

CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and
STD Prevention and Treatment

CHACHSPT

November 13 & 14, 2019 | Rockville, Maryland



Record of the Proceedings

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Designated Federal Officer Opening of Meeting and Roll Call

Laura Cheever, MD, ScM

Associate Administrator

HIV/AIDS Bureau (HAB), Health Resources and Services Administration (HRSA)

Theresa Jumento, PhD

Senior Advisor, Division of Policy and Data, HAB, HRSA

Dr. Theresa Jumento welcomed participants and provided instructions for meeting participation and logistic information.

Dr. Laura Cheever welcomed meeting participants and said the theme was ending the HIV epidemic. She reminded participants that Centers for Disease Control and Prevention (CDC)/ Health Resources and Services Administration (HRSA) Advisory Committee (CHAC) meetings are open to the public and that all comments made during the proceedings are a matter of public record. Dr. Cheever reminded voting members that they should recuse themselves from voting on matters for which they have a potential conflict of interest. Dr. Cheever conducted roll call and asked committee members to state any potential conflicts of interest for the record.

CONFLICT OF INTEREST DISCLOSURES

CHAC Voting Member (Institution/Organization)	Potential Conflict of Interest
Chair: Jean Anderson, MD Professor of Gynecology and Obstetrics Johns Hopkins University	Recipient of (HRSA) Ryan White HIV/AIDS Program (RWHAP) funding, Gilead Sciences trauma-informed care funding, spouse's IRA includes Gilead stock
Marvin Belzer, MD, FACP, FSAM Professor of Clinical Pediatrics and Medicine Division Head, Adolescent Medicine University of Southern California	Recipient of funding through CDC, HRSA, Substance Abuse and Mental Health Services Administration (SAMHSA), National Institutes of Health (NIH)
Demetre Daskalakis, MD Associate Clinical Professor of Medicine, Infectious Diseases New York Department of Health and Mental Hygiene	none
Debra Hauser, MPH President Advocates for Youth	Recipient of CDC and Gilead Sciences funding, on Trojan Sexual Health Advisory Committee
Peter Havens, MD, MS Medical College of Wisconsin	Recipient of HRSA and NIH funding, and CDC funds to Wisconsin for Pre-exposure prophylaxis (PrEP)
Venton Hill-Jones, MS Chief Executive Officer Southern Black Policy and Advocacy Network	Organization receives Gilead Sciences funding
Devin Hursey U.S. People Living with HIV Caucus	Employed by hospital that receives RWHAP funding

CHAC Voting Member (Institution/Organization)	Potential Conflict of Interest
Johanne Morne, MEd Director New York State Department of Health, AIDS Institute	Recipient of RWHAP funding
Kneeshe Parkinson Kneeshe Speaks	Recipient of RWHAP funding
Susan Philip, MD, MPH Infectious Disease Specialist San Francisco Department of Health	Recipient of HRSA and CDC funding
Michael Saag, MD Associate Dean for Global Health University of Alabama at Birmingham	Recipient of funding from HRSA, CDC, Gilead Sciences, Merck
Gloria Searson, ACSW Founding Director Coalition on Position health Empowerment (COPE)	Recipient of funding from Gilead Sciences, Merck
Co-Chair: Bradley Stoner, MD, PhD Associate Professor of Medicine Washington University	Recipient of funding from CDC, HRSA
Lynn E. Taylor, MD, FAASLD Research Professor University of Rhode Island Director of HIV/Viral Hepatitis Services, CODAC Behavioral Health	Recipient of funding from CDC
Pradip Akolkar, PhD Senior Regulatory Scientist Food and Drug Administration	none
Neeraj Gandotra, MD Chief Medical Officer SAMHSA	none
Kaye Hayes, MPA Deputy Director Office of Infectious Disease and HIV/AIDS Policy Office of the Assistant Secretary for Health U.S. Department of Health and Human Services	none
Iris Mabry-Hernandez, MD, MPH Medical Officer Center for Evidence and Practice Improvement Agency for Healthcare Research and Quality	none
Richard Wild, MD, JD, MBA, FACEP Chief Medical Officer Centers for Medicare and Medicaid (CMS)	none

Members not present were Jennifer Kates, Shruti Mehta, and Greg Millett. Mr. Millett participated on Day 2. Dr. Cheever said that a quorum of 14 or more members had been established.

Introductions, Welcome, Adoption of Minutes

Co-Chairs: Jean Anderson and Bradley Stoner

Dr. Anderson welcomed meeting participants and reviewed the meeting agenda. She asked if any members wished to correct or add to the May CHAC meeting minutes. There were no requests for change. Dr. Havens moved to approve the minutes. Mr. Hursey seconded the motion, which was carried unanimously.

Designated Federal Officers Welcoming Remarks

Dr. Cheever welcomed meeting participants. She thanked members whose terms recently expired and those whose terms will expire soon for their efforts, then presented them with certificates and letters of appreciation from HRSA's Acting Administrator. She recognized new CHAC members Venton Hill-Jones, Johanne Morne, and Kneeshe Parkinson currently in attendance. She announced that Dr. Wendy Armstrong of Emory University would join CHAC soon. She noted that Dr. Gandotra would fill the role of SAMHSA's ex officio representative, Dr. Timothy Holtz would be NIH's ex officio representative, and Dr. Wilde would serve as CMS's ex officio representative.

Dr. Jonathan Mermin welcomed meeting participants. He noted that this would be Dr. Philip's last meeting and presented her with a certificate of appreciation for her service. He announced new CDC CHAC members—Dr. Daskalakis, Travis Gayles, Shruti Mehta, and Ms. Searson—and welcomed those in attendance. Dr. Mermin announced that CDC had submitted a nomination package to the HHS Secretary to replace Dr. Philip. The Secretary selected Dr. Jodie Dionne-Odom, Assistant Professor of medicine at the University of Alabama, Birmingham, and Chief of Women's Health Services at the University of Alabama, Birmingham HIV clinic.

HRSA Update

Thomas J. Engels, Acting Administrator, HRSA

Dr. Cheever introduced Mr. Engels. Mr. Engels noted that HRSA is a Federal agency dedicated to ensuring access to high-quality healthcare services for all U.S. communities, serving tens of millions of people annually. HRSA supports treatment for people with HIV, critical programs for mothers and children, rural health programs, clinician training programs, and organ donation programs. In October 2019, HRSA announced that it would award \$319 million in scholarships and loan repayment for clinicians and students in the National Health Service Corps (NHSC) Program. NHSC includes more than 13,000 medical, dental, and behavioral health clinicians who serve more than 13.7 million Americans in rural, urban, and Tribal communities. In fall 2019, HRSA announced \$2.2 billion for RWHAP grants for fiscal year (FY) 2019. RWHAP supports comprehensive primary medical care and essential support services for more than 500,000 people living with HIV in the United States. RWHAP, along with HRSA-funded health centers, supports communities in diagnosis, treating, preventing, and responding to the HIV epidemic.

U.S. Department of Health and Human Services (HHS) Office of Infectious Disease and HIV/AIDS Policy (OIDP) Update on the National Strategies

Tammy R. Beckham, DVM, PhD, Director, OIDP

Mr. Engels introduced Dr. Beckham. Dr. Beckham explained that national strategies are developed through interdepartmental and interagency collaboration. OIDP is coordinating the National HIV Strategic Plan (NHSP), the National Viral Hepatitis Strategic Plan (NVHSP), and the Sexually Transmitted Infections (STI) Federal Action Plan, all of which will expire in 2020. Steering committees are updating them. The STI plan is the first Federal STI Action Plan.

HIV (NHSP) and Viral Hepatitis (NVHSP) Joint Development

Committees aim for strategies that apply efficient coordination. Strategic and action plan updates are coordinated by a joint Federal steering committee comprised of three parallel subcommittees each for HIV and viral hepatitis. Subcommittees focus on indicators, prevention and care, and disparities and coordination. The Federal steering committee aims to align NHSP with the Ending the HIV Epidemic (EHE) initiative. There was a joint public comment process for NHSP and NVHSP but comments relevant to each plan were analyzed separately then shared with the steering committee. The HIV indicators subcommittee will leverage indicators developed for the EHE initiative and additional indicators related to disparities.

Strategies will be informed by information about evidence-based approaches. Steering committee members will develop visions, goals, and strategies, and will identify priority populations and indicators. The steering committee has developed metrics and processes for ensuring accountability for progress in plan development and implementation. Plans will coordinate with Healthy People 2030. Committees aim to release strategic plans in mid-2020.

Subcommittees have adopted visions and goals. The Indicators subcommittee has identified priority populations and indicators other than those related to disparities. The steering committee is reviewing these and considering them for adoption. The Prevention and Care and Disparities and Coordination subcommittees have developed objectives for each goal and have proposed them to the steering committee for review and adoption. Indicators and strategies will align with the EHE initiative.

Steering committee members represent six Federal departments. Representatives of HHS represent 12 agencies. They held 18 listening sessions between September 2018 and March 2019, in multiple settings, including national conferences, and virtual meetings. They received 80 sets of comments through *Federal Register* requests for information. A total of 426 comments received through listening sessions and requests for information were analyzed thematically. Themes for HIV, viral hepatitis, and STI overlapped greatly.

STI Federal Action Plan

The plan addresses the four STIs with the highest impact on the Nation's health: chlamydia, gonorrhea, syphilis (including congenital syphilis), and human papillomavirus (HPV). The steering committee comprises five Federal departments and 15 HHS offices. Subcommittees address primary prevention; secondary and tertiary prevention, including care; disparities and coordination; education and communications; and indicators.

The steering committee plans to release the plan mid-2020. They have adopted the vision, goals, objectives, and strategies, and have identified priority populations. They have identified core indicators, which align with Healthy People 2030, and are developing additional indicators. The plan has a website at hhs.gov/STI.

The steering committee conducted six listening sessions at national conferences and virtual meetings between March and June 2019 and held virtual listening sessions with more than 1,000 participant lines between April and May 2019. A total of 115 sets of comments were received in response to the *Federal Register* request for information from May through June 2019. Comments were analyzed thematically and identified critical topics for the plan to address.

The plan will address all components of the syndemic: substance use disorder, HIV, STI, and viral hepatitis.

The Office of the Assistant Secretary of Health (OASH) developed a scorecard for measuring progress toward strategic plan development. All plans are currently on track.

HRSA HIV/AIDS Bureau (HAB) Update

Laura Cheever

Dr. Cheever read HAB's vision, "Optimal HIV/AIDS care and treatment for all," and mission, "to provide leadership and resources to assure access to and retention in high quality, integrated care, and treatment services for vulnerable people with HIV and their families."

Dr. Cheever announced that the biannual Ryan White conference will be held August 2020. The clinical conference will be August 9-11 and the National conference will be held August 11-14 at the Marriott Marquis in Washington, DC. Abstracts can be submitted November 13 through December 20.

HRSA recently released the first annual RWHAP AIDS Drug Assistance Program (ADAP) client-level data report. HRSA also recently released the first report on oral health data from RWHAP. Another recent release is the biannual report on RWHAP highlights, focusing on advancing innovations. In addition, HRSA published the 2017 RWHAP State profiles; 2018 data will be available soon.

HAB is focused on the EHE initiative, which prioritizes people with HIV who are in care who do not have viral suppression, people newly diagnosed with HIV, and people with HIV who are not in care. Reducing disparities is a priority. Disparities have decreased steadily except those affecting people who do not have stable housing. Stable housing is a priority for HAB. HAB seeks to link people newly diagnosed with HIV to care, then to enhance their engagement in care, especially during the first year when people are most likely to disengage. HAB estimates that approximately 250,000 people in the United States are diagnosed with HIV/AIDS but are not in care.

For those currently in care, HAB aims to improve viral suppression. HAB has simplified how care quality is measured and recorded to reduce administrative burden. HAB has expanded access to housing through RWHAP Part C.

To enhance linkage to and engagement in care, HAB received feedback that eligibility determination was very complicated and inhibiting rapid access to care in some areas. In response

the bureau simplified the process and clarified that RWHAP funds can support a person starting medication. HAB is studying how other organizations have implemented recertification to develop best practices technical assistance.

