

**Presidential Advisory Council on HIV/AIDS (PACHA)
24th Meeting
Hubert Humphrey Building
200 Independence Avenue, S.W.
Room 705A
Washington, DC 20201**

Monday, June 28, 2004, and Tuesday, June 29, 2004

**Council Members—
Present June 28 and June 29**

Co-Chair Louis Sullivan, M.D.
Rosa Biaggi, M.P.H., M.P.A.
Jacqueline S. Clements
Mildred Freeman
John F. Galbraith
Edward C. Green, Ph.D.
Cheryl-Anne Hall
Jane Hu, Ph.D.
Karen Ivantic-Doucette, M.S.N., F.N.P., ACRN
Rashida Jolley
Abner Mason
Joe S. McIlhaney, Jr., M.D.
Henry McKinnell, Jr., Ph.D.
Brent Tucker Minor
Dandrick Moton
Jose Montero, M.D., F.A.C.P.
Beny J. Primm, M.D.
David Reznik, D.D.S.
Deborah Rock
Rev. Edwin Sanders II
Prem Sharma, D.D.S., M.S.
Lisa Mai Shoemaker
Anita Smith
Don Sneed
M. Monica Sweeney, M.D., M.P.H.
Ram Yogev, M.D.

**Staff—
Present June 28 and June 29**
Joseph Grogan, Esq., Executive Director
Dana Ceasar, Program Assistant

DAY 1

MORNING SESSION

Dr. Louis Sullivan, PACHA Co-Chair, called the meeting to order at 8:45 a.m. and welcomed members of the Advisory Council and guests. The meeting began a bit late, he said, because of the swearing-in of several new members. He welcomed Joseph Grogan, new executive director of PACHA, and thanked outgoing executive director Josephine Robinson for her service to the Council.

Dr. Sullivan also thanked several members of the Council who have completed their service: Dr. James P. Driscoll, Katryna Gholston, Joseph Jennings, and Nathan M. Nickerson. He welcomed the new ideas and perspectives of three new members to the Council—Dr. Jose Montero, Dr. Ram Yogev, and Dr. Cheryl Bowers-Stephens (who was not present)—and asked Drs. Montero and Yogev to introduce themselves.

Remarks

Dr. Montero is a native of Tampa, Florida, a physician at Tampa General Hospital specializing in infectious disease, and a faculty member at the University of South Florida Center for HIV Education and Research. His HIV practice is mostly with inpatients in the hospital setting. He thanked the Council for making him part of this “prestigious and important” group.

Dr. Yogev is professor of pediatrics at Northwestern University and medical director for pediatric and maternal HIV infection at Children’s Memorial Hospital, Chicago, Illinois. His main interest is pediatric HIV; as chair of the committee within the Pediatric AIDS Clinical Trials Group (PACTG) that decides which studies will be done, he is working with international efforts in South Africa and Thailand. He said that he hopes he will mesh with the “important people” of this Council.

Dr. Sullivan announced that public comment will begin at 10:30 a.m. The agenda of this meeting covers a variety of topics, including HIV/AIDS in the African American community, the Ryan White CARE Act, and the HIV/AIDS epidemic in India.

Joseph Grogan, Esq.

Mr. Grogan said he was excited and happy to be the new executive director of the Council. He noted that he met some Council members at the Prevention and Treatment and Care Subcommittees meeting and thanked those who have helped him become oriented to his new position, including Dana Ceasar, PACHA program assistant, for her outstanding work. Although Josephine Robinson, the previous executive director, has moved on to another position, she has always been available to provide help when needed.

Josephine Robinson

Ms. Robinson thanked the Council for what she said has been probably one of the best work experiences she has ever had. She said she is saddened to leave the group, and many Council members have become dear friends and colleagues. She moves on to serve as chief of staff of the Office of Public Health and Science (OPHS), U.S. Department of Health and Human Services (DHHS), which oversees PACHA, so she will remain involved. She noted that National HIV Testing Day, a campaign to spread the message about the importance of HIV testing, was yesterday (June 27), and free HIV testing continues for the next 2 days in the Hubert Humphrey Building. She urged all to know their HIV status and to encourage others to do so also. She added that that she was not saying goodbye to PACHA, but rather “thank you.”

Dr. Sullivan also welcomed Carol Thompson, director of the White House Office of National AIDS Policy (ONAP).

Carol Thompson

Ms. Thompson has been ONAP director since February 2004 and acting director since August 2003, and she looks forward to meeting all those on the Council she has not already met. She thanked Ms. Robinson for her exceptional diligence in her leadership of PACHA and congratulated Mr. Grogan on taking over the job.

Last week was an exciting week for those at the White House involved with HIV/AIDS, Ms. Thompson said, with the President promising strong support for reauthorization of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act. Three main principles will guide the work of ONAP: (1) to bring the focus back to critical care and treatment, ensuring that lifesaving drugs get first to the people who need them; (2) to facilitate that by giving more flexibility to the DHHS, and specifically to the Health Resources and Services Administration (HRSA); and (3) to recognize the need for State and local planning, to understand that what works in Cincinnati may not work in Manhattan and Des Moines. It is important to show the American taxpayer that the Office is on track to make sure resources get to where they are most needed.

The President’s recent announcement that \$20 million will be diverted to 10 States to help the AIDS Drug Assistance Program (ADAP) will be a big help, although everyone involved in the fight against HIV/AIDS recognizes that more needs to be done. An important aspect that will be emphasized is the need for focus on AIDS in the African American community—for African Americans between the ages of 25 and 44, AIDS is the second leading cause of death.

ONAP is also focused on vaccine development. Finding a vaccine for the virus is a long way off, but progress is being made. The President also issued a proclamation supporting National HIV Testing Day.

Internationally, the United States has designated \$500 million to fight AIDS in Africa and the Caribbean, and clearly India is another crucial area affected by the pandemic. India is the largest nonfocus country for the United States, with \$20.5 million spent there in fiscal year 2004.

Ms. Thompson concluded her remarks by thanking the Council for its service to everyone who is suffering with this disease.

Discussion

Dr. Sullivan asked Ms. Thompson to comment on the President's decision to make Vietnam the 15th focus country in the President's Emergency Plan for AIDS Relief (PEPFAR), the 5-year global plan, when the problem is more severe in populous countries such as China and India, where efforts are needed to get ahead of the virus. Ms. Thompson said that they were trying to focus on where U.S. resources would go furthest and the countries in greatest need, and felt that Vietnam was the right place to go. While there are now an estimated 130,000 to 300,000 cases of HIV/AIDS in Vietnam, the number is projected to reach 1 million by 2010, and 80 percent of transmission is from sexual contact. The challenge is to keep the epidemic in Vietnam from spreading to the general population, and the United States thinks it can influence the prevention effort, working with faith, community-based, and nongovernmental organizations (NGOs). India is the largest nonfocus country, but a significant amount of global work is going on there, including the work of the Global Fund and the Gates Foundation.

Dr. David Reznik asked how the \$20 million designated for ADAP will be disbursed, and if drugs would be provided at special pricing and distributed to the States. Ms. Thompson responded that the actual mechanism is yet to be worked out. States and organizations in most need will be able to get drugs directly, but it is doubtful there will be special pricing. Ms. Robinson added that in the 10 identified States, the \$20 million is to purchase drugs to alleviate the immediate emergency needs of individuals on waiting lists to receive drugs.

Dr. Yogev asked for clarification that appropriate attention will be given to the adolescent population in African American communities, because that is often where the disease begins, in adolescents as young as 12 and 13 years old.

Jacqueline Clements asked how long it would take for people in the States to get medications, since States are going to get the drugs, not money, and a process to identify the individuals who need the medications will be necessary. Ms. Thompson said that the specific intent is to eliminate excessive bureaucracy, and that is why States will get medications rather than money. Christopher Bates, acting director of the DHHS Office of HIV/AIDS Policy, said that drugs will be issued based on formularies of the States, and the intent is to facilitate movement of these drugs, for better prices and to avoid adding an administrative burden in responding to an emergency situation, and to move people off the waiting lists.

Brent Tucker Minor, Chair of the PACHA Treatment and Care Subcommittee, thanked Ms. Thompson for her remarks, and said it is apparent that the Federal Government has heard the need and responded, and this is good for people with AIDS. Regarding reauthorization of the Ryan White CARE Act, he said that many on the Council see this as a crossroads for good care and treatment, and asked what the role of the Council should be. Ms. Thompson responded that her Office will rely on PACHA and its experience for advice on moving forward. The President has opened the dialogue about what needs to be done, and she welcomes input about reworking the program, what needs to be fixed, and how to fix it, with the principal focus on primary care. She looks forward to hearing from members of the Council over the next months and year regarding specific roles they can take.

Agenda

PREVENTION PRESENTATIONS

- ?? The State of HIV/AIDS Among African Americans: A Demographic Overview and CDC Methodology. Janet Cleveland, Centers for Disease Control and Prevention (CDC), presenter.
- ?? Update on the Status of HIV Reporting in the United States. Dr. Matthew McKenna, CDC, presenter.

Panel Discussion:

- ?? Understanding the Down Low Phenomenon and Why Incidence of HIV/AIDS Is Higher Among African Americans. Greg Millet, CDC, presenter.
- ?? Barriers to Treatment of HIV/AIDS in African Americans: Including Addiction and Mental Health Issues Specific to African American Men. Dr. David Malebranche, Emory University School of Medicine, presenter.
- ?? African American Women's Issues and HIV. Dr. Jean R. Anderson, Johns Hopkins University School of Medicine, presenter.

Dr. Sullivan noted that the Prevention Subcommittee, chaired by Anita Smith, organized the agenda for this meeting. Ms. Smith said that the agenda is a joint effort of the Prevention and Treatment and Care Subcommittees, whose members felt it was important to address the issues of both these groups. This meeting's presentations began with an epidemiological overview of HIV/AIDS in African Americans, because data are needed to start the conversation. In the afternoon, after the three speakers, the presenters answered questions together, as a panel.

The first presenter, Janet Cleveland, deferred briefly to Mr. Bates who informed the Council that DHHS Secretary Tommy Thompson has expanded rapid HIV testing with oral rapid testing, an accurate test that does not require drawing blood. This has provided expanded opportunities for testing and increased ability to learn who is HIV-positive and connect him or her with services. The Substance Abuse and Mental Health Services Administration (SAMHSA) has become involved with this effort and will be using rapid

testing kits employing both blood and saliva at methadone clinics. These are major developments in advancing the work of identifying individuals who are HIV-positive and connecting them with services.

Dr. Reznik clarified that it is oral mucosa that is tested, not saliva. He emphasized that this is an important differentiation, made to avoid rekindling fears that HIV is spread through saliva. Dr. Sullivan noted that one of the advantages of rapid testing is that a patient can get immediate counseling, but it is not clear how that will be an advantage for those who do not return to the clinic.

Karen Ivantic-Doucette asked if guidance would be provided to States about new rapid testing. Mr. Bates said that guidance packages about using the new technology will be put together and distributed, and information will be disseminated through train-the-trainer programs. Just fewer than 1,000 persons have been trained, and progress is being made, but no final protocol is yet in place. His Office is working with the CDC and others to give guidance in clinical settings. Ms. Cleveland added that the CDC is planning to train trainers associated with SAMHSA in methadone clinics. Dr. Monica Sweeney said that the issue is not so much technical training, but to readjust thinking, so counselors can quickly assess a client's coping skills—instead of a week, they have 20 minutes to adjust to a diagnosis. Counselors need to be retrained to deal with that, she said, and mental health backup onsite should be available for people who need it.

**The State of HIV/AIDS Among African Americans:
A Demographic Overview and CDC Methodology**

Presenter: Janet Cleveland, Deputy Director for Programs, Divisions of HIV/AIDS Prevention, National Center for HIV, STD, and TB Prevention, CDC

Looking at cases, deaths, and persons living with AIDS in the United States from 1986 onward, there has been a steady rise in newly diagnosed cases. In 1993, when the actual definition was implemented, and shortly thereafter with the advent of protease inhibitors, the numbers of newly diagnosed cases and deaths started to decline, but the number of persons living with AIDS has continued to increase.

Great disparity is seen when comparing rates by race and ethnicity. The rate of cases in African Americans far exceeds rates in other groups; it is 10 times the rate of whites. There has been considerable discussion about the disproportionately rising rates among African American women, which are thought to be largely the results of injecting drug use (IDU) and being partners of IDUs. From 1999 to 2002, the estimated number of HIV/AIDS diagnoses in African American women, derived from 30 areas supplying confidential HIV reporting since 1998 (29 States and the U.S. Virgin Islands), was more than five times the number of white women and more than three times the number of Hispanic women.

Looking at numbers of diagnoses by mode of exposure, the rates among men having sex with men (MSM) has gradually increased in recent years, with a 17 percent increase between 1999 and 2002. The number of diagnoses in IDUs has stayed relatively stable,

with a slight decrease recently in IDU cases. The number of cases due to heterosexual contact has remained stable, as has the number of individuals classified as both MSM and IDU.

More than 65 million people in this country are currently living with an incurable sexually transmitted disease (STD), with approximately 18.9 million additional infections each year. In addition to HIV/AIDS, African Americans in the United States are also disproportionately affected by other STDs, specifically chlamydia, syphilis, and gonorrhea. This is an issue of great concern.

A closer examination of the impact of HIV/AIDS in African Americans shows that 50 percent of the more than 42,000 AIDS cases diagnosed in 2002 in the United States were in African Americans. The leading cause of HIV infection in African American men is sexual contact with other men, followed by IDU and heterosexual contact. Heterosexual contact is the leading cause of HIV infection in African American women. People might want to believe that women who contract HIV/AIDS are of a certain socioeconomic status (SES), but infected African American women are found in all strata of life. HIV/AIDS is among the top three causes of death for African American women aged 35 to 44 and African American men aged 25 to 54. In 2002, 62 percent of children born to HIV-infected mothers were African American. However, perinatal prevention has been one of the great success stories in the AIDS epidemic in this country.

By age, gender, or however the HIV/AIDS data are interpreted, there is a huge discrepancy related to race in the United States. From 1998 to 2002, African American men and women were infected at a considerably higher rate than white men and women. In 2002 the racial breakdown in diagnoses was 54 percent African American, 32 percent white, and 12 percent Hispanic. Looking at MSM, 60 percent of cases reported through 2002 have been in African American men.

The CDC has responded to the epidemic in the African American community in a number of ways. A minority initiative began in 1988, with funds for national and regional minority organizations to provide technical and capacity building assistance to community-based organizations serving communities of color. That effort continues today. Since 1989, the CDC has funded HIV prevention efforts by some 142 organizations. The CDC also provides national oversight and guidance for State and local health departments, which play a crucial role. The Division of Adolescent and School Health (DASH) takes the lead in this endeavor, and since 1990, the CDC has funded State and local education agencies to ensure that every child in the United States is provided effective education to protect themselves and others from HIV now and all their lives.

Goals of CDC's HIV strategic plan through 2005 for prevention are to decrease new infections; increase knowledge of serostatus; increase linkage to prevention, care, and treatment; and strengthen monitoring, capacity, and evaluation.

The Advancing HIV Prevention (AHP) initiative offers new strategies for a changing epidemic. The prevention strategy is a three-pronged approach comprised of HIV counseling, testing, and referral; prevention with persons living with HIV; and prevention with persons at high risk for HIV. These approaches, working with other Federal partners such as HRSA and SAMHSA, have the purposes of reducing barriers to early diagnosis of HIV infection and increasing access to and use of quality medical care and treatment and prevention services for persons living with HIV. Prevention for high-risk individuals who are seronegative and people with HIV infection is an important component.

The four priority strategies of AHP are to:

1. Make voluntary HIV testing a routine part of medical care.
2. Implement new models for diagnosing HIV infections outside of medical settings. The CDC is working with community-based partners and training personnel to promote this effort.
3. Prevent new infections by working with persons diagnosed with HIV and their partners.
4. Further decrease perinatal HIV transmission. The goal is zero, and there is no reason this cannot be achieved.

DASH works closely with the Divisions of HIV/AIDS Prevention to ensure that the prevention message is getting to school youth. It targets more intensive prevention efforts to youth at highest risk for HIV infection and conducts behavioral research to learn why youth are at risk and provide a science base for effective policies and programs.

Another CDC effort is targeted to the South. For a long time, many thought HIV was not a problem in the South, but it is clear that trends have moved southward, particularly in African Americans. Looking at estimated diagnoses by region, numbers were relatively stable from 1999 to 2002, with a slight incline in the West, a decline in the Northeast, and a steady incline in the South, enough to raise some concern. In a study of people with AIDS in four southern States (Delaware, Georgia, South Carolina, Florida), most were infected in metropolitan urban settings, most had moved back to southern communities to be closer to their families, and most did not believe they were at risk for HIV.

High-risk behavior was reported in both southern and urban settings. Those infected from urban areas were more likely to engage in alcohol and drug use, exchange sex for money and drugs, and have a partner who was an IDU. Issues related to prevention and care need to be rooted in considerations of where resources will come from for people who are infected in urban settings and return to their families in less urban areas, without the resources of big cities, and what impact that has on the South.

The CDC recently investigated an outbreak of HIV in North Carolina that had been widely reported in the media. The situation began in November 2002 with the identification of two cases of acute HIV infection in African American college students in the State. In May 2003, 56 cases were identified in college students. In African American college students and nonstudents, 49 cases of HIV were diagnosed among MSM. In August 2003, the CDC was invited to assist in an epidemiological investigation.

A number of schools were involved, including but not limited to historically African American colleges and universities.

Based on a case-control study to assess the differences between HIV-positive and HIV-negative MSM, the CDC concluded that high-risk behaviors are occurring in young African American MSM college and noncollege students. But venues for meeting partners are not limited to college campuses, providing ample opportunity for sexual mixing. A plethora of complex issues is involved. Prevention messages need to be related not only to HIV but also to other STDs. And men who have sex with men but do not self-identify as gay or bisexual may have casual or steady female sexual partners and function as a vector to the female community. [These men were examined more thoroughly at this meeting in a subsequent report on the “Down Low.”]

The CDC responded to the North Carolina outbreak with funding to the State’s DHHS to adapt a community-level intervention, which relies on trained peer volunteers to endorse safer sexual behaviors, diffuse these messages to their social network through casual one-on-one conversations, correct misconceptions, and promote HIV prevention. The CDC is also increasing its efforts among historically African American colleges and universities and currently funds nine governmental organizations to strengthen the schools’ HIV prevention services. The CDC also will provide \$450,000 to conduct a survey among students attending historically African American colleges and universities about HIV knowledge, attitudes, risk behaviors, and prevention and testing services on campus. A group of schools in Atlanta recently took a lead in these efforts, with a policy discussion convened by local representatives to Congress on how they can lead the prevention initiative and diffuse knowledge around the country.

Ms. Cleveland ended her presentation with a quote about hope from Frederick Douglass that underscores the severity of today’s epidemic and the role of personal responsibility in combating it:

Notwithstanding the great and all-abounding darkness of our social past, notwithstanding the clouds that still overhang us in the moral and social sky ... it is the faith of my soul that this brighter and better day will yet come. But whether it shall come late or come soon will depend mainly upon ourselves.

Discussion

Don Sneed asked what percentage of the recent community-based testing initiative is focused on testing individuals, compared to other efforts. Ms. Cleveland responded that testing is an integral part of the program, with about one-third of the funded organizations specifically working on testing and counseling, and others that may also do prevention work. Counseling and testing is the main thrust of the CDC prevention program, she added.

Mr. Sneed followed up with a question about the large number of African Americans still living in the South, and the history of racism in that part of the country. He asked if there is evidence that racism and discrimination in the gay community affect resource

allocation, citing an article from the June 27, 2004, New York Times, “For Young Gays on the Streets, Survival Comes Before Pride.” Ms. Cleveland said she would defer to other members of the Council on this question, and Mr. Sneed said he knows there is indeed an impact. Ms. Smith said there would be further opportunity to discuss this issue in the afternoon session.

