Presidential Advisory Council on HIV/AIDS (PACHA)
Thirty-second Council Meeting
Hubert Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

February 27-28, 2007

Council Members Present
Marilyn A. Maxwell, M.D., Chair, PACHA
Robert R. Redfield, M.D., Chair, PACHA International Subcommittee
David A. Reznik, D.D.S., Chair, PACHA Domestic Subcommittee
Troy Benavidez
Rosa M. Biaggi, M.P.H., M.P.A.
Robert Bollinger, Jr., M.D., M.P.H.
Cheryll Bowers-Stephens, M.D., M.B.A.
Freda McKissic Bush, M.D., FACOG
Jacqueline S. Clements, B.S.
Shenequa Flucas
Edward C. Green, Ph.D.
Franklyn N. Judson, M.D., M.P.H.
Robert Kabel, J.D.
Herbert H. Lusk II, M.Div.
David J. Malebranche, M.D., M.P.H.
John C. Martin, Ph.D.
Jose A. Montero, M.D., FACP
Beny J. Primm, M.D.
Barbara Wise, B.S.
Ram Yogev, M.D.

Council Staff Present
Anand Parekh, M.D., M.P.H., Acting Executive Director, PACHA
Dana Ceasar, B.S., Program Assistant, PACHA

Guest Speakers
John O. Agwunobi, M.D., M.P.H., M.B.A., Assistant Secretary of Health, U.S. Department of Health and Human Services
Deborah Parham-Hopson, Ph.D., R.N., Assistant Surgeon General; Associate Administrator, HIV/AIDS Bureau, Health Resources and Services Administration
Tanya Pagán Raggio-Ashley, M.D., M.P.H., Director, Office of Minority Health and Health Disparities; Chief Medical Officer, Health Resources and Services Administration, U.S. Department of Health and Human Services
Andrea Weddle, M.S.W., Associate Director, HIV Medicine Association, Infectious Diseases Society of America
Jennifer Rainey, M.A., Program Coordinator, HIV Medicine Association

Christopher Bates, M.P.A., Acting Director, Office of HIV/AIDS Policy, U.S. Department of Health and Human Services
Jean Flatley McGuire, Ph.D., Senior Clinical Professor, Bouvé College of Health Sciences, Northeastern University
Raul Romaguera, D.M.D., M.P.H., Associate Director for Prevention in Care, Division of HIV/AIDS Prevention, Surveillance and Epidemiology, Centers for Disease Control and Prevention
Dennis DeLeon, J.D., President, Latino Commission on AIDS
William Steiger, Ph.D., Director, Office of Global Health Affairs; Special Assistant to the Secretary for International Affairs, U.S. Department of Health and Human Services
Carolyn Williams, Ph.D., M.P.H., Chief, Epidemiology Branch, Basic Sciences Program, National Institute of Allergy and Infectious Diseases, National Institutes of Health
Edmund C. Tramont, M.D., MACP, Associate Director, Special Projects, Division of Clinical Research, National Institute of Allergy and Infectious Diseases, National Institutes of Health

DAY ONE

Welcome Remarks
PACHA Chair Marilyn Maxwell welcomed members and guests. She congratulated previous Co-Chair Alan Holmer, J.D, on his new appointment, and noted that PACHA would be losing three additional valued members after this meeting because their terms are completed: Dr. David Reznik, Ms. Rosa Biaggi, and Ms. Jacqueline Clements.

PACHA Acting Director Anand Parekh welcomed everyone to the meeting and reviewed the materials in the conference notebook.

DOMESTIC ISSUES
David Reznik, D.D.S., Chair, Domestic Subcommittee
Dr. Reznik expressed gratitude for the many accomplishments to date but said significant challenges remain—among them, the need to fill vacancies in key leadership positions. He welcomed Dr. Deborah Parham-Hopson.

Ryan White Implementation, Deborah Parham-Hopson, Ph.D., *Title XXVI of the PHS Act as amended by the Ryan White HIV/AIDS Treatment Modernization Act of 2006*
Dr. Parham-Hopson summarized the Act's history and noted that the new law maintains its purpose. Listing structural aspects of the new law, she stressed the fact that Ryan White would sunset after FY 2009; activities aimed at maintaining its services must therefore precede that time. The major changes in the Act are in Parts A and B. Changes in Part A, Title I, include shifts in EMA (Eligible Metropolitan Area) and TGA (Transitional Grant Area) eligibility requirements. Since EMA and TGA status can be retained until three consecutive annual failures occur, areas will be maintained until expiration of the current Act. Data will be used from every jurisdiction regardless of name or code use. The waiver provision will be implemented, although listing criteria for a waiver creates conflict with the “rulemaking” requirement. Dr. Parham-Hopson said

that the Health Resources and Services Administration (HRSA) is trying to see whether the waiver can be carried out on an *ad hoc* basis. HRSA is also exploring how worthy programs whose proposals may be weak can be funded within a competitive grant process. Title 1 funding is now spread out over March, April, and August; programs will not know exactly how much funding they will receive until August 1. Technical assistance on dealing with this delay is available.

Under changes in Part B, Title II, the definition of medical services presents a challenge—if provided by a consortium, they are not eligible as medical services. The Minority AIDS Initiative (MAI) is now funded by a competitive application process, so States won't know how much they will receive. Changes in AIDS Drug Assistance Programs (ADAP) mean that all States and Territories can participate and must make available all listed drugs. Base and ADAP Formula awards go out in April, ADAP supplemental awards in June, MAI awards in August, and State supplemental award times are undetermined. Ongoing technical assistance will be provided, and States will have a full year to implement programs.

