybe not working for them because they are black, and if so, I want to talk to them about that. I've never gotten a bad reaction. Sometimes they say to me, 'I'm not worried about it' which I think really means they ARE worried and they won't believe what I'm saying anyway."

Uncovering the Truth

Lori Fantry, M.D., M.P.H., AAHIVS, medical director of the Institute of Human Virology/University of Maryland Infectious Diseases Clinic in Baltimore, says similar concerns exist among African American patients there, with patients often being distrustful of their doctors – attitudes that complicate matters for providers.

"There are some people who hide their situation, or who acknowledge being bisexual because that is more accepted in society," she said. But there are also difficulties for providers who may experience discomfort in discussing a patient's sexual orientation and practices, thus having difficulty determining if a patient blaming his condition on IV drug use is actually practicing MSM and not acknowledging that.

"We may not be tuned into how to effectively discuss these issues," she admitted. "Maybe the patient is reluctant because of cultural taboos."

ROUTINE HIV TESTING AND REACHING COMMUNITIES OF COLOR:

The Bronx Knows!

BY ROB BANASZAK, DIRECTOR/ AAHIVM COMMUNICATIONS

THE BRONX, NEW YORK CITY, is celebrating a life-saving milestone: the one year anniversary of "The Bronx Knows," New York City's largest HIV testing initiative in history.

Launched in June, 2008, The Bronx Knows is a partnership between the NYC Department of Health and Mental Hygiene (DOHMH) and more than 68 community partners, including doctors, clinics, hospitals and community organizations. The goals of the three-year initiative are to test every Bronx resident between the ages of 18-64 for HIV who has never been tested, and to identify undiagnosed HIV-positive persons in the Bronx and link them to care. The Bronx Knows is also part of a wider effort to make HIV testing a part of routine medical care. The community knows first-hand about racial disparities involving HIV/AIDS. According to the 2000 U.S. Census, the Bronx is predominantly populated by

communities of color: 48.4 percent Latin American/Hispanic, and 35.6 percent Black/African Americans. "As is true in most other areas of the city, HIV/AIDS has disproportionately affected communities of color in the Bronx," said Dr. Monica Sweeney, Assistant Commissioner for the DOMOH's HIV/AIDS Prevention and Control. "By the end of 2007 (the last year of complete data), 50.8% and 43.7% of the Bronx's new HIV diagnoses were among blacks and Hispanics, respectively."

Because it has the highest HIV/AIDS rates of all the city's boroughs, The Bronx was selected by New York City as a pilot for the massive HIV testing initiative. In 2006, 829 Bronx residents tested positive for HIV – almost 25 percent of the New York City total. Also in 2006, 357 Bronx residents died of AIDS – nearly a third of the total AIDS-related deaths in New York City.

According to Thomas A. Farley, MD, MPH, Commissioner of New York City's Department of Health and Mental Hygiene, the initiative is well on its way to reaching the nearly 250,000 Bronx adults who have never had an HIV test, with an increase of HIV testing by 28 percent since last summer's kickoff.

An Interview with Dr. Sweeney

HIV Specialist recently interviewed Dr. Sweeney about The Bronx Knows and its impact on the community.

Q: How does this disproportionate impact on communities of color affect the messaging of The Bronx Knows program?

A: The New York City DOHMH works closely with its community part-

continued on page 25



Monica Sweeney, MD

Communities COLOR

BREACHING THE BARRIERS,
OVERCOMING THE CHALLENGES

In Charlotte, NC, J. Wesley Thompson, MHS, PA-C, AA-HIVS, DFAAPA, a physician assistant, works in a clinic with five other providers with a patient population of about 900 black, 500 white, 200 Hispanic, and 120 Asian. Fifty-five percent are male, and new cases are 73 percent MSM or MSWM and 48 percent black.

"The first challenge," he said, "is to establish trust and get accurate information on what risky behaviors might be going on and their readiness to take their medications."

But then there is "the Ninja." "Some will say, 'I can't ask someone out because I've got the Ninja (HIV),' " said Thompson. "A lot won't even try dating because they don't

out acknowledging their unsafe sexual practices.

"That's very much a piece of this as bad choices are made when you are chemically altered," he said, adding that some patients in Native American and Latino cultures, as well as from some Asian and African cultures, believe that by having sex with both men



Dan Wlodarczyk, MD

and women, "you are a higher or more evolved spirit," and others yet would say "There are no black gay men in the south!"

