

**HRSA/CDC Advisory Committee on HIV and STD Prevention and Treatment
Meeting Summary**

**May 15-16, 2003
Atlanta, Georgia**

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CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment

Members in Attendance:

Terje Anderson, M.S.W.
Renee Cobos, M.D.
David Farabee, Ph.D.
Donna Futterman, M.D.
Deliana Garcia
Gale Grant, M.A., C.P.P.
Thomas Liberti
Dorothy Mann
Sandra McDonald
Jean Flatley McGuire, Ph.D.
Freda Bush McKissic, M.D.
Jesse Milan, Jr., J.D.
Judy Goforth Parker, Ph.D. R.N.
Beny J. Primm, M.D.
M. Keith Rawlings, M.D.
Stephen Tabet, M.D., M.P.H.
Alejandro Torrez
Antonia Villarruell, Ph.D.
Mildred Williamson, Ph.D., M.S.W.

Members not in Attendance:

A. Cornelius Baker
Carlos Del Rio, M.D.
Patricia Fleming
Robert Fullilove, Ed. D.
Loretta Sweet Jermott, Ph.D.
Ron MacInnis, M.P.H.
Arnold Perkins
Michael Tapper, M.D.

Introductions and Welcome

Jesse Milan, Co-Chair of the CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment (CHAC), welcomed meeting participants to the first meeting of the combined committee. He announced that Jean McGuire would be standing in for Co-Chair Robert Fullilove, who had undergone surgery and was unable to attend. He said the CHAC's thoughts were with Dr. Fullilove.

He then asked members to introduce themselves, noting several new additions to the roster. Following introductions, he introduced Dr. Deborah Parham, Ph.D., Associate Administrator of the Health Resources and Services Administration's (HRSA's) HIV/AIDS Bureau (HAB) and Dr. Ron Valdiserri, Deputy Director of the Centers for Disease Control and Prevention's (CDC's) National Center for HIV, STD and TB Prevention (NCHSTP).

Dr. Parham welcomed participants on behalf of HRSA and announced that Dr. Elizabeth Duke, HRSA Administrator, would be unable to attend due to her participation in terrorist drills being held in Washington, DC.

Dr. Valdiserri thanked members who had rotated off the former CDC committee — Edwin Sanders, Gail Bolan, Willard Cates and Laura Leviton for their efforts on behalf of people living with HIV.

Review of Committee Charter

Dr. Valdiserri explained that the role of the CHAC is to advise the Secretary of the Department of Health and Human Services (HHS) and CDC and HRSA on HIV/AIDS and STD related policy and programmatic issues. The committee's authority is established in Federal law and, as a result, certain conditions must be met, such as the scheduling of public comment periods.

He said the CHAC is an expert advisory committee, providing diverse perspectives on HIV and STD care and prevention issues. Each meeting of the committee is posted in the *Federal Register*. The committee will have up to 26 members who meet twice annually. Each agency will nominate half of the members. Those nominations must be approved by the HHS Secretary. At least four members must be people living with HIV. The committee also has non-voting ex-officio members and liaison.

The CHAC must generate an annual report that identifies members, talks about meeting dates, and outlines activities of the meetings and the workgroups or subcommittees.

Dorothy Mann asked about the workgroups that existed previously? Dr. Valdiserri responded that they had technically come to an end, but that the CHAC could re-establish them.

Dr. McGuire requested that a list of pre-existing workgroups go out to all CHAC members, as well as the minutes of their meetings.

Previous Work and Accomplishments of CDC & HRSA Advisory Committees

Dr. Milan reported that for the last two years, the CDC and HRSA advisory committees had met jointly. These meetings included work on issues related to CARE Act reauthorization. As part of those efforts, a letter had been sent to Secretary Thompson requesting development of a national plan for getting more people into care, given unmet need requirements of the amended legislation. Additionally, members of the HRSA HIV/AIDS Advisory Committee (HAAC) had met with Assistant Health Secretary Claude Allen to outline vulnerable populations that required special attention, including women, prisoners, and youth. Additionally, both committees had made recommendations to the CDC and HRSA on data sharing.

Other HAAC activities have included:

- Briefings on specific target populations;
- Site visits to HRSA grantee and demonstration program sites; and
- A meet-and-greet at the HRSA All Titles meeting in August 2002.

Dr. McGuire was concerned that as combined meetings proceed, members would have to work harder to make the most of their time together. She said that there had been many long-time members who had rotated off the committees, and as the CHAC moves forward it will be important to identify where expertise is missing and ask each agency to bring that information to the discussion.

She said that CDC had been very responsive to, and supportive of, the CDC advisory committee. In 1998-99, a committee workgroup focused on external review of the budget. Other initiatives focused on young men who have sex with men (YMSM), STDs, syphilis elimination, core surveillance efforts, behavioral surveillance, and community planning activities. Also, along with the HAAC, the committee focused on the coordination of care and prevention activities.

Ms. Mann said she hoped to see continued emphasis on care and prevention coordination. Deliana Garcia asked about keeping STDs on the radar screen. Edwin Sanders urged members to be intentional about discussing the STD issue.

The issue of time came up as a concern. How would the committee give adequate play to both prevention and care issues in a day and a half? Dr. Milan said that in creating the agenda, the co-chairs had tried to be respectful of issues raised individually by each committee. He also said that the work of the committee would be carried out by workgroups, calls and listservs, in between full committee meetings.

Dr. Valdiserri stressed the importance of identifying priorities. He suggested that the group identify agenda items for their next meeting, before the two days were over. Dr. Milan urged committee members to communicate with him and Dr. Fullilove in between meetings about issues they wanted to have addressed through the CHAC process.