Under Part C changes, 75 percent of funding must be spent on core medical services; waivers are allowed. Ten percent is allowed for administrative costs; preference is given to programs serving underserved areas with high sexually transmitted disease (STD), tuberculosis (TB), hepatitis B/C, and drug abuse rates. Changes in Part D cap administrative costs at 10 percent, enhance opportunities to participate in clinical trials, and call for an annual program review and reports to the Government Accountability Office (GAO). Dr. Parham-Hopson's slides (included in the conference notebook) also detailed the relatively minor changes in Part F, covering the Special Projects of National Significance (SPNS) and dental programs, and general provisions regarding coordination and audits. She stressed the importance of developing a severity-of-need index, and pointed to a new provision on public health emergencies in the aftermath of Hurricane Katrina. HRSA has determined that 5 percent of Part A funds can be used for public health emergencies.

Most provisions will be implemented this year; some trigger in later years. HRSA's first activities have focused on helping grantees understand what to expect and how to write strong applications. It is also trying to sensitize reviewers. HRSA will work with grantees but not subgrantees on the use of MAI funds. Information on the Act is on the HRSA Web site.

Comments

- Funding questions remain. While the list of ADAP drugs is guaranteed, it is unclear whether people can be assured of additional treatment. Funds are available through different streams, such as minority AIDS funds. If EMAs have carryovers, they can apply to use them. Creativity will be necessary.
- One of the challenges is ensuring that people who apply for assistance have access to services. HRSA welcomes suggestions.
- The legislation didn't increase funding, yet more than five times as many people will be eligible for services. Women are the fastest growing segment of those with

HIV; how will they be served? Dr. Parham-Hopson said all Ryan White programs serve women and children but cannot serve all infected people. She is committed to spending all appropriated dollars.

- Regarding mental health services, discretion is left to communities, but a list of core services does include mental health.
- No changes have been made regarding community-based organizations (CBOs). Changes apply to EMAs and TGAs. CBO recourse is at the grantee not the Federal level.
- The Act does not provide incentives to States; it rewards people for more cases. HRSA is looking at actual measures.
- Robert Redfield said he wondered whether more State participation could be stimulated. What is the HIV burden that we're trying to raise the insurance support to meet? He suggested HRSA consider ways to provide a high-quality program for patients who are under/uninsured. Dr. Parham-Hopson said this would require a joint effort by the Centers for Disease Control and Prevention (CDC) and the Department of Health and Human Services (DHHS).
- Given changes in EMA and TGA requirements, are people in great need, such as patients located in the South, left on the margins? Competitive grants will not supply the amount of money needed for treatment. Dr. Parham-Hopson said HRSA realizes all patients don't live in EMAs; however, rural patients in general do not have the same access to services as urban dwellers. HRSA is concerned about populations who would be eligible for Ryan White support and is trying to capture information on unmet needs.

Greeting, John Agwunobi, M.D., M.P.H., M.B.A., Assistant Secretary for Health, DHHS

Dr. Parekh introduced Dr. Agwunobi, who expressed gratitude for PACHA's service as a Presidential advisory body. He expressed special thanks to the three outgoing PACHA members, and volunteered to answer questions. Dr. Reznik said PACHA would be making a motion on the need to fill leadership positions, including the acting directorship of PACHA. Dr. Agwunobi said he was committed to responding to those concerns—"You will not be disappointed."

HIV Workforce, Tanya Pagán Raggio-Ashley, M.D., M.P.H.

Dr. Raggio-Ashley addressed the health care worker shortage, listing programs and funding levels of HRSA's workforce training and citing specific education training center programs that target funds on HIV/AIDS care. Of the current health care workforce, only about 50 percent actually work in health care settings. HRSA's previous report on shortages pointed to the major problem of maldistribution of health care workers, with particular shortages in rural areas. Within its aim to improve health status, overcome health disparities, and maximize health quality, HRSA's Bureau of Health Professions funds a range of programs—mostly under the Health Care Services Act—focused on training people who are socially, economically, and educationally disadvantaged. Most funding is geared to training primary providers in general pediatrics, internal medicine, pediatric dentistry and dentistry, and physician assistant programs. Special consideration

goes to practitioner preparation for underserved populations, and many graduates take up practice in rural settings. Sixty percent undertake additional HIV/AIDS training.

In response to the extreme shortage of registered nurses, training programs support nursing faculty and students. Some programs target correctional facilities; some focus on HIV/AIDS and underserved groups. Grantees note a lack of knowledge and resistance on the part of health workers to working with people with HIV/AIDS. University-based Area Health Education Centers have trained more than 3,000 individuals. Of the approximately 1,000 health centers funded by HRSA, the majority focus on primary care. Dr. Raggio-Ashley noted the potential for increased capacity building.

Comments

- Some places, such as Alabama, have one doctor for 20 counties. People often don't know a medication exists. PACHA has been concerned about the quality of HIV care, the need to increase specialists in HIV/AIDS. Dr. Raggio-Ashley said some health centers have dually trained practitioners; we need to increase overall capacity.
- Adolescent care is the most lacking; there is no incentive, training, or interest. Dr. Raggio-Ashley said funding blocks do not allow adolescents with HIV to be tagged, but new outcome measures should shed more light on adolescents with HIV. All programs must now keep a log on patients.
- While capacity building is needed, students are unlikely to choose an infectious disease career when they graduate with huge medical school loan debts. Dr. Raggio-Ashley said the National Health Service Corps helps participants with school debts.
- In an era of competing health care resources, the time people spend in training is time they don't spend functioning. Outcome-related research is needed to determine whether this education improves health outcomes.
- Since HIV is not a popular medical choice, this area of medicine needs special help.