Ms. Clements asked if the CDC would do the same for other States that identified unexpected, acute cases as it did for North Carolina. Ms. Cleveland said it was her educated guess that it would, and it depended on available resources. She asked Dr. Matthew McKenna, also of the CDC, to respond. Dr. McKenna said that the North Carolina program uses a test that picks up components of the virus and identifies infected persons in 1 week, while others take several weeks, and this is extraordinarily expensive technology, costing \$100,000 to \$200,000 per case. He added that the CDC will do other demonstration projects in other arenas as proof of the concept. One of the issues is that even with identification of infected individuals, this test finds only a fraction of what is found with a standard test.

Dr. Henry McKinnell commented that the quote from Frederick Douglass is meaningful, but in his experience, action precedes hope. He said that the first thing to do is consider the goal to reduce new infections—in running his business [he is chairman and chief executive officer of Pfizer, Inc.] the only goals that would be acceptable, for example, would be reducing transmission from mother to child to 0, and 100 percent of people knowing their serostatus, and an AIDS-free generation. In fighting a war, he emphasized, it is necessary to know the enemy, but the enemy now being fought is the enemy described 10 years ago, and fresher data and an updated perspective are necessary.

Dr. Sullivan said that he was part of the session at Atlanta University where a group of college presidents said they had not seen any sort of HIV outbreak as described in North Carolina. He asked if the CDC’s survey would cover all traditionally African American colleges and universities or just a sample, and Ms. Cleveland said the plan is to cover all in the United States, but it may be necessary to take a sampling, depending on the accessibility of the schools. She thanked Dr. McKinnell for his input on the need for real goals, but added that this initiative complements the strategic plan, which is available on the CDC Web site: www.cdc.gov/nchstp/od/hiv_plan/Table%20of%20Contents.htm.

Dr. Sweeney said that prevention efforts seem to be mostly secondary and tertiary, and keeping this focus is not the best way to get ahead of the epidemic. Also, she asked about infection in women as IDUs or sex workers or in correctional institutions. Ms. Cleveland responded that she is aware of the issue of secondary and tertiary prevention, and it is the reason for a focus on prevention in people living with AIDS and a commitment to prevention in people at high risk. Unfortunately, there are limited national resources, and the CDC must look at the epidemic from a national perspective. Local jurisdictions need to meet their own local needs in prevention, working with community-based organizations that are funded from a national level.

Regarding female IDUs and sex workers, Ms. Cleveland said, a greater number of African American women are becoming infected with HIV through heterosexual transmission, and IDU cases are declining. Sex workers are definitely another facet of transmission, as well as persons trading sex for drugs, and the CDC funds organizations that address prevention needs of sex workers and others who put themselves at risk. But she emphasized that the overall national picture shows African American women contracting HIV from heterosexual transmission.

Introduction of Motions

Mr. Minor said that some of the proposed motions require changes, particularly the one concerning ADAP, since funding has been announced. Few amendments are expected from the Council, so rather than introducing them at this point in the meeting, they will be introduced at tomorrow's session. Dr. Beny Primm noted that the Council requested \$25 million for ADAP and \$20 million was granted, and he would like to go on the record as asking for the remainder. Dr. Sullivan said that will be discussed tomorrow.

Public Comment Session

Public Speaker #1

Dr. Gene Copello, executive director, The AIDS Institute

Dr. Copello applauded the Council for the advisory role it played and continues to play in communicating to the President and DHHS the needs for life-saving medications of low-income Americans living with HIV/AIDS. ADAP, a component of Title II of the Ryan White CARE Act, is in a serious crisis, he said, with more than 1,600 low-income Americans on waiting lists and many more ineligible for services. This is one of the most pressing issues facing domestic AIDS policy. The AIDS Institute is encouraged by the President's announcement on June 23, 2004, to provide \$20 million in immediate assistance to reduce the ADAP waiting list. The Institute hopes this is only a beginning to finding a long-term and sustained solution to the crisis. Consistent access to HIV antiretroviral drugs, as outlined by Public Health Service (PHS) guidelines, is recognized as the central component of HIV medical care today. Consistent access to these medications and the primary medical care needed for their appropriate delivery extends life, improves quality of life, and serves larger public health concerns.

Recently the Institute of Medicine (IOM), in its study "Public Financing and Delivery of HIV/AIDS Care: Securing the Legacy of Ryan White," documented the need for consistent access to substance abuse treatment and mental health services as important modalities for client adherence to HIV antiretroviral drug therapy, Dr. Copello continued. A large percentage of Americans living with HIV/AIDS are dealing with substance abuse and mental health concerns. The treatment of these conditions should be considered key if increased availability of HIV antiretroviral drugs is to have its greatest impact. The AIDS Institute endorses this view and encourages the Council to consider recommendations for the full integration of these modalities into the national HIV/AIDS health care delivery system.

Consistent and coordinated access to substance abuse and mental health treatments, along with consistent access to primary medical care and medications as outlined in the PHS guidelines, need to be considered as part of the HIV/AIDS standard of medical care. The AIDS Institute encourages the Council to consider these issues as it makes recommendations about reforming the domestic HIV/AIDS health care system, including discussion of the 2005 reauthorization of the Ryan White CARE Act.

Public Speaker #2

Laura Hanen, Director of Government Relations, National Alliance of State and Territorial AIDS Directors (NASTAD)

Ms. Hanen thanked the Council for the opportunity to present comments. NASTAD represents HIV/AIDS directors in the States and Territories who have programmatic responsibility for HIV prevention and care programs and who coordinate programs across the continuum of HIV prevention and care, including administration of ADAPs funded through Title II of the Ryan White CARE Act.

State HIV/AIDS programs face a number of important issues, and Ms. Hanen highlighted three of them. The first is the recent announcement by the Administration of the purchase of \$20 million in drug therapies for the 10 States that currently have ADAP waiting lists. The State AIDS directors and NASTAD are extremely thankful for President Bush's and the Administration's commitment to increasing access for Americans to lifesaving treatments. NASTAD is also appreciative of President Bush's comments supporting the reauthorization of the CARE Act.

HRSA has begun to consult with the 10 eligible States. NASTAD, while appreciative, is concerned about the time and effort it will take to put this effort into operation. The eligible ADAPs are expected to determine the treatment regimens of more than 1,600 individuals and administer the delivery of HIV therapies. This means that States must work with their case managers and treatment providers to determine the current treatment regimens for every person on their waiting lists. While this may not be too difficult in States like Iowa or Alaska, with fewer than 10 individuals on their waiting lists, it could easily overwhelm a State such as North Carolina, which must determine the treatment needs of more than 700 individuals. It is unclear how long these individuals will receive treatment and what will happen if their treatment regimen should change. States will require technical assistance to implement this unique and complex effort. NASTAD plans to work with HRSA and State AIDS programs to ensure this process goes as smoothly as possible.

While those who administer State AIDS programs are thankful that treatment will now be available for those on waiting lists, NASTAD cautions that this will not solve the ongoing structural deficit that ADAPs continue to face. There are a number of States on the verge of instituting waiting lists, and those patients will not receive this relief. There are currently 10 States that anticipate new or additional access restrictions before the ADAP funding year ends on March 31, 2005. The future of ADAP will very much depend upon a continued Federal commitment in FY 2005 and FY 2006.

The second matter for attention is the notification NASTAD recently received about HRSA's decision to discontinue funding NASTAD as a technical assistance (TA) provider to State AIDS programs. This has been a decade-long relationship. This is extremely alarming to State AIDS directors, who are in the midst of an ADAP crisis and about to embark on the reauthorization of the CARE Act. HRSA has informed NASTAD that it is not funding any agency to specifically provide TA to States or specifically address the needs of ADAP program coordinators. This is troubling, as Title II is the largest title of the CARE Act and begs the question as to whether HRSA recognizes the legal responsibility of States as the central authorities of the Nation's public health system. Ms. Hanen pointed out that it is the State AIDS directors through NASTAD who created the ADAP Crisis Task Force, which saved the Federal Government \$65 million through its negotiations with the manufacturers of antiretrovirals to maximize the resources available to all State ADAPs.

Ms. Hanen also drew attention to the development and implementation of the Medicare Part D Prescription Drug Benefit. NASTAD, along with the HIV/AIDS community, has been following the issue closely and asks that PACHA place this on its agenda for consideration. The Notice of Proposed Rulemaking (NPRM) will be out sometime this summer, and Ms. Hanen requested that members of PACHA submit comments that will ensure that people living with HIV/AIDS who take part in the Part D benefit have access to plans that include all medically necessary drugs to treat HIV on their formularies. NASTAD is waiting to see how ADAPs will be handled in the NPRM. The Alliance would like ADAPs to be recognized as State pharmacy assistance programs or SPAPs and allowed to wrap around the Medicare Part D Drug Benefit. If this does not occur, ADAPs will only be allowed to fill in coverage gaps in the benefit, but these expenses to ADAP will not be counted towards an individual's out-of-pocket expenses, which are needed to hit their catastrophic limit. Therefore, ADAPs will see little savings from low-income individuals leaving their rolls to enroll in the Part D benefit and may choose to cover co-pays and out-of-pocket expenses for those whose Medicaid program had once picked up these costs.

Public Speaker #3

Dr. Rita Wutoh, African Futures Forum, Inc.

Dr. Wutoh said she appreciates this timely Council meeting to discuss the President's plan on HIV/AIDS in Africa. A cursory review of the President's plan shows a crucial gap in the future implementation of programs. Dr. Wutoh considers the role of youth and youth organizations to be critical and necessary.

For example, African Futures Forum, Inc., a voluntary youth-based organization that she represents, is partnering with other African youth organizations to sponsor workshops on youth leadership development and their role in HIV/AIDS. This includes proposal writing and funding for community initiatives.

This initiative, Dr. Wutoh added, is a window of hope for youth to be involved in changing the course of this devastating disease affecting youth and the workforce. She urged the Council to consider how youth can be integrated into the President's plan on HIV/AIDS.

Public Speaker #4

Diana Bruce, National Family Planning and Reproductive Health Association (NFPRHA)

Ms. Bruce expressed concern about the language in the draft motion about mother-to-child transmission; specifically, the limitation to married and monogamous women in the second "whereas." Public health messages should be crafted to address all women at risk, she emphasized, and messages that exclude the realities of many women's lives are dangerous to women and their children. She recommended that the second "whereas" be revised to delete "within marriage or monogamous relationship."

Public Speaker #5

Bill Arnold, director, ADAP working group

Explaining that his group is a coalition of AIDS organizations, service providers, and pharmaceutical groups that manufacture AIDS drugs, Mr. Arnold thanked the Council for getting ADAP on the President's agenda. However, he emphasized that the \$25 million requested to clear the waiting lists was not an arbitrary figure, and the \$20 million promised can take care of people on the waiting list today, but within days or weeks the list will return. He said \$20 million will not fix the problem over the next 12 months, and additional appropriations are needed for FY 2005. There are no shortcuts, and if the money is not spent here, someone else will have to spend it somewhere else.

Dr. Sullivan thanked all the public speakers and said that their comments would be taken under advisement.

Agenda

HIV Reporting in the United States

Presenter: Dr. Matthew McKenna, chief, HIV Incidence and Case Surveillance Branch, Divisions of HIV/AIDS Prevention, CDC

An enormous amount of data from his unit is available, Dr. McKenna said, and his primary intent at this meeting is to discuss the process of reporting and the difference between HIV and AIDS reporting and to comment on CDC activities to achieve a national HIV reporting system.

Looking at AIDS rates compared to HIV rates, AIDS data underestimate the true burden of the disease. In a survey of 25 States, in only one case—a State with an older epidemic—do AIDS cases outnumber HIV infection. It is clear that just counting AIDS does not accurately describe the environment.

In AIDS case data, the proportional distribution by behavioral risk factor declines in the 1990s in MSM categories and increases in heterosexual contact transmission. States with long-time HIV reporting, however, are seeing upticks in MSM cases. Increases in the dual MSM/IDU transmission category are seen since 1999, and this is of great concern. There has also been an increase of syphilis in this period. In IDU transmission, there has been a modest decrease, and a modest increase is seen in heterosexual transmission.

The HIV and AIDS numbers differ because they encompass conceptually difficult issues. HIV infection is an occult event, and epidemiologists will always be estimating behind the curve. The measures of HIV/AIDS are morbidity and mortality. In the early years of the epidemic, young men were developing unusual opportunistic infections (OIs); now it is possible not only to measure when people develop OIs, but also when they have immunologic AIDS, with a T-cell count under 200. This allows health care providers to do a better job at moving earlier in the spectrum of disease, but medicine is still burdened by some anachronistic concepts that created the distinct HIV/AIDS categories. For example, when a person has T cells of 201, he or she does not have AIDS, but AIDS is the diagnosis if the count is 199. This is an artificial boundary. It would be ideal to know the rate of transmission, when the virus moves from one person to another, just as the business world has real-time information about sales. But the ability to measure incident HIV infection is relatively recent and still evolving.

The cycle of HIV disease, depicted as buckets that feed one into another into another, begins with an infection rate that remains at about 40,000 new infections per year. Undiagnosed cases are estimated at about 240,000 in total, but because of the large pool of previously undiagnosed cases, more are diagnosed each year than infected. About one-quarter of HIV diagnoses each year are in individuals who have gone undetected and already have AIDS, with compromised immune systems and OIs.

The challenge at the national level is to pull together the data needed to make decisions. This means addressing the basic tenets of national surveillance programs. The word “health” does not appear in the U.S. Constitution, and most of the health authority resides with State governments. State governments establish all reportable disease programs and diseases (i.e., AIDS, anthrax, syphilis, breast cancer) reported by patient name, except for HIV infection not yet classified as AIDS. The CDC provides funding and technical assistance and coordinates activities with States for aggregation of data to achieve a national system.

A long tradition of confidentiality and privacy rules is associated with HIV/AIDS surveillance data. State and Territorial laws for protection of public health data apply to HIV/AIDS. The CDC requires explicit physical security for records—that they be maintained in physically secure environments with limited access by authorized personnel only, with sanctions imposed if breaches occur. State surveillance programs certify that they meet program requirements, and identify an overall responsible party for ensuring confidentiality, with written confidentiality policies in place. Patients' and physicians' names and other personal identifiers are not sent to the CDC, only randomly assigned numbers. These files are also protected from the Freedom of Information Act.

Community resistance to HIV reporting is based on a number of factors, which might or might not be valid. Communities fear that inappropriate release leads to stigma and discrimination. Dr. McKenna has investigated charges of inappropriate release and found only one to be true in 20 years. When information is released inappropriately, the source is usually social networks or providers or other sources, not State agencies. Another fear is that requiring HIV reporting will delay testing and diagnosis, but that has been investigated and is not corroborated. People experience anxiety about testing, but not about reporting; in fact, most people don't know if reporting occurs. The most legitimate concern is that data will be used for prosecutorial purposes. This is a violation of guidelines and frowned upon, but it does happen; there have been cases of surveillance personnel required to testify in attempted murder trials, for example, but this is rare.

Implementation of HIV surveillance has been staggered, and there has been some controversy about some of the systems. Some of the largest morbidity States only recently put systems in place. New York put a confidential name-based system in place in June 2000; California started its system using a code in July 2002; Pennsylvania in October 2002, but without contributions from Philadelphia until about 6 weeks ago; and Georgia in January 2003, with a name-based system. Currently, Kentucky is one of three areas moving from a code-based to a name-based system. Surveillance in Maryland and Texas has been code-based, but gross underreporting of HIV was detected. Texas reverted to name-based, but Maryland still has code. Oregon is the only State that has gone from name to code, converting for long-term storage purposes. Currently, 35 States or Territories use names, 8 and the District of Columbia use code exclusively, 5 use a name-code, and 2 use some combination.

A limited but growing number of States have quality HIV surveillance systems in place, but HIV data in general are not representative of the high-morbidity States of New York and California. There are other limitations—AIDS surveillance measures only late-stage disease, and HIV data measure diagnoses, not new infections, so that all infections are incompletely enumerated, and the number is affected by access to care and testing, and transmission rates.

The CDC laid out precepts for developing a single integrated HIV/AIDS reporting system in *Morbidity and Mortality Weekly Report (MMWR)* in 1999 (48:1–31). The guidelines recommended an integrated HIV/AIDS case definition; advised use of confidential

name-based reporting; recommended criteria for evaluating important attributes of HIV surveillance, regardless of reporting method; and set standards for security and confidentiality.

Funding to develop and pilot standard evaluation methods of HIV case surveillance began in 2002 for 10 States (7 name, 3 code), and data are anticipated by late 2004. Intra-State standards are for:

- ?? Completeness of reporting (> 85 percent)
- ?? Behavioral risk factors (> 85 percent)
- ?? Accuracy (< 5 percent duplicates or false matches)

On a national inter-State level, evaluation indicates the overall duplication rates of HIV meet the standard, with 35 States exceeding the standard. AIDS duplication rates meet the standard in all States. As the Nation enters the chronic care disease model with HIV/AIDS, people are likely to be reported multiple times during the course of the disease, and this must be coordinated and adjusted for. Some people have been counted as many as eight times, which is very problematic for distribution of funds. It is up to the CDC to ensure that people who receive care in multiple areas are counted just once, and the agency has done a rigorous evaluation and developed a code using the Soundex Indexing System. Timeliness of reporting has been good with name-based systems. However, there are 14 different codes in States that use codes, so that not only are States with codes unable to exchange or coordinate information with States that use names, they usually can't communicate with other States that use code either.

In summary, requirements for an equitable national reporting system include:

- ?? Standard methods of evaluation and quality control
- ?? Adherence to ethical and legal principles of public health practice, especially for confidentiality and security
- ?? Standards for data presentation and dissemination
- ?? Single patient identifier
 - By name is the only scientifically mandated and validated method, and this will take a 2-year implementation period.
 - Code or name-to-code requires validation, and implementation will require resources for studies and at least 6 years.

Discussion

Ms. Smith asked Dr. McKenna to address categories of patients, and if the high percentage of no-identified-risk people skews data. Dr. McKenna said that the program standard is for 85 percent of records to identify risk factors, and currently only about 50 percent of reports do so. One of the reasons is that as areas have transitioned from AIDS reporting to lab reports of CD4 counts, health departments must identify providers and query them, and some areas are much better at this than others. In some cases, the information is provided at a later stage, and that is used to make inferences about that totality of data. Statistically that is a valid approach, Dr. McKenna said, but it does not

provide the full impact of real people living with real disease. The CDC is about to provide \$250,000 to States to improve collection of these data. Dr. McKenna agreed that persons with HIV/AIDS may be identified in more than one way, and that someone who was reported with HIV very well might be counted again when he or she was reported with AIDS years later.

Rev. Edwin Sanders asked if there is a chronological overlay that can be applied to the graphic of the spectrum of HIV/AIDS morbidity and mortality. Dr. McKenna commented that there are many fascinating data implied by this graphic. One is the difference in the length of time from reporting HIV to converting to AIDS. At the beginning of the epidemic, the average time from AIDS diagnosis to death was 18 months; today 80 percent of patients are alive 5 years postdiagnosis, an enormous improvement. A person diagnosed today is looking at living with HIV/AIDS at least 20 years, and that is with no further advances in treatment. Rev. Sanders said that he is concerned about what happens after diagnosis, and that a statistical basis for significance is needed. He added that the decline in IDU cases can be attributed to syringe exchange, and the numbers could be decreased even more if funding was provided for syringe exchange, a proven method of HIV/AIDS prevention.

Dr. Yogev said that he is concerned that data do not come from all States and questioned whether the increase in the South is an actual increase or a reflection of lack of treatment. Dr. McKenna said that he hoped his presentation communicated his concern that only 25 States are reporting. If it were possible to obtain data from all States with confidential name-based reporting, which takes 2 to 3 years to get in place, it would capture 70 percent of cases. He said the CDC is working on this, but nonetheless assured Dr. Yogev that he shares his anxieties. Dr. Yogev added that there is a perception that pediatric AIDS has been conquered, but an estimated 15,000 young people are infected but are not dying from AIDS and he did not see that in the report.

