

Presidential Advisory Council on HIV/AIDS (PACHA) 42nd Meeting

U.S. Department of Health and Human Services (DHHS)
Hubert Humphrey Building
Washington, DC
May 26, 2011

Council Members Present

Helene D. Gayle, M.D., M.P.H., PACHA Chair
Antonio Cornelius Baker
Dawn Averitt Bridge
Douglas Brooks, M.S.W.
Humberto Cruz, M.S.
Ernest Darkoh-Ampem, M.D., M.P.H., M.B.A.
Kevin Robert Frost
Patricia Garcia, M.D., M.P.H.
Robert Greenwald, J.D.
Kathie M. Hiers
David R. Holtgrave, Ph.D.
Michael Horberg, M.D., M.A.S., FACP, AAHIVS
Ejay L. Jack, M.S.W.
Jack C. Jackson, Jr., J.D.
Naina Khanna
Anita McBride
Douglas A. Michels, M.B.A.
Sandra Torres Rivera
Phill Wilson, B.F.A.

Council Members Absent

Praveen Basaviah, B.A.
Rev. Dr. Calvin Otis Butts III, D. Min., M.Div.
Mario J. Perez
Rosie Perez
Malika Saada Saar, M.A., J.D.

Staff Present

Christopher Bates, M.P.A., Executive Director, PACHA, DHHS
Melvin Joppy, Committee Manager

Presenters

Mayra Alvarez, M.H.A., Director, Public Health Policy, Office of Health Care Reform, DHHS
Jeffrey Crowley, M.P.H., Director, Office of National HIV/AIDS Policy (ONAP), The White House
Andrew D. Forsyth, Ph.D., Office of HIV/AIDS Policy (OHAP), DHHS
Ann Gavaghan, M.P.H., Chief of Staff, Office of the Global AIDS Coordinator (OGAC), U.S.
Department of State
Ronald Valdiserri, M.D., M.P.H., Deputy Assistant Secretary for Health, Office of the Assistant
Secretary for Health, DHHS

MORNING SESSION

Welcome and Roll Call

PACHA Chair Helene D. Gayle welcomed everyone. It is good to be back together. This will be a 1-day meeting of the full Council. It is shorter than the usual 2-day meeting for a variety of reasons. If we are focused, we can make good use of the time and get to some of the core issues.

Dr. Gayle asked who could stay an hour or so later than scheduled today. It seemed many could. She asked if members had received messages about changes in flights. Some received them. Some did not.

Dr. Gayle announced that the meeting might go as late as 6:30 p.m., ending with an Executive Session not open to the public.

Mr. Bates conducted roll call. The result is shown in the members present and absent listed above. It was thought that some physically absent members would join by telephone. Telephone lines were left open for that purpose.

Opening Remarks by Jeff Crowley, M.P.H., Director, ONAP, The White House

Introducing Mr. Crowley, Dr. Gayle said many issues would be discussed today, some of which have come up in e-mails to her and others. These will be discussed over different parts of the agenda, primarily with the public in attendance.

Mr. Crowley thanked all for coming and all for the work they are doing. Like many, he is in a reflective mood given the 30th anniversary of the identification of AIDS and, subsequently, of the HIV virus.

Exciting things are happening with the National HIV/AIDS Strategy (NHAS). A few weeks ago, Mr. Crowley received a call from Dr. Carl Dieffenbach about a prevention breakthrough, and there is movement at the Federal, State, and community levels in improving HIV/AIDS care, treatment, and prevention, but we still need to assess gaps.

Important people have recently reiterated the interrelationship of testing, linkage to care, and adherence. In terms of new prevention strategies, one can frame adherence as a challenge, but one can also not be sure what to do about that. What should be standardized? What should we scale up? These are some of the questions he has been thinking about.

ONAP Annual Report to the President

ONAP is beginning to focus on its annual report to the President. Staff have met with the interagency working group to discuss operational plans in terms of implementation of the NHAS. ONAP welcomes PACHA member feedback, particularly as pertains to the private sector and the States.

Budget Preview

Meanwhile, Ronald Valdiserri will provide a budget update. There have been significant events since PACHA last met, including a Continuing Resolution to cover FY 2011. This is a major

challenge the President faces every day. HIV/AIDS is important to him, and in the budget fight, the Administration protected needle exchange and worked hard in different environments to increase money for the Ryan White CARE Act's AIDS Drug Assistance Program (ADAP), won healthy increases for some agencies, including the CDC, and also took significant funding hits. In the end, however, HIV/AIDS is a priority for The White House.

PACHA's Role

Mr. Crowley noted that the last PACHA meeting resulted in a good discussion of PACHA's role. This was helpful feedback. People have talked about the PACHA legacy, so he hopes this meeting will result in more clarity about that. He wants to help provide input, but it is not his job to tell PACHA what its priorities are. It is an important issue, particularly given the composition of this PACHA, for all can make unique contributions.

ONAP Team

Mr. Crowley then noted the members of his team, including those on detail from other agencies. Greg Millett is officially back at the Centers for Disease Control and Prevention (CDC), but Joan Romaine is now on staff, on detail from the National Institutes of Health (NIH) to provide research expertise.

Q&A/Discussion

Responding to David Holtgrave's questions about congressional calls for an annual report and an independent Chief Executive Officer (CEO) for the NHAS, Mr. Crowley noted that Congressman Lee had proposed passing legislation requiring an annual report to Congress and that he sees this as helpful. The President has directed Mr. Crowley to report annually, and that would be done in any case. His intention is to conduct it based on the calendar year. If Congressman Lee's bill moved forward, Mr. Crowley's team would want to look at the timing of the report. Second, the request for an NHAS CEO was a request of the Government Accountability Office (GAO) for analysis, and he sees this as additive, with no downsides.

Jack Jackson asked what the States are doing to assist NHAS implementation, adding that he has been working with Mr. Bates on that to ensure that Arizona is on board and moving forward. He also would like to talk more about that with Mr. Crowley.

Responding, Mr. Crowley said States are being encouraged to develop their own implementation plans. A great deal of consultative feedback has come across the transom on that. States have experienced funding cutbacks and have made it clear that this is a particularly difficult time for new, onerous requirements. States and localities need to move forward, but there may be different ways to do that, depending on the State and the locality. Dr. Valdiserri might say more. Recent consultations have been very helpful.

Presentation by Ronald Valdiserri, M.D., M.P.H., Deputy Assistant Secretary for Health, Office of the Assistant Secretary for Health, DHHS

Dr. Valdiserri said this will be a brief update on a number of activities relative to the NHAS and to the FY 2011 HIV budget.

NHAS

In mid-April, Dr. Valdiserri's Office hosted a consultation with a number of partners, including representatives of PACHA, to discuss the issue of State implementation plans. Since then, there have been followup conversations with ONAP and all of the National Alliance of State

and Territorial AIDS Directors (NASTAD). There is no resolution in terms of direction yet, and important issues are at play, as Mr. Crowley mentioned.

One clear message is that State Governments don't want another planning process mandated by the Federal Government. We need to think very carefully what we ask for and what we have to extend and promote the goals of the Strategy. Just yesterday, Dr. Valdiserri had a very detailed discussion with the Executive Director of NASTAD and colleagues about how to move forward. What he can say is that, philosophically, it is very important that the CDC in its impending guidelines to health departments at the end of June for HIV/AIDS prevention activities and that the Health Resources and Services Administration (HRSA) in its statewide statement-of-need requirements, which have already been released, will reflect what is important so that something else has to be placed on top of that. Dr. Valdiserri promised that PACHA will hear more about that, more specifically, at its next meeting.

In addition, NASTAD and policy people have raised questions about DHHS authority to request State plans. No one disagrees that having a jurisdiction-wide vision is important; rather, the question is how we operate within that realistically at a time of resource constraint.

Prevention for African American Populations

On a more strategic note, DHHS is working very hard to develop and conduct an inventory of prevention activities for African American populations as requested in the Strategy. Andrew D. Forsyth has been working on this, and members will hear more from him later this morning. There is a cross-departmental/cross-agency entity to develop a strategy and specific tools for conducting this inventory. What the Strategy asked us to do is take a look across DHHS, particularly CDC programs and programs funded out of the Secretary's Minority AIDS Initiative (MAI) fund as well as other activities funded out of the base funding for the MAI, to assess the effect of such prevention activities. While DHHS lacks the resources to do that, it has begun a detailed inventory on who is doing what, with a deadline for results by the end of the calendar year.

Prevention

Dr. Valdiserri noted that Mr. Crowley mentioned the recently announced results of the HPTN (HIV Prevention Trial Network) 052 study that explored the preventive effect of engaging heterosexual couples in antiretroviral therapy (ART) when one partner is infected and the other not. The trial was able to demonstrate substantial reduction in transmission, which is good news, but it is pushing us to look again at the availability of ART and also ties in with the results announced last November from a pre-exposure prophylaxis (PrEP) study among high-risk homosexual men in the United States, South America, and Asia that showed substantial reduction in HIV infection given drug adherence. An inter-Departmental group is talking about PrEP and possible followup demonstration projects. The group is also looking at the results of the HPTN 052 trial. Both findings are quite important. Dr. Valdiserri would like to emphasize that once further study is completed, staff will be looking at what needs to be done at policy and program levels to take advantage of this.