Overview of CDC's HIV and STD Prevention Programs

Harold Jaffe, M.D., Director of NCHSTP, did an overview of the organizational chart for the NCHSTP and reviewed extramural and intramural activities. Of NCHSTP's \$1.8 billion in funds, global AIDS initiatives account for 15%, domestic HIV accounts for 59%, STDs 14% and TB 12%.

Global AIDS Program (GAP)

NCHSTP provides capacity building support in GAP countries. Key activities include the provision of infrastructure and capacity development, primary HIV prevention and care and treatment. Examples of CDC GAP projects include helping to deliver antiretroviral therapy (ART) for perinatal prevention initiatives in 14 countries.

CDC is also working to implement the President's Mother and Child Prevention Initiative to increase prevention for women and their infants and improve overall systems of care in Africa and the Caribbean.

Congress has yet to vote on appropriations for the President's Global AIDS Initiative, which proposes \$15 billion for global efforts.

Domestic HIV

AIDS cases in U.S. peaked in the early 1990s and have decreased since. However, the decreases seem to have reached a plateau. With new drugs, the number of people living with HIV and AIDS continues to grow. MSM are still the biggest proportion of cases, but there are big increases among blacks and steady increases among Hispanics. African American case rates are 10 times those of whites.

CDC has supported surveillance since beginning of the HIV epidemic. There is a big focus now on evaluation, and a need to document progress with dollars spent. CDC is working to establish a national behavioral surveillance program to determine the impact of its efforts on rates of HIV transmission. The agency is also doing HIV incidence surveillance, based on an approach developed by Dr. Robert Janssen, M.D., Director of NCHSTP's Division of HIV/AIDS Prevention, Surveillance and Epidemiology that will produce more accurate incidence data.

STDs

Among western nations there is still a significant syphilis problem. The disease is easy to diagnose and treat. Racial disparities exist. CDC efforts have made progress in reducing cases and reducing disparities and Dr. Jaffe acknowledged the efforts of the CDC Advisory Committee in spearheading those efforts. However, in 2001, there were increases in cases among MSM, which was not a community previously targeted by CDC syphilis elimination activities. There have been a series of outbreaks in major metropolitan areas, so efforts must be enhanced and re-focused on areas of greatest need. CDC's National Syphilis Elimination Plan will guide the agency's efforts in this area, with a projected cost savings of \$1 billion per year if the elimination goals are met.

Dr. Futterman asked how much of CDC's new initiative will impact on its extramural program? Mr. Jaffe responded that program announcements will ask health departments and community-based organizations (CBOs) to realign their priorities to be consistent with the new initiatives.

Dr. Beny Prim said that the President's initiative focused largely on Haiti. What about other Caribbean countries, he asked. Mr. Jaffe said he couldn't comment on the President's initiative, but that CDC had regional assistance available to the Caribbean.

Mr. Christopher Bates, Director of the Office of HIV/AIDS Policy (OHAP), said that the Secretary's hope was that all islands would be considered in the President's initiative and that the President's intent is to strengthen the overall care and prevention infrastructure.

Ms. McGuire asked that the CHAC be kept informed as the program rolls out.

Ms. Mann added that there had been no money allocated yet and wondered where it would come from. She said it would be helpful for the committee to understand funding trends in recent years for both agencies.

Dr. McGuire asked how the GAP program related to the CDC's new initiative? Dr. Jaffe said CDC had received \$40 million for an initiative focused on mothers and children, but that it was not clear overall what will be allocated to various agencies for the President's initiative, as the coordination of the program is under the State Department.

Dr. Valdiserri suggested that the CHAC have more in-depth discussions at its next meeting on the global activities.

Dr. Primm expressed concern about the rise in syphilis among African Americans. Dr. Jaffe said CDC would continue to focus on the problem.

The group discussed the need for communication with the President's Advisory Committee on HIV/AIDS (PACHA) to share information on their efforts. Members decided that the co-chairs would craft a letter seeking an official liaison from PACHA, and attendance at the next CHAC meeting.

Dr. McGuire asked about injection drug users, noting that Massachusetts had just cut funding for methadone programs. Dr. Janssen said that CDC would be dedicating \$500,000 per year for the next five years to focus on IDUs as part of its Hepatitis C programs.

Ms. Mann asked if the agencies had done any assessments of the impact of reduced State revenues on HIV programs. She said it would be helpful to look at the full funding picture in terms of how and what programs are able to do, and requested that information from the agencies.

Overview of HRSA's HIV Care and Support Programs

Dr. Parham described HRSA as the “access agency” because of its focus on increasing access to health care for poor and underserved communities. The CARE Act is the largest single source of HIV/AIDS care in the Federal government. While Medicaid and Medicare provide HIV services, the CARE Act is the only dedicated HIV program.

Title I and II funding is provided to cities and States and comprises the bulk of CARE Act funding. Title I money goes to a Chief Elected Official (CEO), usually the mayor, who appoints a Planning Council to set service priorities and make funding allocations. The Title II grant goes to the governor of a State based on a formula that considers AIDS cases. In addition to the base award, there is also money provided for the AIDS Drug Assistance Program (ADAP) and funding for emerging communities, which have high caseloads but do not meet the definition of an EMA. There are two levels of emerging communities: those with between 1000 and 1,999 AIDS cases, and those with 500-999 AIDS cases.

Title III (10% of the CARE Act budget) funds CBOs for early intervention services and also provides one-year planning grants for grantees to establish their EIS programs. Title III also provides capacity building grants for the expansion or development of new services, particularly in areas with few providers.

Title IV funds programs for poor and underserved women and their families. Title IV gets 4% of the CARE Act budget.

Newly funded in 2001 is the community-based dental partnership, which provides funding to CBOs for the delivery of oral health care. The CARE Act still retains the Dental Reimbursement program, which funds dental and dental hygiene schools to cover the uncompensated costs of providing dental care to those living with HIV.