Dr. Reznik said that he has some concerns that the epidemiological presentation hasn't changed much in 5 years, and the conversation of names versus identifiers has been going on for many years. There is confusion about the number of cases, he added—the number of cases continues to rise, the number of cases coming into the system and the number of people with AIDS is going up, yet it still doesn't go over 1 million. He noted that the recent IOM report, "Measuring What Matters," says that the number of cases is an important statistic. Dr. McKenna responded that he worked closely with the IOM on that report, and he does think that its recommendations are being followed. In terms of reaching 1 million cases, there are still 15,000 people with AIDS dying each year, so if there are 40,000 new cases, that means an increase of 25,000. The million mark may be reached this year.

Lisa Mai Shoemaker said that she learned that her own diagnosis had progressed from HIV to AIDS about 4 1/2 years ago, and even if her CD4 count goes up, her diagnosis will remain AIDS. Her question was about cases being counted multiple times—she tested positive for HIV in 1989, but that test result was lost; she was tested twice more in Florida, then in Michigan, and then again when her diagnosis changed.

Does that mean she has been counted five times? That is impossible to say, Dr. McKenna responded. If this scenario had happened in the past 2 or 3 years, she could likely have been counted multiple times. Systems are now in place to help the States communicate and keep that from happening. He added that the issue of labeling patients is a real one, and at a recent World Health Organization (WHO) meeting, it was recommended that the definition of AIDS be expanded to help in the push to disseminate antiretroviral medications. But others thought that the AIDS label should be removed altogether, and references should just be to the spectrum of HIV infection.

Mr. Minor asked if there are any reasons other than funding to report HIV numbers rather than AIDS numbers. He noted that the IOM report said that the formula rather than actual numbers drives funding, and also that using only AIDS numbers is probably undercounting people of color with HIV/AIDS. Dr. McKenna said that the advantage to reporting HIV is having good information, the best science and epidemiology, including information about methods of transmission. Looking at just AIDS is like looking at the stars light years in the future, he said. To understand the true burden of the epidemic, the earlier it is studied, the better. From his perspective, he said, as a representative of an agency that deals with prevention, and as a clinician, the AIDS numbers are not telling him what he needs to know. It makes scientific sense that HIV counts are needed to put a system of prevention in place. In terms of numbers driving CARE Act funding, the talk is of how to divide up the pie, but if people knew how severe the hunger is, the pie might get larger.

Dr. McKinnell asked, if one believes that only that which can be measured can be managed, what impact on data quality, accuracy, and timeliness would reportable versus nonreportable disease have? Dr. McKenna said that, first, he disagrees with Dr. Reznik that this is the same conversation as 5 years ago. Today all States have reporting requirements, although methods are still variable. Dr. McKinnell interjected that we live in a world where five cases of West Nile virus on Staten Island would be reported. Dr. McKenna said that the Federal Government does not mandate these data; it is States that require reporting of West Nile.

Karen Ivantic-Doucette commented that there are new ways of thinking about reporting, but there is a lack of clarity about HIV/AIDS, including the inability simply to keep track of a patient who moves from State to State. This is embarrassing from an international perspective because the United States is considered a leader in data collection. She asked Dr. McKenna what his “dream steps” would be to get closer to capturing the real numbers of this epidemic. Dr. McKenna answered that the country is moving in a positive direction, and the CDC has worked very hard to put data management into place. In the past 18 months, work has continued to identify exactly the cases that Ms. Ivantic-Doucette referenced, and by the end of the year systems will be in place to track these people. Confidentiality and security issues can be tricky, but getting communication between States the best it can be is happening. The insurmountable dimension is ensuring that everyone is using the same system. The same scientifically validated name-based system needs to be used everywhere, to get everyone to the same place.

Dr. Edward Green asked if the increase in MSM noted is in diagnoses or cases. Dr. McKenna said he thinks it is a genuine increase in number of diagnoses, although it is not clear whether that is because of an increase in cases or because more people are getting tested. Dr. Green added that numerous surveys show an increase in promiscuous sex in this group, possibly related to disinhibition resulting from the availability of antiretrovirals. Dr. McKenna said that antiretroviral therapy became available in 1996, but widespread implementation took a little longer.

Dr. Sweeney noted that the epidemic can't be measured without the data, and name reporting is the best method and should be encouraged. She said that it is the responsibility of the Federal Government in general and the CDC in particular to make sure the best science is used. The CDC and PACHA should advocate for name reporting nationwide. Regarding the cases in historically African American colleges and universities, she said that most people in those environments believed they were not at risk. Another problem is the success in treatment, which in some ways serves to defeat prevention efforts.

Mr. Sneed said that his personal belief is that science is not necessarily the salvation of humankind, and as an African American same-gender-loving individual, he sees the epicenter of the epidemic. He suggested calling upon some of the techniques and strategies that were used in the civil rights movement. He also asked, how many of the 16,000 deaths from complications from AIDS in 2002 were of people who were on antiretroviral drugs? Dr. McKenna responded that the larger question is why does *anyone* die of AIDS anymore? He answered his own question: because people develop drug-resistant infections, because they don't have access to treatment, because they don't trust the system, because they are not treated appropriately. A number of studies have looked at this difficult question. Also, he said, it is difficult to classify someone as having been or currently being on highly active antiretroviral therapy (HAART) because people move in and out of care. Why someone dies of AIDS is multifactorial; a current study on morbidity monitoring is looking at this question.

Dr. Primm commented that the majority of people dying from AIDS are dying from hepatitis C, even though they are on HAART. He asked why there is a decrease in the AIDS rate in a State with longstanding reporting. That is a State with a large number of IDUs, Dr. McKenna said, and the decrease can be attributed to a package of interventions, including needle exchange. The State is New Jersey. New Jersey does not have a syringe exchange program, Dr. Primm said. Rev. Sanders noted that they do not have a *legal* syringe exchange program, but they do have people in the State who recognize the significance of this particular intervention.

Rev. Sanders added that the issue of syringe exchange is clearly one of the "elephants in the room," something unacknowledged but with a tremendous impact. Many issues relate to race, Rev. Sanders continued, including the issue of reporting. As the complexion of the disease changes, the stigma is still very real, and many people with HIV/AIDS also have to deal with the larger element of race. This continues to drive some apprehension about a more open system of identification, he said, and safeguards need to be

established. He contrasted immigration laws—a gay male of European ancestry who wants to enter the United States can get in by simply not disclosing his sexual preference, but someone from an African country such as Uganda cannot get into the United States.

Dr. Primm said the HIV/AIDS rate among African Americans in Utah is the second highest in the Nation, and asked how the CDC is addressing that. Ms. Cleveland responded that the CDC must distribute dollars based on a national perspective. It is the responsibility of the community to address local needs, and groups in Utah should work together to comprehensively address the epidemic in that area.

Dr. Sullivan concluded the morning session with the comment that it had been a stimulating session, and the number of elephants in the room keeps growing all the time. The session that followed was an ethics briefing during a working lunch.

AFTERNOON SESSION

Mr. Minor introduced the panel of speakers, noting that the presentation was in panel format because the reports are related.

The “Down Low”: More Questions than Answers

Presenter: Greg Millet, Epidemiology Branch, Divisions of HIV/AIDS Prevention, National Center of HIV/STD/TB Prevention, CDC

Mr. Millet thanked PACHA members for inviting him to speak about the Down Low (DL), a phenomenon that has sparked controversy in the African American community and elsewhere. The Down Low today poses more questions than answers. Also called “on the low” or “low low,” or “men on the DL,” it refers to heterosexually identified African American men who have sex with men but don’t tell their female partners. There are a number of popular assumptions associated with it. One set relates to identity:

- ?? African American
- ?? Male
- ?? Heterosexually identified
- ?? Masculine
- ?? Shun mainstream gay culture
- ?? Transitional rather than permanent status.

Another set of assumptions about men on the DL refers to their partners and practices:

- ?? Casual male partners
- ?? Steady female partners
- ?? Nondisclosure of MSM activities
- ?? Unprotected sex with both female and male partners
- ?? Unawareness of HIV status. If they do know they are HIV-positive, they do not disclose it to their sexual partners.

Cultural assumptions are of the DL as an African American phenomenon, but other racial and ethnic groups engage in identical behaviors. It has become identified to African American culture because the term arose from the African American MSM community, the general African American community identifies the DL as a problem, press about the DL has focused on African American men, and African American men on the DL identify with the term.

DL has become a focus of debate in the African American community. J.L. King, an African American author and public health educator who was formerly on the Down Low, shocked a public health conference with this announcement:

I sleep with men, but I am not bisexual and I am certainly not gay. I am not going to your clinics, I am not going to read your brochures. I am not going to get tested. I assure you that none of the brothers on the down low like me are paying the least bit of attention to anything you have to say.

While the public health community is just beginning to learn about the Down Low, the term dates to the late 1980s and early 1990s, when authors such as E. Lynn Harris and James Earl Hardy wrote novels about aspects of the culture. In the 1990s, musicians including R. Kelly and TLC attracted broader attention to the DL. Elevated rates of HIV infection in young African American MSM have been noted in the mainstream press; one recent episode of NBC's "ER" mentioned a connection between an African American DL rapper and HIV. By mid-2003, there was an explosion of publicity about the DL, including a magazine article in the New York Times in August 2003 and an article in the Washington Post.

The resultant discussion has been sometimes acrimonious. Responses to the New York Times Magazine article, "Double Lives on the Down Low," raised an uproar about the threat this brings to African American women. "We will continue to lose sisters because men will not come out," J.L. King wrote. And a comment posted on the New York Times Web forum contended that the issue may not be exactly what it seems: "too often the DL brother is constructed as the vessel of contagion ... beyond this ... [is a] heterosexual assumption that AIDS is born and bred in gay communities, then venomously spread to pure, sterile black communities ... [the fact is] that many ... straight black people are HIV-positive and spreading the disease among themselves without any help from 'evil' black gay men."

In the 14,334 cases of AIDS in African American men reported by the CDC in 2002, exposures were 32 percent through MSM, 19 percent through IDU, 14 percent through heterosexual contact, and 4 percent both MSM and IDU. Statistics about African American MSM are based on estimates. African American women have the largest percentage of heterosexually transmitted AIDS of all women, and it is unknown how much of this is attributable to DL men. In studies, up to 57 percent of African American MSM say they also have sex with women.

Sexual identity and behavior are not simple or clear-cut. Sexual orientation is based on which gender a person is attracted to. Sexual identity is how people self-describe, to others or to themselves. Sexual behavior is based on with whom people have sex. There are many combinations, including African American men who identify themselves as heterosexual and have sex with both men and women. Most studies are conducted of men who identify themselves as gay or bisexual. In one study, nearly one-third of HIV-positive men who identified themselves as heterosexual also reported having anal sex with men. Condom use with other men was 100 percent inconsistent; with women, 95 percent inconsistent; and 46 percent reported having anal sex with women.

Theories related to Down Low behavior in the face of HIV risk include:

- ?? Homophobia in the African American community, which can lead to compartmentalization. A post on the New York Times Web forum charged: “The ‘reporter’ or anthropological tour guide provided no basis for his assertion that blacks are generally more homophobic than whites. Some studies have found similar attitudes in whites and African Americans about people with AIDS and homosexuals, and that African Americans and whites both have negative associations with gay sex and HIV.”
- ?? Dual minority status. An integrated sexual and racial identity is associated with higher self-efficacy to prevent HIV.
- ?? Nondisclosure of sexuality. Compared to African American MSM who disclosed their sexuality, nondisclosers were less likely to believe they could become infected with HIV. They were less likely to report three or more lifetime HIV tests, but also less likely to be HIV-positive. The nondisclosers were more likely to have had three or more female partners and to report unprotected vaginal or anal sex with women. They were less likely to have had more than five male partners or report unprotected sex with men.
- ?? Incarceration. Few studies have documented homosexual activity among incarcerated African American men. A study of African American MSM in Los Angeles (LA) County found no association between incarceration and HIV status and higher rates of anal sex outside of prison for men of all sexual orientations.
- ?? Drug use, and the presumption that men who use drugs are more likely than non-drug-using men to engage in risky sexual behavior. A study found that HIV-positive men who identified themselves as heterosexual were more likely than controls to use heroin, methamphetamine, and nitrites, and less likely to report condom use when trading sex for drugs.

In summary, sexual orientation, identity, and behavior are not always congruent; most previous research on African American MSM is not applicable to DL men; and theories about HIV risk among DL men must be studied with DL populations. Several research gaps exist, and Mr. Millet suggested how to meet some of them. Additional qualitative and quantitative studies are needed, and the precise meaning of the Down Low needs to be specified. Probability-based methods should be integrated into sampling procedures,

and the sexual risk of DL men needs to be determined and compared with other African American men. Researchers need to investigate contextual factors of HIV risk for DL men, including the effect of the Internet, where DL men congregate. There is a dearth of interventions for African American MSM.

Discussion

Mr. Minor commended Mr. Millet on the very informative presentation.

Dr. Green asked about the generalizability of prison studies. Mr. Millet said that is a conundrum, with African American men more likely to be incarcerated, and higher rates of HIV in incarcerated men. The LA County study is not that generalizable, and the finding that more anal sex is taking place outside prison than within was unexpected and may need further verification.

Ms. Shoemaker noted that her common sense tells her that the language of discussion around HIV/AIDS will have to change. Everyone is at risk at one time or another, although most people don't believe they are. She educates high school and college students about HIV/AIDS and when she says everyone could be at risk, she is reprimanded. But information like that in Mr. Millet's presentation confirms for her that everyone is at risk. She asked if Mr. Millet agrees that language has to change. Mr. Millet agreed that it does. He added that the fear-based methods of HIV prevention that were developed in the early years of the epidemic are not that relevant to today's world, where effective treatment exists. Also, messages about treatment are not getting out. This disconnect between sexual identification and behavior is a double-edged sword, he said. Some of these men may not believe they are at higher risk—and, indeed, when you look at the data, they are not at high risk; men who are not identified as gay don't have that many risky sexual encounters and unprotected anal sex.

Rev. Sanders addressed the mythology around this issue and asked about the relationship of incarceration. He said there could be a tremendous impact on curbing the spread of HIV/AIDS by working in jails and prisons because of the vulnerability of the incarcerated population. Mr. Millet responded that just because data are presented doesn't mean something is true—it's just what researchers have at the moment. Studies of white MSM have found outbreaks of STDs in incarcerated men, but that has not been documented in African American MSM.

Dr. Sullivan asked for clarification of the definition of DL and if it is thought to be a transient phenomenon or more permanent. Mr. Millet said that one of the problems is that there is no definition, and care must be taken that definitions of sexual identity and behavior not be overly constrictive. The popular definition in the media is men who have relationships with women, and also have casual sexual relations with men and don't tell the women. But there is a range of behaviors of people who identify with the Down Low, and the term remains malleable and elastic. Transience is unknown, and may differ for individuals; for some men this is part of a journey, while others may be comfortable with

their sexuality on the DL and want to stay that way. Of greatest concern is men transmitting diseases to unsuspecting women. About 20 studies have shown fairly definitively that African American men are more likely not only to identify as bisexual, but to be bisexually active, and currently bisexually active, than men from other communities.

Dr. Primm asked if the term Down Low has become so popularized in the media and gay community as to have a negative connotation that would further drive people underground, and if there should be an attempt to change it and use a less negative expression. Mr. Millet responded that the term was created within the community and was almost empowering, but now it has been filtered through the media and become negative. These men were already hard to identify, he added, and it is hard to get HIV messages to them. What is needed is HIV messages that get to all African American men, and a more holistic approach to men's health in programs for African Americans.

Dr. Primm asked if so-called "metrosexuals" are people on the Down Low, or just people doing what comes naturally for them, by choice. Mr. Millet said metrosexual is another term used to refer to straight men who flirt with bisexuality and have stereotypic gay characteristics, but the word represents a different phenomenon.

Mr. Sneed said that now that he is 51, he has had 46 years of experience with the types of individuals covered by this presentation, both inside and outside prison. Meanwhile, scientists study and research while people die. Prison for too many African American men is a continuum, and they spend lifetimes in the criminal justice system, involved in drug use and abuse from alcohol to amphetamines, and as commercial sex workers who lack reasonable employment. He does not believe that messages alone will solve this problem. The problem he sees is not lack of information; it is the mood of apathy. Apathy is a more serious situation than lack of information.

Concerning African American women, Mr. Sneed continued, their problem goes beyond HIV/AIDS to the fact that there is a serious shortage of African American men for African American women in this country. This may allow them to let their guard down and engage in less safe sex. Mr. Sneed encouraged the exercise of more common sense in the Council's deliberations. The problem can be solved, but it takes a great deal of effort—it takes science and common sense and love and compassion. He asked that the June 27, 2004, New York Times article about homeless gay men be circulated to the panel, with the understanding that the article is true but underestimates and sugarcoats the problem. Mr. Millet agreed with all of Mr. Sneed's points, and added that people have gone far past science in labeling and stigmatizing, and science is needed to figure out the extent of the problem. It is known that African American women are infected by bisexually active men; what is unknown is the extent of the problem and the actual HIV sexual risk.

Debbie Rock said that her concern is the way all this affects women, no matter what terminology is used. The women and their children are the ones who are suffering, and they never had a choice about any of it. Mr. Millet said that it is known that women are

becoming infected with HIV through bisexual men, but what is not known is if this is a huge bridge like the Golden Gate Bridge or a small footbridge. He clarified that the epidemic seems to be MSM-driven, not bisexually driven.

Dr. Joe McIlhaney said that the issue in Africa has also been HIV-infected men passing the infection to their wives, and the behavior changes in Uganda have resulted in a decrease in HIV. The job of this Council, he said, is to figure out the solutions for this country. Mr. Millet added that the job of the Council is not to demonize DLs, and that sexuality is far more complex than that. A woman may know her partner is sleeping with other men or women, and still choose to be with that partner.

HIV Treatment Barriers for African Americans

Presenter: Dr. David Malebranche, Emory University School of Medicine

Dr. Malebranche thanked the Council for inviting him to speak, after a previous presentation to the Treatment and Care Subcommittee. He introduced himself as a clinician at an AIDS clinic in midtown Atlanta, and he also supervises residents, medical students, nurse practitioners, and physician assistants in internal medicine and does research on the social context underlying the epidemiology statistics. This is to ensure that researchers remember that the numbers represent people. His research focus is on different levels of treatment barriers.

This presentation examines two issues: first, health disparities and HIV treatment for African Americans and why African Americans are dying at such disproportionate rates; and second, barriers to treatment, with voices from a marginalized community to explain some of the barriers. One of three African American men who have sex with men is HIV-positive.

Recent reports have highlighted the unequal treatment for a broad range of health problems for African Americans and whites. More than 100 studies have found that minorities are less likely to receive needed services. Reductions in AIDS mortality among African Americans have not equaled those in white Americans, despite the introduction of HAART. Moreover, African Americans with HIV/AIDS use less outpatient and more inpatient care than their white counterparts, even when controlling for insurance and socioeconomic status. Heavy reliance on inpatient and emergency room (ER) facilities leads to fragmented care and worse HIV health outcomes, while increased outpatient support and ancillary services lead to improved adherence, increased clinical retention rates, and decreased hospital admission rates.

Interpersonal aspects of care, particularly the patient-provider relationship, are important to minority patients and women. However, some researchers have observed physician bias, specifically, physician perceptions of African Americans as less educated, less intelligent, and less pleasant. These perceptions influence physician expectations of their African American patients to engage in risk behaviors and follow medical advice, and it influences their treatment decisions. Meanwhile, patient perceptions of negative expectations from health care providers may influence their adherence to HAART.