Metrics

Dr. Valdiserri said members will be hearing more from Andrew D. Forsyth about work being coordinated by OHAP across the Departments to move forward on harmonizing and streamlining reporting requirements for grantees. Up front, this requires a lot of internal work. If his colleagues from public health departments were here, they would say we have not yet taken steps to reduce their reporting burden. We are receiving a great deal of feedback from departments interested in that.

Coordination

One of the responsibilities of the Office of the Assistant Secretary for Health that has been delegated to Dr. Valdiserri's Office is to coordinate efforts within DHHS and other Federal agencies. Every 6-8 weeks, the Federal leads meet. Last time, they reviewed housing stability and homelessness and the importance of this for people living with HIV/AIDS (PLWHA). As a result, although Howard Koh has not yet signed off on this, there will be a formal communication from Dr. Koh to the chair of the cross-Governmental working group requesting a special effort to look at the whole issue of homelessness. The chair of that group will be or has been reminded of the important needs of PLWHA. Right now, staff are trying to look at the HOPWA (Housing Opportunities for Persons with AIDS) definitions and use those as a standard. This will be pursued further in the next meeting in early July.

12 Cities Project

A handout entitled "12 Cities Project" was provided to PACHA members.

Dr. Valdiserri noted that while this project is not the only DHHS activity in implementing the Strategy, it is an important one. The goal is to see if we can support at the Federal level better integration of programs and bring them to scale at the local level. A number of process steps have already been taken. At the end of April, a DHHS plus Housing and Urban Development (HUD) steering committee, which Dr. Valdiserri chairs, met to review the Enhanced Comprehensive HIV Prevention Plans (ECHPP) from the CDC that are providing resources to these 12 cities to enhance their planning process on what prevention activities to scale up and scale down. DHHS is attempting to build on that at a broader cross-Departmental perspective, one that reaches across many entities, including the NIH and Indian Health Service (IHS). DHHS is also asking health departments to provide direct feedback about local issues and local barriers.

The NHAS says: reduce incidence. When diagnosis is linked to good care provided in a continuous and timely manner, that moves us from the CDC to HRSA programs. And for many living with HIV/AIDS, mental health and substance abuse lead us to the Substance Abuse and Mental Health Services Administration (SAMHSA).

Like so many efforts underway on the Strategy, we can't declare success yet. In fact, Dr. Valdiserri said, we are not even at the middle. But we are making some really good progress in understanding what the needs are so that we can then step back and figure out at the Federal levels what levers we need to pull to address that.

Of the 12 cities, feedback has been received from Miami, Baltimore, and Chicago. Feedback from the other 9 cities (New York, Los Angeles, Washington, D.C., Atlanta, Philadelphia, Houston, San Francisco, Dallas, and San Juan, Puerto Rico) will be obtained over the course of another three to four meetings.

Viral Hepatitis Plan

On May 12, DHHS released the viral hepatitis plan, which will be implemented by Dr. Valdiserri's Office, which has or will have sources for coordinating implementation across DHHS. The plan primarily addresses hepatitis B and C, but the fact that a substantial number of people with HIV/AIDS are coinfecting makes it a particularly important issue for his Office and for PACHA. His Office is beholden to the CDC for agreeing to provide a master's level epidemiologist for this task, beginning next week. Dr. Valdiserri also is grateful that the NIH has agreed to extend Dr. Forsyth's detail another 2 months. Dr. Valdiserri said he wanted to make the point that when he approached the NIH and CDC for help, they have been extremely collegial and willing to help.

The Budget

Dr. Valdiserri said he cannot at present provide a lot of details on how the FY 2011 funds allocated to HIV activities will be spent. There is some confusion about what is actually happening to the HIV/AIDS budget in DHHS. Dr. Valdiserri wants members to know that he was not able to get that information for this meeting but possibly the next. The CDC, despite other cuts sustained, received a \$30 million increase for its HIV/AIDS activities and is still in the process of determining how those funds will be used. The CDC has said it will go to support the goals of the Strategy. NIH staff estimate that the NIH will devote about \$3.06 billion in FY 2011 to research on HIV/AIDS. This is all the information he has at this time. He will try to determine whether the NIH amount is greater or lesser than that in FY 2010.

Meanwhile, the NIH is continuing to support research on treatment as prevention. This will continue to be an important issue. It will raise issues of adherence.

For FY 2011, HRSA received \$40 million for HIV/AIDS activities under the Ryan White CARE Act (RWCA), some for ADAP. Mr. Crowley added that all the agencies took a 3 percent reduction across the board, but HRSA found a way to protect the RWCA and, to a certain extent, ADAP.

Continuing, Dr. Valdiserri said SAMHSA received \$78 million, about the same as for FY 2010. The Secretary's MAI fund is essentially the same as for FY 2010, minus the 3 percent Mr. Crowley mentioned. Here, Dr. Valdiserri noted that significant changes have been made in the way MAI funds are used based on input from a number of Federal staff and non-Governmental consultants so that the MAI can better address the needs of racial and ethnic minorities.

Beginning his conclusion, Dr. Valdiserri noted that some budget details are not yet available. Dr. Gayle asked if anyone from the agencies currently in the audience had anything to add. They did not.

Dr. Valdiserri noted that in the FY 2011 report language, there is reference, in FY 2012, to tapping HIV/AIDS program activities to support implementation in DHHS of the Strategy. DHHS has a related consultation in June to which three PACHA members have been invited.

Q&A/Discussion

Humberto Cruz said he has two recommendations: The first is to pursue treatment as prevention and the results of the HPTN study, because if we initiate treatment on demand, the potential of reducing additional infections is 96 percent. He thinks, however, that an analysis is needed of the increased costs for Medicaid and ADAP, as such a change in course "would bankrupt ADAP." In the short term, costs would increase, but the long-term results could be amazing.

This is an issue involving both care and prevention, and PACHA should make a statement about it. It is the best news we have heard, and it is under our control, Mr. Cruz said.

The second recommendation relates to the NHAS and the need to reduce the burden on the States in reporting requirements and mandates. However, new requirements he has received from HRSA would create 238 pages worth of burden. We need to step in and do an assessment on how this affects the Strategy. Because what is happening in the short term is that the number of report requirements is increasing, not decreasing. This needs to be done quickly. A baseline already exists for such an assessment.

Responding to Douglas Brooks' query about an evaluation component of the 12 Cities Project, Dr. Valdiserri said his Office competed for and received internal DHHS funds for evaluation, and a contract is out to help identify primary process measures. Dr. Forsyth will address some of this, including DHHS working logic models, to show how Dr. Valdiserri's Office is thinking about the different evaluation steps.

Responding to Dr. Holtgrave's query about the additional \$30 million for the CDC for HIV/AIDS, Mr. Crowley explained that The White House allocated monies for the prevention fund for FY 2010 and initially proposed that for FY 2011 but then dropped it and proposed it again for FY 2012. In short, there is no additional funding through the prevention fund for FY 2011. Dr. Valdiserri said he wrote a blog about this subject several weeks ago. Going through channels, about \$3 million of the Secretary's MAI fund has been allocated to the CDC to help it bridge the gap from FY 2011 to FY 2012 for the 12 Cities Project. Also, we carved out of \$12.5 million directed to HRSA, SAMHSA, and the CDC specifically for activities to serve racial and ethnic minority communities in the 12 cities.

Dr. Holtgrave said the Incidence Subcommittee, which he co-chairs, also is interested in community engagement around ECHPP and the availability of the plans. Dr. Valdiserri said he had a serious discussion with the CDC since it owns the ECHPP plans. This was at the end of April, so he now needs to follow up with Kevin Fenton on that. Dr. Valdiserri has heard a variety of comments around community engagement and feelings of inadequate input. A big question mark exists around State plans as well, in terms of level of community engagement. This is an important issue that has yet to be resolved.

Someone from the CDC on the telephone responded that the CDC wants to be able to share the plan but there are two reasons why it has not: first, it is only this week that the agency has had a full set of 12 plans, and, second, some of these plans have longer range goals for partners that have not yet been communicated with those partners. In addition, the CDC is talking about how to share plans with the community more widely. At present, the agency is following jurisdictional leads for the local conversation. This person invited members to watch the CDC Web site for updates.

Mr. Crowley added that his Office has been engaging private sector partners planning to support implementation, including community engagement in the 12 cities.

Antonio Cornelius Baker said that in addition to the 12 cities plans, it would be well to get a resource allocation grid of how resources are being moved to those cities and away from other areas so that PACHA can understand pressures that may be created elsewhere. Supporting scale-up in the 12 cities will help with understanding true costs in the future so that needed resource levels can be advocated.

Going back to Mr. Cruz's statement, Mr. Baker added that the "other" PrEP trial being referred to (not 052) had an average 44 percent success rate across the board but had a 91 percent success rate in the United States, with less than perfect adherence. If we look at future years and how many infections would be averted, we have to consider that. In conclusion, he hopes that the Incidence Subcommittee will begin to look at modeling on this so it can make the case on how both prevention tools might be needed.

