

**Presidential Advisory Council on HIV/AIDS (PACHA)
54th Meeting
Hubert H. Humphrey Building
U.S. Department of Health and Human Services (HHS)
Washington, DC
September 4–5, 2014**

Council Members—Present

Nancy Mahon, J.D., PACHA Chair
David Holtgrave, Ph.D., Vice Chair
Ada A. Adimora, M.D., M.P.H.
Lucy A. Bradley-Springer, Ph.D., RN,
ACRN, FAAN
Gina M. Brown, M.S.W.
Vignetta Charles, Ph.D.
Cecilia C. Chung
William H. Collier
Michelle Collins-Ogle, M.D., FAAP
Patricia Garcia, M.D., M.P.H.
Grissel Granados, M.S.W.
Robert Greenwald, J.D.
Douglas A. Michels, M.B.A.
Ligia Peralta, M.D., FAAP, FSAHM,
AAHIVMS
Mario Pérez, M.P.H.
Alton B. Pollard III, Ph.D.

Harlan H. Pruden
Scott A. Schoettes, J.D.
Rev. Vanessa D. Sharp, M.Div.,
M.A.C.M., M.A.T.M.
Lawrence A. Stallworth II
Elizabeth Styffe, M.S.N.
Mildred Williamson, Ph.D., M.S.W.

Council Members—Absent

Dawn Averitt
Humberto Cruz, M.S.

Staff

Kaye Hayes, M.P.A., PACHA Executive
Director
Caroline Talev, M.P.A., Public Health
Analyst

Federal Liaisons

Eva Margolies, M.P.A., Associate Director for Planning and Policy Coordination, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention (CDC)
Ronald O. Valdiserri, M.D., M.P.H., Deputy Assistant Secretary for Health, Infectious Diseases; Office of HIV/AIDS and Infectious Disease Policy, Office of the Assistant Secretary for Health, HHS

Presenters

Douglas Brooks, M.S.W., Director, White House Office of National AIDS Policy (ONAP)
Kevin Cranston, M.Div., Director, Bureau of Infectious Disease, Massachusetts Department of Public Health

Michael A. Horberg, M.D., M.A.S., FACP, FIDSA, Executive Director of Research,
Community Benefit, and Medicaid Strategy, Mid-Atlantic Permanente Medical Group;
Director, HIV/AIDS, Kaiser Permanente

Joseph Interrante, Ph.D., Chief Executive Officer, Nashville CARES

Wanda Jones, Dr.P.H., Acting Assistant Secretary for Health, HHS

Amy Killelea, J.D., Associate Director, Health Care Access, National Alliance of State and
Territorial AIDS Directors (NASTAD)

Amy Lansky, Ph.D., M.P.H., Deputy Director for Surveillance, Epidemiology, and
Laboratory Science, Division of HIV/AIDS Prevention, CDC

Henry Masur, M.D., Chief, Critical Care Medicine Department, National Institutes of
Health (NIH)

Leandro Mena, M.D., M.P.H., Associate Professor of Medicine, University of Mississippi
Medical Center

Terrance Moore, Director, Policy and Health Equity, NASTAD

Michael Murphree, L.C.S.W., Chief Executive Officer, Medical AIDS Outreach of Alabama

Patrick Sullivan, Ph.D., D.V.M., Center for AIDS Research, Rollins School of Public Health,
Emory University

John Ward, M.D., Director, Viral Hepatitis Program, Division of Viral Hepatitis, National
Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, CDC

DAY 1

Welcome and Introduction

PACHA Chair Nancy Mahon called the meeting to order at 9:11 a.m. and welcomed the 11 new members of the Council, 3 returning members, and meeting participants. Ms. Mahon said it is an enormous privilege to serve on the Council, and she encouraged members to raise issues about which they are passionate. She outlined the agenda and thanked PACHA member David Holtgrave, Ph.D., for taking on the role of Vice Chair.

Remarks by Wanda Jones, Dr.P.H., Acting Assistant Secretary for Health, HHS, and Swearing-In of New PACHA Members

Dr. Jones said Secretary Sylvia Burwell was sworn into office in June and brings a sharp focus to the work of some 300 advisory committees. Secretary Burwell wants concrete, actionable recommendations so that she knows what she can do to make progress on issues that the committees address.

Dr. Jones thanked the outgoing PACHA members for their service. The changes in the field of HIV over the past 30 years have been phenomenal, said Dr. Jones, and the members of PACHA are part of that change. The Affordable Care Act (ACA) represents a significant change in just the past 5 years. It is not perfect, Dr. Jones acknowledged, and there is work to do to ensure coverage and access to care for people living with HIV/AIDS (PLWHA).

The success of HIV treatment shifted HIV from a terminal condition to a chronic disease. Now, too often, hepatitis C virus (HCV) kills PLWHA. In the United States, despite advancements in knowledge and treatment, Dr. Jones noted, we are grappling with the high price of medications and an HCV epidemic. Fewer than one-half of infected people know they are infected. The U.S. Preventive Services Task Force (USPSTF) recommended that all baby boomers (those born between 1945 and 1965) be tested.

Dr. Jones said she relies on Deputy Assistant Secretary for Health Ronald O. Valdiserri, M.D., M.P.H., PACHA Executive Director Kaye Hayes, and others to keep her informed. On behalf of HHS, Dr. Jones thanked PACHA members for their commitment to the Council, the Administration, HHS, PLWHA, and the world. Dr. Jones then swore in the new and returning Council members.

Roll Call

Ms. Hayes called the roll.

Message From Douglas Brooks, M.S.W., ONAP Director

Mr. Brooks greeted the Council on behalf of the President and everyone at the White House. He said he would seek the Council's advice on specific issues and urged members to focus on areas in which action can be taken. The President is committed to doing

what he can “with the pen and the phone,” said Mr. Brooks, and much work is underway.

Across the Federal Government, beyond HHS, people know the goals of the National HIV/AIDS Strategy (NHAS) and are familiar with the care continuum for PLWHA (the steep dropoff at each milestone from testing to suppression of the virus). They are committed to working toward the goal of an AIDS-free generation. In addition to advising ONAP and HHS, Mr. Brooks urged PACHA members to use the prestige of their position to inform constituents and colleagues about the tremendous effort being made by the Federal Government.

The previous ONAP director identified five priorities for the office, to which Mr. Brooks added four more:

- **Further implement the HIV Care Continuum Initiative.** Mr. Brooks set a goal of identifying the 16 percent of PLWHA who do not know their status and the 29 percent who have dropped out of care. He asked for novel suggestions from the Council on how to reach those people.
- **Update the 2015 NHAS targets.** Mr. Brooks recommended the Viral Hepatitis Action Plan as a model for renewing and updating the strategy. He urged PACHA to provide advice on updating the targets and to take ownership of the effort.
- **Monitor the status of the Ryan White HIV/AIDS program and its coordination with the ACA.** The ACA may one day prove to be the most important legislation in U.S. history, Mr. Brooks said, but it should evolve. It is still too soon to cut funding for the Ryan White program altogether.
- **Align resources according to the epidemiological data.** Mr. Brooks urged PACHA to consider how to provide the resources needed as new geographic and population-specific increases in infections are identified, while keeping in mind the consequences of shifting resources and undoing existing systems.
- **Develop public–private partnerships to augment Federal efforts.** Public–private partnerships can offer funding and community connections to advance efforts in ways the Federal Government cannot do alone.
- **Address employment issues for PLWHA who want to return to work.** This issue came from PACHA, and there are some resources available through the Department of Education’s Rehabilitation Services Administration to address it. Mr. Brooks suggested that PACHA convene experts in the field, devise a plan with concrete steps, and make recommendations to ONAP on how to proceed.
- **Address the intersection of violence against women and girls and HIV.** An annual report, mandated by White House Executive Order, is in development; PACHA members are working closely with ONAP; and a public–private partnership with AIDS United is focused on this topic.
- **Reduce HIV and health disparities in the southern United States.** Mr. Brooks appreciated PACHA’s focus on strategies to address the topic.

- **Reduce HIV-related health disparities among gay and bisexual men, particularly men of color.** An upcoming White House-sponsored meeting will be the first step toward developing an action plan for 2016, said Mr. Brooks.