Transitions from jail and prison often result in lost to care. To address this, HAB rewrote its policy clarification notice on how RWHAP funds can be used in jails and prisons.

Many care providers do not know how to access evidence informed interventions they want to implement to reduce disparities. HRSA's Division of Policy and Data and Office of Training and Capacity Development work with the National Institute of Mental Health (NIMH) and CDC to build capacity to utilize implementation science. One HAB strategy is an initiative to identify barriers to implementing evidence-based interventions. Another strategy is identifying best practices and publishing information about them.

A critical strategy for ending the HIV epidemic is engaging community experts in the HIV services planning process. HAB supports people with HIV to enhance skills in planning. The Building Leaders of Color (BLOC) program has been successful and materials are being translated into Spanish.

For the past year, HAB has considered whether RWHAP Part D should be modified to improve its impact nationally. HAB will solicit input about this from communities.

HAB is convening expert panels to obtain input about critical issues such how RWHAP funding can be leveraged to obtain housing for people with HIV, better engage including people who are involved with the criminal justice system, women, and people older than 50 years old.

Given the STI increasing rates in the U.S., including among people with HIV, HAB created a funding opportunity to link HIV and STI surveillance data to facilitate data to care.

HAB is working to help RWHAP grantees leverage SAMHSA funds to strengthen systems of care for people living with HIV and opioid use disorder.

The bureau is working to improve STI screening and treatment among people living with HIV.

HAB issued a cooperative agreement for using evidence-informed interventions to improve health outcomes for people with HIV. Priority populations were transgender women and men who have sex with men (MSM); priority practices were trauma-informed care and behavioral health integration. Expert panels identified evidence-based interventions that are feasible to implement, as well as key intervention components. Grantees implemented these interventions in RWHAP-funded clinics.

Dr. Cheever noted that 45 percent of all RWHAP clients are older than 50 years. While 90.6 percent of this age group is virally suppressed, many are long term survivors with social isolation and medical comorbidities. Also, many are not in care. HAB is increasing work in the area. Efforts to do this include a policy clarification notice issued last year stating that RWHAP funds can pay for Medicare premiums and cost sharing, presentations at National meetings about the projected growth and needs of older adults in RWHAP, a toolkit on the care of people aging with HIV developed by the AIDS Education and Training Center National Coordinating Resource Center, technical assistance on how to leverage Medicare for people living with HIV, and convening a technical expert panel. The technical expert panel is currently in the planning stage.

CDC Updates

Jonathan Mermin

Dr. Mermin noted that STI prevalence has increased over the past 5 years to 2.5 million cases, the highest recorded number to date. It is important to understand why and to identify interventions that will reverse this trend. One reason is that STI programs have closed since the economic downturn. Other causes include serosorting among persons with HIV about 10 to 15 years ago; decreased condom use among vulnerable population; and increased drug use, especially opioids and methamphetamine. Cases of congenital syphilis have increased with more than 1,000 cases reported—a 40 percent increase in 1 year—and 94 deaths. The new STI Action Plan aims to address the problem of increasing STI prevalence.

STI prevalence is increasing among MSM, including MSM living with HIV. Dr. Mermin reported that MSM are at risk for extragenital STIs, with infections in the throat and rectum. It can be difficult to test and treat these cases. Reimbursement for these tests can be a challenge. Dr. Mermin emphasized that it is important to test extragenital sites to reduce STI incidence.

CDC has developed STI fact sheets that are available in Spanish, Chinese, Vietnamese, Russian, and Haitian Creole. The fact sheet page is one of the most frequently accessed CDC resources. CDC is also updating its STI treatment guidelines.

All types of viral hepatitis increased in 2017. Increases are linked to injection drug use. For the first time in 20 years, a continuing national outbreak of hepatitis A started about 2.5 years ago, with more than 27,000 cases, 16,000 hospitalizations, and more than 270 deaths. The outbreak is correlated with drug use and homelessness. Communities most affected by the hepatitis A outbreak are often those most affected by the opioid crisis. Preventive efforts include vaccination, including proactive efforts that do not require those in need to request vaccination in clinical settings. CDC is sharing informational resources about addressing the hepatitis A outbreak that can be tailored with local information.

There are currently 2.4 million people living with hepatitis C and 40,000 new infections annually. In response to requests from State policy makers and practitioners, CDC developed a State policy simulator to support development of policies to reduce hepatitis C. The simulator is available online at [Hep C State Policy Simulator](#). Users can enter data to obtain output based on analytic models regarding intervention effects, costs, and savings.

CDC was awarded \$5 million in FY 2019 to respond to the infectious disease consequences of the opioid crisis. These funds are leveraged with funds from the National Center for HIV/AIDS, Viral Hepatitis, STI, and TB prevention (NCHHSTP) and resources allocated for addressing the opioid crisis that are managed by the National Center for Injury Prevention and Control. Infectious disease consequences include hepatitis, HIV, juvenile idiopathic arthritis, and soft tissue infections. Resources have been used to increase testing for viral hepatitis and to increase linkage to care in high-impact settings, such as syringe services programs and emergency departments, for people who inject drugs.

CDC has issued awards for improving hepatitis B and C care cascades to nine jurisdictions. Awards amount to an average of \$450,000. Hepatitis C care cascades to cure. Hepatitis B is incurable but highly treatable. Awards support testing and linkage to care.

In FY 2019, CDC awarded \$12 million to support State and local health departments develop comprehensive EHE plans, and \$1.5 million to the National Alliance of State and Territorial AIDS Directors (NASTAD) for national capacity building. CDC provides guidance on ensuring community involvement in the planning process, including membership in jurisdictional planning bodies. Awards were made to 32 health departments serving 57 local jurisdictions. Most local jurisdiction grantees are medium to large cities.

CDC changed the name of the Act Against AIDS campaign to “Let’s Stop HIV Together,” to emphasize the importance of acting together. The campaign offers online resources.

CDC is redesigning its HIV homepage and recently launched a new HIV Nexus website to help clinicians communicate with patients and caregivers about HIV prevention, screening, and treatment.

Most adults in the United States have never been tested for HIV. Most people at high risk for HIV are not tested as frequently as recommended. About one in seven people with HIV do not know they have it.

CDC produced a video called “The Journey to Undetectable” with funding from the Minority AIDS Initiative. The video is available on YouTube and promotes HIV treatment adherence and viral suppression.

CDC increased its efforts to encourage families and schools to protect youth from future health risks. A 2019 CDC study found that connecting to school and family during adolescence protects against health risk behaviors well into adulthood. Lack of family and school support is linked to higher health risks, especially for people with a history of adverse childhood experiences.

CDC recently released a new webpage on high-risk substance use among youth in response to youth risk surveillance data indicating that substance use continues to be an issue among high school students. Data showed that 14 percent of youth misuse opioids. In response, CDC provides information about the consequences of substance misuse and about substance use interventions.

In the past few months, CDC issued new recommendations for TB screening and testing of healthcare personnel. Annual TB testing is no longer recommended unless a person has a known exposure or ongoing transmission due to low yields and high rates of false positive results.

CDC and HRSA on Updates - Discussion

Dr. Cheever invited questions regarding CDC and HRSA updates.

Dr. Saag said that about 30 percent of the patients at the hepatitis C clinic where he works in Alabama are covered by Medicaid. The State Medicaid agencies refuse to pay for treatment for any patient with a fiber scan score of less than 5.7 kilopascals and for anyone who has recently used alcohol or other substances. Dr. Saag has seen patients with cirrhosis and who have had a drink within the past week who have been refused reimbursement for care. The clinic must then rely on compassionate use programs, which is very time consuming. Dr. Saag asked if there is a way to compel State Medicaid agencies to stop restricting treatment access in the interest of the

goal to eliminate hepatitis C. Dr. Mermin said this issue is a priority for CDC and several State health departments. CMS issued a letter recommending against restricting access to hepatitis C care. However, State departments have a lot of independence. CDC is working with several States to change their policies restricting access, emphasizing that the changes will result in cost saving for the State and Medicaid. Dr. Mermin expects this strategy to be successful over the next couple of years.

Dr. Saag said that the trend of increasing STIs may be caused by increases in sex without condoms or a consequence of PrEP, but he thinks it is more due to decreases in support for centers that offer testing, treatment, and support services, and due to restricting access to care among those who are at high risk for STIs. He asked for Dr. Mermin's thoughts on this issue. Dr. Mermin said he believes rates of sex without condoms have decreased slightly over the past decade. But STIs are increasing across industrialized nations, though not in all communities. He noted that there have been successful efforts to stop STIs from spreading and suggested considering these for addressing the current epidemic. He invited Dr. Gail Bolan of CDC to comment. Dr. Bolan agreed that timely detection and treatment are critical, and that the closure or reduced hours of STI clinics is a problem. She added that there is an increase in patients with medical homes, so that many who have STIs are being treated in a medical home setting rather than an STI clinic. While this is generally desirable, it is also associated with delayed reporting. She noted that surveillance is conducted only on disease, not infrastructure. Knowing number of cases does not indicate how to reduce prevalence through workforce and infrastructure.

Dr. Taylor thanked Dr. Saag for his comment. She said that CMS issued its letter regarding not restricting access to care several years ago. There has not yet been coordinated large-scale national action. Overturning restrictions one State at a time is going slowly. Hepatitis C prevalence is "mushrooming" in the United States, while other parts of the world are eliminating the disease. She encouraged participants to read the 2015 *Annals of Internal Medicine* article presenting legal arguments against restricting direct-acting antiviral therapy and discussing coordinated lawsuits as a strategy for overturning restrictions more quickly.

Dr. Taylor added that National Viral Hepatitis Roundtable (NVHR) works with Medicaid in all States to support access to the medication.

Ms. Searson agreed that lack of infrastructure is a major barrier to accessing hepatitis C treatment. She said that funds should be invested in supporting care providers and community health workers who know high-need communities and have a history of successful engagement with those communities. People with this expertise and experience are most likely to be successful in linking patients to care.

Dr. Belzer said that STIs are a problem for adolescents and young adults, who tend to use primary care services only for acute problems or chronic health issues. He added that primary care providers often do not follow all current testing and treatment guidelines. He said it should be a priority to encourage adolescents and young adults to use primary care services for STI testing and treatment, and to improve STI services in primary care settings. Dr. Belzer said Medicaid should cover STI services at all types of settings.

Dr. Philip said that disease intervention specialists are critical for addressing hepatitis, HIV, and associated disparities. She said training and modernizing the workforce should be central to strategies and action plans being developed in 2020. She said that current models of care are often based on approaches that worked in San Francisco 20 to 30 years ago, and these need to be updated.

She said the field needs to define new goals, objectives, and performance measures. She recommended needs assessments to determine best models for care delivery, what disease intervention specialists should know, and what types of training and resources are needed to support care providers. Dr. Bolan concurred and said training should be more client-centered and should teach the importance of contextual factors and how to link clients to a broad range of services. This approach would address root causes of diseases rather than only biomedical causes, which will reduce the likelihood of recurrence.

Dr. Bolan said CDC plans to explore opportunities to use technology to communicate with patients. For example, some people prefer to share information via text message rather than talk in person or over the phone. Some State agencies have insisted on collecting data in person based on outdated assumptions about client preferences. These assumptions should be examined and updated.

Dr. Bolan said CDC is considering how to improve outcomes as quickly as possible. They are exploring reducing costs of hepatitis C medication because reduced costs increase rates of cure and reduce overall costs. Lowered medication costs reduce the consequences of State restrictions on paying for care since it becomes easier to pay for treatment without assistance.

Ms. Morne said standardized school-based educational programs on STIs for youth would likely reduce STI prevalence. She said that trauma-informed care is critical. She emphasized the importance of addressing health disparities.

Dr. Taylor said RWHAP has been highly effective in linking patients to care. She said similar programs would be useful for linking viral hepatitis and STI patients to care. She said care services should be co-located, physically or virtually, in order to effectively serve vulnerable and at-risk populations. Co-location can compensate for workforce shortages.