Moving on to the African American inventory, Mr. Baker asked if Dr. Forsyth will continue to lead this effort. Dr. Valdiserri responded that the task will be taken up by someone else when Dr. Forsyth returns to the NIH, the assessment process will not be suspended, and a summary report will be written.

Dr. Gayle commented that as PACHA begins to talk about new tools and technology, she does not want to talk about either/or. PACHA's approach could be to discuss rational use of a broader prevention portfolio than we have ever had, and also about how we build this out to a more comprehensive strategy. Responding, Mr. Baker said he totally agrees, adding that it is still the case that there was a different effect in the United States in terms of the PrEP study. Dr. Gayle agreed, adding that this only emphasizes we do have a heterogeneous epidemic in the United States and that some strategies may have a greater impact on some populations than others.

Phill Wilson said that scientists have clearly done a remarkable job over the past 2 years. The question for us is what we are going to do about that. We have an obligation to make recommendations to the President on how we are going to use those tools. We now have the tools to end the epidemic. We do not have a resolution at the moment, but let us move expeditiously with some recommendation on how we should be using these tools. We need to do that before the next meeting.

Picking up on an earlier discussion, Mr. Crowley said the Administration has not yet gone to the community to talk about scale-up. He has been asking what the agencies are planning. It might be beneficial to hear what the agencies are planning, and that might help PACHA as it drafts a resolution.

Kathie Hiers said she is thrilled by the results of all this new research, but some 8,300 PLWHA are on ADAP waiting lists, and the vast majority of them are in the South. Therefore, attention needs to be paid to the South because the disproportionateness of the ADAP waiting lists is shameful.

Responding, Mr. Wilson said he thinks this may be one of those cases where the science is a mechanism to save ADAP, because the program is not sustainable at present. "We are not getting people on treatment early enough to prevent the infections that are happening."

Mr. Cruz said there are tools. There are economic realities. There is this Nation's tendency to look at matters 1 year at a time. We need to analyze the costs attendant to using these tools and the savings generated. These are important mechanisms for advocacy and education over the longer term. In the end, he agrees that this body should come up with a powerful recommendation.

Dr. Gayle said all this can be discussed more this afternoon.

Presentation on HIV Prevention Metrics Involving Members/Representatives of the PACHA Metrics Working Group, the 12 Cities Steering Committee, and the Metrics Working Group

Incidence Subcommittee Co-Chair Dr. Holtgrave began by noting that PACHA has four Subcommittees that have decided to contribute to a cross-Subcommittee working group on metrics (the PACHA Metrics Working Group). So far, the working group has at least one member from each Subcommittee.

The working group asked Dr. Holtgrave to facilitate for the time being.

In the recent past, the group had two phone calls around metrics—one with the CDC to talk about prevention indicators and another with Mr. Bates.

This presentation is about HIV/AIDS metrics overall, not just prevention, and also specifically about how well we are doing in achieving the NHAS.

In the Government there is a 12 Cities Steering Committee and a Metrics Working Group. There is a cross-working group, and Drs. Forsyth and Valdiserri are on it. During the first call, with the CDC, members of the PACHA Working Group thought the CDC was being very thoughtful in its responses. So now, Dr. Forsyth and his colleagues will do a presentation, and Dr. Holtgrave will ask PACHA Working Group members to comment. Then there will be general discussion.

Development of 12 Cities Metrics

Dr. Forsyth provided a brief update on activities in Dr. Valdiserri's Office to develop 12 Cities metrics to gauge the impact of the strategies related to the Strategy. This has been endorsed by the Secretary to reduce inefficiencies and reduce costs. In addition, common metrics across activities will help in the identification of gaps and measurement of impacts.

Already, extensive efforts are underway to develop a list of common metrics and indicators focused on, ultimately, indicators that can be used across the agencies. These fall into roughly three categories: screening and diagnosis measures, process or management measures, and outcome measures (with credit in part to "Considerations of Issues Related to National and Multiagency HIV Care Quality Measures," by Michael Horberg, PACHA member and Director, HIV/AIDS Kaiser Permanente, Executive Director of Research, Mid-Atlantic Permanente Medical Group, Clinical Lead, HIV/AIDS, Care Management Institute, and Vice-Chair, HIV Medicine Association). Also needed is a larger picture of 12 Cities performance measures.

The Government's two main working groups on this are the 12 Cities Steering Committee and the Metrics Working Group. Recently, there was a call with CDC colleagues working with grantees at each of the 12 Cities sites to develop process measures. A second group, coordinated out of Dr. Valdiserri's Office, is a metrics subgroup for the 12 Cities Project with broad representation and the task to develop qualitative and quantitative measures to assess impact.

Progress to Date

Since January, there have been monthly and even more frequent calls involving both of the Government's main working groups. Last night, Dr. Forsyth received a copy of process measures and logic models that the CDC has been developing for the 12 Cities Project. This is a pretty solid preliminary list of process indicators that will help provide evidence for the activities the CDC will be facilitating. The other working group on metrics now has a list of available measures/indicators across the agencies to use for assessing comparability, gaps, and the ability to measure in the future.

In addition, OHAP has developed a matrix of indicators process variables and many outcome variables of the 12 Cities Project, so this is one place where we can see how well we currently shape up in the three main indicators areas and across targets. Dr. Forsyth said he wants to highlight the fact that OHAP has initiated detailed discussions with HUD, CDC, and other entities to find a way to use existing data sets to provide more information on what is happening in the 12 Cities. HRSA has good data in terms of RWCA programs, but there is a need to understand what is happening beyond that.

In his handout, Dr. Forsyth included a slide entitled "Development of Core DHHS 12 Cities Performance Measures" to provide a sense of the process for developing core indicators for the 12 Cities Project. This has been informed by PACHA member Dr. Horberg's work as well as work by UNAIDS.

An Institute of Medicine (IOM) working group is already at work identifying the data needed for treatment performance measures. Once these and other core indicators have been generated, they will be submitted to DHHS for approval and endorsements, then the hope is that they can be streamlined and used in a consistent manner.

Dr. Forsyth noted his handout includes two logic models, one that provides a snapshot of inputs, processes, outputs, impacts, and vision for the NHAS, and another, more complicated Appendix A that will also guide DHHS efforts.

Next Steps

Next steps include analyzing variables, gaps, and data needs. Related to this are the issues of Federal reporting requirements and the number of variables involved. There are some 1,200 overlapping, redundant variables grantees have to report, so the hope is that the process that is evolving will help guide thinning these out and streamlining them. Dr. Forsyth said there is some room to consider ways "to tweak" the 12 Cities Working Group so that DHHS takes a more active role in it and expedites movement toward a common set of metrics. The ultimate hope is that much of this work will end up informing recommendations in the States' plans and that "we arrive at a set of indicators that addresses each layer of the onion and doesn't increase burden."

Q&A/Discussion

Dr. Holtgrave said the detailed logic model Dr. Forsyth provided is particularly useful.

Noting that she and Mr. Wilson chair the Disparities Subcommittee, Ms. Hiers said that section of the Strategy is fairly limited in terms of outcomes, so she wonders why there seems to be no analysis or recommendation to look at gender and even geographical disparities. Other issues include the baselines used for funding and for assessment. Most HIV/AIDS funding is still based on the number of AIDS cases, not those living with HIV. Because "that is crazy," Ms. Hiers said she wants to know when we are going to change this to represent the actual disease burden.

Patricia Garcia said she would like to add "age" to Ms. Hiers' list, as there are nuances in terms of the disease burden there that need to be understood and tracked.

Back to the Presentation

Returning to the presentation, Dr. Horberg noted that his slides, which he has provided to the IOM, have also been provided to PACHA members, so he will not go over them in detail today. One of his bottom lines, however, is the critical importance of the concept of harmonization. Even between the Department of Veterans Affairs and his system at Kaiser Permanente, the numerators and denominators used are different, and this kind of problem is quite pervasive.

This leads to Dr. Horberg's next point, which is, as we develop all these Federal and even State measures, we have to make sure the private sector is called in on this and that the metrics are the same, "not just thematically but the nitty gritty."

Last, everyone wants to measure what is of interest to them, but the issue is what is actually actionable. Gaps are gaps "where there is opportunity for improvement." Gaps are also

“about not being able to demonstrate success.” Community viral load, Dr. Horberg said, “could be a measure of success.” In addition, he knows that the CDC is concerned about the maturity of its metrics, “but we might have to compromise for the purposes of getting a more readily available and broader picture.”

Concluding the presentation, Dr. Holtgrave said that what he took away from the call with the CDC was the sense that the agency is making a concerted effort to provide incidence updates on a more annual basis and as close to real time as possible. He also thinks that the CDC is trying to come up with an annual progress report that tells a story about the epidemic and how it is going related to the Strategy.

Q&A/Discussion

Naina Khanna noted that consulting key stakeholders is explicitly part of the DHHS NHAS logic model process, so she wonders how that will inform metrics development and evaluation. She also advocated a gender analysis and a consultation on women.

Responding, Dr. Valdiserri said at present there are no specific plans for a consultation on women and/or gender, but such will be taken under serious consideration. He added that his Office’s ability to do this depends on personnel and financial resources.