Mr. Brooks encouraged communities and organizations to think about strategic alliances, including links with large medical providers, that are vital to ensuring that PLWHA get care, as well as links with social and behavioral services. Finally, Mr. Brooks said, it is important to collect and analyze surveillance data more rapidly. The best data available for updating NHAS targets for 2016 come from 2013.

Panel: HIV/AIDS in the Southern United States: Implementation, Best Practices, and Solutions

Moderator: Ada Adimora, M.D., M.P.H., PACHA Member

Mission: To End the AIDS Epidemic in the United States

Vignetta Charles, Ph.D., Senior Vice President, AIDS United, PACHA Member

The AIDS United effort known as Southern Reach focuses on strengthening local networks, developing State coalitions, advocacy training, educating policymakers, and combating HIV criminalization. These efforts have resulted in some unusual and innovative partnerships. For example, the North Carolina Harm Reduction Coalition transformed conservative law enforcement personnel into advocates for syringe decriminalization and needle-stick prevention efforts. Progress by AIDS Alabama in meeting housing needs for PLWHA sparked new housing initiatives around the region.

Other best practices spawned by Southern Reach include the Louisiana Public Health Institute's program for formerly incarcerated PLWHA in Baton Rouge, which has expanded to other cities. Researchers at the University of Virginia are piloting a smartphone application in rural Virginia that promises to be a scalable, cost-effective intervention.

Dr. Charles said the best practices her organization has identified are:

- Supporting organizations that leverage broader systems
- Working collaboratively for social justice
- Seeking to end HIV exceptionalism
- Thinking beyond "the usual suspects."

Nashville CARES: Pursuing the Goals of the NHAS in Middle Tennessee

Joseph Interrante, Ph.D., Chief Executive Officer, Nashville CARES

To increase access to care for PLWHA, Nashville CARES trained medical, dental, pharmacy, and public health students to train others on screening in clinical and community health settings and integrated the training into curricula for nursing and

dental students. These cost-effective efforts contribute to workforce development and expose students to issues related to HIV screening, counseling, and linking to care.

Since 2008, Nashville CARES has provided assistance to families and individuals to purchase comprehensive health insurance. A peer management system identifies clients who have not seen a provider for 3 months and prompts contact to enhance retention and treatment adherence.

I Am Strong is a peer-designed and peer-delivered program that focuses on optimal health. Developed and tested through the Vanderbilt Institute for Global Health, *I Am Strong* participants are more likely to get care and achieve viral suppression than are nonparticipants. The program recognizes the unique and varied challenges PLWHA face.

Nashville CARES is analyzing survey data from 300 PLWHA who are getting services but not medical care. The data will be used to create a weighted risk scale to estimate the risk of dropping out of care, which will be used to target interventions to clients at risk. Dr. Interrante concluded that the work of Nashville CARES is summarized by a principle of *I Am Strong*: When “I” is replaced by “we,” “illness” becomes “wellness.”

Open Arms Healthcare Center: A Partnership To Address the HIV Prevention and Care Needs of Young African American Men Who Have Sex With Men (YAAMSM)

Leandro Mena, M.D., M.P.H., Associate Professor of Medicine, University of Mississippi Medical Center

Dr. Mena described a dismal combination of poverty, lack of access to care, and high rates of HIV in Mississippi, particularly among YAAMSM. Any effort to improve access to high-quality HIV prevention and care services must address the State’s socially conservative environment. Even PLWHA with insurance sometimes avoid care because of concerns about confidentiality and provider competency, as well as past experiences with the health care system.

The Open Arms Healthcare Center is the product of numerous collaborations to provide HIV clinical services, primary care, counseling, and treatment and social services such as free transportation, meals, and medical assistance. State public health laboratories conduct all of the Center’s laboratory analysis at cost. Philanthropists provide technical assistance. The University of Kentucky conducts research; research dollars provide clinical support. Everyone working at the clinic receives competency training.

Key to the collaboration is developing mutually beneficial partnerships in which all partners respect the contributions of the others. Such partnerships need time to grow and mature. Partners should be willing to compromise, Dr. Mena noted.

HIV in the South: Implementation, Best Practices, and Solutions for Raising the Bars

Terrance Moore, Director, Policy and Health Equity, NASTAD

Mr. Moore summarized NASTAD's priority issues for 2014, including its focus on addressing "the bar before the bars"—that is, the stigma and social determinants that affect an individual's care along the continuum before a diagnosis is even made. He described three projects funded by the Federal Care and Prevention in the United States Demonstration Project in southern States.

Tennessee created social networking strategies among African American MSM and reached out to the corrections community. It improved clinical outcomes by targeting resources to PLWHA who have been out of care or have had a suboptimal response to care. It also is addressing the bar before the bars by focusing on ingrained mistrust, stigma, and homophobia. The State is reducing barriers to employment and housing.

To improve HIV testing and linkages to care, Virginia relies on community health workers to re-engage those who drop out of care, taking a "warm hands" approach and focusing on African American MSM. It initiated a pilot project to provide temporary housing for PLWHA recently released from prison.

Louisiana has been a leader in the use of surveillance data. Working with State laboratories and hospitals, the State has identified PLWHA who are not linked to care and engaged and retained them in care.

Telemedicine: Innovation With a Southern Accent

Michael Murphree, L.C.S.W., Chief Executive Officer, Medical AIDS Outreach of Alabama

Certain counties in Alabama have a concentration of disparities, including high HIV infection rates, high poverty rates, and shortages of health providers. Medical AIDS Outreach of Alabama provides clinical care to PLWHA in collaboration with State providers who offer social services. Thanks to telemedicine, the network of providers has expanded to cover most of the State.

Mr. Murphree described some of the technology that supports telemedicine in remote areas. Clients have come to accept and appreciate the approach. Telemedicine can be effective in any setting and is useful for social work services, mental health care, and even pharmacologic treatment.

Among the barriers to telemedicine are buy-in from collaborating partners and State and local leaders, upfront investment in technology, and work space issues. Mr. Murphree said Alabama's political environment is a significant barrier.

Social Determinants of HIV and the South

Patrick Sullivan, Ph.D., D.V.M., Center for AIDS Research, Rollins School of Public Health, Emory University

Dr. Sullivan pointed out that the incidence of HIV among YAAMSM in Atlanta is 12.1 percent, compared with 1 percent to 3 percent for other groups. African Americans in Atlanta reported greater stigma than whites even in the same geographic areas, which likely contributes to African American MSM bypassing care or not revealing their status to their providers. An analysis of the infection rate found that two key characteristics accounted for the higher rate of infections among YAAMSM when compared with whites: lack of health insurance and a sexual network of other African American MSM.

Dr. Sullivan recommended some areas to consider:

- Health insurance is critical, and tools are available to help more people obtain insurance. For example, Emory created a mobile application that helps men assess their own risk of HIV and encourages them to sign up for health insurance through a link to the State health exchange.
- Efforts should be made to engage around the issue of HIV in YAAMSM; the high prevalence of HIV among YAAMSM is entrenched and requires attention.
- Both short- and long-term plans are needed to address stigma, including more investment and leadership in the science of stigma and stigma reduction.

Questions and Answers (Q&A)

What are the challenges, costs, pitfalls, and sustainability concerns of providing health insurance assistance?

Dr. Interrante responded that Nashville CARES has research demonstrating the effectiveness of peer management programs. He stressed the importance of good communication between community providers and researchers. *I Am Strong* is part of a larger university program. The startup cost of *I Am Strong* was approximately \$50,000, Dr. Interrante estimated.

Nashville CARES has had to pressure some city clinics to comply with the ACA and help enroll eligible clients. Nashville CARES has a custom-built data system that helps the organization manage costs, gather rebate data, and avoid errors. When Tennessee eliminated its expanded Medicaid program, Nashville CARES had to move its clients into a guaranteed-issue policy, and premiums rose. Overall, about 2,100 people enrolled at a cost of \$9 million in 2013, but Nashville CARES brought in \$10 million in rebates, which made up 30 percent of the State's safety-net funds.

The Nashville CARES approach would not be sustainable without rebates and Ryan White program funds, said Dr. Interrante. Mississippi and Alabama have expressed interest in developing systems similar to that of Nashville CARES.

Can the Nashville CARES approach be replicated in other States? We need data on outcomes but also on the funding generated from the effort that contributes to care.