Thompson cited an interesting "language issue" involving a Hispanic patient who had read a warning on his meds cautioning against taking them with alcohol. He stopped taking the pills every Friday and Saturday night when he drank his beer. "So I had to change him to medications that allowed him to drink," Thompson said.

Dan Wlodarczyk, MD, AAHIVS, who works at the Southeast Health Center in the Baviw Hunters Point neighborhood in San Francisco and operates the Center's Early Intervention Program, has seen a significant shift of patients from primarily gay white men to many more people of color over his 25 years' experience.

The clinic's patient population is almost entirely African American, he said, and there an outreach staffer works the streets frequently visiting the jail, to connect with people who need to be tested for HIV.

"We have to work on all of their social needs, housing for the homeless, treating substance abuse, trying to get people into programs," he said. The clinic offers a \$10 Safeway card to patients if they come to the clinic and take their meds. Funded by the state of California and the San Francisco Department of Public Health, the clinic also provides healthcare services to the

partners of its HIV/AIDS patients.

"Some patients present really late," Dr. Wlodarczyk said, pointing out the tragic impact this can have on ultimate outcomes. "We try to work with them. They are seeing all of the members of our team. We have conferences and discuss patients' situations and needs. It is a multi-disciplin-

QUESTION 5 If you answered "no" to question #4, what else do you think the government should be doing?

		RESPONSE PERCENT	RESPONSE COUNT
Increase RW funding	<div></div>	77.3%	68
Revamp the Medicaid eligibility for chronic HIV/AIDS patients	<div></div>	61.4%	54
Include HIV/AIDS patient needs specifically in the healthcare reform package	<div></div>	78.4%	69
Other (please specify)	<div></div>	25.0%	22
Answered question			88
Skipped question			20

want to acknowledge their situation or they won't take their medications to other homes or out in public because they don't want people to see their medications."

Also, there are the "problem pastors."

"There are pastors in town that tell patients that they have to get over their homosexuality and that God is punishing them. I have heard pastors quoted and saying God will heal your HIV once you stop being a homosexual. That just frightens me," Thompson said. "I tell my patients that no loving God would ever treat you that way or expect you to do this. I have only practiced in the south, so I can only speak to practicing in the south, but guilt and guilt trip religion is so pervasive here that sometimes my first and most important step is to give the patient permission to forgive himself. We are all imperfect creations and make mistakes. My patients sometimes tell me no one else knows about their HIV status except me and, in effect, I become Father Confessor for those patients."

Many of Thompson's patients are also MSMs doing drugs with-



Lori Fantry, MD, MPH, AAHIVS

Photo at left courtesy of Lori Fantry; Photo above courtesy of Dan Wlodarczyk

ary approach. We talk to them about prevention, discuss their sexual practices, and how they can be safer.”

To do that, Jefferson-Saboor believes society needs to be much more aggressive when it comes to HIV testing and prevention.

“The prevention messages are not working. The focus is on safer sex for positives, taking a once daily pill and you will be fine. There is no fear of this disease.

“The preventive message we continue to communicate is to get on treatment and you’ll live a long life, and if you get your viral load undetectable, then you have decreased your chances of transmitting the virus,” she explained.

“I see it all the time. Women come in pregnant. They, as well as their partners, are convinced that as long as they keep their virus undetectable, the chances of transmitting the virus to their partner or unborn child decreases. This is true; however, there is still a chance of transmitting the virus because it is not 100 percent certain. I think a lot of people are willing to play Russian roulette,” she said.

“I don’t think we are getting the real story out about what it means to live with HIV, about the side effects of these meds and what that means, about the day-to-day life of having to take these anti-retrovirals and living with HIV,” Jefferson-Saboor asserted.

“The message for HIV prevention needs to be very powerful and about changing behavior. We need commercials like the fried egg commercial years ago about drug abuse; the one about ‘This is your brain on drugs.’

“Being honest and open with our patients and keeping it real,” she said, is the approach that is needed. “We sugar coat it. We don’t want to talk about sex, and sex is what is killing our community.”