Anita McBride noted that the DHHS operational plan document does refer to the Office on Women’s Health and a conference. A spokeswoman from the Office on Women’s Health, present at the PACHA meeting, was uncertain whether this conference had taken place. Dr. Valdiserri said that it may have.

Ms. Khanna said she is not asking for a conference; she is advocating a consultation. Linking to this, Dr. Garcia said that while she is thrilled with the news about treatment as prevention, she is not seeing the same enthusiasm for “fem” preexposure prophylaxis (PrEP). PACHA needs to look at what these advancements mean for women and youth and why we not seeing the same advancement there in prevention science.

Responding, Dr. Forsyth said progress on the microbicides front is likely to benefit women in part as part of the combination package of prevention tools and strategies going forward now. However, he said Dr. Garcia’s comment is well taken.

Robert Greenwald asked about the role the Centers for Medicare & Medicaid Services (CMS) and HRSA’s HIV/AIDS Bureau (HAB) will play in the 12 Cities campaign.

Responding, Dr. Valdiserri said HAB and HRSA’s Bureau of Primary Healthcare have been consistent partners on this and participate in the 12 Cities Steering Committee. As previously mentioned, his Office was able to ask DHHS and HUD to provide data on the 12 jurisdictions that were then funneled to the CDC, and “we have since heard back about the variability and inconsistency of that data, so we have plans to try to get better information.” Dr. Valdiserri added that “it is very difficult to find out in one place about all the Federal HIV programs,” but both HRSA’s HIV/AIDS and primary health care bureaus have had primary officer training around this.

In terms of CMS, “it has been a partner, but there are bigger issues there in terms of what PACHA and some of the States have asked for.” Additional technical assistance (TA) is needed “so that folks on the AIDS program side can work with the State Medicaid directors and, hopefully, get more PLWHA covered.” If PACHA is requesting specific CMS and HRSA HIV/AIDS and primary health care bureau information, “we can provide it.”

Responding, Mr. Greenwald said his concerns are around falling short of care goals before 2014 unless systematic thought is given to the assistance that will be needed before then, in terms of both TA and additional resources. After 2014, much will depend on successful implementation of health care reform. While he is quite happy to talk about prevention, “access to care seems to be constantly missing from the conversation.”

Dr. Valdiserri said that NASTAD looked at the role of community health centers in implementing the Strategy and the soon-to-be-released viral hepatitis action plan, and the good news is “there are some good models out there.”

Responding, Mr. Greenwald advocated identification of new investments in health care reform that can be targeted and coordinated with the 12 Cities campaign.

Mr. Baker said we lack good real-time incidence data and a good process for releasing them to the point where the Government may need to rethink using peer review of the data. At present, without timely data, “we’re making decisions in a vacuum and, at a certain point, participating in genocide.” Men who have sex with men (MSM) and young men is where the epidemic is in the United States, “but we’re not seeing a resource shift.” In addition, “those becoming infected aren’t necessarily in those 12 cities.” We “need some population-centric measures, including gender, that can help us in addition to the 12 cities, which reflect historic data, not current incidence.”

Responding, Dr. Valdiserri said that in terms of the 12 Cities Project, one objective—and it has not yet been achieved—is to get a better, more well-informed sense of what kind of measures the CDC, HRSA, and SAMHSA require of their grantees. After that assessment is completed, there will be an assessment of harmonization. At the same time, “there is an expectation that the Strategy can be achieved with the resources we have.” If all this can be figured out in the 12 jurisdictions, that can be pushed out to the rest of the Nation. Meanwhile, that does not look at what resources are being allocated and to what populations; rather, it emphasizes streamlining and harmonizing metrics in the 12 cities.

Mr. Wilson said he agrees with Ms. Khanna, Dr. Garcia, and Ms. Hiers around gender and youth. It also needs to be stated that the latest treatment as prevention clinical trial involved heterosexual couples, so clearly women were involved. In addition, we are making tremendous scientific advancements in prevention for women, such as with microbicides.

Douglas Michels commended Dr. Valdiserri and his team for pulling their presentations together for PACHA at this point in the process. A challenge now is making crystal clear statements about what one is trying to achieve in the short term. “We must challenge ourselves and the agencies to be precise about this.”

Responding, Dr. Forsyth said he very much appreciates that statement. He noted that last night he received not only revised logic models for ECHHP but also tables that provide the kind of specificity Mr. Michels is advocating. Dr. Valdiserri added that this was for one agency (the CDC).

Addressing the peer review process, Dr. Gayle said it looks at data and tries to make them better. She has seen it bring clarity to a situation and move things in another direction. However, PACHA may want to discuss later the value of release of previews of such information as incidence data prior to completion of the peer review process.

Mr. Cruz said the 12 Cities effort has to fully integrate State participation. At present, the project is “divorced from the State process.” States are invited to participate, but in truth,

they do not have a critical role in the process. This problem must be addressed. New York State, even absent New York City, would still have the seventh highest number of HIV/AIDS cases in the country.

Dr. Holtgrave asked Dr. Valdiserri about metrics timelines, as in what is planned for the next 6 months to a year and how that ties into ONAP's end-of-the-year report. Also, is the Departmental working group thinking of the baseline as 2009 or 2010?

Responding, Dr. Valdiserri said the issue of the baseline depends on what we are measuring. In terms of metrics, among key Departmental goals should be identification of an appropriate, reduced set of metrics for prevention, care, and treatment. Community viral load "is great, but a big issue raised by Mr. Baker is how resources allocations will change in relationship to the Strategy, so we would probably look at FY 2010/2011 as base."

Dr. Valdiserri's Office has done some analysis on the budget information in the operational plan, trying to get a sense of how allocation of resources relates to the epidemic, and it has underscored the tremendous interest among health departments and other stakeholders in what the new CDC cooperative agreement on prevention is going to look like. Changes in RWCA would require legislation, so the cooperative agreements will be a key piece. The CDC has looked hard at the Strategy and its goals and is trying to use that to inform these agreements. They are not yet available.

Dr. Holtgrave asked members to wrap up discussion by stating their preferences for how the PACHA Metrics Working Group should work going forward. Should it invite additional comments over the next week and then have another call? As a body, "we should maximize our input each step of the way," he added.

Responding, Mr. Baker suggested that the group meet to come up with core indicators rather than 50 pages of report and then "we have a meeting on an annual basis to address where we are based on the data."

Mr. Greenwald recommended that a senior-level person from CMS be invited to talk to PACHA members about health care reform implementation and innovations that can be integrated into the process that will influence some of the outputs and outcomes. Responding, Dr. Valdiserri said that a CMS contact has been consistently invited to participate in the metrics effort but has not. Responding, Mr. Greenwald said "we need to fix that problem."

Ernest Darkoh-Ampem said he had not yet heard an answer to Mr. Cruz's comment about the States. The top of the agenda, Dr. Darkoh-Ampem added, should be how to operationalize these targets at the State level if there is currently no process for doing so.

Responding, Dr. Valdiserri said, for the record, that "there is diversity here, and part of it is in the 12 jurisdictions. Some of the funded entities are the State health departments, and some are the local health departments." His impression is that in the case of Baltimore, the State controls the resources, "but this has not been the case everywhere, which is part of the complexity in trying to achieve the same goals."

In further discussion on this topic, Mr. Cruz said States are given responsibility for public health under our Constitution, and it is the States who have a coordinated role to address HIV/AIDS and other communicable disease. "So to say that some cities but not others are integrated with the State is not correct."

Observing that the issue of resources allocation nationally and in the 12 cities as a baseline is critical, Ms. Khanna asked if that will be part of the ONAP report. Dr. Valdiserri said he could not answer for ONAP. Speaking from the audience, Mr. Millet said the report will address some of the same things Drs. Valdiserri and Forsyth were talking about, such as metrics and metrics for community-based and faith-based organizations, as well as for businesses and others. It will also look at metrics for State organizations, which will move forward as soon as ONAP learns more from the CDC about its cooperative agreements. In addition, ONAP is working with the Office of Management and Budget (OMB), but it has not yet been decided whether ONAP and OMB will talk about resources. "It will depend on modeling," Mr. Millet added, "but even if you do it, a lot will depend on whether things turn out the way you had planned." You "can put that in a report, but whether it will be approved by Congress or be part of the budget is something entirely different."

Responding to a query from Mr. Jackson, Dr. Valdiserri confirmed that the IHS is part of the Metrics Working Group and that he looked forward to talking more with Mr. Jackson about this. He added that IHS does not have clinical resources in all of the 12 jurisdictions, but it is actively involved in all aspects of the interagency effort.

Reflecting that this discussion most likely expanded the thinking of everyone involved, Dr. Horberg suggested that it be synthesized and that the PACHA Metrics Working Group come up with an operational plan. Ms. Hiers added that we need a clear picture of where the Federal resources are by State and major jurisdictions.

Dr. Gayle thanked all for a good and rich discussion. In preparation for later discussion of concrete next steps, she suggested that PACHA's Metrics Working Group members huddle and consider what those might be.

