

THE HEALTH RESOURCES AND SERVICES ADMINISTRATION

and

CENTERS FOR DISEASE CONTROL AND PREVENTION

convene the

CDC/HRSA ADVISORY COMMITTEE ON HIV AND STD PREVENTION AND TREATMENT

Atlanta, GA
May 20 – 21, 2004

Record of the Proceedings

TABLE OF CONTENTS

May 20, 2004

List of Members and Participants.....	2
Introductions and Welcome	3
Update on CDC's HIV and STD Prevention Programs	3
CDC's Futures Initiative Update	5
Update on HRSA's HIV Care and Support Programs	6
Division of HIV/AIDS Prevention Budget Overview	7
Division of Adolescent School Health	9
Division of STD Prevention	10
Highlights from National STD Prevention Meeting.....	11
Investigation into HIV Infection in Young MSM Black College Students in North Carolina.....	12
Update on the Advancing HIV Prevention Initiative	13
Community-Based Organizations and Capacity Building Assistance Program Announcements	15

May 21, 2004

Institute of Medicine Report on Public Financing And Delivery of HIV Care	17
CARE Act Reauthorization Update	19
CARE Act Reauthorization Workgroup Update	19
Public Comment	20
Minutes from the November 2003 Meeting	20
Agenda Issues and Dates for Next Meeting	20

Members in Attendance

A. Cornelius Baker
David Farabee, Ph.D.
Robert Fullilove, Ph.D.
Deliana Garcia
Judy Goforth Parker, Ph.D, R.N.
Gale Grant, M.A., C.P.P.
Dennis Leoutsakas, Ph.D.
Thomas Liberti
Jean Flatley McGuire, Ph.D.
Freda McKissic Bush, M.D
Jesse Milan, Jr., J.D.
Donna Sweet. M.D.

Members Not in Attendance

Patricia Fleming
Loretta Sweet Jermott, Ph.D.
Ron MacInnis, M.P.H.
Dorothy Mann
John Martin, Ph.D. ,
Beny Primm, M.D.
Alejandro Torrez
Antonia Villaruel, Ph.D.

Designated Federal Officials

Ronald Valdiserri, M.D., M.P.H.
Executive Secretary

Laura Cheever, M.D., Sc.M.
Acting Executive Secretary

Federal Liaisons

Pradip Akolkar, FDA
William Grace, NIH
Joe Razes, CMS
Daniel Simpson, IHS

Presenters

Richard Conviser, Ph.D. (HRSA)
Laura Cheever, M.D., Sc.M. (HRSA)
Janet Cleveland, M.S. (CDC)
Janet Collins, Ph.D. (CDC)
Lisa Fitzpatrick, M.D. (CDC)
Sheila Isoke, M.P.H. (CDC)
Marty McGeein (HHS)
Darien Ogburn (CDC)
Raul Romaguera, M.D. (CDC)
Howell Wechsler, Ed.D, M.P.H., (CDC)
Hillard Weinstock, M.D., M.P.H. (CDC)

Introductions and Welcome

The Centers for Disease Control and Prevention (CDC)/Health Resources and Services Administration (HRSA) Advisory Committee on HIV and STD Prevention (CHAC) held their bi-annual meeting in Atlanta, Georgia on May 20 – 21, 2004. CHAC Co-Chairs Jesse Milan, Jr., J.D. and Robert Fullilove, Ed.D. welcomed committee members and public observers to the meeting. Ron Valdiserri, M.D., M.P.H., Deputy Director of the National Center for HIV, STD, & TB Prevention (NCHSTP), welcomed the participants and reminded them that their comments were for the public record.

Dr. Valdiserri announced the departure of Harold Jaffe, who would be taking a position as the head of the School of Public Health in Oxford, England. Dr. Valdiserri described Dr. Jaffe's contributions to AIDS as "legendary" and said he had led the Center in several key efforts.

Dr. Valdiserri then welcomed Janet Collins, Ph.D., as the Acting Director of the Center. Ms. Collins has been at CDC for 15 years, most of which she has worked on HIV, STD and pregnancy prevention in the Division of Adolescent and School Health (DASH).

Laura Cheever, M.D., Deputy Director of HRSA's HIV/AIDS Bureau (HAB) was in attendance representing the agency on behalf of Administrator Duke. Dr. Cheever is the Deputy Associate Administrator of the HIV/AIDS Bureau, an HIV specialist physician.

She welcomed new members to the committee: John Martin, Ph.D., President and Chief Executive Officer of Gilead Sciences, Inc. in Foster City, California; Donna Sweet, M.D., Professor of Internal Medicine at the University of Kansas Medical School; and Dennis Leoutsakas, Ph.D., Assistant Professor at Salisbury University in Salisbury, MD. She announced that on the HRSA side, Terje Anderson, M.S.W., Renee Cobos, M.D., Sandra McDonald, and Mildred Williamson, Ph.D. had rotated off the committee, and that Jesse Milan, Jr., J.D., and Judy Goforth Parker, Ph.D. had been reappointed for terms ending June 30, 2007.

CDC's HIV and STD Prevention Activities

Dr. Collins announced some personnel changes at CDC:

- Dr. Jaffe's departure from NCHSTP
- Dr. Andrew Vernon's new position as Chief of the Clinical and Health Systems Research Branch for the Division of TB Elimination
- Dr. Terry Chorba is serving as Acting Associate Director for Science
- Bill Nichols as Acting Director of CDC's Procurement and Grants Office
- Michael Melneck will serve as Acting Associate Director for Management and Operations
- Dr. Dale Hu will serve as Acting Director of the Division of AIDS, STD and Laboratory Research (DASTLR)

- Susan DeLisle will serve as Deputy Director of the Division of STD Prevention (DSTDP)
- Lynn Mercer will serve as Deputy Director for Management and Operations, Global AIDS Program (GAP)
- Jenny Osorio will serve as Associate Director for Policy, GAP

Dr. Collins then reviewed budgets for CDC's HIV programs. She said that flat domestic budgets have been a challenge given the CDC's implementation of the Advancing HIV Prevention (AHP) initiative, among other domestic needs.