Dr. Interrante said the program requires a significant investment in building a database to manage the program and ensure accountability. Also, it is important to operate as a community-based organization (CBO), not a private entity, so that patient advocacy always comes first. In Tennessee, efforts are funded through a competitive bidding contract, not a grant. Federal funds are used exclusively for insurance continuation, and State funds are used to pay monthly client fees, through which Nashville CARES covers client costs. Administrative funds are not an issue, said Dr. Interrante.

What are the legal and reimbursement issues of implementing telehealth?

Mr. Murphree said that Alabama has finally acknowledged that telemedicine is appropriate care. The Ryan White program, Medicare, and Medicaid in Alabama all allow telemedicine; Blue Cross Blue Shield of Alabama supports telemedicine but will not reimburse for it. Mr. Murphree said the electronic medical records (EMRs) that are part of the telemedicine approach are strongly encrypted and protected.

What can be done to ensure the survival of university-based clinics?

Dr. Mena said funding is always important. Open Arms is a not-for-profit organization, relying on a network of CBOs and advocates, ensuring low overhead costs, and building up services over time. One-half of the clients have insurance, which provides some income to treat the uninsured. Partnerships can help minimize costs; for example, the State public health laboratories perform all tests at cost for Open Arms. The organization reviews its costs quarterly to find better options. Volunteers enroll clients in insurance plans.

Dr. Interrante added that his organization has 10 years of data demonstrating that even before the ACA, the State spent one-third less per client by buying insurance than it did buying medications through the AIDS Drug Assistance Program (ADAP). The approach is “back-door Medicaid,” said Dr. Interrante. It also moves people into the marketplace, where it is cheaper to enroll them in insurance plans, even without subsidies.

Smaller organizations will find it much harder to give up their own rebates, and that is probably the biggest barrier to replication.

Mr. Brooks responded that strategic alliances are especially important for managing such situations.

What is the strategic vision for HIV decriminalization efforts, and what outcomes have been realized?

Dr. Charles said that at the individual level, AIDS United funds training and technical assistance for legal providers and justice advocates. It also convenes people across the Deep South to discuss risk prioritization, specific cases, discriminatory practices, and best practices to address criminalization. At the local level, AIDS United targets specific

legislation. The most well-known effort was support for Women With a Vision in New Orleans, which ultimately overturned a law about crimes against nature that has been on the books since the 1800s. It required all sex workers to register as sex offenders, which meant they could not drop their own kids off at school, among other things. At the national level, AIDS United keeps up with Federal efforts related to HIV criminalization.

Are programs reaching immigrant populations? Are there any estimates of the number of undiagnosed immigrants with HIV in the South?

Dr. Mena said the immigrant population in Mississippi is relatively small. He is among those reaching out and developing community advocacy groups to bring more Hispanics into care. The current political environment poses challenges. Also, reaching men is harder than reaching women, said Dr. Mena, because of the stigma of HIV.

How are Native American, two-spirit, and immigrant communities being engaged?

Mr. Murphree said his organization has a doctor from Peru who works well with Spanish-speaking clients and another person who has gone into the community to bring into care people from Guatemala and Honduras, for example. Alabama has a stringent anti-immigrant law; one federally qualified health center (FQHC) sends workers into the community because so many undocumented people are afraid to drive to the center since the law passed.

Regarding First Peoples, Mr. Murphree said his organization has links with the Cree Nation, which has been a great resource. The Cree Nation has funding from the Indian Health Service and its own casinos that help fund services.

How do we engage people in the ACA, build relationships, and break down walls?

Dr. Charles said that Southern Reach has set aside funds for HIV advocacy in Latino communities in the Deep South. Latino Southern Reach meets regularly and shares information.

Dr. Interrante responded that Tennessee, including Nashville, does not do very well in serving Latinos. The numbers do not justify the effort, so the population is not served, and the State does not know how many people may be affected by HIV. A request for proposals aims to address the Latino community in the State.

Who are the leaders in the science of stigma?

Dr. Sullivan referred the questioner to the literature. He said there are scales and measures about stigma, but there is room for growth in studying stigma interventions.

Is the science of stigma different from stigma as a sociological phenomenon?

Dr. Sullivan replied that the science starts with the concept that stigma influences choices about testing, seeking health care, and disclosing one's status. Research looks at anticipated, perceived, and experienced stigma and how each relates to behaviors.

If we identify the life events that surround an individual's decision to drop out of care—employment problems, coming out to one's family, relationship issues—we see points for potential intervention, said Dr. Sullivan. So the first step is to gather data on health-seeking behaviors as a foundation. At the community level, for example, Atlanta began a public awareness billboard campaign aimed at breaking down stereotypes. The next step is to devise metrics to measure how people respond to the billboards.

Mr. Moore said NASTAD just completed a 2-year quantitative study with researchers at Columbia University that measured stigma in public health practices. It looked at stigma in different categories (race, HIV status, and gender norms) and found high rates of stigma in the South but also in parts of the Midwest. The study results will be used to inform strategies for working with public health providers to reduce stigma.

How much is homophobia and HIV stigma in the black community related to other social determinants of health, such as unemployment and poverty?

Homophobia is pervasive in the black community, and we need to chip away at it, said Mr. Moore. But the focus should be on a long-term strategy to help men—especially young, black gay men—navigate the system. Dr. Charles added that there is research on HIV stigma from other countries also grappling with stigma and care.

Has Southern Reach funded transgender-specific initiatives?

Dr. Charles said the program funds advocacy, and some partners have worked with transgender advocates. For example, OASIS in Florida organizes the Positive Living and Activate U conferences, and Southern Reach gives scholarships to transgender people to attend for advocacy training. Transgender people have always been part of the portfolio but are not a specific target, said Dr. Charles.

Regarding the data on aggravated sexual assault involving prostitutes, how can we change how things are recorded?

Dr. Charles noted that a South Carolina incarceration program has faced the issue of transgender women in male facilities and similar issues. Dr. Interrante clarified that the question refers to an evaluation of 10 years of Nashville arrest records for prostitution. Under Tennessee law, if a person is arrested for prostitution and is HIV-positive, he or she is charged with aggravated prostitution and, if convicted, is labeled a sex offender.

With the upcoming elections, what are your organizations doing to work with the electorate and State leaders opposed to the expansion of Medicaid?

Mr. Murphree said the Alabama Hospital Association is advocating for expansion. The State's Medicaid program will not survive without the additional Federal funding, and the Governor knows that. If the current Governor is reelected, many think he will accept expansion in January.

Dr. Interrante said Nashville CARES is part of two coalitions: a community-based group that mobilizes CBOs and individuals and a super-coalition that includes the hospital association, AARP, and the Chamber of Commerce and aims at power brokers. Dr. Interrante said there was a decision not to prod the Governor, who has been inconsistent on the issue. He said he did not want Medicaid to be a reason for repealing the ACA. The Tennessee coalitions are now focusing on Senate and House leadership. Dr. Interrante believes that people know that the numbers support expansion. Some rural hospitals have closed because of the lack of Medicaid expansion.

Mr. Moore said the biggest barriers are at the State government level. NASTAD is encouraging advocates to better educate State policymakers about quality of care, economics, and the importance of systems change. Most policymakers can get on board with system change. Mr. Moore hoped that after this election, some recalcitrance will eviscerate. Two candidates running for governor in Texas have signaled a move toward Medicaid expansion. Mr. Greenwald raised concern that Texas will fund premium assistance but not implement Medicaid expansion the way northern States have.

What is replicable now, and what can PACHA do to help?

Panelists said the following approaches can be replicated now:

- Telehealth, smartphone applications, increased use of technology in rural areas
- Insurance assistance programs
- Community-based centers for health and services, scaled-up models for linking to care
- Research that focuses on outcomes (such as viral load), use of iterative data, transparent data, gathering data at finer geographic levels (e.g., mapping the HIV/AIDS Care Continuum Initiative by race down to the city level)

Panel: Hepatitis C and the Impact of the Affordable Care Act

Moderator: Patricia Garcia, M.D., M.P.H., PACHA Member

The Role of Public Health in the Test and Cure Era for Hepatitis C

John Ward, M.D., Director, Viral Hepatitis Program, Division of Viral Hepatitis, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, CDC

Dr. Ward described the prevalence of HCV (an estimated 2.7 million people in the United States) and its natural history. Two-thirds of those with HCV were born between 1945 and 1965 (known as the birth cohort). Before 1989, most infections were caused by contact with unscreened blood; now, injection drug users (IDUs) have the highest prevalence.