AFTERNOON SESSION

Presentation on Affordable Care Act Implementation by Mayra Alvarez, M.H.A., Director, Public Health Policy, Office of Health Care Reform, DHHS

Ms. Alvarez said that in the past year, the Administration has made progress in making health care in the United States more affordable, fair, culturally competent, patient-centered, and family-centered. In the past year, “we have laid the foundation for the new health care system for the future, but this won’t happen overnight.”

In the past year, 4 million small businesses have begun to have access to a tax credit to offer their employees greater access to affordable health care, just as large businesses do. In terms of Medicare, \$150 rebate checks have been sent to seniors to help close their drug doughnut holes. In addition, Medicare patients with HIV/AIDS were allowed to add ADAP costs to their out-of-pocket costs. Also, HRSA sent a letter to RWCA providers to make those services available to more people. Persons locked out of the insurance market have access to plans operated by the States or the Federal Government until 2014, when health care insurers will not be allowed to discriminate based on preexisting conditions.

In addition, early retirees are being offered affordable coverage under rules designed to ensure a fairer system and that 80–85 percent of our dollars go to pay for services, not overhead. Resources for premium rate reviews have been released to the States so that “if you have a rate increase of more than 10 percent, this must be justified under new rules.”

Today, consumers have a better understanding of what health insurance is and what they should have available to them in the future.

Under the Affordable Care Act, another key change is in lifetime limits. Those with long-term health care needs, such as PLWHA, have found they can run into lifetime limits quickly, but such limits are no longer allowed. Preventive services have been brought to the fore as well as elimination of copays for these services.

These reforms and bridges are the beginning of implementation. Beginning in 2014, there will be State-based insurance exchanges, undergirded by the concept that “our health insurance will be there despite changes in our personal lives.”

Ms. Alvarez said that, like some other people, her family does not understand the concept of an exchange. So she provides the example of buying plane tickets competitively online. There are usually many options. As an informed consumer, one makes informed decisions about that. Unfortunately, with health insurance today, it is not easy to know the details. So the concept is to work with the States to make sure the exchange options are transparent.

In addition, the Affordable Care Act invests millions in prevention and public health, including support of community-based interventions. In FY 2010, \$500 million went to a fund for that. In FY 2011, distribution will be \$750 million. Goals include provision of primary health care in integrated settings, increased capacity, and support of racial and ethnic approaches to community health. “We are shifting the conversation not only over to what we can do to help Americans understand what happens in a doctor’s office but what we can do outside the doctor’s office.”

Another aspect of the Act that Ms. Alvarez appreciates is that it “puts money into the issues and into leadership.” Under the National Prevention Council, 17 different Departments, Agencies, and Offices “are having real conversations about prevention.” This includes the U.S. Department of Agriculture (USDA), the U.S. Environmental Protection Agency (EPA), and the U.S. Department of Interior. The goal is to emphasize prevention and wellness, not just sickness and disease. In addition, there is an advisory group around prevention that brings representatives from the States, communities, and businesses together to further consider how to prioritize prevention. “The best resource for implementation is ourselves and our communities,” Ms. Alvarez said, and yet 25 percent of the American people think that the Affordable Care Act has been repealed.

Concluding, Ms. Alvarez asked to partner more closely with PACHA so that members can help get accurate information out about health care reform, in part because the current information gap “is very challenging.”

Q&A/Discussion

Dr. Horberg asked two questions. First, does the National Prevention Strategy discuss knowing your status and call out specific subgroups? Second, an informed public is good and necessary, in part because many treatments are lifestyle changes, whereas the recent 052 trial results point to drug regimens that cost \$15,000--\$20,000 per year. How then can one make sure these different diseases/treatments will be covered under a law as large as the Affordable Care Act?

Ms. Alvarez said a key is the link between clinical and community prevention and identifying where people are coming from so that they can feel comfortable engaging in the health care system once again. Part of the challenge is bridging that gap. Often the answer will lie outside the health care setting. Also, under development is a DHHS look at the recently released and relevant U.S. Department of Labor (DOL) survey. DHHS has also asked IOM to give it recommendations. All this deals with an essential benefits package.

Mr. Greenwald commented that the essential benefits package is the baseline for Medicaid expansion, so it is probable that no other provision is as important to ensure that we are geared up not just for exchanges, which will primarily be for healthy people, but also for people with HIV/AIDS and other chronic conditions. This is number one on the table right now.

Ms. Khanna welcomed the emphasis on prevention. She noted that a great deal of new data are leading us to getting people into care early, into treatment early, and keeping them in care and treatment as a cost-effective and good strategy. She noted that PACHA passed a resolution about the need for the U.S. Preventive Services Task Force (USPSTF) to change its HIV testing recommendation from one that results in reimbursement only when an individual is considered high risk. This is problematic, particularly for women who often do not present with high individual risk behavior. It is important for the task force to act on PACHA's request for reconsideration and that it be worked into the women's health package as well.

Mr. Baker said the partnership idea is important. What he hears from community-based organizations is that once something goes into effect, there will no longer be a need for them, so it is not clear how they fit into the future of health care. We know that just having a doctor and even having insurance is not sufficient. We have been trying to educate them about how their work will not go away but, rather, just be different. As pertains to the essential benefits package and minority populations, we have very little health data about gay men, and our data collection systems do not collect data by sex orientation, so we are establishing guidelines and benefits without understanding needs.

Ms. Alvarez said she appreciates the education Mr. Baker and his colleagues have embarked on. Yes, she added, things will change. The safety net programs will change, including RWCA programs. The model of RWCA providers "is one we want to replicate with anyone living with chronic disease. Medicare and Medicaid can definitely learn from Ryan White. We will still need a safety net. We know this law does not cover everyone. Until then, the net will be as essential as ever. "

In terms of data collection, Ms. Alvarez said one section of the Affordable Care Act looks at this very specifically, and her Office is looking at how to implement that section. The information that is collected cannot always be compared, however, so it will be useful when we have comparative analysis, "which is long overdue for lesbian, gay, bisexual, and transgender (LGBT) populations."

Mr. Cruz said he is concerned about the overall perception, by the legislature, by people at large, and by State officials that Ryan White is no longer needed. That is an issue of education and of serious consequences to the Nation because there is a gap between Ryan White and full implementation of health care reform; that is, Ryan White will come up for reauthorization in 2013. We cannot expect to use the experience of health care reform for Ryan White at a time when the reform has not been fully implemented. The other issue is lack of understanding about what Ryan White pays for versus health care. It is not clear in many people's minds. Ryan White is a wraparound system that provides resources to facilitate engaging in care. Health care reform does not cover that.

Mr. Cruz then advocated that PACHA engage in a process regarding this, beginning with an analysis and then a recommendation on the relationship between health care reform and Ryan White reauthorization. He predicted that such a report and more will very much be needed to educate relevant parties about the need to continue Ryan White.

Mr. Jackson noted that he is from Arizona, one of the States suing the Federal Government over the Affordable Care Act. Responding, Ms. Alvarez said the Federal Government is implementing health care reform. The States have autonomy to create their own exchanges. But the Secretary will also establish a Federal exchange.

Mr. Greenwald commented there is no strong correlation between who is in the lawsuit and what the States are doing. On the implementation side, some States are taking all the money they can get and working closely with reform advocates to implement reform. Other States are missing opportunities, and that is probably where the Federal exchange comes in.

Ms. Alvarez said the Government knows the reform act is not perfect, and all social laws, such as civil rights, evolve over time. She has no doubt the same thing will happen with health care reform. Already changes have been made to it that make it better. However, "the Administration is not ready to rehash the basic debate, and it is moving forward with implementation."

Mr. Greenwald asked how PACHA can try to inform this process. He noted that Ms. Alvarez addressed new investments, which are incredibly important to the HIV/AIDS community, but in 2011, there are zero dollars for prevention activities. How then can we make new investments happen? Second, in terms of exchanges, even though PLWHA can access these, in many cases, there are no providers of HIV/AIDS care in those systems. Last, who is leading the discussion internally around HIV/AIDS, and how does PACHA try to move it? "We can't make moves to change the system we have until we know this works."

Ms. Alvarez noted that PACHA could contact the Office of External Affairs within the Office of Intergovernmental and External Affairs. The External Affairs Office's job is to link groups like PACHA and others to the appropriate officials "to the extent allowable." Ms. Alvarez added that "it is important for us to hear how we can do better." Ms. Alvarez also noted that DHHS has 10 Regional Directors. In the last Administration, these Directors were not utilized "as well as they should have been." This Administration has worked to improve that, and now these Directors "are our eyes and ears on the ground." So, "that's a way we can have the conversation, as well."

Ms. Alvarez added that the prevention and public health fund is part of the same process as other policies and programs. It goes through the same budget process. "This makes it fair." Some of the programs that will be funded will have an effect on PLWHA. "We can no longer look at programs in such a siloed way," she added.

Thanking Ms. Alvarez, Dr. Gayle said PACHA will continue to want to hear updates on all this over time.

Presentation on the United Nations (UN) High-Level Meeting on HIV/AIDS by Ann Gavaghan, M.P.H., Chief of Staff, Office of the U.S. Global AIDS Coordinator (OGAC), U.S. Department of State

Ms. Gavaghan began by saying that "there is always a good chance we can link the domestic and international response." She then went on to provide background on UN high-level meetings on HIV/AIDS that predate the one that will be held June 8–10, 2011.