Dr. Malebranche wanted to examine these communication gaps from both physician and patient points of view. In preliminary investigations, he spoke with a group of HIV-positive African American men. One stated that he thought his doctor was just trying to make money for pharmaceutical companies. Dr. Malebranche established a protocol of qualitative research measures that included eight focus groups of 81 self-identified African American MSM, in Atlanta, New York City, and upstate New York. He had support from the AIDS Education Training Center, and his work was published in the January 2004 Journal of the National Medical Association. His study objectives were to:

- ?? Explore the perceived barriers to health care among African American MSM
- ?? Describe the health care experiences of African American MSM
- ?? Describe the factors affecting adherence and health care utilization among this population.

Dr. Malebranche identified four types of barriers: external, internal(ized), institutional, and pharmacological. External barriers include finances, insurance, access to clinics, transportation, and education and literacy. Some people cannot afford to take time off of work to sit in a doctor's office. They may be faced with a battle whether to give priority to their work or their health care. He quoted a participant from a Manhattan focus group: "What I've realized is you have to have money. That's been my goal, to get a job with insurance. Because if you don't have insurance, it's like you don't exist."

Internalized barriers include racism (racial stress and stereotypes), sexual prejudice, fear, distrust, mental health problems, and substance and alcohol abuse. Dr. Malebranche used quotes from his focus groups to illustrate some of these barriers:

- ?? Racial stress: "Being a black man is a hard struggle. Not just being gay, being straight—being a general black man is an everyday struggle. I don't care how you put it, white America either wants you in a cell or a grave." And: "We [black men] have to wake up in the morning and put on armor every day." And: "Because we're black, we all have the same face. So when you approach someone, they think that you're going to automatically cross them in a very aggressive, intimidating way. You're black first."
- ?? Sexual prejudice: "In school you got peer pressure. Everything, a lot of it revolves around sexuality. 'Oh, he dress gay! Oh, he talk gay! Oh, he look gay!' You know, so when you go to the doctor and he asks you, 'Okay, have you had sexual ...' — 'No!' I mean, that's just how you look at it, because that's just it, this big ol' thing about gayness, it's just no. Just no, no, no."
- ?? Fear: "You know HIV is prevalent in your group, you catch a cold and you're scared to go to the doctor."
- ?? Stereotypes: "As being a young black male, if I would come and say something's wrong with me, they [medical providers] would say, 'Oh, look at this, you know they probably just hip-hoppin' and screwin' down and you know, smokin' the blunts, and then he gonna come here, talkin' about how he sick.' So it's like I'm stereotyped already. And now if you say you're gay, everybody can get the picture of the feminine, gay brother. So I guess it can come to the sexuality, because they feel, 'Oh, you must have been loose in the booty already.' "

- ?? Distrust: “I see doctors as opportunists. They’re like legal hustlers. Just legal drug dealers.” And: “The same way you look at your shoes [right with left] is how they [doctors] look at gays. Gays is AIDS. AIDS is a monkey. In the dark understanding of the virus itself, that’s where it came from, monkeys. And the monkeys represent what? Blacks.”
- ?? Mental health and substance abuse: This is another elephant in the room, rarely discussed.

Institutional barriers are another type of impediment. These include clinic stigma—some patients won’t enter a clinic if it is identified as an HIV clinic. Waiting times can be another barrier; patients may have to wait weeks for a visit to be scheduled, then hours once they arrive, and then get rushed through. They often see multiple personnel, another barrier. They are concerned about confidentiality and who will see their records, and are bothered by impersonal health care workers.

Quotes from the focus groups illustrated some principles relating to institutional barriers:

- ?? Choice of access: “I would rather go to the emergency room than go to my doctor’s office, because I know there [the ER], I’m seeing the receptionist, the nurse, the doctor, and that’s all.”
- ?? Judgments: “I was talking to her [the doctor] about the symptoms I was having. And she’s like, she asked me when was the last time I had anal sex. And I told her, like whenever it was. And she’s like, ‘Well, you know ... the anus really isn’t made for that.’ And this really surprised me. And I was like, ‘Yeah, I know, but it’s a little too late.’ You know?”
- ?? Interpersonal relationship and adherence: “My doctor now, I wouldn’t say she’s uncaring, but she’s not that caring either. She’s like, ‘I wanna put you on medication.’ And I’m like, ‘Why?’ My viral load is undetectable and my T-cell count is in the 700s. And I’m like, ‘No!’ She says, ‘Well, if that’s the way you wanna go, fine. But it’s your life and if you die quicker because of it, then don’t come crying to me.’ And she filled out a medical form for me and said, ‘Refuses to take medications!’ in big letters! That pissed me off!”
- ?? Communication: “I think a lot of times it’s just a culture. And a lot of these people [medical care providers] might be knowledgeable, but they’re not knowledgeable of the people they’re dealing with. So they’re generally mechanical. They know how to do this, they know how to do that, but they don’t know how to deal with you. They don’t know.”

Pharmacological barriers include access, cost, pill burden (which is improving), pill timing, side effects (sometimes seen as trading one disease for another), resistance, and few long-term efficacy studies. Results of studies are just beginning to come in.

In conclusion, the barriers to HIV treatment are multidimensional for African Americans, and not just for MSM, although Western medicine is seen as more detrimental to African American MSM. The culture of medicine as a barrier was a theme that was repeated in all the focus groups, as well as the importance of the doctor-patient relationship.

To have the greatest impact on access and adherence and improve HIV outcomes, the approach must be at all four levels: external, internal, institutional, and pharmacological. An effective HIV vaccine is not expected until 2009 or 2010 or even later, and as African Americans carry a disproportionate burden, it is necessary to look at the whole picture. The weakest link is at the institutional level.

Dr. Malebranche said that the focus groups explained the statistics for him. He listed program and policy implications of these treatment barriers for African Americans in the four categories:

?? External

- Establish a national health care system. This is another elephant in the room, but it should be acknowledged; health care is not a privilege but the right of the American people. Dr. Sullivan noted that 44 million people at any point in time and 60-some million through the course of a year do not have health insurance coverage.
- Increase Ryan White and ADAP funding.

?? Internal(ized)

- Look at HIV in a more holistic context; focus more on the social context of HIV and its impact on health care utilization and treatment.
- Fund social empowerment health initiatives (gender- and culture-specific).
- Hire and retain more mental health providers at HIV community-based organizations and medical facilities. A one-stop-shopping approach is one way to accomplish this.

?? Institutional

- Support partnerships between academic centers and community- and faith-based organizations.
- Fund innovative health and community programs. A good example is Project Brotherhood in Chicago.
- Fund cultural competency programs for ALL medical staff, not just doctors, but also nurses, receptionists, phlebotomists, and anyone who interacts with patients.

?? Pharmacological

- Develop more tolerable, simple medication regimens.
- Develop programs targeting patient facilitators of adherence.
- Support microbicide development.

Discussion

Ms. Rock commented that without good, quality support services, what researchers do means nothing. One example is child care—without it, parents simply cannot get to their appointments. Peer mentoring is another essential; without assistance in understanding medical language (or the English language), medicine can't help much. Dr. Malebranche agreed that social services must catch up with technology. HIV is a social disease—it's not West Nile, and it's not the flu, and it forces the medical profession to look at issues of sexuality and disparities in care. It focuses on the whole individual.

Mr. Sneed noted that when it comes to African Americans, the biggest problem has been the abject failure of African American same-gender-loving men and women to mount a response comparable to that of their white counterparts. Until that is done, the community will remain in hell. Some \$600 billion goes through the hands of African Americans, and if just 10 percent of that could be applied to HIV/AIDS, it could mean huge improvements in prevention and care. Mr. Sneed suggested that pharmaceutical companies could play a motivating role, and government would never provide enough funding to solve this.

Ms. Clements said that the presentation mentioned many issues not usually spoken of. She has asked many people, why don't you make your appointments?—not realizing how threatening and intimidating that can be. The doctor may say, "I'm going to cure you of HIV but you're going to die of cancer if you don't stop smoking," and that person won't return for subsequent care. People going to appointments need an excuse to miss work for 5 hours every month, or to find a babysitter, and may be trying to hide that they have HIV. Regarding the Down Low discussion, women must take action and be more responsible and not be victims, she added, because women can control their own behaviors, even if they can't control others' behaviors.

Dr. Sweeney noted that people who identify themselves as transgenders present special issues and have high prevalence, and should be identified in a breakout category. She asked if any of the cases in 13-year-olds were vertical transmissions, infected at birth. She also asked if medical students are taught interviewing skills in this area. Smoking cessation models have demonstrated that information carries more weight when it is initiated by a physician. In response to the comments about national health care, she said that the National Community Health Center system is the closest thing this country has to a national health care system.

Dr. Malebranche answered that there is even less research about transgendered individuals than African American MSMs, although there are spot programs around the country, including some work in San Francisco. Mr. Millet added that the CDC has a project in New York City looking at transgender populations and HIV prevalence. In the past, they were combined with MSM or simply overlooked, but an outbreak of tuberculosis in transgenders got some attention. Dr. Malebranche said that he didn't think that any of the cases of HIV infection in 13-year-olds were vertical transmission cases. He added that he has found some medical students very interested in learning about human sexuality.

Ms. Shoemaker expressed concern about HIV vaccines or medication regimens, which may give people a false sense of security. She said prescribing information needs to be more detailed for physicians. Dr. Malebranche said that physicians are generally trained in cultural competency, but there are glaring omissions about sexual cultural competence. The general rule for physicians is to listen first and try to hear what patients are saying, and integrating this into general cultural competence would be very helpful.

African American Women and HIV/AIDS

Presenter: Jean R. Anderson, M.D., Johns Hopkins HIV Women's Health Program

Mr. Minor introduced this presentation as another elephant in the room—African American women and HIV/AIDS. Since the Down Low discussion brought to attention the epidemic in women and the disproportionate numbers of African American women with HIV/AIDS, the Council wanted to include this presentation, with information about the level of treatment of African American women. Dr. Anderson was referred to the Council by Debbie Rock.

Dr. Anderson, an obstetrician/gynecologist who began the women's HIV clinic at Johns Hopkins Medical Institutions in 1987, has been caring for women infected with HIV for 17 years. In considering HIV/AIDS prevention and treatment, it is important to realize that African American women also have to deal with the combined factors of gender and race, with unique strengths and challenges associated with each. And differences with other groups of women are a matter of degree more than substance, with similarities more striking than differences.

Dr. Anderson focused her presentation on sociocultural and psychosocial issues because they are the issues that make the difference in prevention and treatment, and the ones that she spends most of her time dealing with. A review of the epidemiology of women and HIV/AIDS shows that women account for approximately 27 percent of all AIDS cases, with the percentage varying by age. Almost half of AIDS cases and more than half of HIV infections are in 13- to 19-year-olds. African American women account for 63 percent of women with AIDS, a rate 23 times higher than for white women. In the South, this rate shoots up to almost 80 percent. Heterosexual contact accounts for more than 60 percent of new AIDS cases in African American women, and more than 75 percent of AIDS cases in younger women.

Issues in prevention and treatment for African American women can be biologic; these include vulnerability to infection, gynecologic problems, pregnancy, and possible gender- and race-specific differences in toxicity or effectiveness of treatment. Issues can also be sociocultural and psychosocial. A body of psychological work examines the way men and women look at themselves—for example, women more frequently define themselves in the context of relationships and when ill they worry about those who are dependent on them, while men worry about who will take care of them. Other sociocultural issues include low status in society, poverty, importance of childbearing, domestic violence, depression, substance abuse, and stigma.

Barriers to HIV prevention include lack of perception of risk. African American women are most often infected sexually and may not be aware of their partners' HIV risk (for example, multiple partners, men on the Down Low, substance abuse). They may not have access to adequate information. Poverty is endemic and brings with it lack of health insurance, limited access to care, child care and transportation problems, responsibility for other family members, and, in some cases, economic dependence on sex work.

Other barriers can be psychiatric morbidity, including depression, posttraumatic stress disorder, and anxiety disorders; substance abuse; low self-esteem; and youth with its implications of peer norms, older partners, inadequate communication and negotiation skills, and myths and misunderstandings.

African American women have less power than their partners in sexual relations. This is often a component of economic dependence, as well as lack of totally woman-controlled prevention methods and fears of abandonment and sexual and emotional violence. In addition, the value of childbearing and pressure to have children may decrease the likelihood of safer sexual practices—condom use also prevents pregnancy, which women may want.

A triad of comorbidities—domestic violence, depression, and substance abuse—are common in HIV-positive and high-risk women. They often coexist, and they increase the risk for HIV, poor access to care, and poor adherence to care and treatment.

?? Domestic violence. The Women's Interagency HIV Study (WIHS) found that two-thirds of women with HIV had a lifetime history of domestic violence and one-quarter to one-third a history of childhood sexual abuse. No significant differences were observed based on HIV status or race. The HIV Cost and Service Utilization Study (HCSUS) found that 25 percent of women reported physical harm after their HIV diagnosis, and half of these said the HIV status was the cause of the violence. And domestic violence is associated with increased risk for HIV. Risk factors for domestic violence include:

- Low Socio-Economic Status (SES) and educational level
- Unmarried status
- Youth
- Depression or substance abuse
- Partner's substance abuse
- Social norms reinforcing male power over women
- Pregnancy.

?? Depression. Across cultures, women have lifetime incidence rates of major depression twice that of men. In women of all races who are HIV-positive, depression rates are more than twice those of men with HIV and the general population. Increased risk behaviors are seen in women with HIV and depression, including inadequate adherence to medical followup and HAART regimens. Untreated depression is associated with more rapid CD4 decline and increased mortality. More positively, treatment of depression is associated with increased likelihood of HAART treatment. However, African American women are less likely than others to use mental health services.

?? Substance abuse. Women are almost 50 percent less likely to use illicit drugs than men, and African Americans have lower rates of alcohol use than whites. Rates of illicit drug use are similar. Substance abuse plays a key role, however, among African American women in HIV transmission, even if it is not the women's own substance abuse. Non-IDU is responsible for a substantial proportion of unsafe sexual behavior and is a major risk for HIV infection. It is a huge barrier to both prevention and treatment.

Biologic vulnerability compounds the psychosocial risks. Women are more vulnerable to STDs including HIV for anatomic and possibly hormonal reasons. Rates of STDs are highest in young African American women, and other STDs increase the rate of HIV transmission.

Women do not have control in barrier prevention methods, but female condoms are being used increasingly by the female African American population that Dr. Anderson treats. While the female condom is female-controlled, it cannot be used without the knowledge of the male sexual partner. The critical need is for an effective microbicide, which can be controlled by a woman and used in secret.

Important barriers to care are late diagnosis and disclosure issues. African American women are more likely than African American men to be diagnosed late in the course of HIV/AIDS, and 56 percent of individuals diagnosed with AIDS within a year of HIV diagnosis were African Americans. This is because of the lack of perception of risk, and a general care pattern that is sporadic and crisis-oriented because of competing demands of life. It is incumbent upon health care providers to talk to African American women about HIV and offer testing. Disclosure issues also loom large. Dr. Anderson knows of many women who have been beaten or abandoned after disclosure of HIV infection to their partner. And stigma has decreased dramatically, but it is still a huge issue.

Other barriers are lack of access to care, often because of lack of insurance, transportation and child care issues, and lack of trust in the health care system; and competing concerns, including food, shelter, drugs for substance abusers, and tending to the needs of children and other family members. Depression is another barrier to care, as are adverse reactions to medications. Many women experience fat redistribution from drugs, for example, which leads to body image changes.

Poverty is a huge issue. The majority of U.S. women with AIDS are unemployed; of those with jobs, 83 percent earn less than \$10,000 a year. Half have at least one child under the age of 15. Women are 1.6 times more likely than men to delay medical care, and having a child increases the likelihood of delay. A HCSUS finding was that women and African Americans had less desirable patterns of care and were less likely to receive HIV-appropriate medications; insurance was a major mediating factor, and care improved with time.

More than one-third of HIV-positive adults in care went without or postponed care at least once in 6 months because of competing subsistence needs such as money for food, clothing, and housing; lack of transportation; inability to get out of work; or feeling too sick. A study found that having at least one competing need was associated with never having received antiretroviral drugs.

Dr. Anderson has seen her HIV-related practice grow from one-half a clinic day per week to a current one-third of the entire clinic population. From the start of the epidemic, she observed frequent gynecologic (GYN) problems in these patients that may or may not have been related to HIV. Dr. Anderson advises all gynecologists to think about HIV when they see women with GYN problems. Of 262 HIV-positive women in one study, 46.9 percent also had at least one continuing GYN condition; and in an inpatient AIDS service, 83 percent of the women had coexisting GYN problems, although only 9 percent were admitted with a primary GYN problem. There is no evidence that these problems vary by race. Commonly observed conditions include:

- ?? Menstrual disorders
- ?? Genital ulcer disease
- ?? Abnormal vaginal discharge
- ?? Pelvic inflammatory disease
- ?? Human papillomavirus (HPV), cervical dysplasia, and neoplasia. HPV is particularly persistent in HIV-positive women, and is viewed as an opportunistic infection.

HPV is associated with cervical cancer, and in 1993 invasive cervical cancer became an AIDS-indicator condition. Women with HIV and cervical cancer tend to be younger and less immunosuppressed compared to HIV-positive women with other indicator conditions. Also, women with HIV and cervical cancer are generally younger than HIV-negative women with cervical cancer.

Pregnancy is an important aspect of being female, and studies have looked at pregnancy after HIV diagnosis. Dr. Anderson observed that many of her African American patients were driven from the health care system by health care providers who were judgmental about childbearing. Some 18 percent to 40 percent of U.S. women become pregnant after a diagnosis of HIV. In the WIHS cohort, 7 percent of women reported conception annually, from 1994 to 2002, and more than three-quarters occurred *with* the use of contraception.

Of U.S. women in general, 36 percent say they want children in the future; that number decreased to 29 percent in a HCSUS study of HIV-positive women. More than half of the HIV-positive women had CD4 counts under 200 and slightly more than one-quarter had partners who were also HIV-positive. As many as 50 percent of all pregnancies are shown to be unintended, and that number has been found to be as high as 80 percent in HIV-positive populations. Dr. Anderson suggested a number of possible reasons:

- ?? Lack of power in sex relationship
- ?? Pressure from partner or family to have children
- ?? Unawareness of contraception options
- ?? Belief that a woman cannot become pregnant if she is HIV-positive
- ?? Disorganized lifestyle
- ?? Taking chances
- ?? Cognitive impairment.

Much of Dr. Anderson's current practice involves preconception care and counseling, mostly with HIV-positive African American women, and sometimes with their partners. She discusses with them how to get pregnant safely and using antiretroviral therapy before conception. She advises other practitioners to discuss pregnancy with their HIV-positive patients at intervals during routine care with emphasis on these situations:

- ?? Interest in conceiving
- ?? Nonuse or inadequate use of contraception
- ?? Change in relationship
- ?? Medications with potential for reproductive toxicity
- ?? Important new developments in pregnancy and HIV
- ?? Risks for unintended pregnancy
- ?? Enrollment in clinical trials.

Treatment goals for these women include choosing drugs effective in reducing perinatal transmission; attaining a stable, maximally suppressed viral load; evaluating and treating antiretroviral side effects that could affect maternal or fetal outcomes (for example, hyperglycemia, hepatic toxicity, anemia); evaluating OIs and the need for prophylaxis; and administering appropriate immunizations.

One of the barriers to adherence is refilling medications, and appropriate social supports can make a difference. Unfortunately, there is a dearth of information about safety and toxicity of antiretrovirals in women, and some indications that severe side effects are increased in women. These include lactic acidosis, pancreatitis, and liver toxicity.

Nevirapine is an anti-HIV drug often used in women, including pregnant women. Recently the Food and Drug Administration (FDA) required a black box warning for women with CD4 counts above 250, warning of a rash-associated hepatotoxicity that is 10 times more likely in women with higher CD4 counts. Hepatic failure and death have been reported among women, including pregnant patients, and this usually occurs early in therapy with little warning. This drug should be used with caution in pregnant women with higher CD4 counts, and generally only when other options are not available or acceptable.