Every day in virtually every HIV/AIDS clinic and practice across the country, HIV specialists wrestle with the challenges posed by HIV and its consequences, challenges that require careful listening, understanding, and the right approach depending on cultures and circumstances unique to patients from America’s communities of color.

They listen. They seek to identify and understand. They try to help. **HIV**

continued from page 23

ners and members of the Initiative’s steering committee to ensure the community’s voice is heard. We make every effort to produce culturally appropriate outreach materials in both English and Spanish, the two most widely spoken languages in the Bronx. The message delivery is also carefully planned, keeping our target audience in mind when considering the best ways to reach them.

Q: What have been the obstacles to routine testing?

A: Obstacles for providers have been staffing, the need for logistical changes in such locations as emergency departments that are already quite overloaded, questions about reimbursement for routine HIV screening, and a paradigm shift away from a risk-based testing model to a routine screening model.

Q: How does The Bronx deal with issues about cost and reaching people who are not currently receiving routine health care?

A: As part of the The Bronx Knows, the New York City DOHMH provides free test kits for all uninsured individuals to be tested and also provides free test kits to community-based organizations in the Bronx who do not have other dedicated funds for HIV testing. The Bronx Knows includes 20 of the largest community based organizations in the Bronx, and these organizations have ongoing relationships with their local client base, some of whom are not currently receiving routine health-care. Testing by these community-based organizations is an important way to reach those that would not otherwise be tested in health care settings.

Q: Are there any attempts to try to identify acute/early HIV infection?

A: Our DOHMH STD clinics now conduct pooled nucleic acid amplification testing to screen for acute HIV infection. By shifting to a routine HIV screening model, we are hoping to identify individuals with HIV early before they have symptoms, so they can have improved health outcomes.

Q: Are these programs paired with partner counseling and referral services?

A: Yes. All individuals who are diagnosed with HIV receive post-test counseling and prompt linkage to care. Partners are elicited by providers, and at some sites, with the assistance of our Field Services Unit.

Q: Has there been adequate local capacity to refer newly diagnosed people into treatment programs?

A: Yes, there has been adequate local capacity. We have received no complaints or concerns regarding the ability or capacity of treatment programs to absorb those who are being newly diagnosed as part of The Bronx Knows. **HIV**





Health Disparities: Wake-Up

DURING A DISCUSSION ON MINORITY HEALTH issues at the White House in June, U.S. Health and Human Services Secretary Kathleen Sebelius said the Obama administration is committed to addressing racial health care disparities, including the higher rates of HIV/AIDS among blacks.

The White House issued a summary report indicating that racial and ethnic minorities have high rates of debilitating diseases such as obesity, cancer, diabetes, and AIDS, adding that 48 percent of African American adults suffer from a chronic disease compared to 39 percent of the general population.

The report stated “HIV bears witness to the most extreme disparity in chronic disease. African Americans experience new HIV at seven times the rate of whites, and Hispanics experience new HIV infections at two and a half times the rate of whites.”

The document pointed out that “proper maintenance of HIV slows the virus from progressing to AIDS at nine times the rate of whites, and Hispanics are diagnosed with the disease at three times the rate of whites.”

“The disparities in healthcare ... demonstrate the need for reform,” the report declared. “Meaningful reform must invest in prevention and wellness and ensure that all Americans have access to high-quality, affordable care. We can no longer afford to tolerate disparities in health.” (The report, *Health Disparities: A Case for Closing the Gap*, is available at: http://healthreform.gov/reports/healthdisparities/disparities_final.pdf)

Healthcare Reform

The day before that report was issued, black, Latino, and Asian lawmakers warned that any healthcare reform bill that ignores health disparities between whites and America’s communities of color will face stiff opposition, saying it would be difficult for them to support a bill without a new

Photo: Stacy Newman / iStock

program providing access to healthcare for all Americans.

“The public health option has to be there,” said Rep. Mike Honda (D-CA), who chairs the Congressional Asian Pacific American Caucus. “If we don’t have a public option, there’s no discussion.”