Ms. Parkinson asked for clarification on screening versus testing. Dr. Bolan said screening refers to identifying people who are unaware that they have a condition, while tests are conducted to determine the cause of symptoms. Dr. Mermin gave the example that everyone between ages 13 and 64 is recommended to get at least one HIV test. The universal recommendation avoids implying that recommending the test means assuming that person has risk factors. Testing involves asking about risk factors such as sexual history, which can be important for determining appropriate care. For example, extragenital testing is recommended for all MSM and heterosexual men and for women whose screening responses indicate the test is needed. Since 2002, CDC has recommended that everyone living with HIV be screened for STIs at least annually. CDC's recommendations for STI screening and testing are available online. The agency has become aware that many clinicians are not aware of this guidance.

Dr. Stoner said that STIs are part of the syndemic and addressing them must be part of the strategy to prevent and eliminate HIV. He concurred with earlier comments that sexual health should be framed as a positive part of health, which will encourage engagement with care. He asked what HRSA and CDC view as barriers to implementing this strategy. Dr. Beckham said this could be referenced in national strategies and policies. Dr. Cheever said offering PrEP through community health centers presents an opportunity to deliver care with a focus on sexual health. Dr. Stoner asked if HRSA will pay for PrEP for HIV-negative people. Dr. Cheever said CHCs funding can be used for navigation, laboratory costs, and medical care related to PrEP. RWHAP funds can be used for targeted testing and referral, and for people who do not have HIV. She noted that Truvada is donating medication for uninsured patients.

Dr. Havens said Federally Qualified Health Centers (FQHCs) are the ideal setting for STI treatment. He noted that screening is not the same at general care sites as at publicly funded sexual health clinics. The latter typically screen at three sites, while this is not typically the case in other settings. FQHCs provide an opportunity to address these types of issues.

Ms. Parkinson emphasized the importance of including women in planning how to implement PrEP programs. She said that adolescent girls and young women have high rates of infection and need the support of navigators who are women living with HIV. Dr. Cheever said there is little data on best practices for engaging women in PrEP. She said that it is important to learn more about this, and the CFARs would be engaged to assist.

Ms. Searson asked if OB/GYNs have been engaged in discussions about advantages of PrEP. Dr. Anderson said the American College of Obstetricians and Gynecologists supports PrEP. However, it is difficult to assess the degree to which recommendations are put into practice. Dr. Anderson said more advocacy with front-line physicians is needed.

Presentation: Update on Ending the HIV Epidemic: A Plan for America

Presenters:

Tammy R. Beckham

Laura Cheever Eugene McCray, MD, Director, Division of HIV/AIDS Prevention, CDC

James Macrae, MA, MPP, Associate Administrator, Bureau of Primary Health Care, HRSA

Tammy R. Beckham

Dr. Beckham said HRSA's strategy for ending the HIV epidemic is built on four pillars: prevent, diagnose, treat, and respond. The President's 2020 budget proposal allocates \$291 million in discretionary investments for CDC, HRSA, Indian Health Services, NIH-Centers for AIDS Research, Office of the Assistant Secretary of Health, and SAMHSA efforts to end the HIV epidemic.

HRSA is conducting listening sessions with representatives of State and local health departments, community-based organizations, and other stakeholders about the Ending the HIV Epidemic initiative in all Ending the HIV Epidemic eligible jurisdictions. To date, sessions have been conducted at more than 80 percent of jurisdictions. Listening sessions have indicated the need to expand testing availability; address social determinants of health, especially stable housing; and work with community- and faith-based organizations. Dr. Beckham noted that more than 50 percent of new diagnoses were made in the South.

Dr. Beckham emphasized that Ending the Epidemic team structure and policies are designed to ensure transparency and accountability. The team has identified leading indicators of success: new diagnoses, linkage to HIV medical care within 30 days after HIV diagnosis, viral suppression among people diagnosed with HIV, and percentage of people with indications for PrEP who have been prescribed PrEP. Data on these indicators will be available in the near future.

Dr. Beckham said that the HHS Secretary and Assistant Secretary did not want to wait for some initiative components to start in 2020, so HRSA allocated some 2019 funds for Jumpstart sites in DeKalb County, GA; Baltimore City, MD; East Baton Rouge, LA; and Cherokee Nation. Each site was awarded \$1.5 million.

Dr. Beckham explained that Gilead Sciences donated Truvada to HHS to deliver medication to up to 200,000 people annually. HHS bears all other costs of medication delivery, including verifying patients' eligibility, enrolling patients, building a network of pharmacies, and distributing medication. Gilead Sciences holds a 6-month contract to administer medication distribution. HHS is holding a full and open competition for the next term of this contract. Gilead is not profiting from the program. All funds are expended on program operations.

The Ending the HIV Epidemic team is developing a PrEP education and awareness campaign that will be implemented with the distribution effort. The campaign aims to increase awareness among providers and other key stakeholders, with a focus on community health centers and State and local health departments. It also aims to increase understanding of vulnerable populations. It employs paid and earned media strategies to maximize reach. The project requires medication distribution to start between late November and early December 2019. The program will have a call-in center and online portals. The team expects that the program will serve approximately 4,250 patients during the first 6 months and up to 10,000 patients during the first year, if this option is exercised. To be eligible, patients must lack health insurance coverage for outpatient prescription drugs, have a valid on-label prescription, and have appropriate testing with HIV-negative results.

The team is developing a data analysis and visualization system to monitor progress toward meeting initiative goals. A static version of the system will be available in December 2019. The team aims to develop an interactive dashboard for decision support by 2022.

The group has awarded funds for State and local health department planning efforts and for NASTAD to provide technical assistance for developing local plans. In addition, the group supports the Prevention through Active Community Engagement (PACE) program. This program supports Regions 4 (Atlanta), 6 (Dallas), and 9 (Los Angeles) by assigning to each three highly trained Public Health Service Commissioned Corps Officers to support implementation of the EHE initiative in FY 2020, and to develop short- and long-term action plans.

Laura Cheever

Dr. Cheever explained the role of HAB in the EHE initiative. HAB's work is to: 1) work with State and local jurisdictions most impacted by HIV to leverage RWHAP resources, 2) provide technical assistance, 3) provide systems coordination, and 4) to support the AIDS Education and Training Center (AETC) program for workforce capacity development. HAB prioritizes community engagement, which has always been a central component of RWHAP. People with HIV in the jurisdictions served by programs are engaged with program planning and priority setting. It has been valuable to get input from State health departments and community-based organizations. Key themes in listening sessions were needs to address issues related to substance use, incarceration, transportation, homelessness, mental health, laws criminalizing HIV, and stigma. Policy makers need to better engage community-based organizations and people living with HIV. Clinicians and clinical staff need more training in cultural responsiveness and cultural humility. HAB plans to fund cooperative agreements, which require the bureau to be more engaged in making decisions than grant mechanisms, which will facilitate ensuring funded projects respond to the priorities identified during listening sessions. Listening session participants have discussed the challenges of educating adolescents about sex when schools prohibit discussion about sex. HHS is discussing how to address this in the STI Federal Action plans. Listening session participants identified workforce

shortages as an important challenge. One way to address this is to train community health workers, peer navigators, and peer specialists from the community.

James Macrae

Mr. Macrae emphasized that HIV prevention services, including PrEP prescriptions, should be part of routine healthcare services. He said that the Bureau of Primary Healthcare (BPHC) supports about 1,400 health centers operating in about 12,000 sites. Organizations offer comprehensive services and are governed by community boards that must comprise at least 51 percent patients. Services are available to all who request them, at a sliding fee scale for patients with an income of up to 200 percent of the Federal poverty threshold. The bureau encourages grantees to collaborate with other HIV service and social service providers.

The Health Center program supports outreach, testing, care coordination, and HIV prevention services. Health centers offer primary medical care, mental health, oral health, vision, enabling, and substance use disorder prevention and treatment services. Enabling services include case management, patient education, transportation, and translation. Capacity for mental health and substance use services has rapidly increased. The Health Center conducts more than 2.4 million HIV tests annually, and serve more than 190,000 patients with HIV. Approximately 600 centers offer PrEP services.

HRSA has allocated \$50 million for Primary Care HIV Supplemental funding. Eligible applicants are health centers with BPHC and RWHAP funding or health centers with memoranda of understanding with RWHAP sites. They are States that have been impacted disproportionately by the epidemic or rural communities. Awards will be made in April 2020. The objectives of this supplemental funding are to get people into care and to increase capacity to test current patients. HRSA is encouraging health centers to implement opt-out testing models, link patients who test positive to care as soon as possible, suppress viral load, and start PrEP with appropriate patients. Participating centers will need more staff, including PrEP navigators, who are critical for getting patients into care and for keeping them in care.

Mr. Macrae reported that State agencies and community-based organizations often express different perspectives during listening sessions and that they are sometimes tense when they address each other.

Listening session participants recommended not expecting people to come to the health center independently, but to actively reach out. They also said that collaboration is critical. Participants emphasized the importance of same-day PrEP initiation, increasing resources to support TelePrEP, and PrEP navigators. Participants emphasized the importance of addressing stigma in the community and among all health center staff. They also said centers should engage faith-based communities, build workforce capacity, create more welcoming environments, be more responsive to patients' concerns, collaborate with community partners, and help patients to navigate the system and address cost concerns. A major point raised is the importance of framing sexual health as a positive part of people's lives.

Eugene McCray

Dr. McCray said that CDC is supporting foundational activities to end the HIV epidemic: Jumpstart sites, community engagement, planning to end the epidemic, and preparing for 2020 implementation activities. Jumpstart sites are implementing routine screening and PrEP. CDC's Division of STD Prevention provided \$1.3 million to support PrEP and STI clinics at the Jumpstart sites. CDC expects this to allow the sites to provide important lessons about PrEP implementation in clinical settings to other jurisdictions.

Two weeks ago, CDC released guidance for Phase 1 jurisdictions on developing EHE plans. CDC has held one webinar and will host a series of webinars on this topic. CDC will hold grantees accountable for developing partnerships and including communities in the planning process. CDC will release an implementation planning notice of funding opportunity (NOFO) soon. CDC hopes that jurisdictions will have completed their initial tailored plans for ending the HIV epidemic and will be prepared to begin implementation at the beginning of the funding cycle.

Dr. McCray said that workforce planning is like a fifth pillar for ending the epidemic. CDC will work with grantee communities to establish teams of experts across multiple disciplines, including epidemiology, social and clinical services, and public health, as needed. One Jumpstart program had hired community health workers who are living with or affected by HIV and people who have a history of injection drug use to provide support for newly diagnosed and PrEP patients. CDC has matched 10 early career public health officials from its Public Health Associate Program to interested jurisdictions. CDC also provides funding support to people in their first or second year of training who are interested in work to support the EHE initiative.

Dr. McCray emphasized the critical importance of community engagement and CDC's commitment to support health departments in community engagement.

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Dr. Stoner asked where Gilead Sciences is distributing Truvada donations. Dr. Bolan said this is a national effort being implemented in community health centers and with any eligible providers. The focus is on Phase 1 jurisdictions. Gilead is responsible for distributing products. Patients get tested, get prescriptions and printed identification verifying their eligibility, then fill the prescription at one of the 65,000 pharmacies in Gilead's network.

Ms. Hauser said that conscience clauses and restrictions on sex education in schools are at odds with CHAC's stated goals of de-stigmatizing sexuality. She said these restrictions and changes to Title X are making it hard for youth to get confidential care. She asked how to address this. Dr. Cheever suggested that the CHAC could consider submitting a letter with concerns to the HHS Secretary.

Mr. Hursey asked Dr. Cheever to explain what cooperative agreements are. Dr. Cheever said that they are a funding mechanism in which the government funding agency is substantially involved throughout project implementation.

Mr. Hursey asked if there have been new developments in addressing HIV criminalization. He said that Missouri lawmakers were seeking ways to allow prosecutors access to surveillance data

and that public health professionals are concerned that they will pursue access to detailed service utilization data. Mr. Hursey said Missouri does not take into account prevention strategies such as condom use or viral suppression. The law considers only whether HIV status disclosure can be proven, which is rarely the case. Dr. Cheever said this issue should be addressed at the policy level and that it should be part of the EHE initiative. Dr. McCray said CDC is currently reviewing criminalization laws and is collaborating with partners, many of which are working develop responses including working to change laws and educating district attorneys and prosecutors about treatment, prevention, and risk. There is a toolkit to help jurisdictions address criminalization. Dr. McCray said it would be difficult to use data to document transmission from one person to another. CDC is working with State and local health departments to ensure data are as secure as possible and to ensure that staff understand data protections. CDC monitors data protection procedures annually.