In February, the President announced his five-year emergency plan, which will be overseen by Ambassador Andrew Tobias and the State Department. The plan targets 15 countries and has the goal of treating 2 million individuals infected with HIV, preventing 7 million new infections, and providing care for 10 million infected people and orphans.

As part of the global response, FDA had announced an expedited process of six weeks for approval of drugs from both domestic and foreign manufacturers.

In terms of domestic HIV, the AHP initiative is one year into implementation and has undergone a progress review by DHAP. A tremendous set of accomplishments have been achieved during this first year. Approximately 250,000 rapid HIV test kits have been distributed, 40 rapid test trainings have been held for CBOs and health departments, and numerous demonstration projects are underway.

CDC has also released new recommendations for the treatment of gonorrhea among men who have sex with men (MSM), due to the rise in drug-resistant cases in the U.S. CDC is now urging providers to forego fluoroquinolones as a first-line treatment for gonorrhea among MSM.

Dr. Collins then touched on some of the highlights of CDC's Futures initiative, and efforts to realign and streamline the agency's programs for greater efficiency. Under Futures, the agency will work to maximize accountability, achieve the greatest health impact, reduce health disparities and expand public health research as the foundation of all its work. Dr. Collins said that the agency is borrowing from a business model approach. Those who are served by agency programs will be treated as "customers" and extensive performance measurement will be undertaken to ensure that they receive the best services. She distributed a proposed organizational chart.

Jean McGuire, Ph.D., asked about the status of the global program. Dr. Cheever said that money is moving on several tracks and that the program is being implemented quickly. Jenny Osorio of CDC added that more than \$40 million had been distributed within 30 days and that CDC staff have conducted site visits to all 14 GAP countries and have put together work plans.

CDC's Futures Initiative Update

Dr. Collins explained that CDC Director Julie Gerberding has undertaken an examination of the agency to determine how it might be restructured for greater efficiency. Under the new structure, health departments will be thought of as “partners” and those with HIV will be regarded as “customers.”

She outlined some of the major goals of the initiative:

- Increased performance measurement to strengthen impact;
- Greater integration across organizational units;
- More robust approach to marketing and a more systematic way of pushing out policy and services to customers;
- More streamlined input to the organization from external sources;
- Greater leadership and support for health departments;
- Expansion of global health impact; and
- A greater commitment to the public health workforce, inside and outside the organization.

Dr. Collins then discussed a transitional organization structure that would be further developed in the coming months. The eleven current centers will remain, but four coordinating centers will be established, as well as a new Office of Global Health and an Office of Terrorism Preparedness and Response, the directors of which will report directly to Dr. Gerberding. In addition, a new Office of Human Capital will house the Early Intervention services, preventive medicine and student residency programs.

Dr. Fullilove asked about changes to the committee given the new structure. Dr. Collins said she didn't anticipate any because the committee works on specific issues.

Mr. Liberti asked about the staffing of the coordinating centers. Dr. Collins responded that CDC would be looking at a range of options, including the combining of centers to achieve business efficiencies.

Dr. McGuire expressed concern that the new structure would create a greater distance between CDC and the people they serve. She added that the “customer” language seemed inappropriate because of the obligation to provide services for public health purposes, rather than a market-demand situation where people are requesting services. Dr. Collins responded that she was hopeful the marketing issues would be examined with sophistication by Dr. Jim Marks, who was taking the lead on that portion of the redesign.

Dr. Collins suggested that committee members send additional thoughts and ideas to futuresgroup@cdc.gov.

Mr. Milan asked if the global AIDS program would be moved to Office of Global Health. Dr. Valdiserri said he was unsure, but that his office had recommended that the program continue to be aligned with domestic HIV programs. He clarified that it was within the committee's purview to comment on that issue if they so desired.

Mr. Milan echoed Dr. McGuire's concern that the committee has had a tough time "putting its arms around issues outside NCHSTP," and questioned whether it would be harder to maintain synergy between HIV and STDs under the new structure. Dr. Collins noted his concern and said it would be carried forward.

Update on HRSA's HIV Care and Support Programs

Dr. Cheever reported that HRSA had distributed the bulk of CARE Act funding — \$1.65 billion — into communities through Title I and II awards. Title III, IV, Dental, SPNS and AETC awards were on schedule to be out by year's end.

Secretary Thompson has authorized HRSA to pursue international efforts. The agency continues to provide expert guidance on care and treatment issues, has provided funding to two of four organizations providing Highly Active Antiretroviral Treatment (HAART) on the ground, and continues to fund the international AIDS Education and Training Center (AETC).

Domestically, the HIV/AIDS Bureau is working to better integrate a new opiate replacement therapy for substance abuse treatment called buprenorphine into their programs as appropriate. The drug is similar to methadone but safer to use. It can now be prescribed by primary care doctors, and HRSA will have a consultation and a SPNS initiative in this area.

Since November, Steve Young, M.S.P.H., Director of HAB's Division of Training and Technical Assistance, has been engaged in follow-up efforts with the Institute of Medicine (IOM) to clarify points of their report on the use of HIV data for funding allocations. The Secretary is expected to make a decision by July 1 on the use of HIV data for funding purposes.