Minority Clinical Fellowship Program, Andrea Weddle, M.S.W., and Jennifer Rainey, M.A., ***Preparing the Next Generation of HIV Medical Providers***

HIVMA (HIV Medicine Association) is a membership organization representing more than 3,500 clinicians and researchers devoted to HIV medicine. It is concerned about the lack of a new generation of medical providers trained in HIV because experienced providers produce better health outcomes and more cost-effective care. Needs include support for HIV clinicians, a strengthened care system, and a more diverse medical workforce across specialties. A summary of "HIV Medical Provider Medicare Part D Survey Preliminary Findings, December 2006" was included for PACHA members in the conference notebook. HIVMA recognizes that targeted training is effective. Currently the distribution of medical providers and patients shows more patients in the South, yet fewer providers. The HIVMA Minority Clinical Fellowship Program targets African American and Latino physicians, currently providing support for 2 fellows selected from 28 applicants committed to practice HIV medicine. This is a model program funded by four drug companies and Gilead.

Comments

- HIVMA should consider outpatient programs. Ms. Weddle said this is an option for future years.
- It is unclear what adequate Ryan White funding would be, but the Institute of Medicine has estimated costs and options.
- The criterion of service in a minority-serving program is explored. The program also works with adolescents and pediatric care.
- Few African American physicians treat HIV/AIDS patients; the program should include physician extenders since they provide care "on the ground."

Minority AIDS Initiatives, Christopher Bates, M.P.A., ***Updates on the National HIV Testing Community Mobilization Campaign (NMC), National Women and Girls HIV/AIDS Awareness Day, National Native HIV/AIDS Awareness Day, and AIDS.gov***
The NMC is a national effort to mobilize communities to promote AIDS testing. By encouraging everyone to know their HIV status, the campaign seeks also to eliminate stigma and expand understanding of risk behaviors. Since CDC issued revised testing guidelines, more people are being tested, but one-fourth of those who have HIV/AIDS remain unaware of their status. The campaign involves agencies throughout DHHS as well as State and local partners, encompassing speakers and publications, media campaigns, focused discussions in select communities, Web-based activities, and public health leadership efforts. Awareness Days are major components of the overall education effort to promote testing. The second Women and Girls Awareness Day is March 10; the first Native Awareness Day is March 21, 2007. Some 400 tribes will be represented. The focus population is all sexually active adults, and covers a wide variety of risk behaviors, including alcohol and substance abuse, MSM (men who have sex with men), injection drug use, prostitution, and sex with multiple partners.

Mr. Bates said the campaign hopes to tap into 2,000 events over the next 2 years, including trade shows. An "army" of trained people will be needed. The *AIDS.gov* Web site provides a single resource for AIDS information. The Minority AIDS Initiative (MAI) is moving forward and should be refunded in 2008. Many agencies, however, will be involved in a Program Assessment Rating Tool (PART) performance review at the same time activities should proceed.

Comments

- The Latino community has been involved in Awareness Days; some 1,500 will take part in activities this year.
- Ms. Flucas expressed appreciation for the assistance provided in organizing Observance Days.
- Mr. Bates said employees throughout DHHS would be trained to speak with groups throughout the country. He encouraged PACHA members to look at the Web site calendar to identify events at which they could speak. DHHS can supply materials.

- The lack of MAI infrastructure is troubling, as are new grant competition requirements. Dr. Parham-Hopson said HRSA has funding for bringing in new organizations, creating initiatives, and assisting agencies working with racial/ethnic minorities. Funding is going to organizations serving minorities although they may not be minority organizations.
- The Week of Prayer for HIV will take place in the near future. Mr. Bates said his program partners with Balm in Gilead and has met with many diverse faith/denominational communities.
- Regarding financial incentives for encouraging testing, many believe the increased numbers of people tested is likely to stimulate a discussion of funding needs, given the number of new cases likely to be identified.
- A report is forthcoming on the effectiveness of ABC (Abstinence, Be faithful, use Condoms) efforts. They appear to have had some impact on teen pregnancy and STD rates.

National HIV/AIDS Strategy, Jean Flatley McGuire, Ph.D., *Recommendations for a National AIDS Strategy: A Review of Recent Findings by the CHAC*

Dr. McGuire reported on recommendations and motions of the CDC/HRSA Advisory Committee (CHAC). The recommendations focus on the lack of adequate prevention resources, a current overburdened treatment and care system unlikely to meet the needs of substantial new numbers of infected persons, and the lack of a coordinated, multi-sectoral national HIV/AIDS plan. Failing to meet national goals has created serious problems: 50 percent of people living with HIV/AIDS are in care, 25 percent are undiagnosed, and 25 percent are diagnosed but not in care. We now know that knowledge of status makes a difference; we know a national plan has value; we know what works. Medical interventions are cost-effective. Based on evidence, CHAC recommends that the DHHS Secretary seek supplemental resources allocated for efforts, such as prevention, that have proven effective. Dr. McGuire distributed a copy of CHAC's December 19, 2006, letter to the Secretary of DHHS containing CHAC's recommendations, and a report requested by CHAC on "cost implications of the new CDC Advancing HIV Prevention Initiative on the demand for Ryan White Comprehensive AIDS Resources Emergency (CARE) Act Services…[reflecting] an increased need for care and treatment services due to the implementation of the Initiative."

The major portion of Federal funding for HIV/AIDS is now discretionary. The bulk of prevention funds is now concentrated at CDC. A comprehensive HIV prevention program would include surveillance, program evaluation, research, capacity building, policy, and planning, but we have not moved ahead. Insufficient leadership and strategic partnering, inadequate infrastructure and interventions, and prevention fatigue have all hindered progress. Money is a significant issue, since a large proportion of newly identified persons with HIV are uninsured. Resources are part of the problem, but another is failure to target efforts appropriately to achieve the 50 percent reduction in incidence. If reducing HIV at the community level is the goal, the DHHS Secretary should initiate a national plan with targeting throughout. That is what this epidemic needs.