About 25 percent of PLWHA also have HCV. HIV hastens the progression of HCV. Liver disease caused by HCV is the second leading cause of death for PLWHA. Sexual transmission of HCV, especially among MSM with HIV, has been reported in Europe and the United States.

CDC and USPSTF both recommend HCV testing for all those born between 1945 and 1965, all PLWHA, and others at high risk. Testing offers an opportunity to engage individuals in treatment. Curative HCV treatment is available. Full implementation of the recommendations could avert 120,000 HCV-related deaths. The approach also is cost-effective. Only about one-half of people with HCV know their status. The care continuum for HCV mirrors that of HIV; only 6 percent of those with HCV are successfully treated.

CDC is improving HCV surveillance and monitoring; developing policies for data collection, screening, and treatment; mobilizing partnerships; and building mechanisms into programs to support continuous performance assessment and improvement. Where HCV and HIV overlap, Dr. Ward suggested the following strategies:

- Address HCV in peer education and CBO outreach
- Promote integration of HIV and HCV services
- Ensure that PLWHA receive referrals for other preventive care, including HCV testing
- Support syringe services programs and address the availability of sterile syringes (where allowable)

HCV/HIV Coinfection in Massachusetts

Kevin Cranston, M.Div., Director, Bureau of Infectious Disease, Massachusetts Department of Public Health

Mr. Cranston estimated that approximately 200,000 people in Massachusetts have HCV. Beginning in 2009, the State began seeing more cases of HCV in IDUs under age 30.

Infections among the younger cohort are increasing relative to infections among the birth cohort. Some data show HCV infection in infants, suggesting potential perinatal transmission.

Prescriptions for sofosbuvir (Sovaldi) in Massachusetts' Medicaid program data spiked as soon as it became available. Some patients complete the Medicaid prior approval process but do not get the drugs, so it is important to pay attention to the care continuum even when a payment system is in place.

Reported cases of coinfection of HIV and HCV have declined as a result of decreases in HIV infection. The coinfecteds tend to be older than those who have HCV only. Among the coinfecteds, 14 percent are incarcerated.

Preliminary modeling of the impact of using ADAP resources to treat all coinfecteds people in Massachusetts calculated a total cost of \$2 million. However, all but the incarcerated pay some portion of drug costs. Because of the State's Medicaid expansion efforts and the availability of subsidized plans, reliance on ADAP is shrinking. Mr. Cranston proposed that investing \$1.4 million to cover all drug costs for coinfecteds, incarcerated people—when coupled with housing, employment, and other social support after release—could have a significant effect on HCV.

HCV in Transition: Opportunities for Progress

Henry Masur, M.D., Chief, Critical Care Medicine Department, NIH

Dr. Masur emphasized the speed at which researchers identified HCV and created a safe, effective, well-tolerated cure. However, 2014 data show that only 9 percent of those infected with HCV have achieved sustained viral suppression, and there are many opportunities to improve engagement and retention across the care continuum. The newest HCV regimens have a 95 percent cure rate with few side effects. The barriers to treatment are the cost of the drugs and the limited availability of health care expertise.

Treating HCV does not require advanced expertise but does require more personnel than are currently available. The American Association for the Study of Liver Diseases and the Infectious Diseases Society of America recommend treatment for all patients with chronic HCV infection. In terms of prioritization, the organizations recognize that those with advanced disease may benefit more immediately than others, but the recommendation is founded on the premise that everyone benefits from treatment.

An ideal HCV regimen would be effective against multiple genotypes (and so require less laboratory testing for diagnosis) and, like HIV treatment, be available as combination therapy using fewer pills. Some people with early-stage disease might be successfully treated with much shorter courses of therapy, which would decrease the cost.

Kaiser Permanente Mid-Atlantic States' (KPMAS) HCV Program

Michael A. Horberg, M.D., M.A.S., FACP, FIDSA, Executive Director of Research, Community Benefit, and Medicaid Strategy, Mid-Atlantic Permanente Medical Group; Director, HIV/AIDS, Kaiser Permanente

KPMAS has programmed EMRs to prompt doctors to test all those born between 1945 and 1965 and those at high risk. For those who test negative, the EMR prompts the clinician to counsel the patient about maintaining health. A positive screening result triggers a cascade of confirmatory tests. Those coinfecting with HIV are referred to an infectious disease specialist for management. Those with chronic HCV are referred to a nurse for coordination of care and testing, including disease staging; they also are entered into a registry to facilitate quality assurance and research efforts. Thanks to noninvasive staging tests, clinicians can better stratify individual patients' risk.

Dr. Horberg said no KPMAS member will be denied HCV treatment. However, the cost is substantial: for a 12-week regimen: sofosbuvir costs \$84,000, and simeprevir costs \$66,000. Treating all known HCV-infected members would cost Kaiser Permanente \$4.2 billion, or 84 percent of the organization's total drug budget. Dr. Horberg emphasized that providers want to treat patients but also must be good stewards of the financial resources.

HIV offers some lessons that can be applied to HCV:

- Multidisciplinary care teams are critical for successful treatment, given the interplay of clinical and social factors affecting health.
- Inclusion in the multidisciplinary care teams of providers with experience treating chronic disease and clinical pharmacists who coordinate drug regimens leads to successful management.
- EMRs help team members share information in real time and prompt providers to act when appropriate.

Q&A

There is limited funding for syringe exchange programs or wraparound services. What would be the effect of tying funding for such programs and services to HCV screening?

Dr. Ward responded that both approaches decrease the spread of HCV but not to the same degree as they do for HIV. It is important to look at other aspects of injection drug use that may affect HCV infections, such as sharing of apparatus and drug preparation. Prevention may require a more involved strategy than needle exchange. Dr. Ward added that the incidence of HCV is growing in areas with the fewest services, such as rural areas.

Mr. Cranston noted that in States with a significant investment in needle exchange programs, the Federal limitations have not been a practical challenge, because such programs are not very expensive to operate. However, it is challenging to locate the

programs in the right places. Younger adults need to be engaged in a different way, said Mr. Cranston. Needle exchange programs provide an opportunity to link people to clinical treatment and substance abuse programs. Massachusetts only has five such programs, because each program requires public support from local politicians.

What can be done to prevent HCV infection among IDUs, especially among young people?

Dr. Ward said we need to know a lot more about individuals' entry into injection drug use, their networks, and their social practices; available preventive services; and what can be enhanced. CDC recently funded data-gathering efforts in Cincinnati and Albuquerque.

Mr. Cranston said that community-wide sharing of information among IDUs on decreasing infection led to a dramatic reduction in incidence. Young and old IDUs do not seem to mix very much, which may have benefits but also prevents younger members from obtaining community knowledge. Younger IDUs tend to use more in private than older IDUs. Dr. Horberg reiterated that with HCV, the equipment involved in injection drug use is highly infectious, not just the needles.

What is the thinking related to supervised injection sites for IDUs?

Mr. Cranston said Federal law prohibits States from exploring such options, but he is impressed by efforts in Vancouver, especially the impact on overdosing. Focusing on overdosing can be an effective hook. Younger IDUs are more concerned about overdosing than other IDUs. Programs for the use of naloxone (Narcan) to treat overdose are well distributed.

Dr. Ward said other options are available. CDC is making a considerable effort to deal with overdosing. Increases in opioid prescriptions are followed by overdoses and HCV infection, so there should be more focus on opioid use, he suggested.

Once HCV is treated, is reinfection possible?

Dr. Masur said it is possible. The literature addresses whether some people are less likely to become reinfected after treatment. We need to know how to select patients who will benefit from drug treatment most and not relapse.

Is treatment as prevention a consideration with HCV?

Dr. Masur said that with IDUs, needle exchange is important. There are good candidates for HCV treatment who will continue using. Treatment as prevention makes sense, but the question is how to design an effective strategy.