HRSA continues to work on examining the severity of need indicators. A social indicators model will help estimate severity of need on some level. HRSA continues to engage in the process with constituents to identify a small set of measures and is looking for funding to start the work this year.

Finally, HRSA is considering IOM recommendations as it develops quality measures for HIV programs. This effort is being undertaken by the agency's Center for Quality.

The president's proposed budget for 2005 maintains program funding from 2004, except for the AIDS Drug Assistance Program (ADAP), which gets a \$35 million increase. The 2004 budget passed at the same level as 2003 for all programs except for ADAP, and then Congress approved a .5% rescission, which resulted in a reduction for all programs except ADAP.

Mr. Liberti stated that each year the National Association of State and Territorial AIDS Directors (NASTAD) and the Kaiser Foundation collect data from 50 states and territories regarding the status of ADAP programs. Data indicates that there are ongoing fiscal pressures in ADAPs. Eleven states have caps on enrollment; over 1,263 people are on waiting lists in nine states.

Three states have monthly per capita expenditure limits and ten anticipate needing to implement additional cost containment strategies by March 2005. Three states have

reduced the number of medications on their formularies, and there are wide variations in formularies. For example, one state has only 18 drugs on its formulary, while another has more than 400.

The majority of people served through ADAPs are people of color, including 33% African Americans, 23% Hispanic, and 2% Asian and Pacific Islanders. Of all ADAP clients, 60% are between 25 and 44 and roughly 80% are men

Following his reporting on these statistics, Mr. Liberti emphasized that the current level of funding for the CARE Act is a huge problem threatening the provision of HIV services at clinics across the country. He further underscored concerns regarding the impact of AHP in the face of reduced HIV funding.

Dr. McGuire asked for input from HRSA and CDC staff regarding where to focus the committee's time and efforts. She asked about the involvement of the community health centers (CHCs) in efforts to look at how HRSA's HIV programs will respond to the increase in newly diagnosed clients as a result of CDC's efforts.

Division of HIV/AIDS Prevention (DHAP) Budget Overview

Shelia Isoke, M.P.H., Acting Deputy Director for Management and Operations, reported that DHAP's operating budget for 2004 was \$630 million, part of which was used to support 447 FTES and 213 contractors for a total of 660 employees. Additionally, \$103 million went towards the Minority AIDS Initiative (MAI). Surveillance, epidemiological research, behavioral research, capacity-building assistance, international research, prevention and evaluation are the major activities. Extramural activities account for 92% of the budget and intramural activities comprise 8%.

Ms. Isoke explained that all funding decisions are made according to CDC's HIV Prevention Strategic Plan, the goals of which are to decrease the number of people at risk for HIV, increase knowledge of HIV serostatus, increase linkages to prevention, care and treatment, strengthen the HIV prevention infrastructure, and reduce transmissions in resource-constrained countries. The Division is, therefore, able to evaluate/analyze expenditures under each goal.

Domestic programs include:

- 65 HIV prevention awards through State and local health departments;
- 344 direct awards to non-governmental organizations;
- 65 surveillance grants; and
- 106 prevention and research awards to institutions and academic centers.

Ms. Isoke provided information on budget breakdowns in terms of mission, by race/ethnicity, and by risk categories.

She said that in response to a request from the committee, an internal tracking mechanism had been developed and implemented in 1999. CDC has found the system very useful in terms of staying on track with major priorities.

In response to a question, Dr. Valdiserri said there would be a decrease in the total number of directly funded CBOs, because each grantee would receive a larger annual award than in years past. He explained that hundreds more organizations apply for funding than can be funded based on available funds. He added that there is an extensive analysis by Dr. Janssen and Ms. Isoke looking at racial/ethnic burden, populations affected, and other key factors from a national perspective to ensure an equitable and appropriate distribution.

Mr. Baker asked about the discrepancy between 2003 funding decrease for activities targeting HIV-positive individuals concurrent with AHP implementation. Ms. Isoke said that the data presented was only for activities through the end of 2002, and that 2003 data would show something different. She said information on currently funded jurisdictions was available on the Department Web site.

DHAP reported that they have recalled some field positions to the central office and has a \$4 million contract to provide support to project officers. The Division is also contracting out a number of routine activities so that they have more time for technical assistance, triage and oversight to grantees.

Dr. McGuire relayed some positive feedback from Massachusetts regarding CDC's rollout of the AHP. Dr. Fullilove added his praise for CDC's efforts in the past five years. He requested that they provide information on the geographic distribution of CBO awards to help assess if resource distribution is consistent with identified need and disease burden.

Mr. Liberti commended CDC on their budget analysis, but stated that the level of funding for core surveillance activities was inadequate. "Surveillance is not sexy at the state legislature" he said, and States are strapped because they can't use CARE Act funding for surveillance. "My plea is to try and squeeze some dollars for core surveillance as it is the foundation for every number used in allocations," he said.

Dr. Janssen agreed, but said that CDC has competing priorities. "Until there is an incentive to move to HIV reporting, states will be doing AIDS surveillance," he said.

Mr. Baker said that he hoped a robust surveillance system would be maintained as States move to HIV reporting, because AIDS surveillance can discern different information, such as whether or not people living with HIV are getting care and why they are not getting care. He added that this type of data is especially important for minority populations.

Dr. Janssen said that CDC is trying to secure funding for a project that will use interviews and chart reviews to determine why individuals progress from HIV to AIDS. He said some of the interviews will be conducted with individuals who are not in care.

Judy Goforth Parker, Ph.D., R.N., expressed concern over the level of funding for Native American communities. Were Native Americans providing data that enabled CDC to track funding allocations targeting these populations. Dr. Janssen referenced a study done three years prior examining how to shore up data on race/ethnicity, and said that he was concerned about data on Native Americans because they are scattered everywhere and the needs are great.