Dr. Saag said a continuing resolution for the Federal Government budget would not be adequate to support EHE initiative activities; additional appropriations are necessary. He asked what can be done to encourage adequate support for the initiative. Dr. Beckham confirmed that additional funding is necessary. HRSA and CDC are exploring potential ways to fund 2020 activities. Because new infrastructure is necessary to meet the initiative's goals, it will be difficult to meet those goals without adequate initial funding. Dr. Saag asked if the government could approve supplemental funding given the importance of the work. Dr. Beckham said an effort is underway to communicate the importance of the initiative.

Mr. Hill-Jones shared concerns that Dallas County, a PS19-1906 EHE awardee, has not engaged communities in plan development or disbursed funding for community activities. The funding is allocated for community engagement and Mr. Hill-Jones has advocated for community involvement since March 2019. However, county and State administrators have said that they are currently focused on meeting the deadline for submitting a draft plan by December 31, 2019, then will improve community engagement afterward. Mr. Hill-Jones said administrators are reporting that this is what CDC is advising. He also reported that the Dallas Health Department Director submitted a grant proposal for HRSA-20-78 (Ending the HIV Epidemic: A Plan for America – RWHAP Parts A and B) without notifying key partners, resulting in a proposed budget of \$3 million, substantially less than the \$9 million allowed. The proposed work was only for rapid response teams for cluster identification. When advocacy partners raised these concerns with the local health department, the director responded that only the State health department is developing an EHE plan. Mr. Hill-Jones clarified that the funding was for the State health department to facilitate local plan development. The administrator said that the CDC has not indicated a requirement to engage community partners in the effort. Mr. Hill-Jones said many health department administrators in the South are interpreting the community engagement requirement to mean that health departments create plans without input, then provide them to planning councils. He said it appeared that administrators may not have read it, based on their responses when he referred to written guidance for project implementation. Mr. Hill-Jones requested clarification regarding expectations for plans due on December 31 and how to ensure grantees are aware of these expectations, and for awardee guidance that better defines community engagement. He is concerned that many draft plans that do not reflect community input will be submitted.

Dr. McCray said that guidance was distributed 3 weeks after awards were made on October 1, 2019. Guidance has been communicated through three webinars provided to health departments and community partners with the intent of ensuring community engagement. He said Mr. Hill-

Jones' experience was concerning. He added that other State departments have demonstrated more community engagement. For example, Tennessee is deferring to a Memphis-based organization with extensive community planning and engagement experience. Dr. McCray said the submissions will be drafts, with requirements to document which stakeholders were involved and how they were engaged. Federal reviewers will indicate when plans do not comply with requirements; grantees will be able to engage with communities to revise plans by August 2020. CDC also will work to ensure grantees are aware of and understand requirements and expectations for community engagement throughout the planning process. Dr. Mermin read the guidance section that describes community engagement requirements. He said CDC needs to monitor and ensure engagement, and noted requirements for documenting community engagement, including frequency, location, number of attendees, and descriptions of participants and discussions. Guidance also suggests approaches for engagement. In developing the guidance, CDC had interest that documentation requirements not be excessively burdensome. However, Mr. Hill-Jones's comments confirmed the necessity of the requirements, which will allow CDC to identify lack of engagement efforts early and respond with assistance in ensuring adequate community engagement.

Mr. Hill-Jones stated that meetings are not adequate community engagement. He noted that meetings are often about health department activities. Departments often hold meetings only after numerous requests. He said community members should be employed in professional positions as contributors to plans. Grant implementation guidance should specify building the workforce with community members who participate in all levels of making decisions, not only as peer navigators and community health workers. Dr. McCray agreed and said the guidance should be clearer. He also said that planning budgets do not have enough money to support employing community members, but that implementation budgets should. Mr. Hill-Jones said community members should also be supported for input in planning; they must be decision-makers.

Dr. Gayles noted that current HRSA and CDC support for prevention efforts focuses on medical approaches such as PrEP. He asked whether the agencies would consider proposals for prevention efforts addressing social determinants of health. Dr. McCray said social determinants correlate with engagement with and adherence to medical interventions. He said that Federal and community partners can provide important input on how to address social determinants. He identified SAMHSA and the Department of Housing and Urban Development (HUD) as important potential Federal partners. He noted that stable housing is essential for PrEP adherence. Mr. Macrae agreed that clinical care can only be effective when social determinants are addressed. He said that, while the current NOFO focuses on PrEP, it does recognize a broad definition of prevention.

Dr. Cheever invited Dr. Gandotra from SAMHSA to comment. Dr. Gandotra said SAMHSA recognizes mental health and substance abuse issues as barriers to HIV treatment access. SAMHSA aims to increase grantees' HIV testing and rates of linking HIV-positive clients to treatment. He said that 70 percent of the 290 Minority AIDS Initiative grantees are in areas of high HIV concentration. Approximately 85 percent of grantees' clients have substance abuse disorders and are not linked to care. He said these clients are unlikely to go to a substance abuse treatment provider, but they will seek primary care.

Dr. Stirratt of NIMH agreed that social determinants of health are a critical consideration. He said NIMH prioritizes understanding how social determinants affect care outcomes. He said that stigma is a critical factor that must be addressed to end the HIV epidemic.

Dr. Taylor said there is a higher unplanned/unintended pregnancy rate among women living with HIV than among their HIV-uninfected counterparts. She said positive sexual healthcare for women who have sex with men requires access to prenatal care, contraception, and abortion. Efforts to prevent prenatal transmission must be enhanced. Maternal fatalities have increased at least 27 percent over the past 14 years according to results presented by Harris and Martelli in the August 2019 issue of *Internal Medicine*. This increase is not due to obstetric complications but to lack of care for chronic conditions, substance use disorder, and mental health problems. She asked how to ensure this is addressed in the plan to end the HIV epidemic.

Ms. Searson said funding for community-based care providers should be contingent on specific responsibility. She said that some FQHCs have not routinely offered HIV testing and linkage to care, and have indicated this is not their priority. She said FQHCs are important partners and doctors who work at them should be trained to conduct sexual health assessments. They need to become comfortable discussing sex with patients. This is necessary to engage patients with PrEP.

Ms. Searson said social determinants are complex and it would be helpful to identify the 20 determinants that most impact HIV, then and work with systems coordinators to address determinants effectively. For example, a coordinator could educate providers about best practices and help a broader range of providers to prioritize HIV and not stigmatize patients with HIV. She said people not currently working with HIV care and advocacy need to be involved with reducing stigma. Mr. Macrae concurred. He said more community leaders should be engaged in this effort. He said that sexual health training should be standard for healthcare professionals. He said FQHCs will receive money for testing and HRSA will ensure they engage with RWHAP-supported care providers to learn how to do the work needed for HIV prevention and treatment. Mr. Macrae said HRSA has done similar work with health center administrators and care providers who did not think opioid abuse treatment was not their concern. He added that primary care providers are being asked to increase what they do during a 15-minute visit. The field must identify best practices for primary care providers to address HIV, viral hepatitis, and STIs.

Ms. Searson said RWHAP grantees prioritize addressing hepatitis C, while others providers are often unaware of the urgency of addressing the disease. She said medical education should raise awareness of health issues affecting marginalized people. She also said research shows that students entering medical school tend to be enthusiastic about serving marginalized patients, whereas this is often not the case for graduating medical students. Ms. Searson said medical education should change to prevent this.

Ms. Morne said a framework of positive sexual health is a key element of workforce development. General practitioners are typically uncomfortable discussing sexual health with their patients; they refer patients elsewhere to address sexual health needs. Patients do not always follow up on these referrals, which can have serious health consequences.

Ms. Morne noted the successes of harm reduction efforts such as clean needle exchange programs and said that Federal programs should reconsider restrictions on referrals to and support for these services as part of making progress toward Healthy People 2030 goals. She asked how to make a motion to make a formal recommendation for this. Ms. Dempsey said recommendations and votes were on the agenda for Day 2.

Dr. Anderson said the near elimination of prenatal HIV transmission is a major success. There were about 44 cases during the most recent reporting period. However, pregnant women remain a priority population and are a critical gateway to prevention and treatment in families. Pregnancy

is a period of particular vulnerability. It would be useful to engage women's partners during pregnancy. Partners could benefit from testing and PrEP. Women are at high risk for leaving care just after delivering a baby. Care providers should concentrate on ensuring women with HIV are linked to care at this time.

Mr. Hursey asked when the CDC NOFO for PrEP services will be released and what, specifically, the funding will support.

Dr. Gandotra said he used to serve as Medical Director for the Center for Addiction and Pregnancy. Pregnant women are supposed to be prioritized for opioid use disorder and substance use disorder admissions and referrals. Many providers are uncomfortable treating pregnant women with mental illness or other co-morbidities. Primary care providers and OB/GYNs often stigmatize these patients. Patients who are already mothers fear that telling a doctor they have a substance use disorder will result in Child Protective Service involvement. OB/GYNs and primary care providers need to learn informed and compassionate approaches to linking these patients to treatment. He said CMS should compensate providers for time spent using best practices in communicating about need for substance use disorder treatment.

Dr. Gandotra said treatment capacity has been expanded through training nurse practitioners and physician assistants in outpatient mental health clinics to conduct HIV testing and treatment. SAMHSA is exploring telehealth as an approach to increase capacity in these settings. He said that staffing shortages can be a barrier to offering these services and funding is needed to address this issue.

Panel 1: Building Community Capacity for Engagement to End the HIV Epidemic

Moderators:

Chrissy Abrahms-Woodland, MBA, Acting Director, Division of Metropolitan HIV/AIDS Programs, HAB, HRSA

Makeva Rhoden, PhD, MPH, LCDR PHSC, Senior Program Advisor, HRSA

Presenters:

Antigone Dempsey, Med. Director, Division of Policy and Data, HAB, HRSA

Linda Scruggs, MHS, Director, Ribbon Consulting Group

Tori Cooper, Executive Director, Advocates for Better Care Atlanta

Jovan McLean, ThD, Quality Manager, ECHO Collaborative NC Region 5 MSM of Color

Larry Scott-Walker, Executive Director, THRIVE SS

Oscar Perez, EDD, Director, Avenue 360 Health and Wellness

Jacqueline Bickham, MPA, Prevention Program Manager, Louisiana Department of Health, Office of Public Health STI/HIV Hepatitis Program

Ms. Abrahms-Woodland said the purpose of the panel was to highlight key HRSA and CDC community engagement-related activities and how they related to issues such as health literacy and clinical quality management.

Antigone Dempsey

Ms. Dempsey said it is important for everyone to say what pronouns are correct to use in reference to themselves so that it is less burdensome for people who believe it may be unclear which pronouns are correct for themselves. She said the correct pronouns for herself are “she, her, hers.”

She said that communities have engaged government agencies since the beginning of the HIV epidemic and it is important to acknowledge this history. Community activism has contributed to changes necessary for addressing HIV in the United States.

Ms. Dempsey said sharing stories is an essential component of community engagement. This is the case not just for people with HIV, but everyone affected by HIV. Engagement includes listening to these stories and also developing trusting relationships and partnerships. It takes time to develop these relationships.

Ms. Dempsey said that part of engagement is including community members in all stages of projects, including planning. She provided an example of a project implemented years ago that including parking a van that offered HIV testing in front of a party. When project staff asked community members why no one had used the service, they said they were not interested in getting tested when they were on their way to a party. Ms. Dempsey said project staff should have engaged the community in planning before investing in the van, before deciding that the van would address community needs.

Ms. Dempsey said community members, including herself, were engaged to write the law authorizing RWHAP. One contribution she made was noting that people up to age 21 should not be labeled “adolescents,” since they do not identify as adolescents.

Planning councils and community advisory boards are structural approaches to community engagement. Another approach is inviting people with HIV to serve as grant application reviewers, panelists, and consultants. Finally, partnerships with national advocacy organizations is another way RWHAP engages people with HIV.