HAB’s Division of Training and Technical Assistance (DTTA) provides grantees with training and assistance to strengthen local delivery systems. DTTA also manages the AIDS Education and Training Center (AETC) program, and is responsible for management of HRSA’s Minority AIDS Initiative (MAI) allocations.

Finally, HAB also oversees the Special Projects of National Significance (SPNS) program, which allocates \$25 million annually for innovative service delivery models that improve health outcomes and increase efficiency of HIV/AIDS care and services.

In response to questions about how to institute routine HIV testing into primary care settings, Dr. Parham said that HAB had produced a CD-Rom that provides grantees with guidance on the issue. Ms. Mann urged coordination with Title X programs, citing the fact that they had received increased funding for testing in recent years.

David Farabee asked about the 12% of clients with private insurance that receive HRSA-funded services. Dr. Parham explained that those individuals have limited insurance and that CARE Act funding is used to provide them with services not covered by their insurance providers.

Dr. Primm asked about the CARE Act financing study being conducted by the Institute of Medicine (IOM). Dr. Parham said that final results would be released in October 2003.

Steven Young, Deputy Director of HAB's Office of Science and Epidemiology (OSE), added that IOM has been trying to understand issues of public financing systems for funded HIV services. He said that HAB had not been privy to their recommendations thus far.

Tom Liberti emphasized the need to talk about State revenue issues given the CDC's new initiative focusing on prevention activities with HIV-positive individuals, and the potential impact on care systems. He said that flat funding for the CARE Act combined with decreases in general HIV/AIDS revenue would make it very difficult for care providers to provide services respond to newly identified HIV-positive individuals. Mr. Liberti said that there is an assumption among care administrators that the funding will come from the 23% of the CARE Act budget dedicated to support and planning, but that there is no room in those budgets for funding of care for newly identified individuals.

Dr. Futterman echoed Mr. Liberti's concern, saying that there was a potential for two-three times the number of individuals depending on CARE Act-funded services. Ms. Bush Mckissic asked about the assumption that if you have HIV you get free health care. Was that the focus of the CARE Act? Ms. Parham answered that a large number of those who are not in care are assumed to be poor and/or underserved, and providing care and services to those individuals would be consistent with HRSA's mission. Ms. Futterman added that providing comprehensive care is ultimately more cost effective than not providing care, and added "there are issues aside from the philosophical debate of whether poor people deserve health care."

In response, Ms. Bush McKissic clarified that she supports the new initiative, but also talked about the issue of personal responsibility. Wasn't the goal to reach a point where the CARE Act was no longer necessary? If so, what needs to be required from people to make that happen? Ms. Mann said that the only a national health care system or the willingness of private insurance companies to pay for quality HIV care would eliminate the need for the CARE Act and believed that neither of those events were likely.

Dr. Valdiserri emphasized that while care was very important, prevention was the most cost-effective approach and must be the focus of committee too.

The group again echoed the need for information on trends in State and Federal funding for HIV programs. Mr. Liberti said that the Kaiser Family Foundation was tracking reductions in Medicaid, so that information might be a good place to start. He also suggested having someone discuss Hepatitis C at the next CHAC meeting.

Dr. Milan then summarized the CHAC's requests to date.

- When possible, HRSA and CDC will provide information on allocations under the President's Global HIV Health initiative (\$15 billion).
- CDC and HRSA will provide budget information for past few years so the committee could assess trends in funding.
- CHAC Co-chairs will ask PACHA for official liaisons between two committees.
- HRSA and CDC will ask the White House Office of National AIDS Policy (ONAP) to address the CHAC on IDU strategies.

The CHAC broke for lunch 12:00 p.m.

Advancing HIV Prevention: New Strategies for a Changing Epidemic

Dr. Janssen presented on the new CDC initiative focusing on early diagnosis of HIV and HIV prevention with HIV-positive individuals. He offered the following reason for the program's focus:

- Concerns about a rise in cases among young MSM, and high rates of syphilis and HIV prevalence;
- An estimate that 25% of people living with HIV don't know they are infected, and that 25% of those who know they are infected are not in care;
- One third of those who test in public facilities do not return for results, and a high percentage of those who do get tested progress to AIDS within one year of diagnosis; and
- The rapid test provides opportunity for getting more people tested in diverse settings.

Dr. Janssen outlined four priorities of the new initiative:

- Make voluntary HIV testing a routine part of medical care;
- Implement new models of diagnosing HIV outside medical settings;
- Prevent new infections by working with HIV-infected individuals and their partners; and
- further decrease perinatal transmission.

CDC will provide grantees with a list of standardized interventions including counseling and testing and prevention case management for people living with HIV. Grantees will be able to choose and adapt interventions for local use.

The agency is conducting studies in Massachusetts and Michigan offering routine HIV tests in emergency rooms. CDC will publish guidelines on incorporating routine testing into medical care settings in the summer. The guidelines will also cover voluntary routine testing for pregnant women. CDC is working with HRSA on several initiatives to expand HIV testing.

CDC's Division of HIV/AIDS Prevention (DHAP) is allocating approximately \$145 million into the new initiative for FY 2003, which includes at least \$35 million in new activities. To implement the new initiative, CDC is 1) developing technical guidance – interim guidance was published this summer; 2) funding demonstration projects covering prevention case management, partner counseling, testing and referral; 3) supporting research projects related to initiative strategies; 4) providing training and technical assistance; 5) supporting evaluation and monitoring, including the development of a new software system; and 6) purchasing rapid tests in bulk for use by its grantees.

Dr. Janssen said that CDC is asking health departments to enhance HIV counseling and testing, set targets, and work in lower prevalence settings too. CBOs are also being asked to do more

HIV counseling and testing, and to counsel partners of those infected with HIV. Many indirectly funded CBOs, said Mr. Janssen, will continue to do health education and risk reduction in addition to the activities of the new initiative.