Dr. Ward said multiple models show a profound impact on prevention and incidence with a treatment strategy for IDUs, but we lack field trials to show the best way to implement such an approach. Should we test and treat all, or try to identify the best

candidates for treatment (based, for example, on likelihood of adherence and the ability to monitor patients in a methadone maintenance clinic)? Should we contact partners of IDUs and treat them? We have the models and the tools, said Dr. Ward; we need field experience, especially with such expensive drugs. He added that HCV intervention is more powerful than HIV treatment, so treatment as prevention should work.

What is the role of rapid testing and alternative algorithms for testing?

Mr. Cranston said rapid tests provide rapid results, but they are restricted to antibody results. For surveillance purposes, a whole panel of tests is desirable. Survey data show a tremendous lack of follow-up to confirm infection and then move patients into treatment. Rapid tests have a role to play, though. Massachusetts is moving to more blood-based screening because it better identifies the extent of infection.

Dr. Ward said rapid tests have a role in settings where people need immediate information or in outreach settings (among individuals who are less likely to get routine care). Rapid tests are another tool to increase testing. The critical next step is to confirm the infection and refer the patient to care.

Please address the algorithm for testing.

Dr. Ward explained that if an HCV antibody test is positive, the individual is then tested for HCV RNA, which determines the presence of current infection. Dr. Horberg elaborated on KPMAS' approach. The laboratory collects two blood samples, one of which is tested for antibodies while the other is refrigerated for follow-up testing. The initial antibody tests can be handled by providers, but follow-up testing for HCV requires more intermediate steps than for HIV, so more provider education is needed.

Is there a danger of losing patients? How do you follow those who are not candidates for immediate treatment?

Dr. Horberg said retention is important, and staging the disease is another step in the continuum. The test-and-treat approach is not pragmatic right now. As a result, there are two continuums: one tracks the progress of those for whom treatment is deferred but monitoring is ongoing; the other tracks those who are treated and involves ensuring that the patient gets the right drug, adheres to the regimen, and achieves viral suppression. Even among those with advanced disease, monitoring is still needed to detect ongoing liver disease and the development of liver cancer.

Dr. Masur agreed that ongoing monitoring is important. He questioned whether patients will be sufficiently impressed that the system is investing \$100,000 or more to cure their disease. There is no disincentive to treatment. HCV treatment is not lifelong therapy, as with HIV. We need to develop policies that are ethical and humane. We need more trials to see what works, keeping in mind that what works in one population will not necessarily work in others.

Why does HCV seem to affect predominately white people? Does the demographic profile of HCV look different from that of HIV? Where do lesbian, gay, bisexual, and transgender people fit in to the demographics of HCV?

Dr. Ward said that in the birth cohort, the prevalence of HCV is about twofold higher in blacks compared with all other races/ethnicities. For men in their 50s, the prevalence is as high as 15 percent. Mortality rates are higher among blacks than whites.

Younger adults with HCV tend to be white, Dr. Ward continued. Data from the Youth Risk Behavior Surveillance System indicates that about 2 percent were IDUs. Black boys had the highest likelihood of injection drug use, but that is not reflected in HCV infection data. Dr. Horberg said one theory is that the initial entry to drug use begins with abuse of prescription drugs that belong to a parent, so there could be some socioeconomic or demographic factors associated with that scenario.

How do people get access to treatment in States that are not fully implementing the ACA? Some insurers limit prescription of HCV drugs to gastrointestinal (GI) specialists.

Dr. Horberg said such restrictive policies are “ludicrous.” Infectious disease specialists know how to treat HCV, and many HIV specialists do, too. It also is ridiculous to deem anyone with evidence of active drug use as ineligible for treatment, Dr. Horberg continued. Risk reduction is needed, but prohibiting treatment among IDUs is wrong. However, Dr. Horberg noted, the current cost of treatment is not sustainable.

Dr. Masur said successful treatment depends on clinician experience. Not every health care provider is capable of caring for a person with advanced liver disease. There are only 7,000 liver specialists in the United States. Some people with advanced cirrhosis need a GI specialist, Dr. Masur conceded, but many can be cared for by a primary care provider. The decision should not depend on credentials but on experience. Restricting prescriptions to hepatologists is effectively limiting care. Dr. Garcia pointed out that PACHA could advocate on this topic.

Dr. Ward said most people with HCV are not active IDUs, incarcerated, or on Medicaid. To combat stigma, we should strive for accuracy.

Are pregnant women at risk of enhanced disease progression for HCV?

Dr. Masur said it is hard to see progression over the course of a 9-month event. Most think it is not prudent to treat pregnant women because of questions about teratogenicity.

Is HCV transmitted by the placenta or during delivery?

Dr. Garcia said cesarean delivery is not a recommended method of delivery.

Are there gender differences in acquisition or treatment of HCV? Do we need to pay more attention to the coinfecting?

Dr. Ward said there is a 5 percent risk of transmission if coinfecting. The risk of chronicity in children infected at birth is high (93 percent). CDC recommends that a child born to a woman known to be infected should be tested for HCV. HCV testing also is recommended for everyone with HIV. The current guidelines recommend against testing pregnant women because there is no treatment, but it is time to reevaluate that recommendation, said Dr. Ward.

Dr. Masur said that a pregnant woman with HCV should be treated, but timing is complicated because of the unknown teratogenicity and the opportunity to treat after delivery. Recognizing that the child is at risk is important, however. There are few data on dosing for children or how quickly disease progresses in them. Most trials show a high response rate, said Dr. Masur, and every population tested so far responds to treatment. By reducing the length of treatment, clinicians will be able to find some treatment duration that works for some patients and not others.

Dr. Ward added that men progress faster to severe liver disease than women. Men also have a greater likelihood of cofactors, such as alcohol abuse.

Viral Hepatitis Action Plan and Reflecting Thoughts

Ronald O. Valdiserri, M.D., M.P.H., Deputy Assistant Secretary for Health, Infectious Diseases; Office of HIV/AIDS and Infectious Disease Policy, Office of the Assistant Secretary for Health, HHS

Dr. Valdiserri drew attention to the recently revised document, *Combating the Silent Epidemic of Viral Hepatitis: Action Plan for the Prevention, Care and Treatment of Viral Hepatitis*, first released in 2011. In April 2014, HHS and the departments of Housing and Urban Development, Justice, and Veterans Affairs updated the plan with specific action steps for 2014–2016. The new edition more explicitly addresses what non-Federal partners can do to implement the plan.

Dr. Valdiserri pointed out that the CDC/Health Resources and Services Administration (HRSA) Advisory Committee for HIV and STD Prevention and Treatment (CHAC) also focuses on HIV and HCV. He suggested that PACHA identify a new liaison with CHAC now that Antigone Dempsey no longer plays that role.

Dr. Valdiserri highlighted some key differences between HIV and HCV infection:

- HCV is not transmitted sexually nearly as frequently as HIV.
- There is a definitive cure for HCV.
- The American public has little awareness about HCV, and even health care providers lack understanding of the magnitude of the problem. Globally, advocacy for addressing HCV is just getting started.

- There is no U.S. program to meet the needs of uninsured or underinsured people with HCV. The most tangible success so far has been the USPSTF Grade B recommendation for screening.
- The surveillance systems for viral hepatitis are lacking.
- Research on hepatitis lacks cohort studies.

Dr. Valdiserri reminded the group that State Medicaid directors face difficult budget constraints. Ideally, there would be resources available to treat all people with HCV. However, where there are resource or capacity constraints, there is a framework for stratifying risk. Even those with HCV who are not treated immediately will benefit from diagnosis and care. Because there are not enough doctors available to treat people with hepatitis, provider teams should be considered.

HHS Teen Pregnancy Prevention Programs and Evidence Review Update

Robert Greenwald, J.D., PACHA Member

Mr. Greenwald explained that he and former PACHA member Kathie Hiers worked with the Office of the Assistant Secretary for Planning and Evaluation's Office of Adolescent Health (OAH) to better understand the protocol for designating a sexual education curriculum as effective in meeting the goals of the Teen Pregnancy Prevention Initiative. Specifically, HIV educators and advocates raised concerns about the Heritage Keepers abstinence-only education curriculum, which is included on OAH's list of effective programs despite limited data on effectiveness, questions about medical accuracy, and complaints that it allegedly promotes sexist and offensive stereotypes.