Call

Members of the Asian caucus, as well as the Congressional Black Caucus and Congressional Hispanic Caucus, which combined form the Congressional TriCaucus, issued their healthcare reform priorities:

- **Ensure** universal and comprehensive access to quality healthcare.
- **Ensure** that achieving health equity and the elimination of health disparities are integrated objectives throughout the health reform bill.
- **Strengthen and coordinate** the agencies and offices with health jurisdiction.
- **Reverse** critical health workforce shortages and increase the diversity and cultural competence of health and healthcare professionals.
- **Ensure** that community-centric health efforts – particularly those that will focus on communities hardest hit by health inequities – are integrated in health reform.
- **Prioritize** prevention and public health promotion in both clinical and community settings.
- **Bolster** data collection, expand diversity in clinical trials, and ensure equitable implementation of health information technology (HIT).

Funding

President Obama’s FY 2010 budget request to Congress includes an estimated \$25.9 billion for combined domestic and global HIV/AIDS activities, an increase of about 4 percent over 2009.

The largest component of domestic programs, funded at \$19.4 billion, is for care, with a budget request of \$13.2 billion, up 6 percent over 2009, primarily due to increased mandatory spending for Medicaid and Medicare. The Ryan White Program is funded at \$2.3 billion, up \$54 million over 2009. That increase will be used to expand access to healthcare among uninsured and underinsured individuals living with HIV/AIDS and to help reduce

HIV-related health disparities.

The budget request also includes funding for the Minority AIDS Initiative (MAI), created in 1998 in response to growing concern about the impact of HIV/AIDS on racial and ethnic minorities in the U.S. The program provides funding across several agencies and programs and is funded at \$14.5 million, a slight increase over FY 2009 levels.

Meanwhile the National Institutes of Health announced a plan for HIV-related research that includes a focus on racial and ethnic populations, with two scientific objectives and strategies: Determinants of Risk and Intervention Research.

The Determinants of Risk objective is to develop and conduct population-specific primary research that focuses upon the individual, interpersonal, organizational, cultural, and community determinants of risk. The Intervention Research objective is to develop population-specific, theory-based interventions that focus upon individual risk, community norms, organizational, and socio-cultural factors, as well as biological susceptibility.

AAHIVM MINORITY TASKFORCE

In 2008, the AAHIVM created an HIV/AIDS Minority Taskforce, chaired by Marc Johnson, MD, AAHIVS. Comprised of seven AAHIVM members, the Minority Task Force unanimously identified three immediate priorities for the Academy’s addressing of HIV/AIDS in communities of color, which were approved by AAHIVM’s Board of Directors:

1. **The Academy should assume a strong leadership role in advocating for and the drafting of a National Strategic Plan for HIV/AIDS. That plan should include:**
 - advocating for the reauthorization of and increased funding for the Ryan White CARE Act.
 - advocating for increased reimbursement for HIV providers through Medicare and Medicaid.
 - advocating for HIV workforce expansion—including utilizing the National Health Service Corps Loan repayment Program.
 - collaborating with with other organizations to implement the CDC routine Testing Guidelines.
2. **The Academy should develop and implement an HIV Workforce Initiative to include the following elements:**
 - a system to reach out to and mentor health profession students regarding a career in HIV practice.
 - the development and funding of an HIV Workforce Expansion Grant Program, directed at undergraduate and graduate healthcare training programs.
 - the creation and administration of a Minority Early Practice Fellowship Program.
3. **The Academy should advocate for expanded funding of Part C of the Ryan White CARE Act.**

Communities COLOR

HEALTH DISPARITIES: WAKE-UP CALL

Act Against AIDS

The Centers for Disease Control and Prevention (CDC), as part of its new Act Against AIDS communication campaign, announced in April that it has launched a \$10 million, five-year partnership with 14 of the African American organizations.

The Act Against AIDS leadership Initiative (AAALI) seeks to harness the collective strength and reach of traditional, longstanding African American institutions to increase HIV-related awareness, knowledge, and action across the U.S.

CDC said the program would equip each organization with resources to deliver consistent and sustainable HIV prevention programs. Each organization will disseminate Act Against AIDS campaign materials and other prevention services. Examples of communication, mobilization, and outreach activities to be supported include:

- Integrating Act Against AIDS and other HIV prevention messages into African American community forums.
- Holding education and training sessions on HIV prevention at national and regional membership conventions.
- Giving Act Against AIDS and other HIV prevention public service announcements (PSA) prominent placement in African American broadcast and print outlets throughout the nation.
- Training and funding local chapters to implement community-awareness campaigns.