Ms. Banyan discussed the importance of building community capacity. She said involvement of multiple stakeholders with multiple perspectives contributes to strong infrastructure. HRSA has invested in projects such as BLOC, which provides input on engaging people with HIV in providing insight about individual and community needs, and input on how to address these needs. The BLOC program was initiated 3 years ago. HRSA ensures people with HIV are involved with clinical quality management processes. HRSA also invests in a community health worker project. Ms. Dempsey said community partners are critical for ending the HIV epidemic.

Linda Scruggs

Ms. Scruggs said that pronoun sharing is important and part of all BLOC trainings. BLOC is a collaborative effort with community leaders of color who work to build capacity for people of color living with HIV to be involved with meaningful decisions about strategies for addressing the epidemic. She said BLOC program participants become successful advocates and offered the example of a graduate who initiated efforts to expand education for students in a breast cancer oncology program to include information about serving patients with HIV. Many BLOC participants come to the program with expertise and resources. The program teaches them advocacy skills.

Ms. Scruggs's program offers several trainings annually. Their first effort was a national transgender women's program focusing on equity. At the time, the transgender community had not yet meaningfully engaged with policy decisions. The program offers tools for engagement, including key background information such as the National Minority AIDS Council goals. It was important to assure transgender women that they would be treated respectfully. BLOC participants learn how to engage people in positions of authority and how to identify emerging leaders who could benefit from BLOC training.

BLOC has conducted a national training for 15 transgender women of color living with HIV, 3 regional trainings for people of color living with HIV, 13 train-the-trainer events, two national youth trainings, and four community leadership training institutes. A total of 469 participants have been trained. Trainings have included discussions about how social determinants of health affect people's decisions to assert themselves and how they negotiate. Ms. Scruggs said there is a need for BLOC trainings for Latinx people and for Spanish language training materials.

Tori Cooper

Ms. Cooper discussed TWIST, a CDC intervention created by trans women living with HIV for trans women with HIV. It is the first of its kind.

She reiterated the importance of using correct gender pronouns and personal descriptions in all interactions in order to reduce stigma and isolation. Gender pronouns are not "preferred," which implies they are open for debate. She emphasized the importance of not equating people of color with black people. She said tone and implications should be considered in word choices, such as referring to "target" populations, which can evoke images of hunting, rather than "priority" population.

Ms. Cooper said that community engagement should include encouraging people to leverage tokenism. It is important for people from priority populations to know that they are a priority and that their input is needed.

Ms. Cooper stated that only 4 percent of all international funding for LGBT services is allocated for trans women. Trans women have been "invisible" in healthcare. Trans men are treated as "specters." Trans people are beginning to collaborate to counter this. Gender non-conforming people have recently joined these efforts. Ms. Cooper presented examples of trans people throughout recorded history. She noted that in 1979, Marsha Johnson, a black trans woman, and Sylvia Rivera, a Latinx trans woman, created a housing program to serve trans people. This is an example of a community taking care of itself and an example of why policymakers and service providers should listen to community members regarding how best to address their needs.

Ms. Cooper described the San Francisco Department of Public Health's Gender Health SF program, which was established in response to community advocacy work with the purpose of providing access to gender affirming surgeries, education, and preparation services to eligible uninsured transgender adult residents. The program now provides primary care, prevention, behavioral health, hormone therapy, specialty services, and inpatient care to transgender residents of San Francisco. Transgender advocates also provided input to Resolution 288012, passed by the San Francisco Board of Supervisors in July 2012, encouraging the health department to ensure provision of medically necessary gender transition-related care. Ms. Cooper said HRSA should work to empower transgender communities across the country to advocate for solutions that work

best for them. HRSA should engage transgender people in data, policy, and program research, development, implementation, and evaluation.

Jovan McLean

Dr. McLean said he has been living with HIV for about 3 years. He concurred with Ms. Cooper's point that many people with HIV have education and degrees that are relevant to developing approaches for addressing HIV.

Dr. McLean said the Southern Regional Area Health Education Center (AHEC), where he works, trains clinical peer educators as a key part of its community engagement efforts. The program defines peer educators/quality advocates as self-managing patients and effective communicators who are comfortable with data and technology, effective and supportive team members, and quality-improvement literate.

Dr. McLean said that peer-to-peer counseling includes education being delivered every time a patient visits a clinic, unless a patient specifically asks not to receive education on a particular visit. Peer educators ensure patients understand what their medications are and why they should take them, and that they know what a CD4 count is, what viral load means, and what it means to be virally suppressed.

The Southern Regional AHEC community partner quality improvement effort, the ECHO Project, started in 2018. The project serves MSM of color. In 2018, 81 percent of patients had viral suppression and in 2019 the percentage was 87. The program offers a peer-facilitated, group-level educational intervention. Currently, three peer AHEC employees serve 25 people living with HIV. Educational topics include HIV 101, STI and STI awareness and prevention, health insurance, breaking stigma, abuse, health and wellness and managing comorbidities, and cultural and spiritual awareness.

Dr. McLean said it is critical to reimburse community members for the time and effort expended on generating ideas and other work toward ending the HIV epidemic.

Dr. McLean said it could be valuable to develop a campaign message about how it is good that we no longer fear HIV as we did when the disease first came to public attention but that it is still important to put effort into ending the epidemic.

Larry Scott-Walker

Mr. Scott-Walker introduced himself as Executive Director and co-founder of Transforming HIV Resentments Into Victories Everlasting (THRIVE) Support Services. He emphasized the importance of including people living with HIV in all efforts to address the epidemic. He described his own and others' experiences of isolation and stigma as part of living with HIV and said the emotional effects of HIV must be addressed through non-medical approaches. He said communities can do this for themselves.

Within a month of initiating an online support network, 100 black men in Atlanta who were living with HIV were using the resource to discuss topics such as antiretrovirals (ARVs) and social determinants of health. The number of clients increased to 300 within a year.

Mr. Scott-Walker said black men and trans people living with HIV need true community involvement. People living with HIV and who are at-risk for HIV have an understanding of why they became at risk and must be empowered to impact the epidemic. Policymakers should provide funding to this community and support their goals.

THRIVE's We R 3 program links every client to a person with HIV to Reengage in care, Retain in care, and Reduce viral load. The program has helped to link nearly 400 people to appropriate care. THRIVE also has hosted events to teach best practices in community engagement to care providers in Atlanta. In addition, it is supporting community members in creating a communication campaign with images of people of color living with HIV to counter stigma and promote self-acceptance.

Oscar Perez

Dr. Perez introduced himself as the Director of Health Promotion at Avenue 360 Health and Wellness, an FQHC in Houston, TX, that offers a broad range of services including HIV prevention, viral suppression, family planning, and maternal morbidity, with a focus on serving people of color. Avenue 360 was founded in 1998 as an AIDS Service Organization and became an FQHC in 2009.

Dr. Perez described the Southern Initiative, supported by the HHS Minority AIDS Initiative fund, administered by HAB's Division of Metropolitan HIV/AIDS programs. The National Association of County and City Health Officials, in partnership with Cicatelli and Associates, provides service delivery funding and technical assistance. The cooperative agreement funds four sites: Avenue 360 and sites in Atlanta, Memphis, and New Orleans. The South is disproportionately affected by HIV.

Dr. Perez said that community health worker efforts have resulted in improved health outcomes among people affected by disparities related to diabetes and cardiovascular disease. Avenue 360 applies this approach to HIV education and testing in the community, linkage to HIV medical care, retention in HIV medical care, re-engagement in HIV medical care, and antiretroviral therapy (ART) adherence among people in HIV medical care.

Avenue 360 hired a population health data analyst to identify people at risk for HIV who have discontinued care and who are not adhering to ART and/or are not virally suppressed. Information is updated monthly. Community health workers contact these patients to assess and provide educational intervention. Clinical health workers are integrated with the clinical care team and have access to electronic health records and serve as liaisons between the clinic and the community. Dr. Perez said this approach is part of the reason the viral suppression rate among patients has increased from 66.6 percent in August 2017 to 78.9 percent in July 2019. He credited the funding mechanism for organizational changes that integrated community health workers into the clinical team. Dr. Perez said it is essential for community health workers to be from the community being served. They are able to communicate effectively with community members. Clients have expressed great enthusiasm for and appreciation of the community health worker model.

Dr. Perez said it is important to monitor program outcomes and adjust approaches to care delivery as necessary.

Jacqueline Bickham

Ms. Bickham described the processes and results of the program's pilot project to use community engagement strategies to EHE. Her program applied for and received EHE grant funding to develop a tailored community plan. She described the application process, monthly meetings, community health workers' roles and responsibilities, and community engagement strategies.

Organization staff received the CDC funding announcement released May 30, 2019, for proposals due within 90 days. The organization convened community partners via teleconference. Participants discussed their proposed approaches, application requirements, and budget limitations. The department needed additional infrastructure such as staffing and office space to conduct proposed work. Project staff hold monthly meetings with partners to inform the community about their work and to ensure transparency and accountability.

As part of previous work, the department conducted focus groups with community members about how to engage them. Respondents said they would like to be hired. So, the department hired people living with HIV as State-employed community health workers with annual salaries between \$40,000 and \$45,000 and benefits. This results in staff retention, which supports better outcomes for patients.

Lessons learned from community health workers include understanding that patients do not want to be approached initially with recommendations to be tested for HIV. They want to be asked about their needs first. Community health workers attend medical and social service appointments with clients. They make referrals to PrEP, conduct outreach and enrollment, offer care coordination services, and serve as health educators. Diagnostic services include working with five community-based organizations to increase testing. Partners include an STI clinic, the Department of Corrections, and an emergency department. Treatment services include promoting early ART initiation through a health model program and Rapid Start navigation. The health model intervention has high rates of patient retention and viral suppression. Rapid Start navigators link patients newly diagnosed with HIV to treatment within 7 days. Prevention strategies include telePrEP and referring patients who currently inject drugs to syringe service programs.

The New Orleans Police Department is a partner so that officers are aware of community health workers' efforts, including clean needle distribution, and their safety protocols. The police have offered support and protection for community health workers.

Panel 1 Discussion

Dr. Rhoden served as moderator. She said that key points presented are the importance of community engagement, the value of supporting people in telling their own stories, and the value of applying multiple perspectives and approaches to ending the HIV epidemic. She noted that peers with similar life experiences to community members offer unique value for engaging those community members. Dr. Rhoden supported the recurring theme that words must be chosen carefully. She pointed out that the faith community is not only churches. Another recurring theme is progress from fear-based tactics to engage people with prevention and treatment to health promotion. A key consideration is the context of people with HIV, including factors affecting emotional well-being. Dr. Rhoden supported Dr. Perez's recommendation to monitor and evaluate approaches to healthcare delivery. She also supported Ms. Bickham's recommendations for

supporting and retaining community health workers. Dr. Rhoden invited comments from meeting participants.

Ms. Parkinson said there is a need for funding to conduct effective outreach and engagement to women who are HIV-positive. Ms. Scruggs said sometimes advocates and service providers have to take action without funding support. Her program provides free tools and training tailored to support women in reaching other women with HIV. She suggested recruiting and hiring cis women living with HIV to serve as community health workers. Mr. Scott-Walker concurred. He gave an example of working with partners to integrate PrEP messaging into their communication campaigns, which resulted in more insured clients at THRIVE, leading to revenue that can be used to support services for uninsured clients.

Dr. Belzer said he has extensive experience working with youth, who say mental health and substance abuse issues can only be addressed once housing, food insecurity, and transportation are addressed. Dr. Belzer asked for recommendations on how to engage disenfranchised youth. Dr. McLean answered that partners and community health workers who understand youths' experiences and perspectives can help to engage them. Dr. McLean also said lack of awareness is an issue for many vulnerable populations. Ms. Scruggs said it is important for clinical teams to include members who actively engage with and listen to community members. She cautioned against trying to learn about communities in situations where participants are likely to say what they think data collectors want them to say. Effective engagement requires talking to the most vulnerable populations, such as people who are homeless or people who abuse substances. The community should perceive engagement to be routine and be familiar with community health workers.

Dr. Anderson said that HIV is not always a patient's worst problem. It is important to understand a patient's priorities. She said about 30 percent of her obstetric patients with HIV are undocumented immigrants. She asked for input about engaging and serving these patients. Mr. Scott-Walker said the approach must start with community engagement. Providers should learn how to make their space accommodating to the community they are trying to reach. They should demonstrate care for the communities they serve and work to serve those communities.