The OAH review protocol focuses exclusively on the methodology of the research used to demonstrate the effectiveness of the curriculum. It does not take the content into account. The Heritage Keepers curriculum uses offensive stereotypes throughout and relies on limited and outdated data. The OAH evaluation found the curriculum to be only moderately effective on a single metric: delayed sexual initiation. The Heritage Keepers Web site aimed at parents promotes the curriculum as "proven effective," "nondiscriminatory," and "federally sanctioned."

Mr. Greenwald and Ms. Hiers recommended that OAH screen curricula for discriminatory language and offensive stereotypes, then assess the medical and scientific accuracy of the content before evaluating the methodology of supporting research. If the screening raises questions, OAH should return the curricula for revisions.

To better inform consumers, OAH should amend its labeling and oversight practices. Marketing materials should identify which measures of effectiveness the curriculum did and did not meet. The labels used should be better qualified so that potential purchasers and users better understand them. OAH's assessment of the level of

effectiveness should be prominently conveyed. Finally, OAH should make sure companies understand and follow HHS guidelines for marketing their curricula.

In mid-August, OAH updated its list of evidence-based education curricula and made significant changes to its Web site. Heritage Keepers remains on the list, but users can now see the methods used to evaluate curricula. New language states that meeting the criteria for inclusion does not constitute an endorsement. For each curriculum, the OAH Web site prominently shows which measures were met and describes the quality of the evidence of effectiveness. When viewed alongside the other curricula, Heritage Keepers is clearly an outlier. The Web site now explicitly states that the content of the curricula has not been evaluated.

Mr. Greenwald applauded the progress made and hoped to continue evaluation. He said HHS seems to fear that if its criteria are too strict, no curricula will meet them. He countered that giving students and parents better information increases the likelihood of reducing teen pregnancies and transmission of HIV and other sexually transmitted infections. Mr. Greenwald invited new PACHA members to assist him in his effort.

National HIV “Dashboard” of Critical Metrics

David Holtgrave, Ph.D., PACHA Vice Chair, and Amy Lansky, Ph.D., M.P.H., Deputy Director for Surveillance, Epidemiology, and Laboratory Science, Division of HIV/AIDS Prevention, CDC

Dr. Holtgrave explained that PACHA is charged with evaluating the implementation of the NHAS. PACHA has discussed with many Federal representatives the key metrics aligned with NHAS goals and how data are collected and used.

Dr. Lansky presented CDC data used to measure progress on three of the four NHAS goals. Most data come from the National HIV Surveillance System, the Medical Monitoring Project, and the National HIV Behavioral Surveillance System. These sources collect data at various levels and in varying granularity. It is estimated that the United States has 1.1 million PLWHA. The rate of new infections has been stable for a while at about 50,000 per year, and the death rate has remained at about 20,000 per year.

Goal 1: Reduce new infections.

The overall rate of new infections declined from 2006 to 2010, but has been stable in recent years. Rates of new infections are decreasing among heterosexuals, IDUs, and African American women. Drilling down into data on new infections by race/ethnicity reveals higher rates among younger people of color, with the highest rates among YAAMSM. About one-fourth of new infections occur in people younger than 25 years old. The rate of HIV transmission decreased 9 percent from 2006 to 2010, and the number of people who know their serostatus improved in each of those years.

Goal 2: Increase access to care and improve health outcomes for PLWHA.

Even when the measures of progress are specific, different data sources can reach different conclusions about the same issue. For example, the NHAS goal seeks to ensure that 90 percent of newly diagnosed PLWHA are linked to care within 3 months of diagnosis. While the number of those linked to care reached 80 percent by 2011, the rate was lower (75 percent) for African Americans and higher (85 percent) for whites.

Data from 2010 show that we are far from the NHAS targets for increasing the proportion of PLWHA who are in continuous care and who have permanent housing. However, the denominator used to calculate rates has a significant impact, as does the definition of the measures. The denominator can include, for example, all PLWHA, only those diagnosed (as captured by CDC surveillance systems), or only those receiving medical care (reflected in Ryan White program and Medical Monitoring Project data). Retention can be defined in various ways; “engaged” can mean an individual had one visit or test in a year. Dr. Lansky stressed the importance of using a variety of data to measure progress.

Goal 3: Reduce HIV-related disparities and health inequities.

The overall rate of viral suppression in 2010 was 39 percent, but the rates varied among subgroups—some slightly higher, some lower. CDC monitors other related measures, such as the proportion of late-stage diagnoses, which has remained stable since 2006.

In mid-September, CDC will publish State progress reports on selected NHAS goals. The data suggest that the NHAS 2015 goals may be achievable, but there are gaps to address in some States. The findings highlight the utility of CDC data in demonstrating progress and informing the use of resources. For example, of the 10 States with the highest HIV death rate, 8 are in the South.

Finally, Dr. Lansky acknowledged that the timelines for data collection and analysis are not ideal. Data are collected over 12-month periods, and processing the data—for example, matching them with death records—can take as long as 18 months. Analyzing the data and presenting the findings can take 12 to 24 months. CDC is updating its methods to improve data processing times. However, data for measuring whether the NHAS goals for 2015 were achieved will not be available for 1 to 2 years after the end of 2015.

Dr. Holtgrave asked PACHA to consider some questions:

- Does PACHA want to comment on the data timelines?
- Does PACHA want to further address the HIV epidemic among YAAMSM?
- Should PACHA address the HIV epidemic among young people?
- Does PACHA want to focus on the need for investments in access to care and housing for PLWHA and people with HCV?

- Should PACHA consider a combination prevention strategy that addresses behavior, social determinants of health, and medical preventive care (proposed by the International Antiviral Society)?
- Should PACHA recommend revising the NHAS goals for 2015 or setting goals for 2016–2020?

Discussion

Andrew Forsyth, Ph.D., of the Office of the Assistant Secretary for Health, pointed out that contractors are working with HHS to sift through 1,700 data elements that inform the HIV care continuum, which delays the release of data significantly. Ms. Dempsey, director of the Division of Policy and Data at the HIV/AIDS Bureau at HRSA, said her agency relies mainly on Ryan White program data, which is robust but limited to those who receive Ryan White program services. Those data indicate that only 51 percent of younger people are achieving suppression, and the rates for YAAMSM are even lower.

Ms. Mahon pointed out that her company would never make decisions using 2-year-old data. She asked whether a dashboard of metrics related to PLWHA is feasible given that no single agency is responsible for all the data and that producing data is time-consuming. Dr. Valdiserri pointed out that in the long term, integrated EMRs will improve the timeliness of data collection. He said nine States have laws that either do not allow HIV reporting or do not require it. In the short term, standard systems must become more nimble.

Creating a dashboard using available data is one option, but existing data overlook some subgroups (e.g., transgender men and women and Native Americans), and complete reporting is not required in all States. Asked whether preliminary data could be released more rapidly, Dr. Lansky said releasing preliminary data can be as time-consuming as processing data. Dr. Forsyth pointed out that the story has not changed; he asked how we can use the data we have now to optimize resources for the people who need them most. CDC is considering ways to speed up data collection, such as community-based surveillance systems, and focusing on target groups, such as transgender men and women and sex workers. Future goal-setting efforts should take into account the availability of mechanisms to measure progress. Some assessments can be made using partial data.

Ms. Mahon shifted the focus to the increasing rates of infection among African American MSM, asking whether PACHA should call on the President to declare a state of emergency. There was some discussion about the unintended consequences of a formal declaration of emergency.

Mr. Brooks said ONAP has asked the Institute of Medicine to convene a group of experts to discuss modeling HIV/AIDS data. Also, ONAP is hosting a meeting focused on gay and

bisexual MSM with HIV, and Mr. Brooks hopes to engage the advocacy community on the topic. He urged PACHA to select a few topics on which to focus their energies.

A PACHA member raised some other areas PACHA should explore:

- Younger people want to access testing and technology on their own time, in their own homes, using their own tools (e.g., home HIV testing kits), partly to minimize stigma and partly because they access care differently from older people.
- FQHCs are a safe environment for immigrants and others to enter the care system.
- Clinics are shouldering the burden of patients being discharged from hospital emergency departments because the hospitals want to avoid readmissions.

DAY 2

Call to Order and Roll Call

Ms. Mahon called the meeting to order at 9:35 a.m., and Ms. Hayes called the roll.