Dr. Janssen said that with limited funding, an increased focus on people living with HIV provides the best opportunity for decreasing new infections. He emphasized, however, that CDC would continue to perform other aspects of its comprehensive HIV prevention programs including risk reduction for high risk seronegatives.

Dr. Primm said the new strategy was well thought out, but expressed a “great deal of misunderstanding about it” amongst providers who felt it would take funding and resources away from other services. “We as a committee must help dispel that misunderstanding in our communities,” said Dr. Primm.

He added that there should be an accounting of how the MAI funding has been spent and what the future of the MAI is. Dr. Janssen responded that some MAI funds will be used to support the new initiative, with focus placed on people of color who are HIV-positive. One limitation, he said, is that the funding announcement for the new initiative funding cannot require a minimum level of board or staff who are people of color. He said that based on past experience there has been great turnover in funded CBOs. CDC is crafting language to continue to fund CBOs of varying organizational capacity.

Dr. Jaffe said there is no intent to subvert the purpose of the MAI and that funding will continue to go to providers working in minority communities.

Dr. Futterman expressed excitement about the new initiative, and said it “represents a call to providers to step up to the plate.” She said that in the Bronx they are training primary care providers about how to make testing routine and reinforcing the importance to CBOs and others to support the identification of people living with HIV in medical care settings.

She added that the rapid test is not hard to use and that the AIDS community needs to challenge itself around its “gospels, such as HIV results need to be delivered in person” when other disease results are delivered over the phone.

Rev. Sanders suggested a consultation around developing language for an RFP to get diverse communities engaged in the new initiative. He also urged CDC to look at the kinds of work organizations have done with HIV-positive individuals and use existing models.

Ms. Mann said she likes that the new initiative focuses efforts on people living with HIV and applauded CDC for its work. But she voiced the following concerns: 1) had CDC abandoned counseling and guidelines around risk; 2) was CDC recommending mandatory newborn testing; 3) where is the \$35 million to fund the new initiative coming from; 4) the rapid test could not be confirmed at the point of contact; and 5) Medicaid pays for HIV testing for pregnant women, but where is the payment mechanism to test women who are not pregnant?

At that point, Dr. McGuire called a point of order and the group agreed on an additional 30 minutes to discuss the issue.

Dr. Janssen clarified that CDC was not advocating mandatory newborn testing. Further, new guidelines advocated that risk-reduction counseling is not a necessary component of pre-test counseling, but that informed consent was required, and information on HIV should be provided. He added that the funding came from some existing projects, but that some of it was new.

He acknowledged that the rapid test required a confirmatory test, and said CDC was working on related guidelines for providers.

Stephen Tabet asked if CDC was working with HRSA around voluntary counseling and testing in HRSA-funded clinics. Dr. Janssen said that Massachusetts had taken the lead on providing HIV CTS in medical care settings, and said he hoped to see health departments provide more services in primary care settings. He added that CDC wants to work with health maintenance organizations (HMOs) to provide testing in many settings, and is looking to work with the Centers for Medicare and Medicaid Services (CMS) on this issue.

Ms. McDonald raised the issue of how failing CBOs impact on service continuity. She expressed concern about how to train staff in the rapid test.

Dr. Janssen said he appreciated everyone's comments. He closed by saying that the new CBO grants would be for five years.

MSM: HIV and STD Issues

Anne Rompalo, M.D., Sc.M., Johns Hopkins University School of Medicine, discussed HRSA's role in syphilis elimination. She said that in 2000, the nation was close to reaching goals for elimination. However, there were several outbreaks across the country, primarily in MSM communities, which challenged long-held assumptions that the disease primarily affected heterosexuals.

In rural North Carolina, there was a syphilis outbreak in connection with the illicit drug trade. It was found that 18% of those with syphilis were also infected with HIV. In Baltimore, the syphilis outbreak was accompanied by a 50% decline in STD treatment capacity, a 50% decline in partner notification, a 340% increase in crack use, and an HIV prevalence rate of 18%.

Ms. Rompalo was contracted by HRSA to assess barriers faced by CARE Act grantees in the diagnosis and treatment of syphilis, and other STDs. In summer 2001, she visited several syphilis "hot spots" to meet with grantees and clinicians around the issue. Key experts were contacted to identify high-morbidity areas (HMAs) and potential risk emergence (PRE) areas. Semi-structured interviews were conducted by phone and in person. Findings included:

- all sites followed HRSA guidelines in screening patients for syphilis at enrollment in HIV care;
- all sites had immediate access to treatment;
- only one site had point-of-service testing for syphilis;

- all sites tested for syphilis and other STDs only if patients complained of symptoms;
- all sites reported limited communication between local and State health departments; and
- all sites reported need for provider training and community awareness activities.

Recommendations from the project included the following:

Recommendations: Care systems

- Strengthen behavioral risk assessment and offer comprehensive counseling based on the risk
- Screen all HIV-positive clients, regardless of local morbidity.
- Create written policies and procedures to review syphilis treatment and identify new cases.
- Repeat STD screening every three-six months for clients diagnosed with an STD or at risk

Recommendations: Provider Agencies

- Provider training is needed to interpret STS and existing policies for reporting syphilis and partner notification.
- Adopt interactive, goal-directed counseling focused on client's personal risks.
- Joint training is needed to address screening and counseling issues

Based on the findings and recommendations from the site visits, Dr. Rompalo worked with HRSA to create a training module for clinicians on the prevention and management of STDs in HIV-positive clients. She said the hope is that training will help diffuse clinician concerns about the time required to conduct STD screening. She said as a clinician with those same concerns, doing the module helped her realize that she could do effective screening without taking much more time.