Hazel Dean, Associate Director for Health Disparities, NCHSTP, explained that there were a number of CDC surveillance projects currently being conducted on reservations. Additionally, the agency is providing technical assistance to Native American programs to improve surveillance systems.

Coordinating Center for Infectious Diseases

Mitch Cohen, M.D., head of the Coordinating Center for Infectious Diseases, has been at CDC for 28 years, 14 of which as the Director of the Bacterial and Mycotic Diseases Division. He is also a provider in the Veterans Administration (VA) system where he works with HIV patients. He added that in his organizational experience integrating programs has been effective in bringing common elements, goals and priorities together.

He said that CDC is putting together a transition team to work on implementing organizational changes as envisioned under the Futures Project. He welcomed comments and input from CHAC members.

In response to a question regarding communication and collaboration with HRSA, Dr. Cohen explained that part of the concept of the marketing component will be to determine how best to communicate with stakeholders, as well as communities, grantees and others.

Division of Adolescent School Health (DASH)

Howell Wechsler, Acting Director of DASH, reported on the Division's HIV prevention budget. HIV prevention is the largest activity area of the Division and has a budget that has been fairly consistent for five years. There have been some increases for abstinence programs, and some decreases for projects on HIV/STD integration.

Of all HIV prevention funds within the Division, 14.5% are used for intramural activities and 85.5% are used for extramural activities. Funding is provided to NGOs working to prevent the spread of HIV among youth. Nearly \$10 million of the 2004 budget was used for surveillance, evaluation and research on youth-based HIV prevention. More than \$2 million is dedicated to activities preventing sexual behaviors among school-age youth and will include \$1 million for an abstinence evaluation project. The evaluations will compare the effectiveness of an abstinence-only intervention to an abstinence-based intervention that includes broader sex education messages.

Mr. Wechsler reported that there had been progress between 1990 and 2000 in reducing the number of high school students having sex or multiple sex partners. Daniel Simpson of the Indian Health Service said that funding is also being provided through the Minority AIDS Initiative (MAI) for culturally specific programs for youth.

Mr. Liberti thanked Mr. Wechsler for his presentation and asked him if DASH is reaching out to Historically Black Colleges and Universities (HBCUs). Thena Durham, Deputy Director for Policy, said that CDC is doing a series of things, including surveys of selected agencies, many of which are in the South and have

access to HCBUs. Additionally, she said that CDC will probably be launching an intervention to develop peer education in North Carolina.

Chris Bates, Director of the Office of HIV/AIDS Policy (OHAP) asked about what had been done in terms of HIV/STD integration given the lack of funds. Howell Wechsler answered that not a lot of work had been done in that area, although there had been some progress initiating Collaboration among key stakeholders in some jurisdictions at the state agency level in the area of STD education and prevention.

Division of STD Prevention

Darien Ogburn, Deputy Branch Chief in CDC's Division of STD Prevention, updated the committee on recent developments within the program. Five staff from the Division have resigned and one staff member was promoted to another Center. In the field, DSTDP has 209 staff.

In October 1999, Surgeon General Satcher announced a plan for syphilis elimination. Funding followed in 2001. Since that time, \$10 million has been provided to more than 170 private health care providers, social service providers, civic organizations, AIDS service providers and others for syphilis elimination activities.

Approximately \$27.5 million was provided in 2003 for Infertility Prevention Programs (IPP). Since 1998, a higher proportion of new funds has been distributed to new regions, with a total of 65 project areas.

The Division is getting ready to release a program announcement for American Indian and Alaska Native communities. The program will provide \$463,836 for capacity building STD screening and treatment.

Mr. Liberti said that since the 1980s, HIV funds have been used for partner counseling and referral, and yet he continues to get questioned by CDC about whether this activity should be funded by HIV or STD programs. Dr. Valdiserri said that he would follow up and asked all committee members to notify CDC when they are having these types of problems so that they can be rectified.

Mr. Baker asked how increases in syphilis rates among MSMs fit into CDC's overall syphilis efforts. Dr. Valdiserri confirmed that after roughly a decade worth of decline in primary and secondary syphilis, there have been reported increases among men, primarily MSM. He said that with finite resources, CDC is trying to balance and continue its success in reducing rates of syphilis among women, especially black women, and is also looking to address the resurgence of the disease among MSM.

Further, he added, CDC, HRSA, the National Institutes of Health, and the Infectious Disease Society of America (IDSA) have published guidelines for HIV prevention in clinical settings that call for syphilis testing at least annually. He added that CDC is working on several fronts to get the guidelines into practice, and will evaluate those efforts in the future.

Mr. Baker asked about adult vaccination for gay men and others for Hepatitis B. Deliana Garcia said she did not think health departments were adequately focusing

on Hepatitis B. Dr. Valdiserri said that a letter had been sent to state health departments and other grantees urging them to offer Hepatitis B services in addition to HIV and STD services.

Following the presentation, the group recessed at 12:40 pm.

Highlights from the National STD Prevention Meeting

Hillard Weinstock, M.D., M.P.H., reported on new estimates of STD burden among the nation's youth. Updated estimate presented at the conference showed that of the 18.9 million STDs, the vast majority were due to HPV, trichomoniasis, and chlamydia. Almost half, 9.1 million are thought to be among young persons, 15-24, even though they make up only 25% of the sexually active population.

Outbreaks of syphilis among MSM have occurred in many urban areas across the United States. Data from San Francisco has shown that some independent correlates for early syphilis among MSM include methamphetamine use, Viagra, a combination of the two, and Internet use as a means of meeting sexual partners.