- Working to educate national, state, and local policymakers and community leaders about the role of HIV prevention in advancing the well being of African Americans.
- Extending campaign messages through organization publications, Web sites, and public appearances.
- Working with African American celebrities to produce additional PSAs.

Partnering organizations include:

- 100 Black Men of America.
- American Urban Radio Networks.
- Coalition of Black Trade Unionists.
- Congressional Black Caucus Foundation.
- National Action Network.
- National Association for the Advancement of Colored people (NAACP).
- National Coalition of 100 Black Women.
- National Council of Negro Women.
- National Medical Association.
- National Newspaper Publishers Association.
- National Organization of Black County Officials.
- National Urban League.
- Phi Beta Sigma Fraternity.
- Southern Christian Leadership Conference. **HIV**

MEDIA RESPONDS TO AIDS CRISIS IN BLACK AMERICA

A number of leading U.S. media companies announced in late June a coordinated national campaign to mobilize black Americans in response to AIDS and promote specific calls-to-action to prevent and reduce the further spread of HIV.

Greater Than AIDS – a multi-faceted campaign presented under a common brand that includes targeted public service ads as well as integrated messages in news, entertainment, and community content – seeks to strengthen a sense of community among black Americans in response to HIV/AIDS.

“The central idea behind the campaign is to remind us as black Americans that we are greater than any challenge we have ever faced, and that we are Greater than AIDS as well,” said Phill Wilson, Founder and CEO of the Black AIDS Institute, which is advising on the initiative. “It is about a shared responsibility in the face of AIDS – and hope for the possibility of an HIV-free future.”

The program is being produced in collaboration with the CDC’s Act Against AIDS program, a five-year communications effort intended to re-focus attention on HIV and AIDS domestically.

Company partnerships announced in June were:

- American Urban Radio Networks
- Clear Channel Communications
- ESSENCE Communications
- National Newspaper Publishers Association



**CLEAR CHANNEL
COMMUNICATIONS, INC.**



Research Study Focuses on Black Gay Men & HIV

IN SIX CITIES ACROSS THE NATION, a new study is underway designed as the first step to determining the most effective strategies for HIV prevention within the black gay community. It is hoped the information generated will provide valuable insights for HIV specialists who treat such patients.

Conducted by the HIV Prevention Trials Network (HPTN), the two-year study of sexually active black MSM is intended to uncover effective intervention approaches and prepare for a randomized community-level trial. Cities involved are New York, Washington, DC, Atlanta, Los Angeles, San Francisco, and Boston.

The study is funded by the National Institute of Allergy and Infectious Diseases at the National Institutes of Health, and will involve 2,418 participants, 403 per site.

On July 8, The Fenway Institute and the Multicultural AIDS Coalition announced its participation in the study for the Boston area, pointing out that black MSM currently have the highest rates of HIV acquisition among any minority ethnic and racial group of MSM in the U.S.

The Boston project, called Project S.O.S. (Saving Our-Selves), will evaluate whether the following HIV prevention strategies will be accepted by black MSM:

- **Providing testing, counseling and treatment referrals for HIV and other sexually transmitted infections.**
- **Encouraging black MSM to refer their sexual partners to participate in the study.**
- **Providing a peer health navigator trained to help black MSM access the healthcare services.**

The study hopes to capture information that will allow for a better understanding of black MSM, their lives and experiences, risks, attitudes, prejudices they face, their strengths, and how all of this relates to risk for HIV infection.

"In proportion to their numbers, black MSM are bearing the brunt of the HIV/AIDS epidemic in this country," said Gary Daffin, executive director of the Multicultural AIDS coalition. "We're hoping this study will begin to give us the tools to change that."

Ben Perkins, Project S.O.S. director at The Fenway Institute, said the study is intended to reach a broad cross-

section of Boston's black MSM, including those living as openly gay men, those who are keeping part of their lives private from friends and families, those who do not consider themselves gay or bisexual, and transgender blacks who either were born male or who identify as male.

"The study will recruit infected and uninfected men, trying to get at both acquisition and transmission," Perkins said. It will explore the impact of substance abuse, intimate partner violence; childhood sex abuse and trauma, religion, racism, discrimination and stigma.

"It's really a preventive study, and part of prevention is getting people tested. A lot of providers may not really understand who black gay men are. If a patient is married with a child, they may not be asked if they are having sex with men. But they may be," Daffin explained.