Dr. Tom Peterman, Medical Epidemiologist with NCHSTP presented on a CDC syphilis initiative focused on eight cities with high rates of syphilis among MSM. He said that CDC conducted activities, including local meetings with STD and HIV program directors, to profile the epidemics, consider interventions, identify barriers to screening and treatment of syphilis, and determine potential supplemental funding and programs to address the issues. The cities examined were: New York, Atlanta, Chicago, Houston, San Francisco, Los Angeles, Miami and Ft. Lauderdale.

Epidemiological profiles revealed information about community features, program activities and the status of HIV/STD counseling and testing activities. Between 2000 and 2002, there was a three-fold increase in syphilis cases, primarily among MSM, in these communities. Of the MSM who were infected with syphilis:

- two-thirds of those who knew they had syphilis, knew they were also HIV infected;
- fifty percent of cases were reported by private providers;
- on average, MSMs with syphilis had three- seven sex partners in a three-six month period;
- there were high percentages of anonymous partners;
- venues for meeting sex partners included public cruising spots, the Internet, bath houses, and sex clubs; and

- drug use included crystal methamphetamine, Ecstasy, Viagra, and poppers.

Screening by providers in these cities seemed to be widespread and was being conducted at non-clinical, as well as clinical, sites.

Community characteristics of MSM communities in the cities examined included:

- there are many formal and informal venues for meeting each other;
- circuit parties are common;
- there are disconnects between HIV and STD providers;
- there is coordination with commercial sex venues among providers;
- prevention activities include social marketing, outreach, screening at community events and gathering places; and
- there are concerns around prevention fatigue among MSM.

Barriers to prevention efforts included:

- private providers not conducting syphilis screening;
- lack of services and insufficient outreach and screening;
- staff need training in partner notification and cultural sensitivity;
- stigma;
- competing messages about HIV risk due to drug maker advertising;
- funding; and
- recreational drug use among MSM.

Through its examination of these communities, CDC determined that the following approaches to STD prevention seem to be working:

- social marketing;
- working with private providers;
- community advocacy;
- outreach and partner notification; and
- screening in community sites.

The following strategies were identified as important to consider for further development:

- 1) Media campaigns
- 2) Provider awareness efforts
- 3) Expanded care and treatment
- 4) Increased screening
- 5) Increased treatment based on exposure
- 6) Improved partner notification

Providers also suggested that Web-based interventions and holistic health approaches be considered.

Next Steps will include:

- supplemental funding to cities to enhance syphilis prevention efforts;
- dissemination of findings and information to other HIV and STD directors; and
- coordination of evaluation, research, surveillance and program support.

Dr. Futterman thanked both presenters for their presentations and asked about effective messaging for MSM. Candice Nowicki of CDC said the agency was working with a contractor regarding messaging for MSM and was doing focus groups to test them.

Dr. McGuire asked about MSM who have sex with women. Dr. Peterman said data was inconsistent on that issue. Dr. Valdisseri suggested that with men who are already in care for HIV, there is a great opportunity to do syphilis screening.

Dr. Futterman said syphilis presents lessons on partner notification, acknowledging complications given the levels of anonymous sex and the fact that people don't want to identify their partners. Dr. Peterman said that partner notification was discussed in detail, and that some cities had placed health department personnel in HIV clinics and found that helpful. He said many approached the idea of partner notification by emphasizing its health benefits to partners.

Dr. Milan encouraged committee members to keep the issues of HIV/STD integration at the forefront, and suggested the continuation of the HIV/STD integration workgroup.

Dr. Valdiserri said Dr. John Douglas, who had served on the workgroup, will become DSTDP Director so the agency has operationalized his expertise. He also stated that the workgroup had some trouble moving forward on recommendations, and urged the CHAC to narrow the workgroup focus to make its charge more actionable. Ms. Mann suggested focusing on the context of care.

Rev. Sanders asked if there had been particular consideration around the new initiative and how it will impact on the racial disparities in the HIV epidemic. Dr. Janssen said CDC was looking at how it's spent MAI funding for 2002 and 2003, and consistent with the agency's strategic plan, efforts will be focused on people of color. Rev. Sanders responded that he hoped there would be a deliberate effort to seek a decline in the HIV rates of communities of color.

Judy Goforth Parker asked about initiatives with Native Americans. Dr. Janssen expressed concern about rising incidence rates, especially among MSM, and said there would be racial and ethnic preferences stated in new funding announcements.

Ms. Garcia expressed concern that CDC would be funding correctional facilities but didn't know how to work with Native American entities. How will CDC work with privately operated prisons or the Bureau of Prisons, she asked. Dr. Janssen responded that CBOs are being provided with protocols, not recipes, so they can adapt these to local needs. They will be ready by June next year.

Mr. Liberti expressed concern about how to explain the changes to local communities. Dr. Valdiserri suggested that the information be packaged as consistent with what CDC has been doing for the past three years, and give States latitude in implementing program requirements. Antonia Villarruell questioned whether the interventions for the new initiative were ready for wide distribution, and advocated CBO flexibility in applying them.

The group suggested that CDC could create a "Q & A" around the new initiative, to answer questions raised about the impact on MAI, the use of proposed CDC interventions, grantee requirements under the new initiative, and budget expectations for 2003-2004.

Dr. Futterman made a final comment that interventions should be tested in the field. She also urged the use of the term "sex partner" rather than "partner" to dispel the perception that the new initiative is based on the idea of monogamous relationships.

AIDS Drug Assistance Program (ADAP)

Doug Morgan, Director of HAB's Division of Service Systems (DSS) described ADAP as the most rapidly growing CARE Act program, citing a 10-fold funding increase in the program's first four years of operation – from \$52 million to \$461 million. The President's 2004 budget was requested before the 2003 appropriation, so ADAP will only get a \$25 million, rather than a \$100 million increase.