Comments

- Responding to a question about measurement, Dr. McGuire said a portion of resources was devoted to exploring that issue, but current measurement models do not seem adequate. In her (not CHAC's) opinion, "Good-enough data makes sense to me." While there is certain efficacy evidence of approaches that make a difference in behavior, we haven't empowered any intervention to succeed. Prevention resources have been flatlined.
- The total cost of care includes all of the side effects and factors affecting interventions. These are not included in cost estimates but play a role.

Update on CDC Screening Guidelines, Raul Romaguera, D.M.D., M.P.H., ***Implementation of the Revised Recommendations for HIV Testing in Health Care Settings***

Dr. Romaguera's presentation summarized CDC guidelines issued in September 2006 on HIV testing for adults, adolescents, and pregnant women. Recommendations for pregnant women include rapid testing of newborns if the mother's status is unknown. Guidelines apply only to health care settings, with data showing most testing takes place in private doctors' offices. As part of its work to build partnerships with key medical organizations and insurers, CDC held a meeting in October to determine ways to assist clinicians in implementing the guidelines, identify regulatory barriers, and consider reimbursement strategies for screening. Recommendations from that consultation dealt with resources, tailoring clinical approaches, best practices, and access to State-specific resources. Challenges range from current State/local laws and reimbursement limits to lack of resources for followup care.

CDC implementation activities cover a variety of domains including professional education, health departments, corrections, community partners, STD, prenatal and urgent care clinics, social marketing, and laboratories, with which partnerships can be created through collaborative relationships and public-private working groups. Emergency departments pose special problems related to screening. The Health Research and Educational Trust, the research affiliate of the American Hospital Association, has been examining HIV screening in hospital emergency departments, and is developing a Web site on testing at hospitals. Six regional planning workshops for hospitals are planned; participants must commit to an action plan on testing. Another collaboration involves the National Association of Community Health Centers, which will analyze testing, prevention, and linkages to care policies and develop an operational guide.

Among many lessons learned, it is clear that Ryan White-funded health centers have very different experiences from other types of health care settings, which lack the Ryan White networks and infrastructure. Corrections findings show little testing in jails, although all prisons test. Four States (27 jails) are now engaged in a demonstration project on rapid HIV screening. CDC is developing guidance in collaboration with the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Division of STD Prevention on screening in other settings. The agency is also working with the American Medical Association and other key agencies to reach out to primary providers.

State and local laws differ with respect to signed consent and specific counseling, but screening can be implemented within existing laws. Dr. Romaguera provided the example of the Texas Informed Consent law, which calls for no further consent if a patient signs the general consent form. Colorado includes a form for opting out in order to avoid any appearance of coercion. The New Rapid Testing Initiative (NRTI) aims primarily to increase the number of HIV-infected persons who know their status and link them to medical treatment. Screening will be offered in medical care settings, substance abuse treatment programs, and correctional settings. About two million people are expected to be tested, identifying 20,000 to 40,000 new infections.

Comments

- Since a large proportion of patients do not read the consent form, posters saying "You will be tested" can be put up in waiting rooms.
- Regarding the problem of insurance reimbursement, Dr. Romaguera said insurers are getting more involved as they understand the issue more.
- The NRTI should target high-prevalence areas. Those community health centers that test reveal a high incidence of infection.
- Asked to name the key obstacle to screening, Dr. Romaguera said "money."
- Fewer funds available for the patient load mean fewer efforts to reach out.
- While emergency room (ER) routine testing would likely be productive, many patients tested are unlikely to follow up. Use of the emergency room represents the most expensive mandate for care. It is unlikely the American College of Emergency Physicians will endorse testing in ERs; many departments already operate at a loss.
- Can't CDC develop a simple five-point guide on counseling? Dr. Romaguera said CDC is developing material for providers and patients.
- In response to why antigen testing when people are highly infectious is not done, Dr. Romaguera said some communities are considering this; it is a matter of jurisdictional policies, not money.

Status of the HIV/AIDS Epidemic in the Hispanic Population, Dennis DeLeon, J.D., *Facing Challenges in Treating and Preventing Among Latinos*

There was no progress between 2000 and 2004 in curbing AIDS among Latino men and Latina women, despite major increases in addressing the rate of infection in African Americans. Newly reported Latino HIV infections increased 20 percent between 2001 and 2004, although little public discussion was given to this dramatic increase. Data presented document the high rates of infection for Latin men and women and transmission sources. Latinas account for 16 percent of new AIDS cases in 2005, and are five times more likely than white women to have AIDS. White women are more likely to be infected by injection drug use, Latinas by heterosexual contact. The number of deaths among Latinos remained stable, while white and black deaths from AIDS decreased.

Mr. DeLeon cited two epidemics in the United States: the Northeast and Puerto Rico epidemic fueled by high injection drug use, and the epidemic in the South and Southwest where infection comes mainly from MSM. In all regions, Latino rates of infection have risen. While Puerto Rico accounts for 1.2 percent of the population, it has the second

highest death rate in the United States (after the District of Columbia) from AIDS—16.4 percent per 100,000. The U.S. average is 4.9. The Puerto Rican legislature is not held accountable to the same level as other States for their use of Ryan White funds—a disservice to citizens. Policymakers should question why most infections among Latinos occur in the 40-49 age group and levels of AIDS are continuing to rise. Both Latinos and Latinas are living longer with AIDS—a challenge to medical providers.