"We've got to educate healthcare providers that there are people who may be having sex with men but do not disclose," Daffin explained. "They have got to know enough to ask questions. Providers who are seeing black men need to be asking about risk and encouraging people to get tested. The study will provide information on who black men are, and how to respond and work with them successfully." **HIV**

For more information about this study, HPTN 061, please visit: http://www.hptn.org/research_studies/hptn061.asp.



At the

BY TONIA POTEAT, MMSC, PA-C, MPH, AAHIVS

FOREFRONT

Risk Factors: Black MSM

THE THIRD BIENNIAL MEETING of the American Conference for the Treatment of HIV (ACTHIV) was held in Denver, Colorado from May 15-17, 2009. This state-of-the-science conference delivered clinically relevant HIV management updates for frontline clinicians providing HIV care for adults, adolescents, children, and pregnant women in the United States.

The weekend began with a morning pre-plenary session, "HIV: The Basics," designed as a primer for those new to HIV care or a refresher for more experienced providers. In a little over two and a half hours, six speakers covered topics ranging from the history of the HIV epidemic to HIV pathogenesis, transmission, antiretroviral medications, clinical tests, and guidelines. The session closed with practical suggestions for building a patient-centered care model in the clinical setting.

The opening plenary began in the afternoon with timely discussion of the challenges and opportunities in HIV care and prevention for two of the populations profoundly impacted by HIV in the U.S.: women and MSM of color. Kathleen Squires, M.D., director of infectious diseases and environmental medicine at Jefferson Medical College of Thomas Jefferson University, Philadelphia, reviewed important considerations in the care of women with HIV. Gregory Millett, M.D., behavioral scientist at the Centers for Disease Control and Prevention in Atlanta, GA, discussed the implications of recent research on the HIV epidemic among black men who have sex with men (MSM). As the only session devoted solely to men of color, Dr. Millett's session has particular relevance for this issue of *HIV Specialist*.

Dr. Millett first reviewed a disturbing set of CDC statistics: After a steady decline during the 1990s, HIV/AIDS cases among MSM reached a plateau in the early 2000's and is now experiencing a sharp rise. Young black MSM (ages 13-24 years) have been particularly impacted by the epidemic with a rate of infection approximately two times that of young white MSM.

Dr. Millett challenged the notion that this increased risk of HIV infection is related to higher risk behaviors among young black MSM. Rather, he said, recent research indicates that black MSM are significantly less likely to engage in high risk behavior such as injection drug use and unprotected anal intercourse when compared with their white counterparts. He argues that black MSM are at greater risk for HIV infection because they

have poorer access to healthcare and, therefore, are more likely to have undiagnosed HIV disease. The transmission rate of new HIV infections due to unrecognized infection is more than three times that of people who know their HIV-positive status.

In addition, Dr. Millett said, black MSM are more likely to have sexually transmitted infections, which facilitate HIV transmission, and are more likely to have partners within sexual networks that include individuals at high risk for higher (e.g. older gay men, former inmates, etc.).

So what does this mean for clinicians providing care to black MSM?

Dr. Millett suggests that annual screening for HIV/STD screening is insufficient to keep up with the rate of infection in this population and suggests more frequent routine screening. He also recommended aggressive case management for HIV+ MSM to improve access to HIV care and treatment, thus reducing the likelihood of further transmission. Finally, he says, black MSM must be even more vigilant in engaging in safer sex practices than other groups because of the factors that place them at higher risk of infection even when practicing the same behaviors or less risky behaviors as other MSM.

The remainder of the plenary sessions addressed more typical clinical topics, such as HIV co-morbidities and complications, managing HIV treatment, sexual/reproductive health, viral hepatitis, substance abuse/mental health, and pediatric/adolescent HIV.

The conference provided skills and information that the busy clinician can immediately apply topics were timely, evidence-based, and presented by leading experts in the field of HIV prevention, care, and treatment in the United States.

The conference was so successful that the program committee has decided to hold it annually instead of biennially. Save the date for next year's ACTHIV 2010! More information about the 2009 conference, including copies of speaker presentations can be found at the website www.acthiv.org. **HIV**



About the Author: Tonia Poteat, MMSc, PA-C, MPH, AAHIVS currently cares for patients at Chase Brexton Health Services in Baltimore while completing her PhD in International Health at Johns Hopkins School of Public Health.