Title II base funding has declined, as demand has increased for other services. Grantees have begun to use Title I and Title II base funds to replace State funds.

It is projected that during 2003, 151,730 clients will be served by ADAP, and roughly 89,000 clients a month will receive ADAP services. The number of female and minority clients continues to increase. In many States where Medicaid is rich in services, ADAP is a complement and can extend services to those at higher poverty levels. In States where Medicaid is being cut or has low benefits, ADAP is more constrained.

Cost containment strategies include:

- 340B supplier rebates, which are distributed through pharmacies and other established mechanisms, then channeled back into programs;
- pharmacy discounts;
- wholesaler discounts;
- health insurance premium purchases;
- Federal Supply Schedule; and
- Alternative Method Demonstration Program.

Last resort strategies include: establishment of waiting lists; capped expenditures; capped enrollment; and limited formularies. Mr. Morgan said the issue of ADAP waiting lists has generated lots of discussion within HRSA and the Department. He said that waiting lists change daily and weekly, and one State that does not currently have a waiting list had 75

people on a waiting list two weeks earlier. The State re-certified its enrollees, dropped those that did not respond, and added those from the waiting list.

Current ADAP policies include:

- A flexibility policy, which allows the use of funds for adherence activities, as long as States don't have waiting lists, enrollment limits, or limited formularies;
- A supplemental drug treatment program that provides additional funding to States that demonstrate a severed need for medications and requires a 25% match; and
- An insurance policy that allows the use of funds to purchase health insurance services including the full range of HIV treatments and access to primary care services.

Mr. Morgan said these policies have helped expand ADAP services to eligible clients. He did acknowledge, however, that the required State match for the supplemental drug treatment program had precluded some States from gaining access to the funding.

Mr. Morgan said that HRSA held an ADAP consultation in January to discuss issues related to the program. Some of the issues discussed included the potential of identifying a national need number for the program, how to maximize Medicaid funding for AIDS drugs and having ADAP back bill Medicaid for clients serviced, and ways to maximize the buying power of ADAP funds through 340B programs. In the longer term, there may be consideration given to changing the formula for ADAP distribution.

Mr. Morgan said that the State budget shortfalls have precluded expansion of the program in many States. This raises an issue for mandates requiring CARE Act programs to identify HIV-positive people who know their status but are not in care and get them into care. Even if half those identified are eligible for CARE Act services, tough decisions will need to be made.

Mr. Liberti expressed some of the challenges of managing the third largest ADAP in nation. He said three things drive demand – new clients, drug costs, and “unfriendly” insurance coverage. When CDC revised its “hit hard, hit early” policy, the demand decreased. Additionally, a number of companies have frozen the cost of drugs to ADAPs, which in Florida has resulted in a cost saving of \$4 million per year and no waiting list.

Rev. Sanders asked about documentation on the success of the flexibility policy. Mr. Morgan said he would get that information to the committee. Dr. McGuire offered to share Massachusetts data reporting on the flexibility policy.

Mr. Tabet asked about consideration of treatment criteria. In Brazil, he said, doctors can't provide drugs unless a client's CD4 count is at a certain level, and there has been success with that approach. Mr. Morgan said that issue came up at the consultation, but that the concern around establishing a minimum service level is that it will become a ceiling. He also said that grantees are required to follow PHS guidelines. Ms. Garcia suggested that a lot could be learned from the practices of resource-poor countries, where they try to provide access across the board. It is an equity issue, she said, and there is no equity in the U.S.

The group decided to ask the National Association of State and Territorial AIDS Directors (NASTAD) for data on funding for HIV services.

Dr. Milan then recessed the meeting at 5:00 p.m.

May 16, 2003

Dr. Milan and Dr. McGuire reconvened the meeting at 8:40 a.m.

CDC/HRSA Data, Surveillance and IOM Studies

Matthew McKenna, M.D. M.P.H., Chief of NCHSTP's HIV And Case Surveillance Branch, said that Congressional. CARE Act 2000 amendments mandated HIV surveillance, despite the absence of a national reporting system. The charge to the IOM committee was to determine the status and reliability of HIV surveillance systems across States and how the variability of those systems would impact on the ability to allocate funds equitably. IOM was asked to provide recommendations if it found that HIV surveillance data was not reliable and accurate across States.

Currently all States and Washington, DC have confidential, name-based reporting of AIDS cases. Georgia is the only State without an HIV reporting system, which is due to be in place by December 2003.

The CDC is piloting a set of evaluation procedures to assess the following attributes at an HIV reporting system:

- Timeliness of data;
- Data accuracy;
- Determination of mode of transmission;
- Completeness;
- Validity of data elements;
- Ability to match to other public health databases;
- Follow up on cases; and
- Use of data for public health planning.

CDC has funded 10 areas for these activities. Sites include those that use name-based, code-based and name-to-code identifiers. Preliminary results show that it is very difficult to complete more than 70% of the records for the mode of exposure variable.

Of the 34 areas for these activities reporting, the duplication rates across areas is less than 5%. However, there is no technical fix for the issue of communication across reporting areas to eliminate duplicates in areas with code-based reporting.

Challenges to CDC include:

- Promoting an integrated approach to HIV and AIDS surveillance;
- Work with HRSA to respond to the IOM report;
- Complete evaluation study and disseminate protocols/procedures; and
- Provide TA.

CDC continues to work with States on the technical challenges of HIV reporting systems. CDC is also working with HRSA on incorporation of HIV data into formula funding determinations.

Mr. Young explained that HRSA's charge to the IOM committee was to assess the availability of reliable HIV data in determining severity of need for Title I supplemental awards. Additionally, HRSA asked the committee to identify epidemiological and other analytical tools for making allocations, as well as availability of health outcome measures for assessing the quality of CARE Act-funded services.