Mr. DeLeon illustrated "Geography and Latino AIDS Cases" with tables depicting the location of the epidemic by region, city, gender, and nationality origin. While the epidemic is primarily in the Northeast, it is moving into the Deep South where small migrant communities have no links to health/cultural networks. No interventions for heterosexual Latinas who do not use drugs have been developed; "SISTA," targeted at African American women, is not effective with Latinas. Asking agencies to hire Spanish speakers seems excessive but is often necessary to ensure adequate care. Many States have restrictions to medical care, even to the ER. Data show very low rates of Hispanics enrolled in ADAP (AIDS Drugs Assistance Program). Among his recommendations to lower infection rates, Mr. DeLeon included:

- The perspective toward serving Latinos needs to be more nuanced—assumptions hurt effectiveness and maintain stigma. Culturally competent health care is crucial.
- Focusing on testing alone is insufficient—why can't we explore pharmacological interventions that would reduce the likelihood of HIV?
- More DEBIs (Diffusion of Effective Behavioral Interventions) are needed for Latinas who don't use drugs and for heterosexual males.
- Increase access to care by providing transportation and mobilizing communities. Offer routine testing so delayed testing can be avoided.
- Federal support for needle exchange is needed.
- Issue RFPs that target Latinos.
- Address immigration status obstacles to seeking screening and care.
- Develop social marketing that addresses stigma.
- Focus efforts on Latino faith communities. Religious leaders are in a unique position to counter unhealthy beliefs and encourage medical interventions.

Mr. DeLeon said last year's National Latino AIDS Awareness Day had been successful and cautioned PACHA that "Puerto Rico's health system is collapsing as we sit….think of it as your own family."

Comments

- The high rate of Latina infection may reflect high levels of sexual oppression of women. Women often feel unable to refuse sex because of cultural reasons and fear of exposure of their immigrant status.
- There are major barriers to screening or treating Latinas when they are afraid to come into health centers or seek service. Mr. DeLeon suggested training and hiring *promotores* (traditional Latina community health workers), who have been successfully used in the Southwest because they offer one-on-one contact. In urban areas, house parties could bring the stakeholders together.

- Regarding color prejudice on the part of Latinos that prevents their accepting care from African American health providers, Mr. DeLeon cited media discussions initiated in New York on race and color, which resulted in greater trust of black professionals. Many health care settings could benefit from delving into similar "unexplored territory."
- Asked to elaborate on his suggestion that HIV/AIDS funding go directly to programs rather than to Puerto Rican Government agencies, Mr. DeLeon said it is worth trying a third-party approach, which other States and jurisdictions practice frequently. Traditional avenues, including Federal technical assistance, have not worked. The situation has worsened, treatment is unavailable, and people are dying.

DAY TWO

INTERNATIONAL ISSUES

Robert Redfield, M.D., Chair, International Subcommittee

Dr. Redfield chaired the morning's presentations on international issues and introduced each speaker.

Global Fund, William Steiger, Ph.D.

Dr. Steiger said he agreed with Dr. Redfield that the Global Fund is a crucial part of the Administration's health policies. The United States provides 28 percent of the Fund budget, and the majority of the balance comes from 130 other Governments—$7 billion. The Joint Resolution signed by the President represented a significant increase. Private donors play a role, with the largest being the Bill & Melinda Gates Foundation. The remarkable success of the Fund has not taken place without challenges. Much credit should go to its original CEO. The new executive director is the head of the French national AIDS agency.

In November 2006, the Fund filled the full slate of recommended grants; there will be seventh and eighth rounds. Since the sixth round, two countries are no longer eligible because they are wealthier. In the future, Dr. Steiger would like wealthier countries to stay in the program but match funds. The Fund is currently engaged in a strategic planning process to create a roadmap. While the Policy and Strategy Committee is "a committee of the whole," it has been successful in retaining the core focus of the Fund, and the Board has adopted its recommendations. Adopted strategies include:

- Criteria for what to do when a grant reaches its lifespan in years. To be eligible for continued funding, applicants must show evidence of measurable impact. The Secretary must be able to report annually on program accomplishments. Programs can receive 3 new years of funding and potentially up to 11, so long as performance is maintained.
- Commitment to continuity of treatment.
- Efforts to consolidate grants within the same country.
- Exploration of improved market dynamics regarding drug purchases, with continued focus on quality and availability. The lack of approval for in-kind donations from

pharmaceutical companies is disappointing, since it offers great potential for savings. Dr. Steiger hopes that some medications will be acceptable.
- The optimum size of the Fund. An expert team has been asked to explore target size.

Issues coming up include:
- The appropriate role of the private sector, given some hostility to private sector involvement.
- The appropriate role of civil society on the Board. In many places, Governments "have a heavy hand." By including private institutions on the Board, the Fund has encouraged democracy, in Dr. Steiger's view.
- General health system needs. A larger share of funding for larger issues would be beneficial.
- The relationship between the Global Fund and UNAIDS. Currently no formal relationship exists, but negotiations are ongoing to resolve funding allocations.
- Need for greater transparency regarding commitment of funds. Past stories about inadequate controls were followed by recommendations, which were carried out. There was no serious malfeasance and it did not affect the 450 grants, but “we need to be able to demonstrate performance better. We are committed to making it work.”