Also, there have been increasing cases of Fluoroquinolone-resistant gonorrhea among MSM. Fluoroquinolones are the only CDC recommended orally administered drugs available for the treatment of gonorrhea. The CDC has now released new guidelines urging providers not to use those drugs as a treatment for gonorrhea in MSM.

Dr. Valdiserri said that the STD Division has undertaken some disease-specific strategic planning, although it is not abandoning its comprehensive approach to STDs. Dr. McGuire expressed a hope that future committee members would have expertise in STDs.

Freda McKissic Bush, M.D., asked about the status of partner notification efforts. Dr. Weinstock said that CDC has been challenged in this area given the rise in instances of multiple, as well as anonymous, sex partners. Dr. Valdiserri said CDC is looking at new approaches to partner notification.

Ms. Garcia said that Cipro is being prescribed for everything in health departments and asked about the response to CDC. Dr. Sweet suggested that might be a regional practice, because the drug had been removed from her State formulary.

Dr. Weinstock said that while the Division works through conferences, programs, the MMWR and its Web site to distribute information about new treatment guidelines, they do not have sufficient data on the prescribing patterns of doctors in the private sector.

Mr. Baker asked about rates of anal cancer in MSM. Dr. Weinstock suggested that the agency's cancer program would have better information on the issue. Dr. Valdiserri said that CDC reminds policy makers that HPV is associated with anal cancer in MSM.

Mr. Liberti added that the CDC will conduct a study in eight cities to assess implementation of the CDC's STD Treatment Guidelines which include the recommendations related to Hepatitis A and B vaccines for high risk populations. Regarding Hepatitis A and B vaccine availability for high risk adults in the United States, he argued that they should be more widely available, and urged CDC to look at funding as the barrier to access.

Finally, he said that HIV partner referral and counseling has been occurring mostly through STD programs, but that there is seldom comprehensive information from CDC on what is happening with these services. Will CDC be expanding its data system to incorporate that information. Dr. Janssen responded that CDC has compiled data recently and is looking to collect more detailed data in the future from the STD MIS system.

Investigation into HIV infection in young MSM black college students in North Carolina

Lisa Fitzpatrick, M.D., M.P.H., reported that during the latter part of 2001 and 2002 there were a number of HIV cases detected among MSM college students. The majority was in the Raleigh-Durham and Charlotte areas of North Carolina.

CDC conducted a case-control study to detect differences between HIV- positive and HIV-negative MSM. The survey took about 45 minutes to administer, and was implemented by a team of five people who tried to identify as many cases as possible.

Survey results indicated that many of the men had met their sexual partners at nightclubs, rather than on campuses. The survey also found that many did not identify as gay, and as such many did not consider themselves at risk for HIV.

Next steps will involve development of an HIV intervention based on the Popular Opinion Leaders model. Additionally, CDC will involve other health departments within the state in its efforts. CDC will also be releasing an MMWR on the issue.

Dr. Fullilove expressed concern that the idea of college as being a place where you get HIV would counteract efforts to increase the number of black men who attend college. Dr. Fitzpatrick emphasized that while that's not the message CDC intends to convey, it is important to dispel misconceptions regarding the HIV risks faced by college students.

Mr. Baker suggested that the cohort demonstrated the impact of conservative institutions like the church on the self-perception and behavior of MSM. Dr. Fitzpatrick said that questions regarding stigma were asked in focus groups held by CDC staff. She said respondents indicated that homophobia within the black community helped fuel stigma, but that homophobia was not mainly attributed to the existence of conservative institutions or campuses. Many students in the focus groups said they'd be happy coming out if it was acceptable.

Mr. Baker suggested that CDC partner with organizations involved in Black Pride and other similar activities within the gay, male, black community to address the issue.

Ms. Durham added that CDC is conducting surveys on other college campuses. “My sense is that these are microcosms of the communities from which these students hail,” she said. “So it makes sense for us to look more closely at the situation on campuses to determine the extent of risk behaviors and disease burden.”

Dr. Fitzpatrick said that student’s suggestion inclusion of the media and parents in HIV prevention interventions. She said they also indicated that the cost of HIV tests is prohibitive in some instances. They further had concerns about HIV testing being a routine part of the services offered in college health centers, rather than a special service offered at certain times. This way they wouldn’t feel as if their confidentiality were being compromised.

Mr. Milan suggested that the CDC might consider a youth appointee to the CHAC to help the committee better address some of the issues.

Update on the Advancing HIV Prevention Initiative

Raul Romaguera, D.M.D., M.P.H., said CDC is working with HRSA and the Centers for Medicare and Medicaid Services (CMS) to have them incorporate the AHP into their program guidance. The guidelines encourage voluntary testing for pregnant women receiving Medicaid. CDC is also working with SAMHSA to assist with implementation of their rapid HIV testing program. SAMHSA has received funding for purchase of the rapid HIV test.

CDC is engaged in efforts to assess the impact of State statutes on the implementation of AHP. These assessments are being carried out by Johns Hopkins University and the National Conference of State Legislatures.

More than 105,000 OraQuick rapid test kits have been shipped to CBOs and health departments in 18 states. Data from our Post Marketing Surveillance in 13 states shows that more than 92% of clients choose rapid tests over the ELISA test; there has been an 18% increase in the number of persons tested, a 16% increase in the number of positive tests, and a 43% increase in the number of individuals who receive their test results.

Additionally, NASTAD conducted a 50-state survey on partner counseling and referrals services (PCRS). The results showed that nearly half of States have legal requirement to conduct PCRS, 100% offer PCRS to those who test HIV-positive, and 76% report no prohibition against any CBO or provider conducting PCRS.