Best

BY RICHARD PROKESCH, MD, FACP

PRACTICES

THIRD IN A SERIES **EMR & the HIV Practice**

Implementation: The Moment of Truth

THE HARD WORK IS DONE. Or is it?

You have decided to purchase an EMR and thoroughly researched which product is best for your practice. Now, you're ready to move forward.

Actually, implementing the EMR is the most daunting step in the process and where many practices (up to 50% in some studies) fail—either abandoning the EMR conversion or, more commonly, only partially implementing the full spectrum of functions the EMR can provide. However, with careful planning and diligent execution, your practice can avoid these pitfalls and successfully utilize the EMR for which you made a significant financial outlay.

USE TRAINING TO ITS FULLEST

When choosing your EMR, it is important to understand what training is available. Almost all vendors build a certain number of training/implementation hours into the purchase contract. Do your homework. Check references to see if the vendor delivered on training as promised, and if training personnel were effective. In our case, the first person sent to train our practice was condescending and a poor communicator. My office staff and I got nothing out of the training sessions, and I had to complain loudly and often to get another trainer for our office.

Decide beforehand who will be involved in training sessions. For a small practice it might be everyone, but a larger practice may wish to select a champion for each area: a physician, front office person, billing person, medical assistant/RN, etc. These should be people interested in the EMR, who want the change to succeed, and who have the capability of training other office personnel after they are trained.

It is not a good idea to have the person or persons who are most skeptical or opposed to the change to EMR involved in the initial training because they can easily undermine the entire process.

HAVE A ROADMAP

The trainer should assist your practice in devising an im-

plementation plan, as the process is a logistical challenge. As mentioned in previous articles, I suggest phasing in the EMR rather than trying to implement all functions simultaneously. Consider starting with the piece that is the most pressing need for the practice—something that can be of immediate benefit. For instance, if retrieval of laboratory data has been cumbersome, electronic linkage to your lab could be the initial phase. If the billing process is a nightmare, implement the billing module initially. If clinical documentation is a problem, start with the clinical element.

Realize it is an evolutionary process to achieve full and optimal EMR implementation. It's like your golf game: a work in progress where you will probably never attain perfection. However, you can be extremely functional, and then continue to improve.

Develop a plan to phase-in each aspect of the EMR modules with a timeline, and select a champion to keep the implementation process moving forward. Expect the EMR to initially slow down the practice machinery. Everyone should realize from the start that there is a learning curve, but the end process will be more efficient and often quicker. The champion is the key to continuously reminding practice personnel of the final goal.

In the final article of this series in the next issue, we will discuss EMR implementation with emphasis on the clinical module. Should you go “cold turkey” and throw away all paper or should you start with a “paper light” strategy? Do you only use templates, or is voice activation dictation the way to go? How much of your paper records do you scan into the EMR or store elsewhere?

At the end of this series I hope you will appreciate the benefit for your HIV practice in evolving to an EMR. **HIV**



About the Author: Richard Prokesch, MD, FACP is in private practice in Riverdale, GA. He is chair of AAHIVM's Atlanta, GA chapter, and is on AAHIVM's Board of Directors.



Prevention is Care

BY J. KEVIN CARMICHAEL, MD, AAHIVS

QUIKPICS

TIPS & TACTICS ABOUT:

Incorporating Prevention Messages Into Regular Office Visits

IN THE LAST ISSUE OF *HIV SPECIALIST*[™] we discussed several key points that may offer some guidance in preparing to address prevention messages with HIV-infected patients. This issue, we deal with one of the most challenging points of all: *how do we open this dialogue?*

BROACHING THE SUBJECT

I like my patients to be active participants in managing their HIV—and I emphasize that prevention is part of that. Rather than lecturing a patient about transmission, I remind them that they are doing great on their medications and even though their viral load is undetectable, they can still transmit HIV. I ask if they have questions about how HIV is transmitted. Or, about whether something what they are doing could be transmitting it?

I also find that certain scenarios are ideal for broaching the subject of prevention. Here are a few I encounter fairly frequently and how I've handled them successfully with patients.

If a female patient who has disclosed her HIV status to her partner tells me that her partner refuses to use condoms, I tell her she's doing the right thing by using protection and I ask her to bring her partner in to discuss condom usage with me. Even if you can't persuade the partner, you've shown the patient that you support her.