Comments
- Why is the Fund trying to enlarge if the problem is decreasing?
- Middle East problems have not had a collateral impact on global health spending programs. This program has consistently received large increases.
- Malaria is the greatest success story; in some places it will be eliminated soon, and others show dramatic decreases. Where the Fund is partnered with the President’s Emergency Plan for AIDS Relief (PEPFAR), the impact on HIV is very encouraging.
- In terms of Board emphasis on treatment, prevention, or evaluation, Dr. Steiger said fund allocations are local decisions so emphases have fluctuated. Getting data that track prevention impacts versus treatment has been difficult. We have continual discussions about measurement, but relying on 140 separate reporting mechanisms is challenging.
- The pediatric population is not adequately represented—a problem recognized by the Fund. First Lady Laura Bush launched an effort to produce better pediatric doses, and the United States is committed to using its purchasing power to encourage attention to pediatric needs. However, national Governments can cause long delays in registering a new drug, even after approval in the United States and Europe.
- The Fund can't approve grants until 2 or 3 years of funding for the program is set aside in the bank. This accounts for the perceived backlog of money. The United States agrees that it is better to have the funds available in order to keep commitments. Since some countries are using funds more slowly than is desirable, the United States has argued for a second channel in those places.
- In response to concern for increased investment in Caribbean countries, Dr. Steiger said the Fund has some programs but has problems achieving cooperation among the island nations. More emphasis on the Caribbean is needed, along with

a connection between island populations living on the U.S. mainland and those on the islands.

- Dr. Redfield said drug companies are unlikely to make therapeutic advances and stay in the global arena if they are undercut financially. Dr. Steiger noted ideological differences with countries opposed to private U.S. enterprise; he hopes a balance can be developed. We can't compromise on quality.
- To date, there has been no competition between domestic and global health needs. The public has demonstrated high approval for the international AIDS fight, so funding has not been threatened.
- Grantees have not had to struggle with how to continue after deadlines, since timelines and bridge funds ensure fund availability. Programs not funded by the Global Fund have been assisted through other Government contributions.

Overview of the Data of the Impact of Male Circumcision and HIV Transmission, Carolyn Williams, Ph.D., *Adult Male Circumcision: A "New" HIV Prevention Tool*
Dr. Williams presented slides on the findings of three large research trials conducted in Africa. The presentation began with an illustration of an ancient Egyptian hieroglyphic illustrating that the practice of male circumcision is more than 5,000 years old. She said the biological rationale for lowering HIV and other sexually transmitted infections is understandable because of the vulnerability of the male foreskin to infection. Circumcision thus also lowers incidence of herpes, human papillomavirus, and other infections/diseases for both males and their partners. Its feasibility as a prevention approach for HIV is heightened because of its acceptability by men and women as a hygiene benefit. The participants' and partners' main concerns were cost, pain, and followup care.

Cultural bias previously discouraged testing circumcision as an approach to prevention, but these large randomized clinical trials have now provided solid evidence of its efficacy. NIH wanted to do the trials to understand risks. All three trials were stopped early because of the uniform strength of their findings. The data overwhelmingly show that circumcision reduces the risk of acquiring HIV by around 50 percent. Trials took place in a semi-urban, high-HIV setting with three clinics: Orange Farm, in South Africa; a rural setting with semi-high HIV in Uganda, the Rakai District; and an urban moderate-HIV Kenya site, Kisumu. Only the Ugandan study looked at secondary infection of partners, finding about a 50 percent reduction in HIV transmission. The South African and Ugandan studies included HIV-positive men.

Recruitment was conducted via community advertising, flyers, and radio ads. In response to questions, Dr. Williams said all of the men who came into the study knew they would be randomized, and the consent form stressed that the trial's outcome was unknown. Many men chose to have the procedure because it was regarded as modern and hygienic. Women were as empowered as men in asking questions. The large number of enrollees indicates that findings are "generalizable." Results showed a low overall incidence of adverse events, and fewer as providers became more proficient at the procedure. By 30 days all participants were healed and had resumed sexual activity. When surgery is performed properly, recovery should not take more than a week for most. Interestingly,

there was a high finding of erectile dysfunction unrelated to the procedure and possibly linked to depression. The message to be drawn from these trials is that circumcision is partially protective, but safety will decrease with the addition of partners.

The NIH research agenda calls for long-term, country assessments. UNAIDS/WHO have formed a steering committee to hold a meeting that will look at all trial results, determine optimal models, identify assessment tools to evaluate country needs, and draft a manual. They are also considering levels of health professionals needed or acceptable by countries. Other partners in a very large trial are funded by the Bill & Melinda Gates Foundation. The Clinton Foundation is engaged in an effort to determine equipment and supply needs and negotiate prices.

In conclusion:

- Male circumcision could have a major impact on the epidemic.
- There are additional health benefits, including possible reduction in penile and cervical cancer.
- There is a critical need for specialized surgical services to minimize postoperative complications.
- Behavioral risks could offset benefits.
- Circumcision is an addition to, not a substitution for, other prevention approaches.

Comments

- All studies went through the IRB (institutional review board) process. The IRB was concerned that randomized men would feel circumcision was required, so the study ensured that the process was voluntary. The IRB wanted good referral services for followup. NIH set up clubs. All of the men are to be seen for 4 years. Ugandan men have now been seen for 2 years.
- All of the men were seen over several months and answered questions concerning behavior. The data were fully reported and published quickly—see *Lancet.* It was clear the men felt they had made a healthy life choice.
- It would be a good idea to include young men and boys.
- Of 11,000 men screened, 80 percent came in for the procedure.
- Are these finding that can be used to develop more effective prevention messages on not having multiple concurrent partners?

Impact of Male Circumcision and HIV Transmission, Edmund Tramont, M.D.