Mr. Young emphasized that one third of the Title I supplemental grant is based on the grantee's ability to demonstrate severe need. HRSA is exploring ways to quantify that measure, and is hopeful that it can use the approach identified for other grant programs.

In combination with CDC, HRSA has made available to IOM the following potential measures of severe need:

- Premature mortality;
- Models for epidemiological time series analysis;
- Community need indices; and
- Unmet need estimation framework.

Mr. Young explained that the unmet need framework will be used by grantees to estimate unmet need for primary HIV care among those living with HIV who know their status. He added that many grantees have good client-level data to perform the framework calculations and will be expected to use the framework to generate an unmet need estimate in FY 2005.

HRSA is also asking IOM to come up with quantitative measures for health outcomes to help determine the quality of funded services. HRSA requires all grantees to operate quality management programs. Grantees can choose from several quality program models and indicators, including the Institute of Health Care Improvement (IHI) Collaborative for Titles III and IV, or the New York State AIDS Foundation's HIVQUAL Project.

Examples of IHI quality indicators for Title III and IV programs include:

- 1) Access and retention: 85% of patients have primary care visits within preceding three months
- 2) Viral Load and CD4: 25% decline in number of clients with CD4 counts below 200 and 60% of patients with undetectable viral loads
- 3) Clinical care: 75% of patients on HAART

HIVQUAL indicators include:

- 1) Antiretroviral therapy management
- 2) CD4 and viral load testing
- 3) HIV specialist care
- 4) Adherence
- 5) Syphilis screening
- 6) Basic patient education

Mr. Young said that IOM's work has the potential to stimulate a paradigm shift from AIDS to HIV and to deliver HIV care that is more responsive to the needs resulting from an evolving epidemic.

Some early observations made by IOM are that HIV data is the best measure of disease burden, and that there is the potential for uniform approach to measuring HIV across jurisdictions. There are also questions raised by the move to HIV surveillance, such as how you account for migration of people in and out of jurisdictions, how do you account for variability in capacity at the State and Federal levels, and what are the implications for hold-harmless provisions of the CARE Act.

In response to a comment from Dr. Valdiserri, Mr. Young said that patient education is included under the quality goals of self-management.

There was then some discussion among members about the migration issue and the challenges it presents. Mr. Rawlings, a former HAAC member, asked how the unmet need framework addresses the migration issue.

Mr. Young said that HRSA had pilot-tested the framework, and areas, by using a variety of data, were able to get reasonable estimates of unmet need for those who know their HIV status. Mr. Morgan added that HRSA would be conducting a training for grantees on the unmet need framework in July and August, and would also be holding a conference call in advance of the trainings. Further, grantees would use the framework on a dry-run basis as part of their FY 2004 application. In response to a question of how the framework considers the variability of Medicaid programs across States, Mr. Young said that in for the purposes of the framework, those in Medicaid were considered to be in care.

Mr. Bates expressed disappointment at hearing about the status of HIV reporting at the State level. He asked to what extent the CHAC was making it clear to States that the need for HIV data is fast approaching. Dr. Valdiserri responded that CDC has been unable to provide funds to States specifically for incidence surveillance. In 2004, 34 states will be funded for incidence surveillance which will help the overall HIV reporting infrastructure.

Mr. Bates wondered how to address the issue further. Dr. Valdiserri said that in 1999, CDC went on record with guidelines on HIV surveillance and advised name-based reporting. The agency has shifted resources internally to put a stronger emphasis on HIV reporting, including studies on the time and resources necessary to move to an HIV surveillance system. The CDC advisory committee went on record three years ago advocating name reporting, and so, said Dr. Valdiserri, there has been dialogue, but there is now increased urgency due to the financial considerations imposed by the CARE Act.

Mr. Rawlings asked about States not responding to CDC recommendations. Dr. Valdiserri said that States determine reporting requirements, so even when CDC has said that they need to be doing HIV reporting, state legislatures are really the ones that make the decision. From a prevention perspective, there has been increasing awareness that HIV reporting is important,

but, said Dr. Valdiserri, the urgency was crystallized through the development of HAART and the looming deadlines imposed by the CARE Act.

Dr. McGuire stated that it took a lot of effort from States to get communities to accept HIV reporting, and that she thought a lot of progress had been made on the issue. She cautioned that all data must be considered in terms of its limitations.

CARE Act Reauthorization

Dr. Parham said the purpose of her discussion would be to update the CHAC on HAB's reauthorization activities to date, and discuss a framework for the committee's involvement in HAB's efforts. The Bureau began a formal process in August 2002 at its All Titles Meeting. An open discussion on reauthorization was held, and a lot of input was received from stakeholders. HAB staff also plan to meet with consumers at the U.S. Conference on AIDS.

The Office of Management and Budget (OMB) has provided HRSA with its directives. HAB has begun to talk with national HIV/AIDS policy organizations to discuss issues such as variability of CARE Act programs among States, coordination with Medicaid, and ADAP challenges.

HAB will have submit legislative proposals to the Department in May 2004. The Department will then make its recommendations to Congress. HAB will need the committee's input in time for development and submission of its proposal to the Secretary.

Dr. Milan stated that the HAAC had formed a workgroup on reauthorization and wanted that group to move forward under the new committee. Dr. Parham said that HRSA had set aside funding for the workgroup.

Discussion of Committee's Role at Upcoming Events

Dr. Milan asked members about the committee's role at the U.S. Conference on AIDS and the CDC HIV Prevention Conference. Ms. McDonald recommended having committee representatives at both meetings.

Dr. Valdiserri said he would e-mail members about their attendance at the HIV Prevention Conference. He said all members were welcome, but that funds were available for only five members to attend. He said there would be a session in which committee members would be able to speak with attendees, and could discuss reauthorization in addition to prevention issues.