ACA and Ryan White Program Update

Successes and Challenges in the ACA: Beyond Access

Robert Greenwald, J.D., PACHA Member

As many as 45 percent of PLWHA who had been receiving services under the Ryan White program became insured through the ACA in 2014, whether through expanded Medicaid programs or private insurance plans. Mr. Greenwald said expanded Medicaid coverage generally includes comprehensive care at low costs; many PLWHA are receiving comprehensive care for the first time, and they are very satisfied. However, Medicaid programs do not provide all the wraparound services that the Ryan White program does. The new arrangements are not working as well for PLWHA who moved to private insurance plans, said Mr. Greenwald.

One goal of the ACA was to improve transparency so that consumers could compare options and make informed choices in selecting and using their plans. Yet, plans are providing inadequate information on drugs covered and their costs as well as provider networks. An evaluation of plans in 17 States found that 49 percent lacked formulary information and 15 percent lacked provider network details. States operating their own health exchanges performed less well than those using federally run exchanges. Under some plans, beneficiaries are subject to 50 percent coinsurance costs for certain drugs.

Mr. Greenwald called on PACHA to make the following recommendations to HHS to improve transparency:

- Require all private plans to provide complete, accurate, and accessible formulary information in a standard format, including actual out-of-pocket costs to enrollees.
- Limit the ability of plans to change benefits and costs after the end of the open enrollment period.
- If plans change benefits or costs in such a way as to deny access to care and treatment, allow beneficiaries to change plans under the “qualifying event” provision.

Some plans provide inadequate coverage of drugs, Mr. Greenwald continued. Some single-drug regimens for PLWHA still are not covered, more than one-fourth of HIV drugs are not covered, and new utilization management approaches are being imposed

for HIV drugs. Mr. Greenwald said HHS should consider the following to improve coverage:

- Amend the Essential Health Benefits (EHB) rule to require coverage of specialty drugs (where no generic alternative exists) that are widely accepted in treatment guidelines or best practices (e.g., all HIV antiretroviral drugs).
- Promulgate regulations defining the protections provided under nondiscrimination provisions to ensure that design of formularies and utilization management do not discriminate against PLWHA or people with HCV or other chronic health conditions.

High coinsurance rates put the cost burden on consumers who take medications, and they dissuade PLWHA from enrolling. Strong Federal antidiscrimination regulations are needed to stop insurers from finding new ways to avoid insuring PLWHA and others with chronic conditions. Mr. Greenwald suggested the following to address affordability:

- HHS should amend the EHB rule to prohibit excessive coinsurance for specialty drugs (where no generic alternative exists) that are widely accepted in treatment guidelines or best practices.
- All States should enact laws to limit cost-sharing for specialty drugs.
- Congress should enact legislation to limit cost-sharing.

To address discriminatory practices, Mr. Greenwald suggested the following:

- Ensure that HHS promulgates clear and comprehensive regulations defining the protections under the nondiscrimination provision of the ACA.
- Ensure prompt investigation by HHS of discriminatory practices by plans and aggressive enforcement of ACA nondiscrimination protections.

Mr. Greenwald described SPEAK UP!, a partnership among national and State organizations to monitor and document barriers to HIV care. It has already identified patterns of discrimination and seeks more input from those on the ground.

Discussion

In response to Ms. Mahon, Mr. Greenwald said his organization can spell out the costs to the health care system for PLWHA who do not have insurance coverage, which can help make the case for ensuring access. For States that are not expanding their Medicaid programs, Ryan White program funds remain the most cost-effective way to pay for low-income PLWHA to obtain private insurance. Mr. Greenwald added that more concrete data are needed, but it is important to keep making the case that the ACA is working.

Pharmaceutical companies have funded the efforts to get information about formularies, drug costs, and coverage, and they are an ally in efforts by HIV/AIDS advocates to ensure access to treatment, Mr. Greenwald noted. It has been more difficult to get information about the cost burden on beneficiaries for other interventions. Some States are passing legislation to ensure access, but Federal laws are needed. Changing formularies is a tactic insurers use to keep costs down, and Mr. Greenwald said even conscientious insurers will take this approach if their competitors are doing it.

Mr. Greenwald's organization is creating a toolkit for assessing insurance plans and coordinating efforts across the country to evaluate plans in each State. Coverage options and regulations vary in each State, so patients need help determining their best options.

Open Enrollment Year One: Ryan White Program Successes, Challenges, and Priorities Moving Forward

Amy Killelea, J.D., Associate Director, Health Care Access, NASTAD

Ms. Killelea said 25,000 ADAP clients transitioned to Medicaid expansion or private plans in 2014, which is a good start. She summarized some of the challenges faced in the first year of the ACA. Information from private plans is incomplete or unavailable, so enrollees may not know what is covered or whether coverage will change. Without cost and coverage details, ADAP cannot decide which plans to purchase, and that slows down enrollment. Some advocates have worked with States and plans to get more details, but a Federal remedy is needed to give more force to ACA transparency regulations.

Ms. Killelea translated the data into a real-life example demonstrating the lack of affordability and the critical role that the Ryan White program still plays. For some PLWHA, ADAP has stepped in to meet copays and coinsurance, but at higher costs than anticipated. In some States, ADAP funds pay for insurance premiums; six States without Medicaid expansion also are not using ADAP to help PLWHA purchase insurance.

Insurance coverage is essential but does not replace public health or Ryan White program services. Grantees are gathering more specific details about how Ryan White programs fill the gap when services are not covered, such as providing case management and dental services. Formularies are not covering all HIV drugs. In fact, insurers are using out-of-date U.S. Pharmacopeia (USP) standards to demonstrate that they meet ACA requirements; a simple fix would be to require formularies to use the updated USP categories, said Ms. Killelea.

In addition to determining what is covered for PLWHA under new systems and insurers, said Ms. Killelea, new providers must be held accountable. In assessing insurance plans, advocates and policymakers should determine whether the reimbursement adequately

covers the services and the infrastructure built over many years to provide those services.

Discussion

Ms. Mahon posed the following questions for consideration by PACHA:

- What is the most effective way for PACHA to make the proposed recommendations?
- Who are the allies in this effort (e.g., pharmaceutical companies and advocacy organizations)?
- In the long term, whose job is it to evaluate the quality of plans?

Mr. Greenwald felt PACHA did not need to make formal resolutions; rather, he proposed that a subset of PACHA members, such as the Access to Care Subcommittee, talk with HHS leaders about where HHS support is needed to ensure access and transparency.

Action Item: Mr. Greenwald and Ms. Killelea will develop a document summarizing the rationale and recommendations for transparency and access, then seek endorsement from other organizations to serve as the basis for discussions with HHS.

Lucy A. Bradley-Springer, Ph.D., RN, ACRN, FAAN, said case managers, providers, and others need more education to help them counsel individual patients about coverage options. She suggested PACHA consider what other groups Mr. Greenwald's organization can partner with to expand outreach.

Ms. Killelea added that HHS has taken the lead on determining how plans meet the requirements to include community providers.

Public Comment

Lisa Stand of The AIDS Institute said that four private plans in Florida place all HIV drugs, including generics, in the highest drug tier with the highest coinsurance costs. The practice represents an intention to discourage enrollment and deny coverage, and more plans are likely to use the same tactics. The AIDS Institute filed a complaint with the HHS Office of Civil Rights. Similar access problems are occurring in a number of States, said Ms. Stand. The AIDS Institute and others formed a coalition representing a broad group of people with chronic conditions to urge the HHS Secretary to enforce the strong antidiscrimination provisions in the ACA and to use her authority to bar discriminatory plans from the market. This issue requires immediate attention, and Ms. Stand asked for PACHA'S help carrying this message to the Administration this year.

Jeryl Hayes of Advocates for Youth applauded PACHA for selecting two young people to serve on the Council (Grissel Granados, M.S.W., and Lawrence A. Stallworth II). To reduce HIV rates in this country, we must invest in current and future generations and recognize leadership among young people, said Ms. Hayes. She called for more studies to help understand why HIV infections are increasing among young people and to identify effective strategies to prevent HIV, including comprehensive sex education; access to testing, care, and treatment; and reducing stigma. Advocates for Youth asked PACHA to consider creating youth-specific recommendations for the next iteration of the NHAS. It also encouraged PACHA to recommend that the Obama Administration recognize National Youth HIV/AIDS Awareness Day (April 10, 2015). Ms. Hayes thanked PACHA for addressing the problematic and harmful Heritage Keepers abstinence-only curriculum. Advocates for Youth supports the recommendations regarding the OAH list of evidence-based interventions for preventing teen pregnancy.