Dr. Redfield asked Dr. Tramont to focus his remarks on the impact of the above studies on public policy. Dr. Tramont responded that circumcision, if properly done, is protective. The real issues are the “what ifs”—for example, the effect on partners of HIV-infected men who have circumcisions, the effect of less sterile environments on infections. Although we need more information for policy, we can say absolutely that a circumcised male has less of a chance of infection. This raises the question of how much we should advocate circumcision. Many African men are now asking to be circumcised. It will go forth. There is no need for more trials, but it is unclear how findings on circumcision's effectiveness translate into a recommendation for policy. "I personally don’t feel we have enough information to make this a central piece of health policy."

Comments

- All other prevention options (abstinence, condom use, etc.) demand a decision each time by the active sexual person. Circumcision is a one-time decision. "We don't have to hammer at it."
- When viral loads are high, more transmissions occur. Circumcised men with high viral loads are more likely to transmit infection.
- Counseling regarding the dangers of multiple partners needs to be provided, optimally at the time of circumcision.
- Responding to a comment that findings may be different for MSM, Dr. Tramont said transmission rate studies have not been done. These studies show circumcision protects the male himself. Studying subjects to see if they get the disease poses difficulties.
- Since men of African descent are less likely to be circumcised, what are the implications for Americans? It would be in the best interest for circumcision to be covered by insurance, given findings that circumcision reduces the chance of infection 50 percent.
- Why not take the same public health policy approach as vaccines? Dr. Tramont said vaccines are effective when given universally. The public reaction to universal circumcisions is unclear. The epidemic could possibly be ended, but this is a long-term approach.
- Data are lacking on transmission by infected males. Are there sufficient data for the Government to advocate circumcisions in appropriate settings?

Dr. Tramont concluded that, given the findings, advice would likely focus on the need to ensure appropriate surgical services for circumcisions. Insurance coverage should be provided as an established public health procedure. Global Fund contributions should be used to provide access to circumcision, with caveats on skill/competence. These caveats will be difficult to implement because of local infrastructures. It is unclear when there will be a formal recommendation by the World Health Organization.

PUBLIC COMMENT

Larry Bryant, Housing Works: There is an urgent need for full funding of Ryan White and access to care. It feels like we're going backward. Mr. Bryant noted several cases in which people had been ill-treated because they are HIV-infected. He hopes PACHA will reinvigorate a sense of urgency in stressing that this is a disease of great import.

James Albino, National Minority AIDS Council: The conditions in Puerto Rico are not new; they were covered in a HRSA letter, along with other material recording problems and repeated requests. The Office of Minority Health study looked at ADAP administration. The majority of Puerto Rican clinics have no running water, skilled providers, or other resources. We are asking PACHA to intervene to restore the collapsed system in Puerto Rico.

Ronald Johnson, AIDS Action: We urge PACHA to join CHAC in calling for reforms including, most importantly, lifting the Federal ban on syringe exchange. This move is

backed by ample evidence of efficacy. If we had implemented syringe exchange earlier, many lives would have been saved. Call on Congress to lift the ban.

Michael Knox, Ph.D., Florida/Caribbean AIDS Education and Training Center (AETC): The AETC aim is to ensure that health providers in Florida, Puerto Rico, and the U.S. Virgin Islands receive state-of-the-art information and training on HIV/AIDS treatment and prevention. The President's 2008 budget cut $6 million from AETC funding, a cut of nearly 20 percent to its budget, at a time when increased funding will be needed because of CDC's new guidelines on HIV testing. Cutting funds will lower the quality of health care, increase risks of transmission, and undermine prevention efforts. We ask that you strongly recommend restoration of AETC funding.

James Sykes, Global Advocacy Coordinator, The AIDS Institute: The President's Malaria Initiative (PMI) is an extremely important collaborative program of the U.S. Government and international partners. Interventions include indoor spraying, bed nets, life-saving drugs, and treatment for pregnant women. Since seven PMI-focus countries are also PEPFAR-focus countries, program efforts should be coordinated. Coordination is also needed between public health agencies and faith-based organizations in sub-Saharan Africa if progress is to be made on reducing 50 percent of malarial deaths in the 15 hardest hit countries. The AIDS Institute also supports removing tariffs on medicines and medical supplies in order to remove barriers to access. We must succeed in reaching 85 percent of the most vulnerable groups with proven prevention and treatment measures.

Carl Schmid, Director of Federal Affairs, The AIDS Institute: The AIDS Institute is pleased that CDC incorporated the Institute's suggestions in formulating recommendations on voluntary HIV testing. Medical providers are now involved in the implementation phase, but CDC should continue working with the AIDS community. We welcome the President's proposed $93 million increase for testing but question whether $30 million will ever be spent due to strict grant requirements and suggest different funding targets. Increased testing brings people into care and treatment, but must not supplant other prevention programs aimed at bringing about an AIDS-free society.

SPECIAL PRESENTATION FOR DEPARTING COUNCIL MEMBERS
Anand Parekh, M.D.
Dr. Parekh read a letter of appreciation from DHHS Secretary Michael O. Leavitt, thanking Dr. David Reznik, Ms. Jacqueline Clements, and Ms. Rosa Biaggi for their service on PACHA from 2004 to 2007. Dr. Parekh then presented commemorative plaques to each member, and he and Dr. Maxwell added personal thanks and best wishes.

FUTURE MEETINGS
International Subcommittee, May 15, 2007
Domestic Subcommittee, May 21, 2007
Full Council, June 12-13, 2007
Domestic Subcommittee, September 10, 2007
International Subcommittee, September 17, 2007
Full Council, October 15-16, 2007

Motions and Voting

The following motions were proposed by the Domestic Subcommittee and passed unanimously by the full council following discussion.