A growing number of studies are beginning to show what works to prevent HIV in women. Skills-building techniques focus on condom use, cognitive coping skills, and communication skills. Project RESPECT was one program that was effective in reducing

unsafe behaviors; it employed interactive counseling interventions focused on self-efficacy, attitudes, and perceived norms. The CDC's Women and Infants Demonstration Projects found that media outreach and community mobilization increased condom use.

As a clinician, Dr. Anderson has had an opportunity to observe certain strengths in African American women with HIV. These include solidarity and sisterhood, religious faith, and multigenerational networks. These are not unique to HIV but play a positive role for HIV-infected women.

There is ample information from published literature that supports the need to better identify and use social support networks for women. Use of peer counselors as case managers and outreach workers has been responsible for the success of her program, Dr. Anderson said. Journal clubs are also a good way to identify barriers and supports, and journaling itself can become a tool to enhance adherence and help support.

Knowledge is important, she added, but it is not everything. Women must be engaged "where they are," they must change attitudes and norms, and they must develop communication and negotiation skills. Religious faith is a real weapon against HIV, with the ability to promote prevention and adherence to treatment and provide needed support. Religious beliefs are also associated with safer sex behaviors, attitudes toward sex, and the ability to negotiate safe sex in African American adolescent females.

Dr. Anderson concluded with inspirational and instructive quotes from some of her patients:

- ?? "I thank God for opening the gates of hell and letting me out," said one woman who saw HIV as her second chance in life.
- ?? "I think God placed me here in this situation to help other people, because cocaine will kill you quicker than anything else. Having HIV was a turning point in my life. God got mad at me. So I made a choice: did I want to live with this disease, or did I want to kill myself? God pulled me through this and I don't have to die in secrecy."
- ?? "HIV is not my worst problem." This statement illustrates the need for other services along with HIV treatment to be provided as conveniently as possible, and to address the proximal societal causes of HIV infection such as stigma and discrimination, mental illness, substance abuse, and status of women. Until these are addressed, Dr. Anderson said, the fight against HIV will be a losing battle.

Discussion

Dr. Jane Hu said she learned a great deal from the afternoon presentations, and the three speakers shed light on cultural and social issues related to HIV/AIDS in African American communities. She emphasized that not only health care providers but also the whole of American society should know about these issues. She asked if the Treatment and Care and Prevention Subcommittees could write resolutions to recommend more appropriate social and cultural approaches in the African American community, using information presented by today's speakers. She emphasized the importance of the

President and Congress understanding social and cultural issues of the African American community, because that is what could cause change. Mr. Minor answered that the current motion, contained in the briefing book, asks for more research dollars for prevention and targets the African American community. That will be discussed tomorrow. Dr. Hu added that the African American community, male and female, needs HIV clinics to understand their social and cultural problems.

Dr. Primm asked about the impact of the black box warning for nevirapine. Also, he said he was struck by the information that 77 percent of conceptions occur with the use of some sort of contraception, and knows of condoms that come off during intercourse. Dr. Anderson said that nevirapine is a huge issue of concern. A single dose to prevent vertical transmission has been shown to be safe, and the WHO recommendation for use of HAART includes nevirapine-based regimens for women. There is concern about the implications of these therapies, and no answers yet. Regarding condom failure, she said that condoms are the most common contraceptive device used, and they provide dual protection against pregnancy and disease. She added that she hasn't had complaints from her patients about condoms coming off, but breakage is the most common complaint.

Dr. Green noted a 1995 study from Johns Hopkins that looked at condom use over time in an African American population and found no difference in STD rates between users and nonusers. He also asked how age fits into the concept of biological vulnerability. One of the reasons Uganda has focused on trying to get young people, especially females, to delay sexual debut is because they believe younger females are more vulnerable than older women, with more delicate sexual organs, vulnerable to tearing. Dr. Anderson said there is some evidence of a more vulnerable epithelial covering in younger women, which may be associated with the hormonal factors she mentioned. This also might explain high rates of STDs among adolescent women, although it is not clear if STDs are mediated through trauma. Dr. Green added that maybe a culturally competent message to the African American community should be to delay sexual debut.

Mr. Grogan said that the HCSUS data, although recently published, is about 8 years old, and asked if more recent data are available. Dr. Anderson said she has not seen any recent updates from HCSUS.

Ms. Rock emphasized the importance of the one-stop-shopping approach for treatment and social services. In a dream world, she said, women with children could get treatment alongside their children, as well as support services. She asked if such an approach is doable. It is, Dr. Anderson responded, and a Hopkins study several years ago found that women did better in adhering to recommended care for their children than they did for themselves. She added that perinatal transmission can be reduced to a very low rate (less than 1 percent) with current methods, but won't be wiped out entirely because of women who do not perceive their risk.

Dr. Malebranche spoke of gender role conflict and stress, and what is expected of men and women, and how that pressure affects behavior. One-stop shopping, he said, must be focused on both culture and gender. Concerning biological vulnerability, he pointed to a

body of literature about behaviors that put women at increased risk for HIV, such as overuse of vaginal douches, and the fact that African American women have been found to be more likely to use douches. It is behaviors and practices that transmit HIV—not who is doing something, but what he or she is doing.

Dr. Prem Sharma said that the disproportionate incidence of HIV in African Americans is very striking and asked if there are any data available on the progression from HIV to AIDS based on race, or any biological evidence that it progresses at a different rate dependent on race. Mr. Millet said that two large multisite studies in men and women have looked at natural progression of HIV/AIDS, with African Americans being a large subset of the study. Dr. Anderson said that several studies have shown that women tend to have viral loads about half that of men in early infection, and then the loads start increasing until there is ultimately no difference. Mr. Millet said that one study reported in the MMWR comparing men of different ethnicities after HAART treatment found that African American MSM were less likely to be on HAART, less likely to be in care, and more likely to die than white, Asian/Pacific Islander, or Latino MSM.

Dr. Sharma asked for information about vulnerability to infection according to race or other factors. Mr. Millet said some studies have looked at this, including circumcision studies that have found that men who are circumcised are less likely to contract HIV than those who are not. Studies that look at genetic vulnerability can be controversial, he noted. Worldwide, black populations are less likely to be homozygous, or even heterozygous, for CCR5. Mr. Millet added that psychoneuroimmunological studies have found that disease in men who rated higher on stress and mental health scales progressed more rapidly, and that further genetic and immunological studies need to be done.

Dr. Sullivan, returning to a comment from Mr. Sneed, asked what are strategies to use with people who know they are HIV-positive but still engage in risk behavior, and how they can be more responsible, particularly men who may be engaged in sexual activities to support themselves financially. Dr. Malebranche said that recent studies have found a resurgence of irresponsible sexual behavior, including a behavior called “bug chasing,” which is looking for HIV-positive men to have sex with. White men and African American men may have different reasons for their behaviors, he added, and strategies must meet the person where he or she is and deal with substance abuse, mental health, self-esteem, or whatever other issues predominate in a person’s life. A problem with HIV prevention is that it began with sexuality and a disease-based approach. But HIV is an opportunist, he emphasized, taking advantage of marginalized settings and people. If HIV is eliminated tomorrow, another disease will take its place, if underlying issues are not addressed. A new study examines African American MSM who did not have male role models, looking at definitions of masculinity and how they were raised. Those early issues set the landscape for HIV, and if social context is ignored, the underlying foundation will always be crumbling, and the battle lost.

Ms. Clements reiterated the point that many at-risk women do not consider themselves at risk or think of HIV as a possibility. If they have tested HIV-negative, they often assume that their partner is negative, or else he would have transmitted the virus to them. Dr.

Anderson agreed, noting that more effort must be focused on high-risk HIV-negative women, and that a common myth is that if they are negative, they can continue doing what they are doing. These women present an important avenue of prevention and are shortchanged if it is not taken advantage of. She said that in her program, all counselors are certified in HIV counseling and all pregnant women are offered HIV testing. If they are HIV-positive, counselors follow them. Dr. Anderson also emphasized the importance of normalizing testing and making it part of a regular GYN examination, which is the position of the American College of Obstetrics and Gynecology. She added that women should be counseled along with testing, whether the test comes out positive or negative.

Ms. Ivantic-Doucette said that the discussion of contraception struck home with her, as she herself has experienced four unintended pregnancies. Contraceptive failure is common. She is troubled by the heavy emphasis on biomedical services and medical providers as gatekeepers, even though they have limited education about health outside the biomedical domain. Both Dr. Malebranche and Dr. Anderson said that solutions that work often had little to do with the medical domain. Ms. Ivantic-Doucette suggested broadening the language to talk about primary health care, moving beyond biomedical and expanding interventions—for example, using food vouchers as a health intervention. Not only language, but also the power structure of providing care, needs further examination.

Ms. Ivantic-Doucette also asked about training for health care providers, to move from biomedical and cognitive training to focus on other health interventions. Ms. Cleveland said that programs and policies are driven by research, and most research has been biomedically focused. Most of the social research that has been done has used Caucasian gay male populations, and there is a dearth of information regarding women and communities of color. Programs must be based on the science, she said, and CDC allocates resources along disease-specific lines. It is not easy to put out a program announcement (PA) for integrated approaches, but the CDC is examining housing and other social issues related to HIV.

Dr. Malebranche added that researchers are questioning the [biomedical] institution itself as a viable tool for addressing HIV/AIDS. But alternatives are also difficult. Using churches is one option, but in some churches ideas relevant to HIV prevention cannot be addressed because the church takes a strong stand against any sex outside marriage. His response is that each church is different, and some are very progressive in discussing sexuality. That is also true of different pockets of the Western biomedical culture. He agreed with the need to change some of the language, but also recommended speaking to the larger issue of viability of institutions. Not every church, every medical school, and every medical clinic is the same, and those with viable approaches need to be identified.

Dr. Anderson said that with the explosion of biomedical information and de-emphasis of the art of medicine, the problem is getting worse, not better. Practitioners are busier, patients are more complicated, and complex training needs should be emphasized not just in medical schools but also in nursing, social work, and other related disciplines.

Dr. Yogev said he was surprised that none of the speakers suggested broader solutions, and suggested a number of issues for consideration:

- ?? HIV is the only STD in which partner notification is not required, and perhaps the Council should consider recommending it.
- ?? The CDC's patient information page has removed information about contraceptives for women, and he questioned this.
- ?? He recommended caution about nevirapine, and that clinicians might be blaming it prematurely. International colleagues, particularly, are using it and marveling how easy it is to administer. It seems to be an important drug—40 percent of women resisting with one dose, shows how effective it is—and we have to be careful not to throw out the baby with the bathwater, but more study is needed.
- ?? He questioned comments about perinatal transmission being conquered and warned that the less than 1 percent transmission rate cited was achieved in controlled academic environments. This is an area that needs continued investment.

Dr. Anderson said she did not intend to imply that perinatal transmission is over and agreed that it is still a problem, particularly with many women not knowing their status. Recently in Baltimore, four HIV-positive babies were born to women who tested negative early in pregnancy and became infected later in pregnancy.

Ms. Biaggi commented that the Down Low phenomenon is also common in Latino communities, and occurs across ethnic lines. But she has not heard anything about programs or intervention strategies that have proved effective. She suggested that with all the underlying issues, it would need a very specific intervention that addresses societal issues. Mr. Millet said that is one of the problems; there are few interventions for MSM specifically, very few that are effective, and even fewer for minorities. He knows of eight effective MSM interventions, two of them for minorities—one for African Americans and one for Asian/Pacific Islanders, but none for Latinos. There are many interventions for IDUs and women, but it is glaring that in the third decade of the epidemic, there are so few interventions that target the population at risk. He reiterated that a holistic approach to health is needed for men who have sex with men, with HIV testing as a component. Providers must make sure they are asking the right questions and not making assumptions. Evidence-based information about these populations is needed.

Dr. McIlhaney asked Dr. Anderson if she thinks HIV testing of pregnant women should be required. She said yes, but it should be an opt-out approach, so they should be able to say no if they want to. He asked at what age young women are typically infected, and Dr. Anderson said that she sees perinatally infected girls of 16 or 17, including some who are in the pregnancy program. The adolescent clinic is unfortunately growing by leaps and bounds as well.

Rev. Sanders returned to the issue of expanding the language, which he thinks is important. Discussion of holistic approaches occasionally includes a reference to religion, but spirituality has been largely overlooked. People are religious by choice, but spiritual by nature, and a lack of attention to this area accounts for much of what drives low self-esteem and translates to negative behaviors. People are caught up in dysfunctional belief systems, and spirituality must be addressed—the core, the universal principles at the heart of our belief systems, and how they come to bear in our response to HIV/AIDS. This must be addressed in a way that debunks the religious issue. Some models funded by SAMHSA and the CDC have developed around the issue of spirituality, including one that targets women.

Dr. Malebranche agreed with the need to address spirituality in research. He said that in a study currently being conducted in Atlanta, 30 African American men were asked to rank six qualities that contribute to their concepts of themselves as men, and 67 percent ranked spirituality as most important. However, that still begs the questions of what spirituality is, how it evolves over time, and how it can be factored into health issues such as HIV/AIDS.

Mr. Minor thanked all the presenters. Rev. Sanders thanked the Chair for his accurate reading of the spirit of the discussion and letting the meeting flow. Dr. Sullivan adjourned the meeting at 5:32 p.m.

**Presidential Advisory Council on HIV/AIDS (PACHA)
24th Meeting
Hubert Humphrey Building
200 Independence Avenue, S.W.
Room 705A
Washington, DC 20201**

Monday, June 28, 2004, and Tuesday, June 29, 2004

DAY 2

MORNING SESSION

Dr. Louis Sullivan convened the meeting at 8:40 a.m.

Lisa Mai Shoemaker called attention to a handout she had distributed, with articles from a Family Circle Magazine in 1986 about fears about HIV transmission and another about green tea as a treatment for HIV. The purpose of distributing the Family Circle article was to make the point that the conversation about HIV transmission hasn't changed much in nearly 20 years. She also included some material about Magic Johnson; it had appeared that young people believed he was "cured," which is disconcerting, but this material referred to his saying he is not cured.

Agenda

The morning's agenda was organized by the Treatment and Care Subcommittee, introduced by Brent Tucker Minor, and by the International Subcommittee, introduced by Abner Mason.

TREATMENT AND CARE PRESENTATION

- ?? Ryan White Reauthorization Process. Marty McGeein, Department of Health and Human Services, presenter.

INTERNATIONAL PRESENTATIONS

- ?? HHS HIV/AIDS-Related Activities in India. Dr. Amar Bhat, Office of Global Health Affairs, DHHS, presenter.
- ?? Epidemic in India. Dr. Robert Bollinger, Johns Hopkins University, presenter.
- ?? India at the Crossroads. Teresita Schaffer, Center for Strategic and International Studies, presenter.
- ?? President's Emergency Plan for AIDS Relief. Dr. Joseph O'Neill, Department of State, presenter.

TREATMENT AND CARE

Ryan White Reauthorization Process

Presenter: Marty McGeein, Senior Advisor, Assistant Secretary for Planning and Evaluation (ASPE), DHHS

Mr. Minor introduced the speaker, noting that the President has supported reauthorization of Ryan White CARE funding, and that it is important to acknowledge that the needs of people with AIDS have changed in recent years, and care and treatment need to be considered in light of that. Now is a crossroads time for the treatment of people with AIDS.

Ms. McGeein said that she is reporting on DHHS activities regarding the Ryan White CARE Act reauthorization, and she is the person in charge of pulling this together. Last week in a major address, in addition to announcing that he was making \$20 million available for ADAP, President Bush enunciated the three major principles of AIDS funding:

- ?? Care and treatment: Clinical services must take precedence over all others, taking advantage of the astounding advances in AIDS treatment in the past 15 to 20 years.
- ?? Flexibility: DHHS wants some flexibility in disbursement of Ryan White funds. Current regulations make it impossible to respond to crises.
- ?? Accountability: The Department must have the authority and the ability to assess States' activities and ensure that the funds are being used for their intended purpose.

Achieving these principles will require a fair amount of work, Ms. McGeein acknowledged. She and her staff are in the process of developing and analyzing options, and she coordinates a working group that meets biweekly. They are designing policy

options and the Health Resources and Services Administration (HRSA) has been invaluable in providing an overview and making sure key personnel are well versed. The group has been soliciting input from stakeholders. There are many roads in this particular map, she added.

Ms. McGeein recommended the two Institute of Medicine (IOM) reports, “Measuring What Matters” and “Public Financing and the Delivery of Health Care in HIV/AIDS,” as good information sources about AIDS. She said that she anticipates more interaction and discussion with HIV/AIDS-related groups, and warned that this is not a fast process, but the end result will be a fully developed understanding of where the Ryan White CARE Act should be going and how to make it responsive and responsible.

Discussion

Mr. Minor asked who is on the working group, and Ms. McGeein said it is composed of members of the Office of the Secretary’s staff, including the general counsel, representatives from the Office of HIV/AIDS Policy (OHAP), the Assistant Secretary for Legislation (ASL), and the budget people. Joseph Grogan is also a member of the group.

Dr. Henry McKinnell said that he doesn’t think reauthorization is what is wanted, but rather reform, and that perhaps the language of the discussion should be changed to talk about modernization or reform along with reauthorization. Ms. McGeein said that is understood, but changing the language might impede progress. She added that the Ryan White CARE Act has done a “mountain of good,” but HIV/AIDS care and treatment have changed, and what was good in 1990 and even 2000 might not be good in 2005. She emphasized again the principles: care and treatment take precedence, accountability, and flexibility.

Debbie Rock asked what the PACHA role is. Ms. McGeein responded that she wants to hear from Council members; they should funnel their ideas, concepts, and questions to her, and she hopes that conversation and dialogue develop. She walks away from the conversations both enlightened and burdened, she said—enlightened because they have described something she hadn’t recognized, and burdened because she now feels compelled to fix it. Mr. Grogan is the point of contact.

Dr. Ram Yogev asked if the Council will get feedback from Ms. McGeein from time to time, and Ms. McGeein said that this type of dialogue can continue, and she is willing to come to Council meetings and provide updates on the work her Office is doing.

Anita Smith asked if there are milestones in this long process. Ms. McGeein said that the reauthorization process is a full year’s worth of work, and she knows of no particular point where the group will say, “We wish we’d known this 3 months ago.” She added that the door is open for input. There are no milestones per se, and the final deadline is September 30, 2005.

Mr. Minor noted that with the emphasis on clinical services, and people living longer and needing those services for longer periods of time, if the amount of funding doesn't expand to meet these needs, something will need to be cut. People in the community are nervous about this, he said, and as yesterday's presentations made clear, HIV is not the only problem for most people who are infected. How will that be incorporated into decisions? he asked. On one hand, people have major needs such as transportation, childcare, good nutrition, oral health, and housing. How will that be balanced against the challenge of limited funding? It will require a careful balancing act, Ms. McGeein answered, and like everything else in health care, issues must be prioritized. DHHS does not control the dollars, Congress controls the dollars. Control of funds, competing priorities, and diverse considerations are the crux of why the process will take so long. She did not have a specific answer as to how the multiple challenges will be balanced.

Jacqueline Clements said that while the Ryan White Act provides a variety of services, in some States there is an abundance of services, but in others services are very limited. She asked how to ensure that everyone living with HIV gets at least core services. Ms. McGeein said that this is a formula distribution problem, and some States have more generous formulas, including Medicaid, and she is not sure how this can be addressed. She noted that the IOM report recommending HIV reporting rather than AIDS reporting conceded that changing the reporting would not completely address this.

Karen Ivantic-Doucette asked about consideration of IOM recommendations about expanding use of Medicaid. When people with AIDS stay healthy and do not qualify for disability, Ryan White funds will not be enough for care and treatment. She asked if Medicare could function in a capacity different from its usual role, as it does for dialysis. Ms. McGeein said that the IOM study on public funding is still being reviewed, but she does not think this Administration is in a position to increase Medicaid benefits. She would be concerned about expanding the range of Medicare benefits because of the size of the population involved.