In response to questions from the CHAC regarding the impact of the AHP to date, Dr. Romaguera reported CDC estimates that:

- between 5,800 and 11,500 HIV-positive persons will be identified through the AHP;
- 55% will have CD4 counts of 350 or less; and
- Newly identified cases will be largely male, people of color and will come from the South, Northeast, West and Midwest

Dr. Romaguera reported some limitations to the estimates. They do not take into account the replacement of testing procedures, which could overestimate the impact of the AHP, and do not include any testing supported by other agencies and programs.

Dr. Cheever reported on how HRSA has used the data provided. She first said that collaborative efforts between the two agencies around the AHP have been exemplary. Additionally, HRSA has been working to promote provider training on AHP through the AETCs. The agency had held a recent meeting with representatives from the CDC training groups, the Office of Population Affairs training programs and the AETCs to coordinate training efforts.

Dr. Cheever acknowledged difficulty in estimating how much HIV clinics can tolerate in terms of client load increases. In summary, HRSA estimates that an additional \$30 – \$60 million will be needed to cover the drug and outpatient care costs for HIV positive persons newly identified through AHP in 2004. These additional costs are not only for the CARE Act, but for all patients identified, regardless of insurance.

Mr. Milan asked for some clarification on the estimates for cases that will be identified through the AHP. Dr. Valdiserri stated that the AHP is meant to influence other systems of care, including providers in the private sector. Dr. Janssen added that the issue of replacement testing has made the establishment of estimates challenging. He added that it appears as though more HIV-positive individuals are being identified with the rapid test than with the EIA.

Mr. Baker, while acknowledging the critical nature of CDC's partnership with his own Whitman Walker Clinic, raised the following concerns around the AHP:

- CDC guidelines around testing in community setting appears to be in opposition to what Dr. Fitzpatrick reported about the impact of integrating testing into, for example, college health centers; and
- The estimates of numbers of individuals who will be identified through the administration of the AHP have no bearing on what the Administration is offering in terms of funding to respond to the increased need for care and services.

Whitman Walker will begin to cap its medical care services and will soon be in the position of providing individuals with an HIV diagnosis without being able to offer them referrals for treatment. He added that in the Washington, DC area, the INOVA health care system of Northern Virginia has reached saturation level and has a six-month waiting period. He requested guidance from CDC on the ethical responsibility providing care, for example, if an individual doesn't have a viral load requiring immediate attention.

Dr. Cheever said that HRSA cannot change ADAP because the amount is prescribed by statute. From an ethical standpoint, she said, providers should continue to provide care to those who have initiated treatment, with the next priority being pregnant women and those with low T cell counts. She added that providers will need to make some choices about limiting the range of services they provide in favor of offering core medical services to the most clients possible.

Dr. Sweet mentioned that there are many ways in which the private sector can contribute to the effort, especially if some of the regulatory hurdles can be eliminated.

Dr. Romaguera explained that CDC is considering funding to national groups representing private providers to get them involved in the AHP.

Dr. McGuire added that it would be important for the committee to send a message to the Secretary regarding their support for AHP, but to inform him that it is creating an ethical and financial crisis. Dr. Valdiserri added that in the long run, there will be a cost-saving aspect to the AHP, because it will prevent infections. Dr. Janssen added that 98% of those tested using the rapid test receive their test results.

Mr. Milan voiced his support for a letter to the Secretary that referenced the data presented by CDC on the impact of the AHP. Dr. McGuire made a formal motion to send a letter from the CHAC to Secretary Thompson regarding the anticipated unmet need for HIV care and services based on the data presented by CDC and HRSA. Ms. Garcia seconded the motion. The motion passed by a unanimous vote.

Dr. McGuire volunteered to write the first draft of this letter.

Mr. Milan thanked the CDC and HRSA for all their work in responding to the committee's request for data on the issue.

Community-Based Organization and Capacity Building Assistance Program Announcements

Janet Cleveland, M.S., of CDC presented data on 2002 annual AIDS rates by race/ethnicity, demonstrating the need for capacity-building assistance to providers delivering services to these communities.

The Capacity Building Assistance (CBA) announcement provides funding to national and regional organizations, CBOs, health departments and HIV prevention planning groups to improve, evaluate and sustain HIV prevention services for high-risk racial and ethnic populations.

Ms. Cleveland explained that strengthening organizational infrastructures for the provision of HIV prevention services was critical to having those services proceed. In response to the announcement, CDC received 124 applications for funding and made 34 awards to 27 organizations. The awards ranged from \$250,000 to \$1.8 million.

CDC has also released a new CBO announcement tailored to serve populations disproportionately affected by HIV/AIDS. The project period starts July 1. The grants will support efforts to increase the number of individuals who know they are infected and are linked to appropriate services. Additionally, the goals are to decrease the number of persons at risk for HIV and strengthen organizational capacity to develop and evaluate interventions. Funding will be provided to CBOs serving largely minority populations, as well as those serving all individuals at risk for HIV, for implementation of one or more types of services prescribed by CDC. Within the program, noted Ms. Cleveland, would be \$12 million for outreach and HERR, reflecting CDC's commitment to ongoing prevention efforts with HIV-negative individuals.

Ms. Cleveland then described the process for applicant selection. A panel, including a community person, and epidemiologist, and an external researcher, reviews the application to ensure that all criteria are met. Applications are scored against the program announcement. Based on the results, a pre-decisional site visit is made to programs eligible at this phase. The purpose of pre-decisional site visit is to make sure that the applicant is able to perform as they have indicated.