If a patient repeatedly assures me that he always uses condoms—then shows up with syphilis, I say, "First we have to treat the syphilis—and this shot is going to hurt. Then we have to test your partner. Then we have to discuss how you think this could have happened." Often patients are practicing "safer" sex but most STDs can be transmitted by activities that fall into the "safer" category such as oral sex. We have to be sure patients really understand the

nuances between safe and "safer" and encourage all patients to be as safe as possible rather than labeling them a failure and breeding a nihilistic attitude.

If both partners have HIV and feel they don't need condoms,

I tell my patients that I can understand their thinking. I also inform them that by choosing not to use condoms they could compromise their health by getting another STD or a resistant strain of HIV that's worse than the strain they have now. It's important to emphasize how their actions could negatively impact their health.

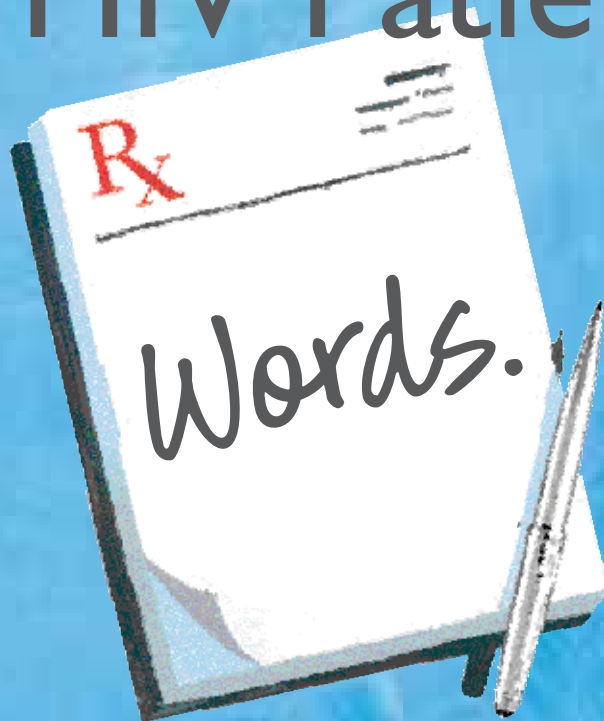
PREVENTION IS CARE
Screen for risky behavior.
Prescribe healthy behavior.

If a patient in a serodiscordant relationship who consistently uses condoms tells me that their condom broke, I first let them know that I appreciate they were trying to protect their partner by using condoms; then, I ask if the partner would like to begin prophylactic drug therapy. It does happen and here, I try to be there to support both partners. **HIV**



About the Author: J. Kevin Carmichael, MD is an AAHIVM-Credentialed HIV Specialist and Family Practice physician who works exclusively with patients with HIV and AIDS at El Rio Community Health Center in Tucson, Arizona which is funded in part by Ryan White Parts B and C. He is also co-chair of the Ryan White Medical Providers Coalition and former board member of the Southwestern Board of AAHIVM. He has been working with HIV patients since 1986.

The Latest Approach to Caring for HIV Patients?



DISCUSSING PREVENTION HELPS PROTECT YOUR PATIENTS AND THEIR PARTNERS

Although people living with HIV often adopt healthy behaviors upon initial diagnosis, many revert back to risky behavior after time. Risky behaviors can lead to acquiring an STD, which can jeopardize a patient's health; and untreated STDs increase the risk of transmitting HIV to partners. Research shows that integrating brief prevention transmission discussions into each patient visit helps reduce risky behaviors. The Centers for Disease Control and Prevention created the *Prevention IS Care* campaign and Web site to support providers who treat people living with HIV. To receive FREE materials that translate scientific evidence into practical tools for providers and patients, visit www.cdc.gov/PreventionISCare or call 1-800-458-5231.

PREVENTION  IS CARE
Screen for risky behavior.
Prescribe healthy behavior.



ACT
against
AIDS

First impressions
matter


REYATAZ[®]
(atazanavir sulfate) 200 mg/300 mg
capsules



Bristol-Myers Squibb

© 2009 Bristol-Myers Squibb Company, Princeton, NJ 08543, U.S.A.
687US09AB08810 04/09