Dr. Monica Sweeney said that one of yesterday's presentations discussed the difficulty in collecting surveillance data, including the facts that reports are coming from only 25 or 30 States, and some by name reporting, some by code. She asked if, in terms of accountability and flexibility and modernization, there is something that could be done to make reporting more user-friendly for States, have it tied to the Ryan White Act, and give States time to get their information technology together and establish a somewhat uniform system. Ms. McGeein responded that the ties between surveillance and the Ryan White Act are exact, and money is disbursed on the basis of AIDS reporting. IOM has suggested reverting to HIV reporting; in the 2000 reauthorization, States were given until 2007 to report in this mode, and 36 States are currently reporting in a mode that is acceptable to the Centers for Disease Control and Prevention (CDC). So the timeline is already in place, but IOM also said that even with clean, accurate reporting, there are still problems, and it will take a huge amount of negotiation to have the money completely follow the disease. In response to another question from Dr. Sweeney, Ms. McGeein said that HIV name-based reporting is what the CDC wants.

Rev. Edwin Sanders made a formal request that Ms. McGeein be in attendance at all Council meetings until the reauthorization process is completed.

Dr. David Reznik said that oral health care is one of the top three unmet needs of people with HIV. As a care provider in a primary care setting, he also understands that patients have many comorbidity factors—for example, substance abuse, poverty—and care and treatment need to be prioritized, but it is also essential to not undersell the importance of some of these support services that allow people to take medications. If someone is homeless, he or she is not likely to take medications. Ms. McGeein answered that she understands that in providing care and treatment, services that allow someone to access care and treatment should not be eliminated.

Dr. Sullivan asked for more information about members of the working group. The members are from the internal Office of the Secretary, Ms. McGeein said. The next phase of the process, beginning in late summer or early fall, will involve conversations with stakeholders, the service providers and other patient advocates. Early in the process, she added, these representatives said they were not ready for meetings, and they have been allowed to complete their work but they will be an important part of the process.

Mr. Minor asked what further accountability is sought and what seems to be missing. The reports required are very comprehensive and time consuming to complete, he said, and present a burden for some agencies, particularly small ones. Ms. McGeein said that an agency may say at the beginning of the year it is going to do something, but when its report comes in at the end of the year, it did something else. HRSA would like to have an explanation of these discrepancies, and the long interim of silence worries some people. However, some States and cities are superb in their accountability, she added. In response to a comment from Ms. Rock about the large number of reports about program progress that are written and filed, Ms. McGeein said there is a need for a feedback loop, which does not currently exist.

Cheryl-Anne Hall asked if, with the burden of HIV/AIDS shifting to the African American community, funds will be shifted to the African American community, where there is a need. Ms. McGeein said that part of the answer is related to the formula. The goal is for the money to follow the disease, and the hope is that by changing the structuring so that care and treatment come first, artificial barriers will be removed and that will be the result.

Remarks

Mr. Minor thanked Ms. McGeein for her presentation. Dr. Sullivan announced that Dr. McKinnell had some comments to share with the Council.

Dr. McKinnell said he shares the President's concern that too many people do not have access to lifesaving medicines, and concluded that the pharmaceutical industry needs to be part of the solution to that problem. In 2002 Pfizer froze its prices on drugs for the ADAP program. Even though the \$20 million designated for ADAP will clear the waiting

lists, they will grow again. Pfizer is announcing that it is continuing the price freeze on HIV drugs through September 2005, he said. There is still concern that people do not have access to drugs, however. Pfizer is also finalizing a program that gives the uninsured access to the lowest drug prices; low-income uninsured will be able to get Pfizer drugs for free for a \$15 monthly access charge. Ms. Hall asked how patients will know about this. Dr. McKinnell said a press release would be issued on July 7, 2004. Dr. Sweeney said that a program called Share the Care helps make Pfizer drugs available to many patients in community health centers and she is glad to hear that Pfizer is making the savings more broadly available.

Dr. Sullivan said that at yesterday's session the transition underway for staff at the President's Office was noted, and he asked Dr. Elizabeth Onjoro from that Office to tell the Council about her new responsibilities.

Dr. Onjoro is with the Office of the Global AIDS Coordinator, which is now focusing on 15 countries, since Vietnam was recently added to the list. The Office handles oversight in these countries, to ensure that the emergency plan is implemented, and that the program is integrated with the countries' own 5-year plans. The goal is to make sure those two purposes are blended, and that tax dollars are spent appropriately and accounted for. All HIV activities in the 15 countries are being coordinated with the goal to provide care in the most effective and efficient manner possible. The countries have not yet been divided, as staff determines the best rationale for teaming countries. She requested support and encouragement from the Council.

INTERNATIONAL

Mr. Abner Mason said that the International Subcommittee has had a busy and productive period since the last Council meeting. The Subcommittee has two resolutions it is proposing. One is to select a 15th country for the President's Emergency Plan for AIDS Relief (PEPFAR), but since that has already been done, that resolution will be modified. The other is to improve the prevention of mother-to-child transmission while still providing treatment options for mothers. To increase understanding of what is happening in Asia, and particularly in India, the Subcommittee has invited speakers knowledgeable about that part of the world to share their experiences and views.

Overview of HHS Activities in India

Presenter: Dr. Amar Bhat, Director, Office of Asia and the Pacific, Office of Global Health Affairs, DHHS

This Office is fairly new, Dr. Bhat said, but global health has been of interest to the Secretary for some time. The Office combined the Offices of International Activities and International Refugee Health about 2 years ago and formulates policy and provides advice to the Secretary and Deputy Secretary and DHHS agencies about their international activities. All of the HHS agencies listed in the Department's organizational chart have important activities in HIV/AIDS. Dr. Bhat's presentation focused primarily on India, but also covered some activities in Vietnam, and the Global Fund to Fight AIDS, Tuberculosis and Malaria, which is meeting this week in Geneva, Switzerland.

The United States has a long history of cooperation in India and has been involved in the country since the 1960s. The Health Office in the U.S. embassy represents DHHS in India. The original intent of the Office was to manage U.S.-controlled rupees (received from India for grain purchases) to fund cooperative health projects, as well as education and cultural projects. Over the past 35 years, the Health Office has directed more than \$200 million in U.S.-owned rupees to fund cooperative health projects in high-priority areas such as HIV/AIDS, tuberculosis, malaria, polio, leprosy, and cancers of various sorts. Some of the projects, for example, in oral cancer, have led to benefits not only for India but also for global populations.

Today the shift is from rupees to NIH dollar grants and CDC technical assistance. The Office's annual budget is about \$40 million, with about half of that designated for HIV/AIDS activities, 1 of 10 Indo-U.S. bilateral programs. NIH grants are increasing rapidly, and the quality of scientists in India has gone up dramatically, partly because of the rupee reinvestment program. The NIH is authorized to make competitive grants to foreign investigators, and most of the awards are to teams of U.S. and Indian scientists. The NIH has a long history of training and capacity building; the NIH Visiting Program funds more than 150 Indian scientists on the NIH campus, and the Fogarty International Center sponsors 30 to 50 Indian trainees in the United States and hundreds in India each year.

Dr. Bollinger will speak in greater detail about NIH-supported research in India in the next presentation. Some of the projects include the National Institute of Allergy and Infectious Diseases (NIAID) Comprehensive International Program on AIDS, the NIH International AIDS Project, and NIAID's HIV Vaccine and Prevention Trial Networks. The CDC also has a number of programs in India, and they are increasing rapidly, covering health problems such as polio, AIDS, tuberculosis, and malaria.

The CDC's Global AIDS Program (GAP) was established in 2001 with offices in New Delhi and Chennai, in southeast India. Headed by Dr. Dora Warren, GAP has had notable activities, including work with the Government Hospital of Thoracic Medicine in Chennai, which has been nearly overwhelmed by a large number of AIDS cases. GAP had been working to help the hospital improve its lab services, information technology, patient management, and care and treatment, particularly using antiretrovirals (ARVs). The hospital is very crowded, and the CDC recently funded construction of a new ward.

India has 4.5 million people living with HIV/AIDS, almost 11 percent of the global AIDS burden and 68 percent of the disease burden for South and Southeast Asia. It faces the threat of being overwhelmed. Efforts must be sustained and prevention closely linked to care. India possesses significant assets that are not present in the rest of the developing world, including a wealth of skills in health and science, medical institutions and infrastructure, biotechnology, and a drug development industry that can help support its capacity to respond to the epidemic. India recently joined the Global Fund as a board member. The country also started its own ARV therapy program, with the admirable goal of reaching 100,000 people in a year.

Dr. Bhat then spoke about the HIV/AIDS situation in Vietnam, which the President just announced will be the 15th focus country to receive assistance from the President's Emergency Plan for AIDS Relief. Except for India, Vietnam is the largest country in Southeast Asia. In a population of 82 million, the HIV/AIDS prevalence is about 0.66 percent, with HIV cases in all 64 provinces and 93 percent of all districts. Vietnam is predicted to have an increase in persons infected with HIV from 130,000 in 2002 to 1 million by 2010. The epidemic is found primarily in injecting drug users (IDUs) in the north and commercial sex workers in the south, but it is spreading to the general population.

DHHS has had activities in Vietnam since 1999, and GAP representatives have been there since 2001. Two CDC staff members plus an attaché from Dr. Bhat's Office are in the country. GAP funding in Vietnam is about \$2.9 million per year, there are a few NIH grants in place, and the U.S. Agency for International Development (USAID) also has some substantial activity. Activities include voluntary counseling and testing, care and treatment, establishment of AIDS clinics, technical assistance (TA), and quality assurance in lab testing for HIV and other sexually transmitted diseases (STDs). A new GAP office is opening in Ho Chi Minh City.

Secretary Thompson is chairing the board meeting of the Global Fund today and yesterday in Geneva. The Fund is considering about \$1 billion of grant proposals, which generally have been 50 percent HIV/AIDS, 25 percent TB, and 25 percent malaria. They will also revisit the issue of continuation of grants after a 2-year limit and how to manage the process of renewing grants. So far the Fund has awarded \$2.1 billion worldwide, but only about \$300 million has been disbursed so far, with the rest pending paperwork.

Discussion

Dr. Sullivan asked for further detail about existing cases of polio in India and elsewhere. Dr. Bhat said that there are six remaining countries with natural pockets of polio—Nigeria, Ethiopia, Sudan, Afghanistan, Pakistan, and India. In India, these are mainly in the north, in Uttar Pradesh and Bihar, and scattered in the south from migration. Technically, the polio eradication program is scheduled to end this year, but mop-up activities will continue. Dr. Sullivan expressed concern that polio has still not been completely eradicated. Dr. Bhat said that until it is, continuing activities will be funded, such as multiple national immunization days. Deadlines are needed for motivation. Most of the problems are at local levels and involve local bureaucracies. In Nigeria, Afghanistan, and Pakistan, health workers encounter misinformation, i.e., that the polio vaccine is unsafe, but that is much less a problem in India. Strong efforts using religious and community leaders and others are underway to counteract the misinformation.

Dr. Sullivan also questioned the selection of Vietnam as the 15th country for PEPFAR. He noted that outside sub-Saharan Africa, more people in India are infected with HIV than in any other country. Other arguments for India are that the country already has NIH scientists, as well as a middle class and a growing economy. Dr. Bhat deferred these questions to Dr. O'Neill of the Global AIDS Coordinator's Office, who will address the Council later in the morning. But he assured Dr. Sullivan that \$20 million for HIV/AIDS assistance has already been committed to India, and funds to India will not decrease because it was not chosen as a focus country. The PEPFAR decision was based on where the United States can have the most impact, and the policymakers feel they can bring Vietnam from the brink of an epidemic. Dr. Sullivan remained unconvinced, commenting that he would like to hear more about the choice of a country of 80 million over a country of 1.1 billion.

Dr. Sullivan also asked about the NIH Fogarty program. Dr. Bhat said it is a university-based program across the country, and the NIH visiting program, which supports 150 scientists per year, is focused on the NIH campus, the University of North Carolina, and other sites.

Dr. Prem Sharma said that Dr. Sullivan's question about PEPFAR is on the minds of many, and asked if the \$40 million designated by DHHS for India is inclusive of \$20 million for HIV/AIDS. Yes, it is, Dr. Bhat responded, although the \$20 million figure actually includes funds from DHHS and USAID. Dr. Sharma also asked the status of leprosy in India, which is not mentioned in the CDC budget. Leprosy activities have wound down through the years, Dr. Bhat said, although some contracts are still

outstanding. Given the biology of the bacillus, much of the TB work has relevance to leprosy.

Dr. Sharma also asked the extent of private sector work related to polio, mentioning efforts of U.S. Rotary Clubs. Dr. Bhat replied that other organizations have also worked on this, but the Rotary stands out, and the international chairman accompanied Secretary Thompson on a recent trip through India. Also, people in India have been instrumental in organizing vaccine efforts.

Dr. Yogev commented that \$20 million to fight HIV/AIDS is not much for a country the size of India. Also, he did not see any mention of work to prevent mother-to-child transmission. Dr. Bhat said that Dr. Bollinger is concluding some studies in that area and asked him to comment on this work when he presents his report.

Dr. Beny Primm said he is concerned about the lack of focus on IDU as a driving force for HIV infection in India, when it has increased by 40 percent in some areas. It seems there would be harm reduction programs supported by the Government, he said, such as use of buprenorphine and needle exchange programs. Dr. Bhat said that GAP programs have not focused on IDU, although there have been some small National Institute on Drug Abuse grants in northern areas. He added that India is not the easiest place to work, there is stigma associated, and lack of interest in the population in attacking this problem, but some NGOs are doing good work focusing on methadone treatment and harm reduction. Dr. Primm suggested that the Council recommend supporting drug treatment programs in India.

Dr. McKinnell challenged Dr. Bhat's assessment, citing Richard Feecham, executive director of the Global Fund, that there is a huge growing HIV epidemic in India. Dr. Bhat called the efforts of the Indian Government admirable, but Dr. McKinnell contended that they are embarrassing. He knows of no drug discovery in India, although there are 22,000 drug companies in India. Many drugs are substandard because there are no patent laws and inadequate regulation. There are more drug companies in India than there are people on ARV, he charged. Dr. Bhat disagreed that there is no drug discovery activity, and said India has increased its own private sector research funding, and more original research is going on. Changes are also underway in patent law, and researchers who began training with U.S. scientists 15 years ago are now moving to leadership positions. However, he agreed that the Indian Government has not played a strong role, but cautioned that in India quiet collaboration works better than negativity and aggression.

Ms. Rock noted that culture can create barriers, and in speaking to people from India, she has learned that physicians may not adhere to confidentiality guidelines, leading to discrimination. She asked if that is being addressed in any way. Dr. Bhat said it is difficult, because it is a cultural issue, and DHHS is not doing much in this area. There is a learning curve for physicians about HIV/AIDS, he added, and training seminars and continuing education programs may be addressing confidentiality issues, but he did not know that for certain.

Ms. Ivantic-Doucette returned the discussion to polio eradication. She asked if vaccination efforts were coming up against pockets of immunosuppressed people (such as with HIV) who cannot mount a response to the vaccine. Dr. Bhat said he could not comment on medical aspects, but the polio vaccination is primarily focused on children, and they are not where HIV is seen in India.

HIV and AIDS in India: Challenges and Opportunities

Presenter: Dr. Robert Bollinger, Professor of Infectious Diseases and International Health, Johns Hopkins Schools of Medicine and Public Health

Mr. Mason introduced Dr. Bollinger, noting that he has been named director of the newly established Johns Hopkins Center for Clinical Global Health Education, which will develop and implement clinical training programs for health care providers in resource-limited settings such as India.

Dr. Bollinger thanked the Council for the opportunity to talk about the HIV epidemic in India. He first worked in India 25 years ago treating leprosy. For the past 12 years he has directed a large Indo-U.S. collaborative HIV research program with a broad menu of activities in Pune, India. The focus of that program includes clinical research in ARV therapy, microbicide studies, vaccine development, and maternal-infant transmission studies.

India is huge and complex, Dr. Bollinger said, as is its HIV epidemic. Between 60 and 65 percent of HIV cases in Asia are in India, with two new infections each minute. The first case of HIV in India was described in 1987. From 1996 to 2002, there was a 60 percent increase in HIV in India. There are different estimates for the total number of cases. The National AIDS Control Organization (NACO) says 4.6 million, the Joint United Nations Programme on HIV/AIDS (UNAIDS) estimates 5.4 million, and the National Intelligence Council estimates 8 million. Whichever number is true, they all describe too many HIV infections and a public health crisis.

Like India itself, the HIV epidemic is geographically diverse. In size and complexity, India is essentially a continent of its own. The distribution of HIV is not uniform. Dr. Bollinger hypothesized that distribution patterns reflect migration patterns in India.

Who is infected with HIV in India? The 61,201 AIDS cases reported to NACO by December 31, 2003, grossly underestimate the number, but the data are informative in that 85 percent of cases are attributed to sexual transmission, with heterosexual contact as the risk factor. The largest risk groups are men who visit commercial sex workers, the commercial sex workers themselves, the wives of those men, and the children of those subsequently infected mothers. Other risk groups are not as large but are also important: IDUs, men who have sex with men (MSM), transfusion recipients, and urban youth. It is unclear what impact HIV has on health care personnel and medical personnel.

Increasing HIV prevalence over time is seen in men who attend STD clinics. This is a sentinel risk group, at higher risk for the epidemic anywhere in the world. About 20

percent of people who come to the clinic are already infected with HIV. The pattern of HIV in this matches what has been seen in other countries, particularly South Africa, only a few years later. The infection rate in sex workers is about 30 percent in most urban areas in India, and about 50 percent in Pune, the location of Dr. Bollinger's clinic. Increase in HIV prevalence is seen in wives of STD patients—married monogamous women whose only risk factors are their husbands.

In trying to determine how generalized the epidemic is in India, a random survey of adults aged 18 to 40 in the community and in wine shops in 24 urban slums around Chennai found a relatively low HIV prevalence in the community (1 percent of men, 0.2 percent of women) but higher rates in the wine shops, which are associated with female sex workers (2.3 percent of men, 8.1 percent of women).

Comparing risk data in India to two African countries, Kenya and Zambia, the overall HIV infection rates in India are much lower—0.7 percent in India, 19.8 percent in Kenya, and 23.2 percent in Zambia. A higher percentage of Indians in this age group are married, and 12 percent of men and 2 percent of women report extramarital sexual contact. The reports of extramarital sex in Africa are much higher—48 percent for Kenyan men, 21 percent for Zambian men, 21 percent for Kenyan women, 15 percent for Zambian women. There is also a higher percentage of condom use with nonspousal partners in India. But the key transmission group in India is men who have sex with female sex workers, Dr. Bollinger reiterated, and then transmit the virus to their wives, who then transmit it to their infants. Most of the epidemic is being driven by these high-risk men.

The goal is to protect wives and their subsequent children. Condoms have been shown to be very effective. In a study of 200 discordant couples, where the man was infected and the woman was not, intensive intervention and couples counseling brought about a very low transmission rate of 1.4 percent, demonstrating the effectiveness of counseling. None of the HIV-negative wives were infected if their husbands used condoms.

Looking at other risk groups, a tremendous increase in HIV rates in IDUs has been seen in India. In a study of male IDUs in Manipur, India, 80 percent became infected, less than 15 percent used condoms regularly, and more than 50 percent of their wives are now infected, which is not surprising. In another risk group, about 6.6 percent of men who come to the STD clinics in Pune reported some MSM activity, usually at an early age, and usually do not consider themselves homosexual. The prevalence of HIV in that population is about 19 percent, which is similar to men in this group who do not report MSM.

HIV prevalence in pregnancy has been fairly flat for the past 10 years in studies in India, Pune, and Thailand. This is in contrast to rising rates in pregnant women in South Africa and in earlier years of the epidemic in Uganda. However, in India even low prevalence translates to large numbers.