Ms. McGuire asked to have a geographic breakout of the CBO grantees. Mr. Baker said he assumed that there would be some transition planning for organizations that lose funding. Ms. Cleveland said that if an organization had not received a pre-decisional site visit, they could be fairly certain that they would not be funded, and should be making plans for how to respond to the loss of funding. She added that CDC has started a training program for the national organizations to get them ready to provide CBA to CBOs, and will also continue to work with CBOs directly throughout the year.

Dr. Valdiserri acknowledged that it can be difficult to balance continuity with the need for competition and openness in the funding process. He said that to the extent that CDC can get feedback on how to sustain organizations in the context of a public health procurement process, it would be helpful.

Dr. McGuire suggested that the goal should be about building a system rather than funding individual entities. She asked how all the training will contribute to the building and development of systems to meet HIV needs, and influence States that can dedicate resources to the effort.

Mr. Milan announced that committee member Dorothy Mann was being honored at an event being held by the AIDS Alliance for Children, Youth and Families, and that greetings from the CHAC would be read at the event.

He then recessed the meeting at 5:22 p.m.

Day 2

IOM Report on Public Financing and Delivery of HIV Care: Securing the Legacy of Ryan White

Richard Conviser, Ph.D., Chief of the Service Evaluation and Research Branch in HAB's Office of Science and Epidemiology, said that the IOM conducted a study in response to a legislative mandate to determine whether it would be feasible to extend public coverage for HIV care to people in relatively early stages of illness, through Medicaid or some other means. IOM considered seven different options and put forth a model they call the HIV Comprehensive Care Program (HIV – CCP).

The model calls for the program to be administered by States and overseen by the Centers for Medicaid and Medicare Services (CMS). Eligibility would be based on an income of less than or equal to 250% of the Federal Poverty Level (FPL). The program would be 100% Federally financed, relieving States of the Medicaid contributions they currently make for the care of people living with HIV. Providers

would be reimbursed at Medicare rates, which are about 20% above current Medicaid reimbursement levels. Benefits would include: HIV medications; obstetric and reproductive health services; mental health and substance abuse treatment; case management; HIV prevention services; and primary care (including specialist, emergency room, and inpatient hospital care).

The approach would eliminate CARE Act Title I, and the CARE Act would largely become a program serving low-income immigrants ineligible for the HIV-CCP. The CARE Act would also provide increased outreach and support to get people into the HIV-CCP program, would fund support services much as it does now, and would pay for voluntary HIV counseling and testing.

The net cost of the new program would be an additional \$574,000 for the first year, which would largely be a transfer from Medicaid programs to the Federal government. Federal outlays would increase by \$2.6 million annually. The program would add 58,000 HAART clients, which may enable reductions in drug prices while leaving drug company profits intact.

Projected outcomes from the new program include a decline of nearly 20,000 deaths in its first ten years and a reduction in new HIV infections of 3,200 persons per year.

Dr. Conviser said that the IOM committee considered other options, including expansion of the CARE Act, block grants, a Medicare expansion, and several Medicaid expansion options. The Committee determined that current data gaps and coverage shortfalls made CARE Act expansion a less attractive option. All Medicaid options considered would result in coverage inequities that made the drawbacks of such options greater than their benefits.

The Committee stated that the current care system was crafted while HIV was a crisis epidemic. They further feel that the standard of care should be one that assures access to HAART and sees that as a core characteristic of a chronic care model. They believe that the HIV-CCP model has the greatest likelihood of ensuring a uniform standard of high quality care. The inclusion of case management, mental health, and substance abuse treatment services in the proposed program was seen as critical for assuring high rates of client adherence with HAART.

Dr. Sweet asked if vets with HIV would come into the new system rather than the VA system. Dr. Conviser responded that under the VA system there is no HIV entitlement in the program, so that vets can receive their care elsewhere, if they choose. While acknowledging beneficial features to the program, Dr. Sweet asked about payment for case management, nutritional, dental and transportation services. Dr. Conviser explained that nutrition and education would still be available through the CARE Act, and that dental would probably be incorporated into primary care. "As for case management, we'd talk to CARE Act programs to figure out that piece," he said.

Dr. McGuire voiced concern about capped enrollment in Medicaid. She asked about hospitalization coverage. Dr. Conviser did not have an answer about hospitalization but later learned from the IOM that hospitalization coverage was included in the primary care component of the proposed program.

Dr. McGuire asked about the CHAC's role in responding to the report. Dr. Valdiserri suggested that other IOM reports have been used by advisory committee members as rich and thoughtful sources of information. He did not envision this kind of program being implemented in the near future, and urged the committee rather to about how to address CARE Act shortfalls in the interim

Dr. Conviser said that in terms of CARE Act reauthorization:

- The CARE Act cannot produce an unduplicated number of clients, so maybe it's time to move toward unique identifiers and client-level data;
- It's unclear that Title I planning bodies have responded to changes in treatment modalities in terms of planning — there may be inertia in the planning process; and
- The IOM committee has laid out a minimum program that prioritizes services, and one of the beauties of the CARE Act is that it is holistic in its approach to care.

Mr. Liberti asked how the IOM came up with a figure of the 58,000 new enrollees. He also said that the absence of a hospitalization benefit was a real problem. Dr. Conviser said that the formula used by the IOM to arrive at the estimate of 58,000 newly enrolled could be found in Tables A-3 and A-4 on pages 192-3 of the draft report.

Mr. Baker said that the characterization of planning bodies as inert was unfair and not based on evidence, because the data doesn't exist. He asked how to get consistent data to make good decisions around allocations and overall approaches.