William McColl of AIDS United stressed the importance of understanding the relationship of the Ryan White program to the ACA and maintaining the Ryan White program as payer of last resort during ACA implementation. To that end, AIDS United sent a letter to President Obama and every member of Congress in April stating AIDS United's commitment to create a consensus document proposing a plan for the future of the Ryan White Program once the impact of the ACA is better understood. AIDS United called on the Administration and Congress for continued funding of the Ryan White program to allow for evaluation of its role and its ability to shift funding toward coverage completion. AIDS United was unable to support legislation introduced in the U.S. House of Representatives in March. Rather, it supports moving forward on reauthorization after the impact of the ACA is better understood.

In recognition of the scale and impact of viral hepatitis, Donna Cryer of the Global Liver Institute requested a systematic review of offices and titles throughout the Administration to better reflect the current and future focus on hepatitis. She said clinical recommendations should not be trumped by cost concerns and urged PACHA to recommend increasing the budget for viral hepatitis efforts for 2016. Specifically, she called for support for CDC's request for \$170 million to address the epidemic and create the Viral Hepatitis Innovation Fund, which, like the Minority AIDS Initiative, would allow HHS agencies to compete for funds to support innovative projects for at-risk communities. Ms. Cryer said there also are opportunities for public-private partnerships to raise awareness and address HCV. She requested that PACHA members from innovator companies share their ideas for working collaboratively to increase the number of people who know their HCV status.

Ms. Cryer called for universal testing for hepatitis B and C, including rapid testing, to better capture all cases, improve surveillance, and facilitate linkage to care. Universal testing would help remove stigma and increase early awareness of liver health. Ms. Cryer asked PACHA to take a role in ensuring that people with HCV do not face discrimination in Federal or State programs or ACA plans. For example, requiring that

patients have advanced liver disease before they can gain access to treatment goes against public health and public policy, because HCV treatment is cost-effective and reduces rates of transmission. Finally, Ms. Cryer suggested moving quickly to increase the number of specialists and other providers with expertise to treat patients with hepatitis, using, for example, scalable models like Project ECHO.

Michael Jones of Iris House said comprehensive support programs for PLWHA work; his organization serves women of color with HIV and has shown viral suppression rates more than 250 percent of the national average. However, such work is in grave danger because of severe funding cuts. Iris House continues to address health issues that affect the community, such as HCV. In New York City, approximately 150,000 people have HCV, and 75 percent are unaware they are infected. With a commitment to testing for HCV, new technologies, and improved therapies, Iris House can meet its clients' needs. The availability of rapid HIV and HCV tests has increased the organization's ability to ensure that clients receive their results and are linked to care. Time that had been spent tracking down clients to provide results is now used to address clients' needs. Mr. Jones urged PACHA to consider reprioritizing support services for women with HIV and proposing increased funding for CBOs for HCV prevention to address health disparities.

C. Virginia Fields of the National Black Leadership Commission on AIDS, Inc., said that African Americans are twice as likely as those of other race or ethnicity to be infected with HCV, and their mortality rate is almost double that of non-Hispanic white Americans. Chronic liver disease is a leading cause of death among African Americans, and 75 percent of African Americans with HCV do not know they are infected. In 2013, her organization sponsored the first annual Nation African American Hepatitis C Action Day to support HCV testing campaigns in major cities, among other steps. Ms. Fields said rapid testing is particularly effective for community outreach campaigns. However, lack of funding is a barrier. Ms. Fields urged PACHA to weigh in with the President on increasing the budget for 2016, specifically to support the CDC request for \$170 million to address the epidemic. At a minimum, at least \$50 million should be included in the 2016 budget for the CDC Division of Viral Hepatitis. Ms. Fields also called for PACHA support for a Viral Hepatitis Innovation Fund.

Marsha Martin of the Urban Coalition of HIV/AIDS Services asked PACHA to consider holding a meeting in one of the southern cities strongly affected by HIV/AIDS, such as Houston, Atlanta, or Fort Lauderdale. Atlanta would be ideal, because it is home to CDC and Emory University, but also because the city is facing increasingly severe disparities related to HIV. When PACHA met on the campus of Howard University in Washington, DC, representatives of many city public health organizations and CBOs attended. Ms. Martin said public health infrastructure is managed mostly at the city and county level. Holding a PACHA meeting in another city would symbolize support for those people in public health who are working toward the NHAS goals. Ms. Martin said urban jurisdictions have tested and modeled best practices and are beginning to see the

impact of their work. A PACHA meeting in one of the affected urban areas would send a message about the importance of that investment.

PACHA's Next Steps and Action Items

Moderator: Mario Pérez, PACHA Member

In an open discussion about PACHA's next steps, some framing concepts came to light:

- Group the ONAP and PACHA priorities into goals and actions/strategies to meet those goals.
- Categorize goals as short-term (by the end of 2014), medium-term (by the end of 2015), or long-term (2016 and beyond).
- Consider both global and domestic issues, and make it clear when issues overlap.
- Keep in mind how to align resources for those most affected and hardest to reach.
- Create detailed, meaningful action plans that describe what will be done, what money will be invested, and how the goals will be accomplished.
- Target issues with the potential for high impact and high likelihood of success.
- Identify specific activities that PACHA members will take on.

In addition to the ONAP priorities and questions raised by Dr. Holtgrave at the end of day 1, members identified the following areas of interest:

- Making the data used to evaluate performance on the 2015 targets transparent so that the public and policymakers have a realistic perspective
- Evaluating the effect of stigma at each stage in the continuum
- Creating public-private partnerships to promote HCV testing
- Creating a public-private partnership to expand obesity prevention efforts to include other health care epidemics affecting youth
- To address gaps in public health infrastructure, creating a public-private partnership modeled on Teach for America that engages physicians (possibly young physicians) to provide services through mobile clinics or telemedicine, particularly addressing youth.

Dr. Valdiserri said his priority issues are HIV in the southern United States, rising HIV infection rates among African American MSM, and helping PLWHA move from Ryan White programs into insurance plans.

Dr. Holtgrave proposed that the PACHA Subcommittees take on the following issues:

- Incidence Subcommittee: 2015 NHAS goals and alignment of resources with need
- Access to Care Subcommittee: HCV, ACA access, and return to work/employment

- Disparities Subcommittee: HIV in the southern United States and rising HIV infection rates among African American MSM
- Global Subcommittee: President’s Emergency Plan for AIDS Relief.

Action Item: Mr. Pérez, Dr. Holtgrave, Ms. Mahon, Ms. Hayes, and Dr. Valdiserri will meet to outline the work of PACHA through early 2015. They will propose some deliverables that align with the priorities identified by ONAP and Dr. Valdiserri and respond to the areas for which Mr. Brooks requested PACHA advice.

Action Item: PACHA staff will assist with reconstituting the Subcommittees, which will select new Chairs. Subcommittees will outline a process for meeting medium-term goals (beginning in 2015) that include:

- Honest reflection on progress toward NHAS goals
- HIV in the southern United States
- Rising HIV infection rates among African American MSM
- HCV
- NHAS goals for 2016–2020.

Ms. Mahon said PACHA can provide advice in many ways. Members can work directly with HHS staff, as Mr. Greenwald and Ms. Hiers did in reviewing the Heritage Keepers curriculum. PACHA can work with ONAP and HHS, sometimes taking on the hands-on work that the agencies cannot. PACHA is a brain trust, said Ms. Mahon, whose members can bring to bear a wide range of experience on the front line.

Closing Remarks and Adjournment

Ms. Mahon thanked the PACHA staff, Ms. Hayes and Caroline Talev, for their good work. She encouraged PACHA members to be active in the PACHA Subcommittees. She also thanked Mr. Pérez for his efforts to provide a framework for the next steps, Dr. Valdiserri for his office’s support of PACHA, and Mr. Brooks for positioning PACHA as a brain trust that can provide valuable input to the ONAP. Ms. Mahon adjourned the meeting at 11:58 a.m.