How bad will the epidemic be in India? With at least 4 million infected persons, India already faces a public health crisis. India has the second largest HIV burden in the

world—at least 12 percent of global infections and more than twice the infection rate as in Vietnam. Every fourth newly infected person in the world is an Indian, and just a 1 percent increase in adult HIV prevalence in India would mean at least 5 million more infections.

The large total population of India puts the problems of HIV on a different scale than faced by smaller countries. There have already been at least 500,000 HIV-associated deaths in India, most in the past 5 years. India is at the beginning of the HIV epidemic, but there is already a significant public health challenge that is reflected in the lower life expectancy in India and will now be compounded by the HIV epidemic.

The public health system in India is already overburdened with infectious disease, and limited resources are available for HIV care. Even some of the best-equipped hospitals have overflowing wards with patients in the hallways. HIV is going to stress an already stressed system. HIV patients present very late to the health care system in India, with 56 percent in one study also infected with TB, a respiratory disease easily spread from patient to patient. The late presentation of HIV also raises questions about the access point to deliver HAART—intervention is needed at an earlier point. In a study of 655 hospitalized HIV patients, the in-hospital mortality rate was 25 percent.

Cervical cancer is another increasingly important problem. It is already the third leading cause of death in Indian women, and HIV significantly increases risk of human papillomavirus (HPV) infection and cervical cancer. This raises great concerns about the impact of HIV on the health of women, which is already challenged by cervical cancer.

Stigma is an important issue related to HIV—and one that is familiar to Dr. Bollinger after his years of work in leprosy control. The community has become more accepting of HIV, he has found, but in urban areas, women have been pushed out of their homes and beaten by their in-laws and lost everything after diagnosis with HIV. But support from husbands for their wives is also seen after counseling. It takes effort and targeted approaches.

For Council members interested in further information, Dr. Bollinger recommended an article in the April 24, 2004, issue of *Science* by Jon Cohen and Malcolm Linton, which he made available to the Council.

HIV treatment is just now becoming available in India. Guidelines for ARV therapy were published in February 2004, and in March 2004, NACO rolled out a pilot ARV treatment program. However, only 1 to 3 percent of people in the country actually have access to ARV. So there is a great need and a great underserved population that needs antiretroviral care in India.

Another challenge is the drugs that are available. A number of companies are producing generic ARV drugs, with only a few companies putting out the great majority of drugs. The quality of these drugs needs to be investigated, but some studies have found

comparable biological responses to the nongenerics. Combinations that require fewer pills per day offer a much better chance for adherence in India and other settings.

The NACO plan initiated in March has a limited and uncertain supply of HAART. It is focused on the already overburdened public health system, even though more than 70 percent of health care in India is from the private sector. To get free care, some patients must now leave their private doctors and move to public health programs. NACO needs to figure out how to bridge this public/private partnership if it wants to have an impact. Like many programs, it prioritizes women and children, but if the whole family, including the husband, is not treated, no one benefits. Only a few urban pilot sites have actually been able to deliver drugs so far, with only a handful of patients. Sustainability and scale-up of this program are uncertain. Initial programs focused on urban areas, but a large percentage of India's population lives in rural India, where one of the challenges would be simply to get a clean glass of water to swallow pills with every day.

Strengths in India are the large number of doctors and nurses and the educated populace. But they don't have trained health care workers who know how to deliver antiretroviral care. They need resources and training.

Dr. Bollinger listed five ways the United States can help India with its HIV epidemic:

- ?? Increase support for HIV clinical care
- ?? Foster public-private partnerships for HIV care and prevention
- ?? Increase support for Indo-U.S. collaborative HIV research
- ?? Increase support for public health research training
- ?? Provide support for HAART, clinical monitoring, opportunistic infection (OI) diagnosis, and treatment.

With more resources, he emphasized, India can overcome the HIV epidemic challenges. With the human capital of India, U.S. dollars can go a long way if spent efficiently and properly.

Dr. Bollinger also described why the battle against HIV/AIDS in India is important to the United States. India, a critical strategic, economic, and political partner, is vulnerable to this expanding epidemic. Increased HIV and TB drug resistance in India will have a global impact. India has a unique infrastructure and many talented people. India's success or failure will have an impact on the HIV epidemic throughout Asia, containing half the world's population. And India has a window of opportunity, but must act decisively, and now.

Discussion

Dr. McKinnell thanked Dr. Bollinger for his presentation, and for his many years of work in India. He asked if the low HIV rates compared to the high cervical cancer rates in India cause him to question the data, and if he is seeing the resistance to nevirapine that is being seen in Africa. Dr. Bollinger said that he is concerned that cervical cancer, already a major problem before HIV, will get worse. HPV infection is exacerbated by HIV.

Resistance to nevirapine is a major concern, Dr. Bollinger said. One of the limitations of HAART therapy in India is that there is relatively little access to protease inhibitors. Most of the combinations available in India include a non-nucleoside reverse transcriptase inhibitor (NNRTI), in most cases nevirapine. So the HAART fixed-dose combinations that are available in India almost exclusively rely upon nevirapine as part of that combination, and there are not many other alternatives.

India also has the world's largest nevirapine program for women to prevent mother-to-child transmission. That is likely to have an impact on the efficacy of the current combinations for those mothers should they subsequently need care. Another challenge is the reliance on zidovudine (AZT). A very high prevalence of anemia is seen in women on this drug, limiting its usefulness. Dr. McKinnell added that if there are problems with nevirapine, there are most likely also problems with other NNRTIs, and options are limited. Dr. Bollinger said that liver toxicity is also associated with nevirapine, particularly in women with higher CD4 counts.

Ms. Shoemaker asked if IDUs are presenting with more OIs because of already compromised immune systems. Dr. Bollinger answered that susceptibility to OIs depends on CD4 counts, and that many people die of TB undiagnosed (but infected) with HIV. Without TB prevention, HAART may turn out to have limited effectiveness in the epidemic in India.

Dr. Green noted the low rates of extramarital sex by women, and asked if there are any strategies to achieve consistent condom use. Dr. Bollinger said his experience is limited to the research setting, but the Pune study demonstrated that it is possible, with 60 percent of couples continuing to use condoms. Whether that can be scaled up in a generalized way for women at risk throughout India is difficult to say.

Dr. Sweeney asked if a model used in New York City for TB therapy, with directly observed therapy (DOT) for patients to take medications 6 days per week, might be of use. Researchers in New York found it could significantly affect outcome. She also asked how to prevent mother-to-child transmission from breastfeeding, and if condoms are available from health departments in India. Dr. Bollinger said that DOT makes a lot of sense for ARV therapy; there are limited drug options in India, but this is not insurmountable. Regarding mother-to-child transmission, a clinical trial in Pune is looking at extended use of nevirapine for infants who are breastfeeding. Earlier HIV-infected mothers were advised not to breastfeed, but hospitalization and deaths of these infants was extremely high because safe formula is not readily available, so the risk of death from not breastfeeding exceeded the risk of death from HIV. Finally, condoms are widely available in India.

India at the Crossroads

Presenter: Teresita Schaffer, Director of South Asia Program, Center for Strategic and International Studies

Mr. Mason introduced Ms. Schaffer, former ambassador to Sri Lanka and current director of the South Asia Program at the Center for Strategic and International Studies (CSIS). Ms. Schaffer said that two other items in her resume might be of interest to the Council: she was science attaché in New Delhi in the late 1970s in an HHS-funded slot, and she also organized the recent trip to India (January 3–10, 2004) that Dr. Sullivan led.

Ms. Schaffer presented findings from the trip to Council members and distributed a report from the weeklong visit to three Indian cities (“India at the Crossroads, Confronting the HIV/AIDS Challenge”). She also made available a short briefing paper on the Indian election. The purpose of the mission to India derived from the intent of CSIS’s HIV/AIDS task force to look at second-wave countries in the HIV pandemic, and to gain a better understanding of India’s current status in combating HIV/AIDS and what that situation means for the worldwide pandemic and, ultimately, for the United States.

The trip provided insights and prompted recommendations. The main finding was that this is a moment of strategic opportunity in India, as it deals with the second largest number of people with HIV in the world. A revolution has taken place in India-U.S. relations over the past decade, with security the most dynamic area. India is a nuclear power, with the fourth largest army in the world and a nuclear neighbor with which it has an unresolved dispute. It lives in a dangerous neighborhood. It has become an increasingly important security presence in that area, and a country that has compatible security relations with the United States.

The future of HIV/AIDS is one of the major wild cards hanging over India’s future. The projections for burden of infection 10 years from now have been presented at this meeting. However, no one has a good estimate of what the economic impact might be. Failure to bring the epidemic under control will sap the nation’s economy and cause terrible social upheaval, as it has in southern Africa.

This is also a moment of strategic opportunity for India in its policy toward HIV/AIDS. As other speakers have suggested, India is more like a continent than a country, with 10 states with more than 50 million people and a relatively decentralized federal system. But there is an important national overlay to HIV/AIDS policy. NACO was established about 12 years ago. Until this year, national policy focused almost entirely on prevention, although the Indian Government was relatively slow to put resources into prevention. The recent trip to India highlighted a dramatic increase in awareness of the epidemic, although it remains spotty in some areas.

What is new is that the Government has decided to become involved in providing antiretroviral drugs. There had been approximately 15,000 patients on ARV, mostly through private sources. Bringing patients who need ARV into the public health system will be a huge burden, requiring new skills and taxing already overcrowded facilities. The next 6 to 12 months are a critical time for India’s HIV/AIDS policy and its public health system. It is important that prevention be considered in the context of care, without the availability of care leading people to ignore prevention.

In India since January, ARV drugs have been made available and a new Government has been elected and installed at national and local levels. The new leaders have a greater commitment to addressing the epidemic. The CSIS delegation spent an hour with the new prime minister, Manmohan Singh, who spoke eloquently on the need to combat HIV/AIDS and the need for a social change movement, as India experienced in the 19th century. The new health minister is a 36-year-old medical doctor from a political family, although without much personal political experience. He has not had sufficient time to get involved with HIV/AIDS, but Ms. Schaffer was confident he will join and support the efforts to fight it.

The impact on state leaders is less clear. One state leader who showed remarkable leadership against the epidemic at the state level was not reelected, and it is uncertain what approach his successors will take. The largest high-prevalence states are relatively well governed. Part of their risk factor is the fact that they are economically stable, thus attracting job-seeking migrants. HIV is a difficult subject for politicians to talk about, but there are tentative signs in India that it is becoming good politics to have an AIDS program as part of state policy. Democracy may be an asset, as is a strong NGO community, and a business community that is beginning to show interest. The largest and most dynamic of India's business organizations, the Confederation of Indian Industry, has sponsored the development of workplace guidelines.

India also has important problems. The cost of providing ARVs on the large scale needed for this huge country must be viewed in the context of a Government managing a fiscal deficit that is more than 10 percent of the gross domestic product. However badly needed, resources for the program are simply not there. A second problem is stigma and discrimination. Recently introduced antidiscrimination legislation did not pass, but it is likely it will be reintroduced. Third, while India has a substantial research establishment, needed linkages between social and biological research are weak.

There are several lessons to be learned from the Indian experience. The United States and the international community have not yet determined how to deal with megacountries, and the HIV/AIDS second wave is occurring in the two megacountries of India and China. The decentralization that is necessary in such large countries almost guarantees an uneven program. Second, how is the epidemic measured in a megacountry? Surveillance resources have been allocated to areas known to have greater prevalence, but it may be that counts are very inaccurate in areas with enormous populations and badly run infrastructures. It is important to determine how to provide the appropriate tools to get to the right populations. This may need to be done at local rather than state levels.

The problem of scale in the programs themselves is related to both of these issues. The Indian Government program and the Bill and Melinda Gates Foundation program are trying to develop scaleable projects that can be adapted from district to district. But in a country where food, language, and social customs vary from community to community, one size will not fit all. NGOs can help address this, and small focused approaches may lead to making large-scale approaches more acceptable in specific communities.

The major conclusion from these observations, Ms. Schaffer said, is that it is time for the United States to step up its involvement. In general, large countries get much less aid per capita than small countries, and India will always have much less assistance on any per capita basis. It is regretful that the Administration decided not to put India on the PEPFAR list, she said, because this is bound to have some impact on resource allocation and available funds are not infinite. India will have a hard time making its own increased investment in the epidemic because of its general fiscal situation.

Established collaborative mechanisms need strengthening, and we may not have heard the last of PEPFAR related to India. Professional engagements through the NIH and the Fogarty International Center are prized in India and need to be expanded. The United States needs to learn from India's experience, not only to be an effective partner with India in combating the epidemic there, but also to better understand the dynamics of this increasingly diverse epidemic worldwide, and so that India can contribute its resources to the broader fight against this terrible scourge.

President's Emergency Plan for AIDS Relief

Presenter: Dr. Joseph O'Neill, Medical Director and Deputy Coordinator, Office of the U.S. Global AIDS Coordinator, U.S. Department of State

Mr. Mason said that questions for Ms. Schaffer and Dr. Bollinger would be deferred until after Dr. O'Neill's presentation, to accommodate his schedule. He introduced Dr. O'Neill as "an extraordinary public servant," who has had a great deal to do with PEPFAR, which has brought enormous hope and optimism around the world. President Bush described Dr. O'Neill as "the architect of the global AIDS initiative ... a pioneer in many ways, a deeply compassionate person."

Dr. O'Neill opened with the comment that he expects a lot of questions about India and PEPFAR, and there is a tremendous amount of misunderstanding about PEPFAR—how it was designed and why certain decisions were made. He wants to provide the Council with an overview perspective and understanding of the thinking behind the decisions, so the Council can best provide its best advice.

When developing the PEPFAR plan, Dr. O'Neill said, President Bush was willing to find and invest money for a significant effort, but *not* to put money into business as usual. Focus was important, as was the issue of the United States taking leadership fighting HIV/AIDS in the world.

The most important reason the Administration established PEPFAR was as an act of compassion, an understanding that an enormous problem exists and the world is not doing enough about it. Dr. O'Neill quoted writer Elie Weisel: "We are responsible for one another. ... If not, we are condemned by our solitude forever" That quote, he said, sums up why the United States is taking action—to help the rest of the world but also to help ourselves as a country. In proposing PEPFAR and requesting \$15 billion over 5 years, the President described it as a "work of mercy beyond all current international

efforts ... to turn the tide against AIDS in the most affected nations of Africa and the Caribbean.”

Budget figures show a significant increase over the years in the U.S. commitment to combat HIV/AIDS globally:

FY 2001	\$ 840 million
FY 2003	1,581 million
FY 2004	2,443 million*
FY 2005	2,821 million*

(* \$15 billion over 5 years, not \$3 billion/year)

This is the largest global health effort directed against a single disease in history. With a \$15 billion commitment, it is important to be intelligent about how it is spent, Dr. O’Neill cautioned. It was decided that the smartest way was to ramp up spending over time because of infrastructure issues, a desire to focus on treatment, and the necessity to train personnel. The U.S. investment is more than the total from all other countries worldwide to fight global HIV/AIDS. It is not true, as sometimes charged, that the United States is lagging behind the world; the rest of the world is lagging behind the United States.

HIV/AIDS is a complex disease involving complex approaches. The President’s initiative focused on treatment, and this represents the most complicated global effort ever to deliver complex medical treatment and prevention strategies to millions of people. The task demands a comprehensive strategy. This includes the Global Fund (to which the United States is the largest donor), which has bilateral activities in more than 80 countries, including India. India, in fact, will receive more money than some of the PEPFAR countries. The 15 focus countries have also received funding from the Preventing Mother-to-Child Transmission (PMTCT) initiative.

The intent of choosing focus countries was to concentrate on regions of the world that need help the most. The 14 countries originally targeted had more than 50 percent of the world’s AIDS cases with the most intractable problems, the least resources, and host governments with the least ability to respond. The goal was to show that American initiative can turn this problem around, and convince other wealthy countries in the world to add their contributions. The Office of the U.S. Global AIDS Coordinator did not want to add a 15th country, but this was mandated by Congress.

Regarding the U.S. role in the Global Fund, the United States made a founding contribution of \$200 million and currently provides almost 40 percent of all pledges to the Global Fund through 2008 and 31 percent of the cash on hand. There are statutory limits on contributions; the United States is prohibited from exceeding 33 percent of total contributions.

PEPFAR recognizes that AIDS is not only complex, it is also an emergency. Years of planning are an unavailable luxury. The strategy must be focused and aggressive, as illustrated by this timeline of U.S. global HIV/AIDS efforts:

?? January 20, 2001: President Bush inaugurated.

- ?? May 11, 2001: President makes founding contribution to the Global Fund and provides technical assistance to implement activities.
- ?? June 19, 2002: President announces \$500 million PMTCT program.
- ?? January 29, 2003: President announces \$15 billion PEPFAR commitment.
- ?? May 27, 2003: President signs authorizing bill.
- ?? January 23, 2004: Congress passes appropriations.
- ?? February 23, 2004: First round of grants (\$350 million) in hands of partners in Africa and Caribbean.
- ?? June 23, 2004: Second round (\$500 million) released.

The rapidity of the response has been remarkable, Dr. O’Neill said, particularly in contrast to the more cautious approach of the Global Fund. In about 6 months, the United States has moved about twice as much money into the countries than any other large international organization has done in 2 years. This was not doing business as usual, but involved overturning an enormous number of apple carts in Washington and around the world to do business differently, to create Dr. O’Neill’s Office to consolidate the funding, to develop a strategy. It is an extraordinary accomplishment.

His Office fought hard to control the money, Dr. O’Neill added, and does have that control, which allows coordination and the ability to operate on the basis of a single unified policy. One thing this coordination has yielded is a common dataset between DHHS and USAID that cuts across countries, which allows uniform evaluation strategies. Dr. O’Neill contrasted this to the beginning of the PMTCT initiative, which had input from 28 different units with 28 different evaluation strategies.

The pharmaceutical issue has received a bit of media attention recently. The U.S. Government expects to spend more than \$4 billion on pharmaceuticals and distribution systems in the 15 PEPFAR countries. This has stimulated a market for pharmaceuticals and greatly increased interest in most target countries to develop their own capacity for manufacture of HIV/AIDS drugs. This is worrisome because of the issue of quality of generic drugs. The United States has a unique responsibility to ensure the quality of the drugs it is purchasing.

The issue of drug resistance is a real one that may not be taken seriously enough. It involves large numbers of people and the potential to harm millions, in the context of weak clinical systems in the countries where PEPFAR operates, compared to the United States, where early warning systems give indications of developing resistance. That is not available in PEPFAR countries, and there is a huge potential for significant impact.

The United States is committed to purchasing high-quality drugs at the lowest possible cost, and is working on mechanisms that will allow for cost reductions by large-scale purchasing. This means regulatory review, as is done in this country. The drugs will be reviewed on a fast track. Some of the PEPFAR countries are countries where inferior drugs have been “dumped” for years. The intent now is to provide the same level of consumer protection to the poorest person in Africa as to the richest person in New York City. The United States will not compromise on drug quality, Dr. O’Neill said, and he is

proud of this ethically sound position. FDA tentative approval is expected to be very quick, with good manufacturing practices already being implemented.

Dr. O'Neill quoted President Bill Clinton on the necessity for "a Government that demands responsibility from industry and producers, but also provides clearer, stricter standards of safety and the means to enforce them." The current initiatives mark the first time this is being done in a serious way internationally.

The PMTCT initiative is on track to achieve its goals of reaching 1 million women and providing ARV prophylaxis to 80 percent of HIV-positive women delivering children in target countries. After 18 months, it has trained 14,700 health workers, 900 facilities have established PMTCT capacity, PMTCT services have been provided to 378,000 women, and 34,000 women have been provided ARV prophylaxis with the bottom line an estimated 4,800 cases of HIV prevented. This real progress is the result of good work by many people, including Council members. The PMTCT initiative has now been folded into the PEPFAR initiative.