Mr. Conviser responded to Mr. Baker's comments on planning bodies by saying that he and Mr. Bates (DHHS) are working on a care system assessment demonstration project, using the Rapid Assessment, Response and Evaluation (RARE) approach to find people who are not coming into care and assessing their barriers. This, he explained, is not something that planning bodies do generally, because they focus on people in care.

Dr. Sweet said that as a physician she was disappointed about this approach leaving the same hole in the system that the CARE Act does by not paying for hospitalization.

Mr. Milan stated that the CHAC had made reauthorization recommendations that encourage the prioritization of care and treatment services. Dr. McGuire asked if the CHAC's recommendations should be revisited in light of the information the committee had received about the AHP and the status of ADAPs. She asked if it might be possible for the committee to meet again in the next six months to discuss these issues more in-depth.

Mr. Bates suggested that the committee meet in Washington, DC so that people can have a chance to digest what's been presented. Dr. Valdiserri mentioned that while there is no prohibition on another full committee meeting, budget constraints may impact the CHAC's ability to convene. He suggested a workgroup.

CARE Act Reauthorization Update

Marty McGeein, Senior Advisor in ASPE, reported that the office is coordinating HHS' effort for CARE Act reauthorization, which will occur around October 2005. HRSA and CDC are supporting the CHAC's efforts on the HHS-wide reauthorization working group and have sent the committee's recommendations forward.

Ms. McGeein said that HRSA has been invaluable in providing guidance on the CARE Act and demonstrating a significant level of expertise around HIV care and the legislation. ASPE has been soliciting information from broad range of stakeholders, including both national and local policy groups. HRSA has been holding internal meetings and has commissioned a series of studies on fiscal, clinical, and resource issues.

ASPE is analyzing two IOM reports on data and financing in the context of the current reauthorization. The staff finds that these reports are good tutorials on HIV disease, and that the findings will have some impact on a reauthorized Act.

Ms. McGeein told CHAC members that her door is always open and that she welcomed their thoughts, comments and input. In response to a question from the committee, she said that it is unclear when HHS recommendations will be submitted.

Dr. McGuire said she was happy that Ms. McGeein had been at the meeting to hear the seriousness of the discussion on AHP. Ms. McGeein said she would relay the committee's concerns to the Secretary.

CARE Act Reauthorization Workgroup Update

Mr. Milan said that the group had yet to establish recommendations regarding distribution of resources, as it was waiting for further data from HRSA, CDC and the IOM. Armed with that information, the Reauthorization Workgroup has now crafted a work plan that includes a Federal Register Notice (FRN) and a posting on HRSA's Web site requesting public comment on the issue by mid-summer. The Workgroup will review the input, work with consultant Robert Greenwald to analyze the data and will also work with HRSA's policy staff to distill the information. Additionally, the committee will use the "Meet the CHAC" session at the All-Titles Meeting to get further input from the community.

In September, the workgroup will reconvene to analyze where it stands and start crafting recommendations on the topic for the November CHAC meeting.

Dr. Leoutsakas asked how many people with HIV would respond to a Federal Register Notice. Mr. Milan said that in the past the response has been good.

Finally, it was determined that Dr. Sweet and Mr. Bates would also join the workgroup. Former CHAC member Terje Anderson would also continue to serve on the Workgroup.

Dr. McGuire expressed concern about the implications of the IOM report for the CHAC's reauthorized recommendations, and asked if the recommendations should be revisited. Mr. Milan suggested an addendum.

Dr. McGuire motioned for a letter to the Secretary requesting a meeting to determine options for near-term responses to the issues raised by the implementation of the AHP, and a recognition of the financial and ethical dilemmas posed by the identification of new HIV cases for policy and program operators.

It was determined that the letter would be:

- A draft of the letter would be written by the co-chairs and circulated to the committee members for review;
 - Signed by co-chairs on behalf of CHAC;
 - Reference the AHP data presented;
 - Reference the importance of AHP for identifying people living with HIV;
 - Reference the seriousness of the ethical and financial implications;
 - Request an opportunity for co-chairs and a delegation to meet with the Secretary;
- and
- Request that the Secretary issue an expeditious response to the request.

Ms. Garcia seconded the motion and it passed unanimously.

Public Comment

(See attached for full text of public comment from Michael Ruppal, Associate Executive Director of the Washington, DC- and Florida-based AIDS Institute)

Minutes from November 2003 Meeting

There were some slight changes noted to the minutes from the November CHAC meeting in Washington, DC. Mr. Milan made a motion to approve the minutes with the revisions. The motion was seconded by Ms. Garcia and passed unanimously.

Agenda issues and date for the next meeting

The group identified the following issues for discussion at the next CHAC meeting:

- The role of crystal methamphetamine in fueling STD rates and HIV transmission;
- An overview of resources available in syphilis elimination and how efforts are being maintained in historic populations and increased in MSM populations;
- CDC data on Native Americans;
- An update on the first year of rapid testing;
- An update on the CDC corrections project and its results;
- Information on collaboration between CDC and HRSA on Hepatitis C and immunizations and how that will be integrated into health centers; and
- Information on international efforts.

The committee requested selected sections of the IOM report on expenditures. HRSA said it would distribute those to committee members.

Dr. Valdiserri urged members to email Paulette Ford-Knights with suggestions for new members, especially those that could fill knowledge and expertise gaps, such as youth, those with expertise around STDs, migrant issues, etc.

Drs. Sweet, McGuire, Goforth Parker and Mr. Milan will be at the All-Titles “Meet the CHAC” session.

Mr. Baker recommended that terms of expiration be placed on the committee member roster.

Mr. Milan applauded the CHAC for being in quorum and adjourned the meeting at 11:44 a.m.