Background

- In 2000, the UN Security Council held a session on AIDS in Africa that linked AIDS to national security.
- In 2001, the UN General Assembly (UNGA) held a special session on HIV/AIDS that resulted in a declaration of commitment on HIV/AIDS to demonstrate political will to tackle AIDS and agreement on targets for 2005.
- In 2006, UNGA held another special session on HIV/AIDS to review progress on 2001 commitments and to renew efforts around HIV/AIDS with targets for 2010.

The June 2011 meeting goals are to review progress on items from the 2001 and 2006 commitments and to reaffirm and recommit the world to action. It also will be an occasion for heralding global accomplishments and major achievements over the 30-year history of the epidemic, thanks in large part to civil society, member States, and accountable goals.

We are at a time, however, Ms. Gavaghan said, when "people are saying, we have treatment, so why is global AIDS an issue?" The UN meeting thus will also allow us to say, "No, AIDS is not over, and this is our chance as a world to recommit ourselves once again." Therefore, OGAC's goals include how this meeting can be used as an impetus for action over the next 5 years.

Continuing with her slide presentation, Ms. Gavaghan noted that in March 2011, the Secretary General released a report entitled "Uniting for Universal Access." It contained five recommendations to guide further discussion:

- Champion a prevention revolution.
- Revitalize the framework to achieve universal access to HIV prevention, care, treatment, and support ("what is stopping us in terms of continuum of services").

- Deliver more effective, efficient, and sustainable programs.
- Ensure responses to HIV and promote health, human rights, security, and dignity for women and girls (“women in sub-Saharan Africa suffer from HIV/AIDS disproportionately, and in some countries, drug users who are positive are being denied care”).
- Commit to forging robust mutual accountability mechanisms (“how can we make sure we are measuring programs”).

The U.S. Government (USG)’s response to the Secretary General’s report has been:

- To support mapping the epidemic and target response to the most at-risk populations.
- To continue to scale up services while working with partner Governments to increase their commitments.
- To work to reduce prices of drugs and service delivery (such as increased use of generic drugs).
- To expand gender response and work to address stigma and discrimination.
- To continue developing Partnership Frameworks (the 5-year joint agreements) and continue working with the Global Fund on accountability mechanisms.

The March report led to negotiations (and additional regional UN meetings) on a new UNGA Outcome Declaration (like the declarations from the 2001 and 2006 meetings), the goal of which is to create a “concise and action-oriented declaration that reaffirms and builds on the Declaration of Commitment on HIV/AIDS to guide and monitor the HIV/AIDS response beyond 2010.” In addition:

- All member States have a voice in the negotiated text.
- The Secretary General held a Civil Society Hearing in April 2011.
- The USG also held such a meeting in April 2011.

The U.S. delegation to the June meeting will include U.S. UN representatives and representatives from the private sector and civil society. OGAC is still working on the make-up of the delegation.

USG goals for the meeting are:

- To reaffirm the USG and global commitment to fighting HIV/AIDS (“it is important to signal that the USG is concerned about a major foreign policy of ours”).
- To support efforts to increase efficiencies and shared responsibility for the global AIDS epidemic (“we need to make sure the response is a global response, as we are currently funding 59 percent of the donor response”).
- To affirm linkage of public health response with respect for human rights (“in the long term we see public health as a tool for advancing human rights”).
- To call for a global goal to eliminate pediatric AIDS through accelerated prevention of mother-to-child transmission (PMTCT); (“PMTCT will be a major meeting theme, and Ambassador Goosby is co-chairing a task force on this”).
- To promote attention to the epidemic’s impact on women and girls and the need for a robust response, including ending sexual violence.

Q&A/Discussion

Mr. Wilson said we have a Strategy, core, measurable goals and objectives, and a defined commitment, so how does that in principle stand up to the declaration we are working under? Given recent scientific breakthroughs, what are we doing around needed investment? This is a deciding moment in the epidemic. We have an opportunity to change the trajectory of the epidemic and save billions of dollars down the road by taking action now.

Responding, Ms. Gavaghan said that PEPFAR is a big fan of measurable goals, objectives, and commitment. The Secretary General's report sets forth some suggested commitments there. The document is still being negotiated among all member States, but she can tell Mr. Wilson this: she will take his statement back to the U.S. negotiators. Ms. Gavaghan added that the declaration was under negotiation before the recent scientific breakthroughs were announced. However, Mr. Wilson is correct: they are revolutionary. She wants PACHA to know that OGAC understands what a big deal this is and is considering how to work with its partner countries.

Ms. Khanna asked how OGAC sees its role in communicating a USG position on homophobia and anti-gay and HIV criminalization legislation. Ms. Gavaghan said this goes way beyond OGAC. The Secretary of State has spoken out against this type of legislation. OGAC says also that this type of legislation will have negative consequences in the public health realm.

Ms. Khanna asked if OGAC is accurately reporting what is going on in MSM populations around the world. Ms. Gavaghan noted that "we recently issued MSM guidance about knowing your epidemic and targeting. This is not new policy."

Observing that it is important to look at lessons learned, Douglas Brooks said that it would be wonderful to write a paper on public health as a goal for advancing human rights. He asked if Ms. Gavaghan has resources related to gender to share with members who are working on metrics and outcomes. This could also help advocates such as amfAR talk about the value of the USG investment. Last, he wondered about requests to address the UN Security Council.

Responding, Ms. Gavaghan said there was a planned event involving the UN Security Council, "and now there isn't." She invited members with questions or comments about the event to give them to her.

In terms of metrics, PEPFAR has its indicators, but the challenge is one the entire Government faces now. There are gender indicators out there. One question is what the best gender indicators are. There is UN work around how to harmonize indicators regarding HIV/AIDS.

Kevin Robert Frost congratulated PEPFAR because as pertains to the UN, in terms of the outcomes declaration, the USG contribution has been very positive. Having said that, however, "there are areas of problems, and it is my hope that PACHA will speak to those issues now, before it is not too late."

Continuing, Mr. Frost said there is a draft of the outcomes declaration that includes USG edits to the draft, and "in many cases it feels these are to water down commitments, not strengthen them. In many cases, including commitment to treat goals, to increased resources, and even to eliminate PMTCT, these have been watered down by the U.S. delegation." In addition, it is difficult to understand the whole section about increased use of generics, as "there are USG efforts to remove that, possibly the U.S. Trade Office." So, he asked, where is this coming from?

Ms. Gavaghan said she cannot comment on any ongoing negotiations or drafts that have been leaked. "The USG is committed to providing treatment and to eliminating MTCT, and our commitments do not appear only in what we are saying at the UN but also in our actions on the ground."

Ms. Gavaghan added that she gets Mr. Frost's concern around language, but "in the end, what matters is the numbers." She said she would be happy to talk with Mr. Frost about any of his specific concerns, but she cannot comment on ongoing negotiations or specific drafts.

Mr. Frost responded that he was raising these points so that Ms. Gavaghan can raise the concern to OGAC. PACHA also has the responsibility to talk to other Offices of the USG that might be involved, such as Trade Policy. He would hate to take away the message that the Administration worked to water down these commitments, so he hopes Ms. Gavaghan will take his concerns back and that PACHA can speak.

Ms. Gavaghan said she will be taking that back to OGAC and other negotiators' Offices. She will reaffirm the role of PACHA in speaking to the Administration and on international issues.

Ms. McBride said that the USG donor commitment in 2000 and 2006 depended largely on political will as well as data collection because the data showed such terrific results. Her question, based on Ms. Gavaghan's knowledge in discussion with other donor countries, is whether that same kind of data collection is the tipping point? If we don't continue to maintain our leadership position, she added, "There won't be the same political will coming from someone else."

Responding, Ms. Gavaghan said the USG is a leader in international HIV/AIDS response, and "that is not changing anytime soon." It matters "across the Government." She is very excited by the UN meeting because it is a chance to reaffirm that and make it clear. "The data are hopeful. We are particularly proud of the latest UNAIDS report, which shows the differences in global HIV/AIDS since 2000, and part of that is the global response. Now we have to ask about where incidence rates are dropping and where they are not. And where we can target."

Mr. Wilson asked about the importance of civil society in this process. Ms. Gavaghan replied that negotiations at the UN are conducted by member States. Responding, Mr. Wilson said, so that means that civil society is not active in the negotiations? Dr. Gayle said "that doesn't happen." Ms. Gavaghan added "we're interested in your opinion. If you have something you need us to know, let us know."

Mr. Baker said new, innovative interventions and our goal to reduce burden lead to the question of how that science is being integrated into discussion, given that many Nations will not have the ability to implement this widely. "We need to get 15 million on treatment for both treatment and prevention purposes, so the question is, is the USG prepared to lead that discussion?"

Ms. Gavaghan asked, are we prepared to lead it where? "This discussion is already happening, not only in the treatment realm but in the prevention realm. We are asking what we need to do on the ground for conditions to roll out successfully. How does science translate into program? You raised some of the barriers. These discussions are happening. So what issues do you see, and how should they be tackled?"

Responding, Mr. Baker said "this needs to be clearly articulated, within a goal, like President Bush had a clear goal around treatment."