Dr. Mermin asked what panelists think would be the most effective way to address social determinants of health for their clients. Dr. Perez said working with a personnel contractor to hire community health workers has increased efficiency. In addition, some of the workers hired might not pass a drug test, however, they are essential gatekeepers to key patient populations. Dr. Perez said hiring people who may not meet standard hiring criteria is likely an essential strategy. He recommended training staff at all levels of a care facility to serve patients and to overcome unconscious biases. Ms. Scruggs said the national community health worker model is effective and should not be diluted in practice. She said that it is important not to become complacent working with client populations that are engaged but to continue to broaden outreach. Providers need to continually learn about their patients' experiences.

Dr. Gayles requested advice on how to increase opportunities for meaningful community engagement and how to decrease tokenism. Dr. McLean said populations to be served should lead projects to address their needs. Program developers and policymakers should continually monitor which populations are not represented in decision-making, then reach out to engage those populations. He recommended acknowledging and addressing tokenism whenever it is suspected. Project implementation should not proceed without equitable representation.

Panel 2: Engaging People with HIV Who Are Out of Care: Changing the System

Moderator:

Heather Hauck, MSW, LICSW, Associate Administrator for HAB, HRSA

Presenters:

Michael Stirratt, PhD, Scientific Program Officer, National Institute of Mental Health, Division of AIDS Research

Ann Avery, MD, Associate Professor of Medicine, Case Western Reserve University MetroHealth Medical Center

Peter DeMartino, PhD, Director, Maryland Department of Health Infectious Disease Prevention and Health Services Bureau

Michael Kharfen, Senior Deputy Director, DC Department of Health HIV/AIDS, Hepatitis, STI, and TB Administration

Kimberley Butler-Willis, PhD (c), CHES, CDP, Director, Roper St. Francis Healthcare Ryan White Wellness Center, Managing Director, GOODSTOCK Consulting

Ms. Hauck said people with HIV who are out of care may have left care after their needs were not met. They may not have felt welcome in the clinical setting or have had a bad interaction with a service provider. Their needs for housing, substance use treatment, or behavioral health care may not have been met. Ms. Hauck said the panel would discuss how providers can change the service delivery system to encourage engagement with care. Ms. Hauck introduced the panelists and their presentations.

Presentation: NIMH Research to Inform the Federal Ending the HIV Epidemic (EHE) Initiative

Michael Stirratt

Dr. Stirratt said mental health and HIV care services must be integrated to improve retention and engagement in care. Integration requires collaboration and partnerships. The NIMH Division of AIDS Research's (DAR's) mission is to support research to reduce the incidence of HIV/AIDS throughout the world and to reduce the burden of living with HIV/AIDS, with a central focus on mental health. Behavioral social science and neuroscience strengthen HIV prevention and treatment. Phase 1 in the current plan to end the epidemic acknowledges that HIV is a social issue as well as a biomedical condition. Ending the epidemic will require addressing social determinants of health, mental health issues, and stigma. Social and community support and healthy structural environments strengthen the impact of medicine.

NIMH DAR is focusing on advancing implementation science to support the HIV care continuum and PrEP delivery. Implementation science is the study of methods to promote the integration of research findings and evidence into healthcare policy and practice. Implementation science studies accessibility, feasibility, cost, and coverage. Its aim is to support effective implementation of evidence-based interventions to improve health outcomes. Dr. Stirratt presented the example of

the Keep It Up intervention, an online education intervention about HIV/STI risk reduction and PrEP for young MSM (ages 18-29 years). A randomized trial demonstrated that participants who received Keep in Up had 40 percent less STI incidence at 1-year follow-up than control group participants. Implementation science considers how to implement and disseminate effective programs such as Keep It Up. NIMH is funding a study to compare effectiveness of two outreach strategies—online and community-based organization delivery to HIV testing clients—for Keep It Up in 75 high-incidence U.S. counties. Outcomes are number of MSM reached, cost per infection averted, and facilitators and barriers to program success.

Dr. Stirratt presented work conducted by NIMH to support CDC's Project PRIDE, a large-scale demonstration project with U.S. public health departments. Project PRIDE comprised two types of projects: 1) PrEP delivery and 2) use of surveillance data to identify MSM and transgender people not in HIV care and to enhance linkage to care. NIMH grantees are conducting implementation science research within Project PRIDE to improve PrEP navigation, advance provider PrEP prescribing, understand PrEP persistence, and develop PrEP continuum metrics. Outputs include a manualized curriculum for PrEP navigation.

NIH Centers for AIDS Research (CFAR) and NIMH AIDS Research Centers (ARCs) serve as platforms for EHE implementation science. FY 2019 EHE and HHS Minority HIV/AIDS funds supported 65 Implementation Science Planning Supplements. Projects addressed all pillars of EHE. The Mpowerment Project in Texas is an example. It is a community mobilization program that relies on community opinion leaders and influencers to reach difficult-to-reach populations using evidence-based strategies to increase PrEP use among young black and Latino MSM. Another example project is convening HIV care providers and mental health specialists to identify strategies, barriers, and facilitators for integrating behavioral health into HIV primary care. This project is being conducted in New York, NY, and San Juan, Puerto Rico.

Mental health disorders, which impede care, are disproportionately prevalent among people living with HIV. Dr. Stirratt presented a graph showing that more time spent with depressive symptoms is associated with higher viral load. Every 25 percent increase in days with depressive symptoms is associated with an 8 percent increase in likelihood of missed appointments, a 5 percent increase in likelihood of detectable viral load, and a 19 percent increase in mortality risk. Mental health issues also are associated with challenges in delivering HIV treatment. Less than half of HIV patients who have experienced a depressive episode within the last year have been diagnosed; only 18 percent receive treatment, only 7 percent receive adequate treatment, and only 5 percent achieve remission.

NIMH research supports work to improve delivery of mental health care for people living with HIV. One example is a transdiagnostic approach, which aims to address multiple mental disorders with the same intervention. The project adapts an existing curriculum (the Common Elements Treatment Approach) for adults in HIV care by integrating content on care engagement and ART adherence. HIV clinic social workers will deliver the intervention. The intervention is being pilot-tested for acceptability, feasibility, fidelity, and indications of impact at 1917 Clinic in Birmingham, AL.

Trauma-informed care aims to change healthcare systems, culture, and clinical practice to address the ways trauma affects people. There is limited evidence about how trauma-informed care affects HIV outcomes. NIMH is supporting a project in Region IV to identify opportunities to implement a trauma-informed HIV care model and challenges to doing so. Researchers also will assess

whether trauma-informed care increases key RWHAP quality indicators—retention in care and viral suppression.

NIMH is working in partnership with HRSA and the National Institute on Drug Abuse to support a FY 2020 initiative, “Implementation Research in HRSA Ryan White-funded Clinics: Screening and Treatment for Mental and Substance Use Disorders to Further the National Ending the HIV Epidemic Goals.” The initiative’s purpose is to advance EHE goals by enhancing screening and treatment for mental health and substance use disorders in Ryan White-funded clinics through implementation research. One focus area is developing models of mental health care for people who are disconnected from care using strategies such as technology, peer-to-peer support, or collaborative care.

Potential future efforts include collaborative work to monitor and address stigma associated with HIV and other factors, which is a barrier to engaging with care, and PrEP delivery expansion. This work would be accomplished in partnership with the NIH, HRSA, and CDC Federal Implementation Science Workgroup.

Presentation: Engaging Out of Care Populations: Targeting Services for Inmates

Ann Avery

Incarcerated populations are disproportionately affected by HIV. About 1.5 percent of the State and Federal prison population has HIV/AIDS. This percentage is 0.8 in Ohio, where Dr. Avery works. Dr. Avery reported that in the United States, 150,000 people with HIV leave prison or jail every year. There is rapid turnover in jail populations.

Dr. Avery briefly explained the distinction between prisons and jails. People do not have to be convicted to go to jail. Jails hold defendants awaiting trial or sentencing. The average length of stay is 21 days, ranging from a few hours to 2 years, with specific length of stay unknown. Prisons hold sentenced offenders for a specified length of time.

Dr. Avery led a project to evaluate effectiveness and feasibility of jail-based HIV testing and linkage case management programs. The project was conducted between 2007 and 2012 at ten sites nationally. A key issue was that time in jail is unpredictable. Knowing how long prisoners will be incarcerated makes it easier to offer services, including discharge planning. Serving people held in jail requires starting services immediately. It does not allow scheduling appointments at the same site in a week or two. Dr. Avery’s team developed the Assess, Test, Link: Achieve Success (ATLAS) program for people held in jails. The program offers voluntary opt-in rapid testing, linkage case management, weekly education sessions, and individual risk reduction counseling. Topics covered in the education sessions included HIV, hepatitis, and TB. The team collected follow-up evaluation data.

Current services offered by Cuyahoga County Corrections include opt-out HIV testing, jail-based case management, and telemedicine for people living with HIV. Annual testing is conducted for people who have recently injected drugs. A staff member regularly meets with clients in jail to ensure they are connected to care.

ATLAS data show that 89 percent of participants had seen their usual healthcare provider within 30 days prior to incarceration. But only 36 percent had had CD4/VL drawn within 6 months of incarceration, indicating that they were not engaged in HIV care meeting current clinical

guidelines. Half of participants reported taking HIV medication prior to incarceration. Only half of those who reported taking medication said that they were taking them consistently. Reasons were that they couldn't afford it, there were too many side effects, and that they did not want to take the medication.

The Special Projects of National Significance study of more than 1,200 participants who were in jail showed that 65 percent reported significant mental health concerns, mostly depression and anxiety. More than half reported cocaine use within 30 days prior to incarceration; 27.5 percent reported heroin use within the past 30 days; and 22.3 percent reported drinking to the point of intoxication within the last 30 days. About one-third of participants had been homeless within the past 30 days and a third reported food insecurity. Telemedicine provides an opportunity to see patients who are in jail, where they do not have stressors of life outside jail, are not homeless, and are not intoxicated. Lucidity allows meaningful conversations with case managers and clinical care providers who can point out to patients that they feel better when sober and encourage them to view that sense of well-being as an incentive to stay sober and make healthy choices.

Dr. Avery's team assessed engagement in care 6 months and 1 year after enrolling in the ATLAS program. The study sample was 132 people, 66 of whom had been released a year after enrollment. At 6-month follow-up, 83 percent of participants were linked to care; at 12 months, 35 percent were linked to care. Engagement at 12 months was significantly higher among patients who had been connected with a Ryan White community-based case manager.

Dr. Avery said people with HIV who are in jail are vulnerable and out of care. They need to be engaged. Funding is necessary to support efforts to engage this population.

To be successful, interventions with this population require active support from medical and correctional staff. They also require space to meet with client. It is important not to disclose patients' HIV status inadvertently. So, Dr. Avery's team offers broader health education and screening. Program staff should be familiar with community resources.

RWHAP providers reported that the program helped them to be more aware of their clients' needs, to feel more connected to clients, and also helped them to know where their clients were. Clients found testing services to be very useful. Many said they had been off medication because they did not want to disclose their status in jail. They were relieved to have an opportunity to go back on medication. The intervention team provided education about HIV for correctional staff.

While the 83 percent retention at 6 months is a success, 35 percent retention at 12 months is disappointing. Other challenges are high rates of re-incarceration, high rates of being sentenced to prison, difficulty linking patients to mental health and substance use services after incarceration, and difficulty getting patients to participate in HIV testing when it is not part of a standard intake process. When patients are not incarcerated, it is more difficult to get to them to make and keep appointments.

Dr. Avery said that it is difficult to support jail-based case management as a full-time job, but staff should be in the jail at least three times per week. Jail-based staff must be culturally competent and must adjust to requirements of work in jails. Staff must understand that safety is the primary concern in correctional settings. Items such as paper clips may not be allowed. Staff movement in jails may be limited due to head counts or lockdowns. Staff must identify strategies to ensure privacy and confidentiality in jail settings.

Jail settings offer a unique opportunity to identify patients with or at-risk for HIV and patients with HIV who are out of care. HIV prevention and identification and engagement in care is feasible and should be routine.