Domestic Subcommittee Resolution #1

WHEREAS male circumcision has been associated with a lower risk for female-to-male HIV transmission in international observational studies and in three randomized, controlled clinical trials, and

WHEREAS in 1999, the American Academy of Pediatrics changed from routinely recommending circumcision to a neutral stance on circumcision, which was reaffirmed in 2005, and

WHEREAS this change in policy has influenced reimbursement for and practice of neonatal circumcision as 16 States (CA, ND, OR, MS, NV, WA, MO, AR, NC, MT, UT, FL, ME, LA, ID, MN) have eliminated Medicaid payments for circumcisions that were not deemed medically necessary, and

WHEREAS male circumcision may also have a role for the prevention of HIV transmission and sexually transmitted infections in the United States, then

BE IT RESOLVED that the Presidential Advisory Council on HIV/AIDS calls on the Secretary of Health and Human Services to work closely with the American Academy of Pediatrics, the Centers for Medicare & Medicaid Services, and the Centers for Disease Control and Prevention (CDC) to ensure that all Americans, regardless of economic status, have access to routine neonatal circumcision.

Domestic Subcommittee Resolution #2:

WHEREAS the continuing high HIV infection rate in the United States leads to ongoing and growing economic costs, lost economic opportunities, and increased individual and family suffering, and

WHEREAS the director of the National Institute of Allergy and Infectious Diseases, Dr. Anthony Fauci, recently reported to members of the American Association for the Advancement of Science that the fight to lower HIV infection rates will take a long time and the all-out elimination of AIDS is not likely, and

WHEREAS Dr. Fauci told members of the American Association for the Advancement of Science that waning public interest in AIDS exacerbates the problem because "once you take it off the radar screen it's hard to get out the message of prevention," and

WHEREAS, due to advances in medical management, more Americans than ever, an estimated 1,039,000 to 1,185,000 persons in the United States, are living with HIV/AIDS, with 24-27 percent undiagnosed and unaware of their HIV infection , and

WHEREAS the CDC's new Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women, while an important change for health care providers, will result in substantial new numbers of infected persons attempting to access the overburdened public health treatment and care systems, and

WHEREAS the largest percentage of newly diagnosed persons are expected to be African American, poor, and uninsured, and

WHEREAS the CDC/HRSA Advisory Committee on HIV and STD Prevention and Treatment in a recent letter to Secretary Leavitt expressed significant concerns over existing HIV prevention, testing, and treatment resources, then

BE IT RESOLVED that the Presidential Advisory Council on HIV/AIDS calls on the Secretary of Health and Human Services to instruct the Centers for Disease Control and Prevention to develop projections for the number of newly identified HIV patients that will result from their revised testing recommendations, and

BE IT FURTHER RESOLVED that the Presidential Advisory Council on HIV/AIDS calls on the Secretary of Health and Human Services to work with the CDC to develop reasonable estimates on the costs of implementing the new testing initiatives, and

BE IT FURTHER RESOLVED that the Presidential Advisory Council on HIV/AIDS calls on the Secretary of Health and Human Services to work with the Health Resources and Services Administration (HRSA) and the Centers for Medicare & Medicaid Services (CMS) to develop reasonable estimates for the costs of treatment and care for those newly identified, and

BE IT FURTHER RESOLVED that the Presidential Advisory Council on HIV/AIDS calls on the President and Secretary of Health and Human Services to initiate the development of a multi-sectoral National Plan for HIV/AIDS Prevention, Awareness, Treatment, and Care that involves all relevant aspects of the Federal Government and the private sector.

Domestic Subcommittee Resolution #3:

WHEREAS the Office of National AIDS Policy (ONAP) was created to provide broad policy guidelines and leadership on the Federal Government's response to the national and global HIV/AIDS pandemic, and

WHEREAS the Office of National AIDS Policy focuses on coordinating our continuing domestic efforts to reduce the number of new infections in the United States, in particular in segments of the population that are experiencing new or renewed increases in the rate of infection, and

WHEREAS the Office of National AIDS Policy coordinates an increasingly integrated approach to the prevention, care, and treatment of HIV/AIDS, and

WHEREAS the Office of National AIDS Policy has been without a director for over a year, then

BE IT RESOLVED THAT the Presidential Advisory Council on HIV/AIDS calls on the President of the United States, the Secretary of Health and Human Services, and their designees to address this vacancy with all due haste.

A fourth motion was proposed by the International Subcommittee and passed unanimously by the full council following discussion.

International Subcommittee Resolution #4:

WHEREAS prevention of new HIV infection remains a critical component of global HIV care, treatment, and prevention efforts; and

WHEREAS evidence-based data should drive support for intervention efforts; and

WHEREAS male circumcision of men not infected with HIV has been associated with a significantly lower risk for HIV infection in international observational studies and in three recently completed randomized, controlled clinical trials; and

WHEREAS the impact of male circumcision of HIV-positive men on transmission of HIV infection to their sexual partners remains uncertain; and

WHEREAS circumcision, given appropriate training and appropriate medical equipment and facilities, is a safe procedure;

BE IT RESOLVED that the Presidential Advisory Council on HIV/AIDS recommends that circumcision of adult heterosexual HIV-negative men be supported in settings where the procedure can be performed safely and where the regional epidemiology supports favorable risks, costs, and overall benefits.

BE IT FURTHER RESOLVED that PACHA also recommends that the President's Emergency Plan for AIDS Relief (PEPFAR) and other U.S.-supported global HIV prevention programs include circumcision for HIV-negative heterosexual males as a component of a broader comprehensive HIV prevention program.

Dr. Redfield indicated that the Subcommittee had planned to submit a resolution regarding the importance of reauthorizing PEPFAR, but had decided to gather more information before crafting a resolution. Discussion will proceed via e-mail among members.

Adjourn

Dr. Maxwell thanked members for their participation and adjourned the meeting.