Dr. Parham said that HAB has reserved time at the U.S. Conference on AIDS to discuss reauthorization with attendees. She said if committee members need to have travel paid for, to let her know and she'd see what she could do. Ms. Joan Holloway said that CHAC members would receive an e-mail with the date and time of the session.

Ms. Cobos stressed the need to focus on prevention in terms of cost-effectiveness. She said as a taxpayer she thought it important for the committee to look hard at the cost of HIV services and programs, and make recommendations in the context of their cost benefits.

Ms. Williamson said that one of the things the CARE Act has done is provide a glimpse into what quality health care systems should look like. She said the process chosen by the committee to develop its recommendations on the CARE Act should demonstrate that fact even further.

She then asked about the OMB directives. Dr. Parham explained that there were no constraints from OMB per say, but that the agency stressed outcomes as critical to funding. She added that all HHS agencies are being graded through a new system called the program assessment rating tool, which will be used in part to determine agency funding levels and allocations. She said that under the rating system, the CARE Act had received a score reflecting the need for improvement, and that OMB had provided recommendations that HAB and HRSA are taking very seriously.

Dr. McGuire suggested that the CHAC request information on the parameters used to assess the performance of both CDC and HRSA, because there was concern about the criteria and how it was applied.

Based on an earlier discussion of who get care under the CARE Act, Ms. McDonald said "there is a need to look at the notion of a "free ride." I run an organization for individuals who are poor and there are no people we serve who got HIV so that they could have medical care. Being poor and ill is a difficult place to be."

Ms. Cobos responded that she did not think people deliberately get HIV to get care, and that she recognized that being poor and ill is very hard. She added that prevention should be a major part of the CHAC's work," so that the epidemic doesn't continue to be out of control." She also emphasized the need for accountability around who gets care.

Dr. Bush McKissic reinforced Ms. Cobos point about prevention. She also suggested that the committee should consider the role of insurance companies in HIV care, and brainstorm around ways to better involve them in the payment and delivery of care and services to people living with HIV.

Dr. Milan said that he felt lucky to have been able to live with HIV for 21 years, and also felt lucky that at no time during those years was he in a position where he would qualify for CARE Act services. "It is my goal to eliminate HIV, but also to improve the quality of life of those who are living with HIV," he said. "I know we are all in agreement on this."

He also directed committee members back to the discussion of the reauthorization workgroup. He asked for decisions on membership, and suggested that the workgroup would have to craft recommendations for review by the CHAC at the fall meeting, and that the committee would have to finalize its recommendations by the spring meeting. Dr. Valdisseri suggested that the committee make decisions on which workgroups it would like to constitute, and solicit membership by e-mail.

Ms. Williamson, Ms. Cobos, Ms. McDonald, Ms Goforth Parker, and Dr. Bush McKissic all volunteered for the reauthorization workgroup. Mr. Milan said he would serve as ex-officio, and Mr. Anderson would convene the group.

Summary of Requests, Follow-Up Items, Recommendations

Dr. Milan then summarized committee requests from both agencies:

- 1) A description of each agency's involvement in the GAP program
- 2) An update on the President's global AIDS initiative
- 3) A future presentation on the President's global AIDS initiative
- 4) A summary of HIV/AIDS appropriations and information on budget trends
- 5) A copy of the new initiative "Q & A"
- 6) Clarification from CDC on guidelines and training for all new initiatives as they roll out (by email)
- 7) Support for NASTAD in getting information on State revenues for HIV and related programs
- 8) Clarify roles and commitments of drug czar and other Federal AIDS leadership

Follow up items for the committee included:

- 1) Identify members of reauthorization workgroup within 30 days
- 2) Include on next agenda a broader discussion of how the committee will address both prevention and care issues
- 3) Include on next agenda a discussion on role of insurance companies in funding care
- 4) More discussion at the next CHAC meeting on the implications of HIV surveillance for funding of services
- 5) Communication from co-chairs to PACHA requesting a formal liaison between the two committees
- 6) Continue HIV/STD integration workgroup with greater focus on those who are HIV-positive

Recommendations were as follows:

- 1) CDC development of a "Q & A" on the new initiative and other new programs initiated in the last six months
- 2) Committee development of a letter announcing the new committee, to accompany the "Q & A"
- 3) Summaries of all CDC and HRSA advisory group meetings will be sent to committee members

Dates for Next Meeting

CHAC members agreed that they would meet next between September 30 and December 1. Ms. Gordon and Ms. Ford-Knights will circulate an e-mail to select dates.

Public comment

Mr. Michael Ruppel, an Assistant Executive Director for Florida AIDS Action spoke from a written statement (see attached) (**Shelley – is there a way for us to attach this statement to the summary??**)

Mr. Rudy Carn from National AIDS Education Services for Minorities spoke as a “black gay man with HIV.” He stressed the need to continue focus on primary prevention adding that while the rapid test is an important tool, people are not knocking down doors to be tested. Black men often do not reveal their sex partners, he said, and there is still a lot of stigma around HIV. He again emphasized that for these reasons, primary prevention is critical and further urged CDC not to forget the role of smaller CBOs in prevention efforts.

He added that with respect to the CARE Act, MAI funding is not getting out to minority communities. He asked HRSA to look at the issue.

Dr. Milan thanked the public for their comments.

Wrap-Up and Adjournment

Dr. McGuire asked committee members for any recommendations on improving the meeting process. She also requested that both CDC and HRSA support committee involvement in major national meetings, to the extent that they can, acknowledging that resources are limited.

Committee members commended the co-chairs for their leadership.

Dr. Milan made a motion to adjourn, and Ms. Garcia seconded. The meeting adjourned at 11:26 a.m.