Housing: Contracting as Intervention

Peter DeMartino

Dr. DeMartino read the Maryland Department of Health's mission and vision, which emphasize partnership and serving vulnerable populations. The department is decentralized. Dr. DeMartino presented a summary of Maryland's 5-year plan to address HIV, which includes strategies for serving the general population and vulnerable populations with emphasis on linkage to care and using surveillance data. Dr. DeMartino said the national strategy goal to achieve a more coordinated national response is a current focus. He presented data showing a 42 percent decrease in HIV diagnoses in Maryland over the past 10 years. As initial priorities are addressed, the department must continue to improve.

Dr. DeMartino said that, in Maryland, people with HIV frequently migrate between planning regions or out of State between time of first diagnosis to current residence. Maryland is up to date in meeting its EHE goals and anticipates meeting its 2030 goal early. However, some jurisdictions have much higher rates of HIV than others. The statewide rate of viral suppression is 61.8 percent. Raising this percentage will require community engagement. Communities have identified housing, oral health, substance use recovery services, mental health recovery services, and transportation as priorities, with housing mentioned most consistently. The health department assessed its budget resources to consider how to address community needs. Approximately 35 percent of funds are Federal, most of which are RWHAP funds. Only 7 percent of Federal funding in the budget are for housing. The department determined it would have to work with partners to address communities' housing needs. Potential partners included the Baltimore City Health Department and the Baltimore Mayor's Office on Human Services. Partners first worked to reduce redundancy, which required trusting each other enough to share budgetary information.

The Baltimore HIV Housing Taskforce reviewed housing liabilities, assets, needs, and desires. A key finding was that the waitlist for the Housing Opportunities for People With AIDS program had closed in 2010 when it reached 500 individuals and families. The taskforce worked to increase housing options for people on this waitlist. The taskforce worked to increase staffing capacity and to support a coordinated access system. The taskforce created a steering committee to assess housing needs of people living with or at-risk for HIV, coordinate funding efforts, and create a better service delivery system.

Substance Use and HIV Care

Michael Kharfen

Mr. Kharfen reported that HIV diagnoses in DC have decreased over the past 10 years. Drugs were the mode of transmission in about 10 to 11 percent of cases. In 2018, there were only nine new diagnoses of HIV among people who inject drugs. In DC there is a 31 percent co-morbidity rate of HIV co-occurrence with hepatitis C among people who inject drugs. While the overall rate of linkage to care within 90 days of diagnosis is 80 percent, the rate is only 64 percent among people

who inject drugs. The overall rate for viral suppression within 12 months is 65 percent; among people who inject drugs it is 43 percent.

For 10 years prior to 2008, Congress banned DC from having a publicly funded needle exchange program. After the ban was lifted, new HIV diagnoses among people who inject drugs decreased 95 percent. The DC Department of Health considers this evidence that the needle exchange program is effective.

National HIV Behavioral Surveillance data show that 93.6 percent of people in DC with HIV who inject drugs also have used other substances within the past 12 months. A large proportion of people in DC with HIV who inject drugs participated in substance use treatment (45.2%) during the past 12 months and another 12.9 percent tried to get into treatment in the past 12 months. A large sample (n=8,507) study of substance abuse among people with HIV in DC showed that about one-third (34%) of participants had used a history of substance use disorder at some point in their lives. Substance use disorder was disproportionately high among African Americans, Latinx people, and men. Barriers to HIV and substance use care include stigma; lack of health and social service care resources; systemic factors that limit access to housing, food, and transportation; and difficulty navigating the healthcare system. The war on drugs traumatized communities, as did opposition to syringe service programs.

Integrating opioid treatment and ART is a key strategy for addressing HIV. Opioid substitution treatments include buprenorphine/naloxone and naltrexone. They are associated with treatment retention, reduced opioid use, increased rates of initiating treatment, and more HIV primary care visits. Treatment is associated with a 50 percent lower likelihood of continued opioid use, a 50 percent increase in ART, and a 200 percent increase in viral suppression.

Crystal meth use is increasing among MSM with HIV. Use within the past 4 weeks is associated with poor ART adherence. Reasons for using meth are that it can help cope with HIV diagnosis, it enhances sexual pleasure and facilitates meeting sex partners, it facilitates escaping rejection and depression, and that it makes users feel confident and more attractive.

DC's current integrated care and prevention plan includes an objective to transform RWHAP HIV support services to improve viral load suppression rates throughout the eligible metropolitan area. The first strategy for achieving this objective is to increase access to HIV support services, including services for mental health, housing, and enhanced economic opportunities. Approaches have included integrated behavioral health, HIV screening, and substance abuse screening and services in the RWHAP provider system, including medication-assisted treatment and syringe services. The department hires peer community health workers and navigators. The department removed the application question about having a criminal record; it is important to hire peers with life experiences that are helpful to fulfilling their job responsibilities. But new hires were still subject to a background check. The department addressed this by hiring through a contractor. Those hired are fully credentialed health department employees. These employees are critical for re-engaging people who have been out of care.

Mr. Kharfen said it is critical to consider incentives for treating substance use disorder when drugs offer relief from trauma. Sobriety is not enough for a person to be well. Therefore, DC Department of Health trains RWHAP staff, including community health workers, in trauma-informed care.

Marking Sense of the Patient Experience: Engagement and Retention Strategies of the Ryan White Wellness Center at Roper St. Francis Healthcare

Kimberly Butler Willis

Ms. Willis said that marketing professionals are trained to engage consumers by appealing to the five senses—sensory marketing. She said this approach could be effective for engaging people in healthcare. The Ryan White Wellness Center, where she works, aims to influence patients through its vision, mission, and culture. It uses an approach that aims to engage patients' five senses. It is a comprehensive sexual health care setting in a non-profit hospital system that serves seven counties in South Carolina. It serves about 800 to 950 patients annually. Services include pharmacy, mental health, housing, insurance, and legal aid. The center will offer dental vision services soon. The center's rate of HIV care retention is 91 percent; 93 percent of patients are virally suppressed and 97 percent of newly enrolled patients are fully engaged with care for the first year. Each patient is assigned an all-inclusive care team comprising a healthcare provider, social worker, and peer navigator with whom they meet frequently. The care team communicates frequently. The center has 150 active PrEP patients, whose care is not funded through RWHAP.

Young African-American men are most likely not to be retained or virally suppressed. Stigma continues to be an issue. The center is located in a rural area with poor public transportation. Center leadership responded to poorer outcomes among young African-American men with training in racial equity, cultural competence, and cultural humility. Conversations were productive and resulted in staff feeling more connected with each other. The team learned about how systems affect people and the importance of building systems that support engagement with care. The team invited patients to participate in discussions about their needs and cultural competence. Ms. Willis emphasized the importance of being willing to learn from others, acknowledging their experiences, and accepting them for who they are. She has learned to act as a servant leader supporting her team's needs.

The center joined the End the Disparities campaign, a national initiative designed to increase viral suppression rate, increase quality improvement capacity, and reduce health disparities. Priority populations are African-American MSM, women of color, young adults, and transgender women, all of whom are disproportionately affected by HIV with viral suppression rates at least 7 percent lower than the general population of people with HIV. These populations represent 50 percent of the center's newly engaged patients.

The engagement approach that appeals to hearing that the wellness center uses is live telephone calls from nurturing staff who develop trusting relationships. They are supportive but also assertive about convincing patients to make and keep appointments. Patients will sometimes confide information to these volunteers that they do not share with clinicians or case managers. Office décor is designed to appeal to patients' sense of sight. All staff decorated their offices to reflect their personalities, be welcoming, and set patients at ease. The office uses aromatherapy oil diffusion to appeal to smell. Taste is engaged through donations from a food pantry community partner. The center also provides toiletries. Other local businesses have donated items such as blankets and socks. "Touch" is engaged through frequent contacts from the comprehensive care team and peer navigators, who are involved with clinical care team decisions. The wellness center has a rapid entry program to begin care within 7 days of diagnosis for newly diagnosed patients.

Since focusing on vulnerable populations, the wellness center's viral suppression and retention rates have increased for all patients. Engagement strategies were successful for the entire patient population.

The center is dealing with some ongoing challenges. There are few facilities in their system that will offer opt-out HIV testing. The system offers only delayed HIV testing. The local health department is working at capacity, which has led to slow referrals to care. Wellness center staff have responded by offering to complete some of the paperwork if department staff will give them just information necessary to contact patients. The center is able to offer only limited services to people who are HIV-negative but at high risk.

Key lessons learned from implementation include: the value of community health workers and peer navigators; viral suppression should be a routine topic of conversation at every medical appointment regardless of viral load; apply team-oriented management strategies that allow staff to demonstrate their strengths and passion; services should be co-located; after developing a trusting relationship, avoid referring a patient elsewhere; and continue gradual program building in order to reach long-term goals.

Panel 2 Discussion

Ms. Hauck asked CHAC members to consider what CDC and HRSA could do to improve engagement and retention.

Dr. Taylor said some RWHAP centers are using corporate business models that make it difficult to deliver care in the ways recommended during panel discussions. Some offer 15-minute visits, no walk-in visits, and no accommodations for people who are late to appointments. Some staff say that efforts to make clinics welcoming and culturally sensitive are “enabling” unhealthy behavioral choices. Clinicians want to provide culturally sensitive, engaging care, but may be prevented by administrative policies. Dr. Taylor asked how engaging, culturally sensitive care can be incentivized or required. Without incentives or requirements, these practices will not be implemented in many settings.

Dr. Taylor said it would be helpful if clinicians could provide buprenorphine and naloxone patients with sterile injection equipment. In areas without syringe exchange programs, people should be able to purchase single syringes over the counter without a prescription. She said that while she does not want to convey lowest expectations, the Nation is having an opioid crisis and these are appropriate response measures. Dr. Taylor said substance use should be decriminalized. She said the people who are incarcerated must have access to opioid agonist therapy and antiretroviral therapy and the Federal Bureau of Prisons should require that people with HIV have a plan for care and access to medication when they are released from prison. She asked if there were Federal Bureau of Prison policies in place and said that, if not, she would like CHAC to collaborate with the Federal Bureau of Prisons at the next meeting to develop policies.

Mr. Kharfen agreed that people with substance use disorders will not engage with care unless service environments are welcoming and service providers convey cultural humility. He said harm reduction is a core guiding principle. In DC, programs' harm reduction approaches have facilitated retention in care.

Dr. Taylor said it would be useful to have information about standards of care for adjunctive pharmacotherapies and toolkits to support clinical decisions regarding treatments for substance

misuse beyond opioids. Dr. Taylor said it would be helpful if medication-assisted therapy were available for substances other than opiates.

Mr. Hursey said the field should consider how stigma affects immigrants with HIV. He asked what types of education are needed for corrections personnel. He said that prisoners with HIV are sometimes penalized more severely than other prisoners for physical altercations, especially for biting or spitting. He asked if Dr. Avery had observed this. Dr. Avery said corrections officers need very basic education, even the information that HIV is a chronic disease. Lessons have discussed treatment and prevention and how they benefit both individual and public health. Corrections staff have been receptive to education about HIV. Dr. Avery said HIV professionals must network with professionals from other relevant fields such as primary healthcare, correctional health, and community health. She explained that judges, not correctional officers, decide whether to mandate HIV testing for prisoners who have been in a physical altercation and what the consequences will be for these prisoners. She said HIV should not be criminalized and invited meeting participants to the HIV is Not a Crime training academy in Columbus, OH, in 2030. Dr. Avery is on the planning committee for the event.

Mr. Hursey said that criminal history is often used as a proxy for race. He asked if employment restrictions on hiring peer staff with criminal histories had impacted ability to hire people of color. Mr. Kharfen said the system of hiring peers through a contractor had allowed the DC Department of Health to hire peer staff with criminal histories. He said nearly all hires had been black or Latinx. He said the department is also working to remove criminal history as a barrier to public service work.