Current projections are to have more than 200,000 people on treatment by the end of PEPFAR's first year and expose millions to information that will prevent HIV infection. Dr. O'Neill expressed confidence that the first-year projection will be met, putting the project on track to provide treatment for 2 million people by 2008 and achieve its noble and substantial goals.

Discussion

Dr. Sullivan commended the strategy and reiterated the need to get in front of the epidemic in second-wave countries such as India and China, which contain one-third of the world's population. He asked why the United States is not more involved with those countries, warning that in 10 years it will be too late and they will look like sub-Saharan Africa. Dr. O'Neill responded that this needs to be put in context, and before the 14 PEPFAR countries were even announced, the United States had doubled its global assistance for HIV/AIDS. The 14 countries selected were picked because they have the least amount of resources to dedicate to the battle, and it is necessary to ask if other donor countries are doing all they can, and if India and China are doing all they can for their own people.

Dr. O'Neill emphasized that the United States is not turning a blind eye to the rest of the world, but can't solve the HIV/AIDS problem on its own. One important purpose of PEPFAR is to provide leadership to the rest of the world and dispel the feeling that this work is hopeless, with no possibility of impact. India is getting \$20 million in U.S. assistance without being a PEPFAR country; Vietnam is getting \$16 million. India also gets money from other donors; there is little of this going on in Vietnam. The projected rate of infection from 2000 to 2010 will increase eightfold in Vietnam, compared to fivefold in India.

Dr. Hu agreed with Dr. O’Neill that the U.S. Government is doing what it should and doing it well, and commended the choice of Vietnam as the 15th PEPFAR country. She emphasized the importance for awareness of the HIV/AIDS epidemic in Asia, so what has happened in Africa can be prevented. While India and China have more resources than African countries, on a per capita basis, they are still very poor countries. But there are many things the United States can do to encourage other countries to take more responsibility for their own people, including stipulations in trade negotiations and requirements for matching funds.

Ms. Ivantic-Doucette asked for guidance on PMTCT issues and recommendations during lactation. A motion on this will be presented to the Council, based on preliminary data that are compelling but limited about single-dose nevirapine resistance. However, it appears that projects in PEPFAR countries are using single-dose nevirapine therapy to prevent mother-to-child transmission. Dr. O’Neill said that sufficient data are not available to definitively answer the question. PEPFAR works in sovereign nations, and its job is primarily to work with policy and clinical recommendations and standards of care developed by health ministries and provide them with technical assistance. When data do not lead in a clear direction, he said, he would be reluctant to countermand what a sovereign nation wants to do. The United States should tread lightly regarding this issue.

Dr. McIlhaney said that drugs are not available to treat everyone, but he is concerned that the availability of medication might produce disinhibition and decreased behavior change. He emphasized the importance of behavior change to produce dramatic decreases in HIV, and cautioned against losing that focus. Dr. O’Neill said that what is needed is good behavioral science research in this area. However, provision of treatment is a key element in the prevention strategy. This may mean perturbing the system, but it’s a world that needs change—but it is important to be cautious about unintended consequences. The system needs to be set up to figure out unintended impacts and intervene quickly.

Discussion—Part 2

(related to presentations by Dr. Bollinger and Ms. Schaffer)

Dr. Yogev referred to data introduced by Dr. Bollinger that childhood mortality in India is higher than in South Africa. He fears that the enormity of the HIV/AIDS problem for children is being ignored. He described an “unfavorable experience” in Thailand, where a combination drug not authorized for pediatric use was being broken into smaller doses for children but still proving to be toxic. The drug was withdrawn by the World Health Organization. Dr. Bollinger said this reinforces his point that health indicators are already difficult, and bringing HIV into the situation translates to a major problem with limited treatment options. He said he shares Dr. Yogev’s concern.

Dr. Yogev asked if any liquid formulation of drugs is available. Dr. Bollinger said it is, but the quality is unclear. In the absence of an alternative, people are using them and children seem to respond favorably. Dr. Yogev also asked why the number of infected women in Pune almost doubled in the past 5 years, and Dr. Bollinger said that refers only to a specific subset of women whose husbands are at high risk and is not representative of

the whole population. Any epidemic reaches a threshold, and that threshold can have a different inflection point for different populations and different diseases. A concern is whether that threshold is being reached in India, and that the inflection will be seen. Ms. Shaffer added that it is also important to recognize geographic differences. Dr. Yogev emphasized the narrow window of opportunity for intervention, before the threshold is reached.

Dr. Yogev also commented that nevirapine resistance is an *in vitro* phenomenon with unknown clinical effects, and caution should be exercised in suggesting that it has exhausted its usefulness and promoting substitution of a more expensive, more complicated therapy. Dr. Bollinger argued that concern is warranted about the issue of resistance and limited ability to treat a mother with nevirapine resistance. It is also not clear if her child could benefit from treatment with nevirapine. Resistance is a bigger issue in India than elsewhere, because of the potential for distributing highly resistant virus worldwide and in the region on a scale that couldn't happen, for example, in Vietnam. He is very concerned about the potential regional and global impact, and if India's ARV program is not properly managed, it could have worldwide implications.

Dr. Primm suggested a push to establish drug treatment programs to thwart the escalation of IDUs. Dr. Bollinger said he and his team have looked at the population in Pune and talked to others in other parts of country and determined that IV drug use is an important problem in some areas, but the majority of patients seen in urban India do not have IV drug use as a risk factor. The reason is simple—drugs are expensive, and the people are poor, and there is not much of a market except in certain areas such as Manipur, where drugs flow freely. But IV drug use at this point is not a generalized problem in India, and not a driving force outside of Manipur. Alcohol use and other risk behaviors have more of an effect on behavior than IV drugs do. Ms. Schaffer added that one of the programs she visited in New Delhi had started as a treatment clinic for IV drug users and then had branched out.

Dr. Sullivan concluded the session with the comment that while his task force was in India, they ran into a congressional delegation that expressed strong interest in what was going on. The CSIS task force has two honorary chairs, Senators Bill Frist and Russ Feingold, so there is strong congressional interest. He wants to see other nations around the world do their share, but there is no question that as the wealthiest nation on earth, the United States can do more—not only because it is compassionate and humane, but it is in our country's own self-interest. The United States must provide leadership; without the resolve to try to change the reality we confront, these meetings are a waste of everyone's time.

The full Council adjourned at 1:05 p.m., with members moving into a working lunch and Subcommittee breakout meetings to consider motions and other business. Mr. Grogan announced the room numbers and staff for each.

AFTERNOON SESSION

The full Council reconvened at 2:40 p.m.

Treatment and Care Subcommittee

Mr. Minor brought up two issues he has discussed with Ms. Smith and Mr. Mason, the other Subcommittee Chairs. First, there was some confusion about the meeting schedule for the Subcommittees and he asked that it be clarified. Mr. Grogan said that the next full Council meeting will be early in October 2004, and the PACHA budget will be discussed this week, and then the Subcommittee meetings will be planned. Mr. Minor thanked him and noted that with interim Subcommittee meetings, Council members can be better prepared.

Mr. Minor then said he would like to request a meeting with the President, to sit down and discuss these many issues that Council members know are close to his heart. He emphasized the importance of the work that the Council does, and that it be communicated at the highest levels. Mr. Grogan said he would pass the request along.

Before getting to the motions, Mr. Minor brought up a letter to Secretary Thompson that was included in members' packets. The letter had three purposes:

- ?? To recognize the appointment of Carol Thompson as director of the White House Office of National AIDS Policy, which represents a strong commitment of the Administration to the work of ONAP.
- ?? To recognize the President and Secretary Thompson for their support on reauthorization of the Ryan White CARE Act.
- ?? To recognize the extraordinary work of Josephine Robinson as executive director of the Council, and to recognize Mr. Grogan as her successor.

Mr. Minor moved that the Council adopt this letter and send it forward. The motion was seconded and passed unanimously.

Next, Mr. Minor followed up on a motion to request a White House Summit on the domestic HIV/AIDS agenda, unanimously passed at the last Council meeting. He has received considerable feedback on the idea of a Summit, and based on that, suggested the meeting for next summer, to coincide with the reauthorization of the CARE Act, as an opportunity to showcase new ways that the CARE Act will propel care and services and highlight the domestic HIV/AIDS agenda. The Summit would include the President and be inclusive and nonpartisan. With a national election coming, Mr. Minor acknowledged that planning for 2005 could be uncertain but he wants to be prepared, with the Summit as a placeholder and on the radar screen. He asked if any other Council members had thoughts about the Summit.

Rev. Sanders suggested that late spring or early summer would be a good time for an HIV/AIDS Summit, because the CDC National Prevention Conference is held in late July or early August, and it would be good to have the Summit in advance of that conference.

Dr. Yogev asked if he could get a copy of the motion regarding the Summit, and Mr. Minor said he would provide a copy of the motion and the comments he has received about it.

Mr. Sneed apologized for missing the morning session and assured Council members that he was “attending to the people’s business.” He expressed support of a Summit and emphasized the importance of the details in planning such an event. He said that he believes that as the country moves through reauthorization and addresses disparities in health outcomes, a Summit will help people refocus and become reenergized. Also, a new generation of people is being affected by HIV/AIDS, and this would help bring them on board.

First motion: ADAP

Mr. Minor noted that with the President’s announcement last week of \$20 million for ADAP, the motion in the briefing book had to be redrafted to reflect the President’s leadership on this issue. ADAP continues to be of critical importance for people living with HIV and AIDS, and the justification for the motion now deals with why ADAP is important, what its role is in helping people with AIDS, and how the current crisis is currently affecting communities.

The modified motion now reads as follows:

**PRESIDENTIAL ADVISORY COUNCIL ON HIV/AIDS
TREATMENT AND CARE SUBCOMMITTEE**

DRAFT MOTION

WHEREAS, the AIDS Drug Assistance Program (ADAP) is the primary source of Public Health Service (PHS) recommended antiretroviral therapies for 136,000+ uninsured or under-insured Americans living with HIV/AIDS each year¹, and

WHEREAS, highly active antiretroviral therapy for HIV infection has reduced the death rate from AIDS by 72 percent since 1995 and are cost effective overall, and

WHEREAS, recent scientific studies have found that people living with HIV/AIDS receiving highly active antiretroviral therapy have a 60 percent reduction in infectivity to partners, making treatment an important tool for prevention, and

WHEREAS, in May of 2004, 11 ADAPs had waiting lists representing 1,629 people, and 8 ADAPs have put cost containment measures in place, and 10 ADAPs are anticipating instituting cost-containment measures including closed enrollment to new clients and reduced formularies¹, and

WHEREAS, any long-term solution to the ADAP crisis cannot be instituted until the Ryan White CARE Act is reauthorized in 2005, a short term resolution to the problem facing Americans awaiting access to life-sustaining drugs must be addressed immediately, and

WHEREAS, any changes to the present formula distribution of Federal earmark ADAP funds will not go into effect until FY07,

WHEREAS, the President has recognized the importance of eliminating the ADAP waiting list and recently authorized the expenditure of \$20 million to address this issue,

BE IT RESOLVED that PACHA thank President Bush for his leadership to address the ongoing ADAP crisis and for making the elimination of waiting lists a top priority in his AIDS agenda, and

BE IT FURTHER RESOLVED that these funds are targeted to those areas demonstrating the greatest need and are spent expeditiously to maximize their benefit to the community, and

BE IT FURTHER RESOLVED that the President and Secretary continue to ensure the availability of funds for HIV/AIDS medications until a long-term solution is enacted.

Citation

1. *The ADAP Watch*, June 2004; National Association of State and Territorial AIDS Directors (NASTAD)

Discussion

The intent of the motion, Mr. Minor said, is to thank the President for his leadership and highlight the need for eliminating the waiting list, to target funds to places with waiting lists, and to direct that money be spent quickly since this is an ongoing crisis.

Mr. Minor moved that the ADAP motion be adopted. The motion was seconded.

Ms. Ivantic-Doucette noted that the motion has no provisions about formularies, and just covers allocation of resources and not monitoring. Mr. Minor responded that the Subcommittee did not want to fix formularies or add drugs, just simply recognize the current status for people who are eligible. Dr. Reznik added that formularies cannot change until the money is allocated. Ms. Ivantic-Doucette said that perhaps the Council could consider standardizing formularies and establishing clinical guidelines at a later meeting. Mr. Sneed suggested a grammatical revision changing “thank” in the first *be it resolved* to “thanks.”

Motion carries

The motion was passed unanimously as amended. Dr. McKinnell said that he supported the motion but abstained, given the absence of a general waiver.

Prevention and Treatment and Care Subcommittees

Second motion: African American Resolution

Mr. Minor asked that Rev. Sanders introduce the motion. Rev. Sanders noted that the motion came out of a joint meeting between the Prevention Subcommittee and the Treatment and Care Subcommittee. Considering the available data, he said, the whereas clauses, the justification for the resolution, could have continued for pages. The whereas that follows the first statement is driven by the epidemiological data that were presented to the Council yesterday and presented to the Subcommittees last month. This topic was the byproduct of cumulative information presented at Council meetings over the past couple of years describing the disproportionate and devastating impact of HIV/AIDS on the African American community.

The motion was introduced as follows:

PRESIDENTIAL ADVISORY COUNCIL ON HIV/AIDS PREVENTION AND TREATMENT AND CARE SUBCOMMITTEES

DRAFT MOTION

The Treatment and Care AND Prevention Subcommittees have met jointly to consider the state of HIV/AIDS among African Americans;

WHEREAS, in 2002, the AIDS annual rate for African Americans was 10 times greater than the rate for white Americans (78.5/100,000 versus 7.8/100,000);

WHEREAS, in 2002, African Americans accounted for 50 percent of the more than 42,000 estimated AIDS cases diagnosed in the United States;

WHEREAS, HIV/AIDS is among the top three leading causes of death for African American men ages 25–54 and African American women ages 35–44;

WHEREAS, the leading cause of HIV infection among African American women is heterosexual contact;

WHEREAS, the leading cause of HIV infection among African American men is sexual contact with other men, followed by injecting drug use;

WHEREAS in 2002, 62 percent of children born to HIV-infected mothers were African American;

WHEREAS African Americans represented approximately 64 percent of all AIDS cases among women in 2001;

WHEREAS it is estimated that approximately 1 in 160 African American women is infected with HIV, as compared to 1 in 400 Latina women, and 1 in 3,000 white women;

BE IT RESOLVED that PACHA recommends to the President and the Secretary of Health and Human Services that all programmatic initiatives and resource allocations follow the epidemic and in particular address the devastating and disproportionate impact HIV disease currently has among African Americans.

BE IT FURTHER RESOLVED that PACHA advises the President and Secretary to encourage African American leaders from the political, faith-based, corporate, education, health care, and support services arenas to speak out more forcefully about HIV disease to stimulate discussion about both its consequences and means of prevention.

BE IT FURTHER RESOLVED that PACHA recommends expedited funding of additional and targeted behavioral research to identify cultural, institutional, and societal issues that can inform future prevention, care and treatment initiatives to effectively alleviate the impact of HIV in the African American community.

Discussion

Rev. Sanders moved that the motion be accepted. It was seconded.

Mr. Sneed proposed that the motion be amended to add a definitive focus on young people aged 16-25. Dr. Sullivan suggested adding “youth leaders” on line 2 of the second “be it (further) resolved,” and Mr. Sneed asked that it read “community youth leaders.”

Dr. Sharma said that the role of media is not discussed and needs to be addressed. Mr. Minor said that could be implied under the “corporate” heading, to avoid an extensive “laundry list” of subjects. Dr. Yogeve said emphasis on adolescents is needed because the age when youth become sexually active is ignored, and research should be encouraged in children as young as age 8. Mr. Minor said that could either be amended now, or the Subcommittee could simply be asked to include language that would address this, since it doesn’t affect the goals of the resolution. Dr. Sullivan said he would accept the latter.

Ms. Ivantic-Doucette suggested that the second “be it resolved” specifically reference African American leaders “from all sectors.” Dr. Primm agreed that media should be specifically mentioned, and Mr. Minor agreed it could be included. Dr. Sweeney endorsed the inclusion of media. Dr. McKinnell added that the Council might want to consider the broader role of media. Ms. Smith said that the Prevention Subcommittee has discussed this extensively and will be introducing a motion about media.

The second “be it resolved” was amended to read:

BE IT FURTHER RESOLVED that PACHA advises that the President and Secretary encourage African American leaders from all sectors, including the political, faith-based, corporate, all media, education, community youth leaders, health care, and support services arenas to speak out more forcefully about HIV disease to stimulate discussion about both its consequences and means of prevention.

Motion carries

The motion was passed unanimously.

International Subcommittee

Mr. Mason announced that the motion concerning preventing mother-to-child transmission would be tabled pending more information about the nevirapine issue, and the Subcommittee will bring it forward at the next Council meeting.

Third motion: Asian AIDS epidemic

Several small changes were suggested for the Asian motion and incorporated. The amended motion was introduced as follows:

**PRESIDENTIAL ADVISORY COUNCIL ON HIV/AIDS
INTERNATIONAL SUBCOMMITTEE**

DRAFT MOTION

WHEREAS, the Asian AIDS epidemic, with more than 10 million cases, is second only to the Sub-Saharan epidemic, is expanding faster, and is expected to overtake the Sub-Saharan epidemic by 2010.

WHEREAS, the XV International AIDS Conference in Bangkok this July will focus international attention on the hitherto neglected Asian epidemic.

WHEREAS, in Asia, as in Africa, the AIDS epidemic, if unchecked, threatens to destabilize whole countries and is currently a factor in destabilizing Myanmar, and whereas the AIDS destabilization threat to Asia is as real as it is to Africa, the major difference being the timeframe.

WHEREAS, the worldwide economic and geopolitical consequences of destabilization in China, India, and Southeast Asia would be grave.

WHEREAS, Asia, while undergoing rapid economic advances, is politically less stable and its health care infrastructure is less well developed than in Europe and North America.

WHEREAS, many Asian countries are recognizing the implications and extent of their AIDS epidemics and want to act.

WHEREAS, these countries often have the basic economic resources to provide ARV treatment but lack the expertise to quickly implement AIDS treatment and prevention programs.

WHEREAS, the United States has wide experience and expertise in implementing AIDS treatment and prevention programs.

WHEREAS, there is a window of opportunity in both India and China to block the bridging of HIV infections from high-risk groups to the general population.

WHEREAS, appropriate preventive interventions can have significant impact on national HIV prevalence prior to such bridging.

BE IT THEREFORE RESOLVED that PACHA recommends to the President that HIV/AIDS prevention and treatment be on the agenda at all appropriate bilateral discussions with these two countries, and that discussions be initiated in the near future with India and China on establishing cost-sharing programs to facilitate access to American expertise in implementing AIDS prevention and treatment.

Discussion

Mr. Mason moved to approve the motion, and it was seconded.

Motion carries

The motion was approved unanimously.

Housekeeping Chores and Adjournment

Mr. Minor said that the meeting went very smoothly and he commended the good work of Joseph Grogan and Dana Ceasar.

Mr. Sneed said that there is a new television program from the youth leadership development program in the heart of the inner-city urban ghetto in south Dallas featuring same-gender-loving males, and if anyone wants a DVD copy, he can supply it.

Mr. Mason said that it is important that all Council members know what Subcommittees are working on in the future, and suggested that Subcommittee Chairs give what is on

their agendas for the next few months to Mr. Grogan, to help the Council work together more cooperatively.

Rev. Sanders asked about the status of the guiding principles that were discussed at the last meeting. Mr. Minor said it was very interesting that the President's recent comments on HIV/AIDS spoke of three guiding principles, a significant reference that reaffirms the need for context for the Council's decisions. He suggested this be discussed in September, in relation to the Summit. Rev. Sanders asked that the record reflect that the motions from the International Subcommittee and the one that dealt with the African American community were clearly a reflection of points that were made in the guiding principles.

Dr. Sullivan adjourned the meeting at 3:28 p.m.