Ms. Gavaghan said she would take that back.

Dr. Garcia said it is important to focus on family planning in addressing PMTCT.

Mr. Frost noted Mr. Wilson's statement about how we have a defining moment here to address the epidemic, but in order to utilize the new prevention toolbox, the barrier to be overcome is lack of resources. Is the USG prepared to commit increased resources?

Ms. Gavaghan replied that the Administration has committed more resources to HIV/AIDS than any other Administration in history, and “you will continue to see that reflected.”

Mr. Frost said he knows Ms. Gavaghan cannot comment, but the declaration calls for increased resources, so is that congruent with the Administration’s position? Ms. McBride observed that what the Administration faces in Congress and given the battle that we had to go through for PEPFAR reauthorization, a lot of education will be needed.

Ms. Gavaghan said the Administration’s FY 2012 budget request is out there, and it reflects an increase in global health and HIV/AIDS funding even in the face of PEPFAR’s having taken a hit for the first time in its history in the FY 2011 budget struggle. The domestic program also faces cuts, “but not because these are being suggested by the Administration.”

Mr. Frost asked if PACHA “is going to bicker over the next 5 years about treating a few people hoping for a bold outcome or are we going to recommend bold action?” Mr. Wilson replied that, as the President’s advisory council, PACHA should make a recommendation to the President, and “we do a disservice to him if we don’t. The latest breakthroughs are our medical man on the moon.”

Continuing, Mr. Wilson said the Administration has indeed asked for a global funding increase and has stood its ground, but “that won’t get us there. We need \$22 billion to reach universal access by 2015. To reach that number, we have a gap of about \$6 billion. So that’s the ball game we’re talking about. If we were to make up our fair share of that, it would be \$2 billion to \$3 billion. So we should make a recommendation to our President saying we should continue the leadership we have had that bridges the gap.” At present, for every one person on treatment, two get infected, he added, and “we’re not going to win that way. We have an opportunity now to break it on both sides of the game.” And remember, he said, “a little more than a year from now, the whole world will be in Washington, D.C.”

Dr. Darkoh-Ampem said we need to test. In some countries, 30 percent “don’t know their status.” If “we’re going to benefit from any preventions, people need to know their status.” Meanwhile, “commitments have been flat-lined, so scaling up testing without being able to provide services...There will be a crisis, and I don’t have an answer.”

Dr. Gayle said PACHA may want to consider crafting some sort of recommendation following on what Mr. Wilson has been saying, whether it is just increasing resources or being more comprehensive in what we do. Mr. Wilson’s point is correct. “There is a possibility, if we are going to do work, that we state here are the things we need to be doing, such as incorporating new prevention strategies, possibly for fewer people.”

Ms. Gavaghan noted that testing is always part of what people are talking about, and with PMTCT, there will be a huge emphasis on this and how to make sure it is linked to antenatal care that makes sense. In short, “we’re talking about what you’re talking about all the time, too.”

Dawn Averitt Bridge thanked Mr. Frost and Mr. Wilson for “going where we need to go.” She said she has struggled over the past year because “we have had these incredible crescendos that went nowhere.” Now “we need to be big and bold. A perfect opportunity is the UN session. We have the data, and this is the moment.” Ms. Averitt Bridge added that she is not sure whether PACHA’s action should be a resolution, as “this has been a largely unsatisfying experience for some of us.” However, “we have an obligation to move forward. The United States is deeply entrenched, we have been incredibly successful in the global community, and

PEPFAR is the little engine that could. While we're not quite there yet, we do a disservice to our community and to the global community if we just stop here."

Concluding, Ms. Averitt Bridge said PACHA should figure out what it takes, either right now or in the Executive Session later today, "to make a big, bold statement about how critically important our continuing leadership is in this work."

Mr. Brooks agreed and asked how that big, bold statement can be made in the most effective manner. "It might be a disservice to recommend a \$3 billion increase in our contribution with a Congress who would then ask, where are you going to cut? So perhaps we should consider making a suggestion about where the money could come from."

Responding to Ms. Averitt Bridge, who said she felt like she was "hanging here," Dr. Gayle said PACHA would come back to this today along with other issues.

Presentation on Medicare Performance Indicator: HIV Testing by Phill Wilson, Co-Chair, Disparities Subcommittee

Disparities Subcommittee Co-Chair Mr. Wilson said the Subcommittee would like to raise an issue involving Medicare and the need to establish HIV testing as one of Medicare's measurements. The Subcommittee thinks this is a relatively simple thing to do and that it would have a huge impact. What it would mean is that every hospital with Medicare would have as one of its measures HIV testing. The Subcommittee is requesting the full Council's support for this recommendation.

Q&A/Discussion

Discussion highlights included:

- Mr. Cruz voiced support for routinized testing once an individual is in a clinical setting.
- Mr. Wilson clarified that what the Subcommittee is asking for is a performance indicator that would affect all patients. If PACHA's recommendation is about routinized testing, that would even be better.
- Mr. Crowley said he thinks that under current law, Medicare "could not go further on routinized testing than it already has" and that it would help if the USPSTF changed its testing recommendation.
- Dr. Gayle said next time PACHA will ask Mr. Wilson to tell the full Council more about where the Subcommittee is in other aspects of disparities.

Public Comments

Marcia Martin, Get Screened Oakland, encouraged PACHA to come to Oakland to hold a meeting. She noted that Oakland was recently the site of an International AIDS Society meeting. For friends of ECHHP, she would like to invite them to consider shadow cities, such as Oakland, where the epidemic "is alive and well." We have many shadow cities in the United States not on the radar in terms of Federal recognition, she added.

At present, the State of California funds Get Screened Oakland, and the Federal Government "has no idea what we're doing." Now is the time for the USG to add another set of cities to the 12 Cities strategy.

Last, the Kaiser Family Foundation met recently, which prompts Ms. Martin to encourage PACHA to borrow some of the things from the Global Health Initiative (GHI) and bring them back to the domestic epidemic. We “need a high-level meeting so we can say to the global community how our country is doing.” We “need help from PACHA and the Federal agencies to help us go to a GHI-like strategy for our domestic implementation of the National Strategy.”

Aging, gender equality, and preservation of the policy continuum have all been discussed today so far. We also have challenges to sustainability in the United States “that we haven’t talked about at the community level.”

Ruth Royster from Norfolk, Virginia, said she has been living with HIV for the past 23 years. In Norfolk, black women like her account for 76 percent of all HIV cases. She is part of Virginia women’s groups where women come together to discuss issues for black women living in Virginia, including affordable housing for women and children, transportation, and having reproductive choices and rights. She is witnessing young women who were prenatally infected who are adults now. She is glad to have lived in a time when she could survive and have a voice.

The young women she is referring to talked with her and other women recently. They have many issues around becoming mothers. Many of them have been very ill, and they feel like no one is concentrating on this anymore. Back then, we were talking about those babies, but these young women feel no one is talking about them. She is here to be a voice, and she hopes and prays “it doesn’t stop here.”

Carl Schmid, Deputy Executive Director, The AIDS Institute, said the Institute has come before PACHA several times over the past 2 years to ask members and the Obama Administration to address the crisis in ADAP. While some steps have been taken, they have not been enough. When this PACHA first met in February 2010, there was a wait list of just 362 people. Today, the wait list stands at a staggering 8,300 in 13 States.

Wait lists are just one measure of how a State ADAP is functioning. With increasing frequency, States are closing enrollment or changing eligibility requirements and removing people from the program in the process. In both these instances, people do not appear on wait lists because they are no longer eligible for ADAP. However, they will need to receive their medications. Florida went so far as to remove 6,000 patients from their ADAP for 6 weeks. During that time, patients received their medications through a drug company-sponsored foundation. The cost of the donated drugs was over \$23 million.

ADAP enrollment continues to climb. HRSA reports that between FY 2008 and FY 2009, 30,252 additional people were enrolled into ADAP for a total of 205,446 people, or about one in four people with HIV who are in care today. Funding to the program, particularly from the Federal side, has not kept up with this unprecedented growth in demand. NASTAD reports that State funding actually increased by \$150 million last year for a total of \$346 million. Pharmaceutical company rebates grew to more than \$522 million. Federal funding now accounts for less than half of all ADAP spending.

While it is far from enough, the Institute was pleased the Congress, while cutting discretionary spending by \$40 billion, nonetheless approved a \$50 million increase this year for ADAP. One-half of that amount is a continuation of the \$25 million in emergency funding that was added midyear, so the real increase is \$25 million in new money going to the States or enough to serve about 2,200 additional clients. NASTAD estimates the true need is an increase of \$360 million. The ADAP Coalition is requesting an increase of \$106 million, enough

to help about 9,200 clients. The President has proposed an increase of \$55 million, which will assist fewer than 5,000 clients. The AIDS Institute is asking PACHA to support an increase of at least \$106 million, which is the authorized level under the Ryan White HIV/AIDS Treatment Extension Act of 2009.

The ADAP crisis' impact is not only on the PLWHA who need access to medications but also on the entire Ryan White program. There is growing pressure on the other parts of the program to contribute financially to a State's ADAP. In addition, staffs that are hired to provide care and support are forced to use their time to ensure that patients have access to medications from other sources. The ADAP crisis is also negatively impacting HIV prevention. States are shifting money from prevention and using it to fund ADAP. Also, the wait list can be a deterrent for people's getting tested.

Everyone is excited by the recent news that we can now prove that treatment is prevention. In order to achieve these preventive benefits, the treatment must be available. The Institute urges PACHA to continue to prioritize Federal funding for ADAP and the entire Ryan White program and to encourage the Obama Administration to support increased levels of funding with the Congress as the FY 2012 spending bill is debated.

A representative of the Sexuality Information and Education Council of the United States (SIECUS) noted the importance of funding for the DASH program for adolescent and school health, particularly for education about AIDS and other risk behaviors. As the Nation moves forward in implementation of the NHAS, it should be recognized that a large proportion of HIV/AIDS infections are among youth.

The President recently preserved funding for DASH, but SIECUS is concerned about what will happen to the program as the CDC goes through its reorganization. Therefore, SIECUS has a few requests, including that DASH funding continue to go directly to educational agencies. The local educational agencies in the 12 Cities should all receive DASH funding for education of youth before they are sexually active.

The SIECUS representative also asked for objections to HR 1215, which would reclassify parts of the program as discretionary, "effectively killing" DASH. SIECUS has asked the Administration to issue a veto threat on this.

In conclusion, the SIECUS representative asked PACHA as a whole or for individual members to weigh in with the Administration in this matter so that this important infrastructure can continue to exist across the States for sex education.

Leo Rennie from the American Psychological Association said he welcomes the NHAS and the 12 Cities Project for integration of mental health and substance abuse services. Also, the presentations by Drs. Holtgrave and Forsyth were very important. External stakeholders should have a process for getting earlier input from external groups. Of particular interest are indicators related to SAMHSA. Mr. Rennie thanks Dr. Holtgrave for raising the need for community input, for he hears there has not been sufficient engagement on the ECHHP's program by community groups, and there needs to be. Sharing is not just about grants, it is also about encouraging and/or directing health departments to engage and work with community stakeholders on development.

Further, incidence estimates and getting the latest estimates out is really important. There will be potential for some groups to be pitted against others. We know that the Strategy says follow the epidemic. That makes timely data even more important. Mr. Rennie advocates across the board for all populations, but he needs data to do that.

Patrick Packer, Executive Director, Southern AIDS Coalition, described the Southern AIDS Coalition, then thanked PACHA for providing a portion of its meeting to hearing from the public. The work PACHA does is critical in the lives of so many living with HIV disease in this country. People across the country who are fighting to end this epidemic and most specifically those in the Southern Region see this Council as the voice for all the people of the AIDS community.

Mr. Packer knows PACHA is aware that the people of the South are carrying an ever-increasing burden of the domestic AIDS epidemic. The CDC has reported that the South accounted for 45 percent of new AIDS diagnoses in 2009 and has the greatest number of people estimated to be living with AIDS. Those facts are even more serious when one views this in the context that 8 of the 10 States with the highest rates of HIV infection diagnoses are in the South (as of 2009). The case rate data for 2008 show that 9 of the top 10 cities for HIV infection are located in the South.

The Southern AIDS Coalition is here today to speak for those who live in the South, those who make up that 45 percent of newly diagnosed, and mothers in rural and small towns who do not have access to the same services as those who live in large metro areas. All need PACHA's help and voice.

The ADAP crisis continues to expand across this land. As of May 20, 2011, NASTAD reported that 8,310 people are on ADAP waiting lists, and 94 percent of those individuals live in the South. Of the States that have waiting lists for life-saving medications, more than 60 percent are Southern States.

Because of those facts, the Coalition asks PACHA for its help in acting to ensure adequate ADAP funding to all, including Southerners desperately waiting for those life-saving medications who, even more than their counterparts elsewhere, truly have no other resources to turn to. Many of PACHA's members have been in this fight for most of the 30 years of this AIDS epidemic, and some have been on this side of the table requesting and in some cases demanding the attention of our Government to respond to the devastating effects of AIDS. Now the Coalition asks the members of one of the most powerful councils in this country that can shape the systems that are broken to listen and act on these issues with the passion, understanding, and sense of morality and responsibility of the advocate.

The NHAS and its operational and implementation plans are exciting and truly welcomed by the South. The Administration's energy around the 12 Cities Initiative is supported by many Southerners. The Coalition supports any effort that brings attention and resources to any persons living with HIV and certainly understands the need to shore up efforts targeting the highest prevalence jurisdictions.

The Coalition's concerns, however, are that all the low- to moderate-prevalence jurisdictions are increasingly being left out of this effort, and given that many Federal agencies are now beginning to follow the ECHHP model as a format for redirecting existing resources and for distribution of new, that rural and resource-poor regions are being asked to fulfill the same obligations by Federal funders while taking away already limited resources. The exclusion of many of the cities in the South from this initiative and possible source of new funding is a major concern. The severity of the need to be able to respond to the increasing burden to provide care and treatment as well as prevention services to our communities should have also been included in the selection of participating areas. The Coalition is also extremely concerned about the effects of this focused approach on these 12 Cities as it impacts targeted populations, including women, African Americans, MSM, and future funding streams.

The 12 Cities Initiative is seen by so many as not being helpful to those who have dedicated their lives to this work in the most challenging geographic areas, with the hardest-to-reach and most stigmatized populations living within the extremely culturally complex and resources-deprived region that is our beloved country, the South.

The Coalition is keenly aware that this project is moving forward. It is not too late to ensure that any funding or activities around the next steps include the communities that have the highest rates of newly diagnosed. We encourage the Administration to review the process that uses old jurisdictional lines of MSAs (Metropolitan Statistical Areas), because that might not be the best model to address the complexities of this epidemic, particularly in rural communities and medium- to small-sized cities in the South.

The epidemic continues to grow in the South due to a number of factors, some of which the Federal Government can influence and some of which the Southern States will need to tackle. There are other factors that are the responsibility of localities and communities.

Today, the Coalition asks PACHA to take a critical look at the ways it can influence the systems that are playing a major role in preventing Southern State HIV/AIDS departments, AIDS service organizations, and HIV/AIDS clinics from providing the high quality of care, treatment, and prevention services to the many individuals in their communities.

John Hassell, Washington Director for UNAIDS, said that if anyone from PACHA wants to consider attending the Security Council meeting mentioned earlier by Ms. Gavaghan, they should contact Steven Gee in New York.

Gregg Fordham from Norfolk, Virginia, noted that Virginia is a State with an ADAP waiting list. One good thing came out of this, and that is that Mr. Fordham found out that people were now able to declare ADAP as true out-of-pocket expenses, thanks to health care reform.

When folks are transitioned off of ADAP, Mr. Fordham hears nothing else from that point on. It is like hearing the diagnosis for the first time. People are scared and don't know what to do. Trying to get them on patient assistance programs when they have so many different medications and need to get and take all of them on a consistent basis—that's not helping people and that is happening.

The 12 Cities Project as far as he is concerned? Mr. Fordham said he is like the lady from Oakland except he does not have a city to shadow. It sounds like none of those 12 Cities is anywhere like where he lives. He does not live in Washington, D.C., and Tupelo is not like New York. It is not going to be a cookie cutter project.

Daria Boccher-Lattimore, Director of the New York/New Jersey AIDS Education and Training Center (AETC) (the role of translating science to practice is, in large part, what AETCs do) and Vice President, National Alliance for HIV Education and Workforce Development (NAHEWD), said that, at PACHA's last meeting, she conveyed the Alliance's support for the NHAS. Today, she shares a two-page document prepared by the Alliance that discusses how the AETCs are working to address each of the Strategy's three major goals in a timely and coordinated way.

As the two-page document attests, the AETCs are working hard to help provide coordinating services and workforce development. An example from the New York/New Jersey AETC is its work with a community health center in New Jersey serving poor, minority, and immigrant populations. With help from the AETC's local performance site at ID Care, the community health center has established protocols and clinical processes to implement testing and

provide comprehensive HIV care. The center now serves approximately 35 persons with HIV previously not engaged in care. In the past few months, the center diagnosed two young pregnant women with HIV. The center receives continuing clinical guidance from the AETC as it develops its expertise.

The AETC also has an individualized longitudinal training program targeted for minority and minority-serving providers to obtain enhanced, hands-on clinical training and opportunities to network with and receive clinical guidance from the leading clinical experts in the field. Similar work is being done across the country by the AETCs to address the NHAS goals of increasing access and reducing health-related disparities.

Last, Ms. Boccher-Lattimore emphasized that the AETC program has at its core a regional structure that allows it to bring the expertise of the Nation's finest academic medical centers and leading clinical providers directly to the community-based providers who serve those most in need of HIV prevention, testing, and care services in an effective and sustainable manner. The AETC regional centers are complemented by national centers that provide on-call resources and facilitate a coordinated and unified response to help health care providers throughout the United State provide quality treatment and prevention services.

Dr. Gayle noted that it was time to end the Public Comments Session and asked members of the public to leave the meeting room as it was now time for the Executive Session for members only.

Executive Session (Members Only)

After the Executive Session, Dr. Gayle adjourned the 42nd meeting of the full Council.