Dr. Mermin said that many people use drugs intermittently, some who acquired HIV through injecting drugs no longer inject drugs, others initiated drug use after contracting HIV. He asked what the implications are for patients and for treatment. Mr. Kharfen said his team is working to better understand this issue. Dr. Stirratt said behavioral and mental health, including drug use, is not static. It should be monitored long term. Care providers should understand the contextual factors that affect health status and viral suppression, such as drug relapse, depression, and housing instability. Research is needed to study behavioral health predictors of HIV outcomes. Ms. Willis said RWHAP case managers are required to assess risk behaviors. Mr. Kharfen said the DC Health Department explored using electronic health records (EHRs) to assess behavioral health factors and found they did not offer adequate data. He asked what would be better data sources. Dr. Avery said it is also important to define valid measures. For example, is someone who has used meth, but has not for the past 2 months, an addict? She also said that clinicians should consider whether recording some behaviors in EHRs will contribute to stigma. For example, if drug use is in a patient's chart, that patient may be denied pain medication for tooth extraction. Dr. Saag said EHRs are not good sources of accurate data. He said that patient self-reports tend to be more accurate.

Dr. Saag asked Mr. Kharfen to explain how the DC Health Department and CFAR administration interact in his work. Mr. Kharfen said the health department defines its priorities based on input from the field and develops proposals; CFAR contracting officers have inquired about department priorities and initiatives. He said it is critical to share ideas and lessons with other organizations.

Dr. Saag asked Ms. Willis the same question. She said the wellness center formed a collaborative with other local RWHAP grantees called SHAPE (Sexual Health Awareness, Prevention, and Education). The group meets monthly to discuss clinical surveillance and community outreach and meets twice a year to discuss best practices and collaboration. They have published one paper and

are producing another, and present together at conferences. They have a task force in Charleston sponsored by the mayor's office. Dr. Saag said Mr. Kharfen and Ms. Willis had presented examples of the types of collaboration necessary to end the HIV epidemic. It is important for people to work together rather than compete. He also said the day's presentations indicated that engaging populations should involve the population determining solutions to problems affecting them. Ms. Willis added that it is useful to recognize when other providers are better at providing specific services such as housing support or prenatal care, rather than being territorial.

Dr. Gayles asked whether Dr. Avery was aware of demographic correlates of recidivism. He also asked for elaboration on the relationship between depression and HIV outcomes. Dr. Avery said she could only discuss her impressions, not formal data. She said she had observed poverty to be a major correlate of recidivism. Violating probation by using drugs or missing an appointment with the probation officers are other major reasons for returning to prison.

Dr. Stirratt said that people with depression who are disengaged from healthcare are usually not taking care of themselves in several ways. Suicide is one potential consequence. NIMH and the Department of Defense recently studied mortality and suicide among members of the U.S. military, which is high. Study results indicate exposure to trauma and violence are causes. This is also the case outside the military. For example, there is a gun violence epidemic in the United States that includes suicide with firearms.

Ms. Morne said it is critical to address criminal history and substance use as employment barriers to peer community health workers. Many people with criminal histories are excellent advocates. She asked for more information about the impact of crystal meth. Mr. Kharfen said there are few options for addressing meth use. Social factors drive use. Sometimes initial use is not consensual. Use is correlated with factors such as lack of stable housing, which clinical care providers cannot address. Refusing to provide care for people who use meth can exacerbate problems and create new barriers to positive outcomes. Harm reduction approaches may be useful. Providing stability first may be necessary for reducing substance use. Coping with diagnosis and stigma can also contribute to use.

Dr. Avery said there are stages of behavioral change. People who inject drugs may be ready to give up injection and take a pill instead. They may not be ready to make lifestyle and cognitive changes necessary for long-term recovery. If people are motivated to get high, they will. Meth will get someone high when suboxone has blocked the intoxicating effects of opioids.

Dr. Bolan said meth use is dramatically increasing among women, who often do not trust the healthcare system. They may be arrested and incarcerated if they give birth to a stillborn baby, which drives them further from the healthcare system. Meth is associated with increases in congenital syphilis. Risk factors for meth use include poverty, low health literacy, lack of stable housing, and incarceration. Dr. Bolan said this is an underrecognized problem.

Recap Day One

Jean Anderson

Dr. Anderson said that overarching themes discussed during Day 1 were:

- The value of interagency collaboration and systems integrations for ending the HIV epidemic, and for addressing viral hepatitis and STIs;
- The critical importance of community engagement;
- The necessity of integrating community health workers into the healthcare system in professional roles, rather than volunteers, and for overcoming challenges to accomplishing this;
- The need for treatment and prevention programs to address social and behavioral determinants of health;
- The role of implementation science in making progress toward targeted outcomes.

Dr. Anderson noted that themes in HRSA and CDC updates also included the importance of community engagement and implementation science. They prioritized three populations: people in care who are not virally suppressed, people who are dually diagnosed, and people who are out of care. Updates called attention to increasing STI rates, including congenital syphilis, and all types of hepatitis, which is related to injection drug use.

Updates focused on the EHE initiative. Dr. Anderson recognized progress in implementing this initiative over the past 9 months. She said the group recognized a syndemic of substance abuse, hepatitis, HIV, and STIs. The group discussed gaps in community engagement, the need to address stigma, the need for cultural humility, workplace shortages, and the need for funding PrEP services.

Key points from the Panel 1 presentations were:

- Community engagement, especially through people who have shared important relevant life experiences;
- The importance of respectful communication about gender pronouns;
- Leveraging tokenism;
- Greater visibility brings greater responsibility;
- The faith-based community is more than church;
- Medication cannot address the emotional effects of living with HIV;
- The importance of meeting people where they are, addressing the needs they prioritize;
- Including health issues other than HIV;
- The need to address social determinants of health;
- Communities are best qualified to determine solutions to their own problems;
- The need to identify which community members who have not yet been engaged with decision-making.

Key points from the Panel 2 presentations were:

- Healthcare should address social determinants of health;
- The role of implementation science in improving outcomes;
- Federal agency collaboration;
- Challenges people with HIV who are involved with the criminal justice system have while incarcerated and with reentry to the community;
- The challenges of addressing the HIV epidemic in communities with high rates of migration;
- Priority of housing to meet community needs;
- Critical importance of and challenges associated with delivering care to people with HIV and substance abuse problems;
- The relationship between treatment and viral suppression;
- The value of cultural humility;
- Building systems within community.

Key points in discussions were:

- Lack of Medicaid treatment coverage for people with less severe disease or substance use disorders;
- Need to modernize and train the healthcare workforce about STI prevention and treatment;
- Need for more client-centered treatment;
- Need to use technology better;
- Benefits of co-located services;
- Potential of trauma-informed care to address effects of violence and improve mental health;
- Importance of framing sexual health positively;
- Prioritizing understanding needs of documented and undocumented immigrants;
- Cultural competence and stigma;
- Women's treatment and prevention needs.

Dr. Anderson reminded the CHAC that the Day 2 business meeting would present an opportunity to make recommendations and pass resolutions.

Day 2, November 14, 2019: Opening Session

Laura Cheever

Dr. Cheever welcomed the CHAC and reminded participants that the meeting was open to the public and that all comments are made public. She took roll call and established quorum.

Recap of Day 1

Jean Anderson

Dr. Anderson thanked the CHAC for their work. She said that themes discussed on Day 1 included government agency coordination, collaboration, and integration in addressing the epidemics of concern; the necessity of community engagement; the value of community health workers; the need to address social determinants of health; and the role of implementation science. Dr. Anderson then reviewed the agenda for Day 2.

Panel 3: Prioritizing PrEP to Support the End of the HIV Epidemic

Moderator:

Dana Hines, PhD, RN, Nurse Consultant, Division of Community HIV/AIDS Programs, HB, HRSA

Speakers:

Kirk Henny, PhD, Senior Epidemiologist, CDC

Dawn Smith, MD, MHP, Behavioral Intervention Activity Lead, CDC

Tanchica West, MPH, MA, Senior Public Health Advisor, Division of Policy and Data, HAB, HRSA

Angela Powell, MPH, Director, Bureau of Primary Health Care, HRSA

Megan Coleman, DNP, MSN, FNP-BC, Director of Community Research, Whitman-Walker Health

Richard Elion, MD, Clinical Professor of Medicine, George Washington University School of Medicine, DC Department of Health, DC Health and Wellness Center

Dr. Hines welcomed the CHAC and introduced the panelists.

Presentation: CDC Preparation and Implementation

Kirk Henny

Dr. Henny reviewed the goals of the EHE initiative: to reduce the annual number of new HIV cases by 75 percent in the next 5 years and by at least 90 percent in the next 10 years. The approach to achieving these goals rests on four pillars: diagnosis, treatment, prevention, and rapid response.

The focus of the current panel is prevention. The strategy for achieving prevention goals is to accelerate efforts to increase PrEP use, especially in populations with the highest rates of new HIV diagnosis and low rates of PrEP use among those with indications that PrEP would be beneficial. CDC's approach for implementing this strategy is to work with jurisdictions developing plans to meet EHE goals and strategies for PrEP. Planning activities may include maximizing current activities to appropriate scale for populations most in need; developing innovative activities that align with local jurisdiction needs; and using and adapting CDC and other media campaigns to increase knowledge about and to promote HIV prevention, including PrEP. The initiative presents an opportunity for grantee jurisdictions with State or local health departments with HIV surveillance and prevention programs to scale up or enhance their activities in order to maximize success of PrEP-related efforts. Grantee jurisdictions can use funding from mechanisms such as 19-1904 awards to strengthen HIV prevention workforce capacity and performance with additional expertise and technology resources. Funds also will support grantees' EHE planning efforts.

Dawn Smith

Dr. Smith said CDC has developed clinical practice guidelines for primary care clinicians serving patients at risk of acquiring HIV infection, substance abuse treatment providers, reproductive health care providers, and STI treatment specialists. Policymakers are a secondary audience. CDC issued interim guidance for prescribing PrEP to MSM in 2011 after initial clinical trial results. More interim guidelines were issued in 2012 after results of clinical trials with people who inject drugs and heterosexually active people. FDA approved PrEP in 2012. CDC issued comprehensive guidelines in 2014 and updated them in 2018. In 2018, FDA approved adolescent PrEP use. In 2019, FDA approved emtricitabine/tenofovir alafenamide (F/TAF) prescription and the U.S. Preventive Services Task Force (USPSTF) recommended PrEP. CDC is currently developing updated guidelines that refer to the recent FDA approval and include an updated systematic literature review on clinical issues related to PrEP. CDC surveyed clinicians on how they would like guidelines to be formatted. Respondents requested more figures and tables, less text. They wanted clinical advice at the beginning of guidelines. CDC will make these changes. CDC also logs comments as they receive them.

CDC's procedure for guideline development starts with a writing team developing a draft. The PrEP guidelines are developed in consultation with the Division of STD Prevention and the Division of Viral Hepatitis. Designated CDC staff review and clear the draft guidelines. The revised guidelines are then submitted for peer review and public comment. The writing team revises the guidelines in response to the commentary, then conducts final review and clearance before publishing on the Division of HIV/AIDS Prevention website and AIDSInfo. Dr. Smith said CDC is working to release guidelines as quickly as possible, but the process can be time-consuming.

Topics to be addressed in the 2020 guidelines update include an updated evidence review; F/TAF for PrEP; frequency of renal function testing; assessing HIV status when starting, continuing, or discontinuing PrEP; information about HHS's drug distribution program; and primary care considerations for persons on PrEP, such as whether other tests, such as hepatitis screening, are indicated. The guidelines will include protocols for same-day PrEP start; transitioning from PrEP to treatment when a patient acquires HIV; restarting PrEP after discontinuation; and advice about the 2-1-1 regimen for MSM, which is an off-label practice.

Presentation: HRSA Guidance

Tanchica West

Ms. West said RWHAP strongly encourages providers to use PrEP, but funds cannot be used to support PrEP medication or related services such as lab costs of office visits. However, RWHAP infrastructure can support PrEP. RWHAP funding covers HIV testing and referral, psychosocial support for affected family members, and risk reduction education for partners of people who have HIV. In 2016, HRSA published a PrEP program letter recognizing the importance of PrEP and the role of RWHAP infrastructure in supporting PrEP. The letter also clarifies legislative parameters for use of RWHAP funds. HRSA developed a PrEP training webcast about leveraging RWHAP infrastructure to support PrEP within legislative parameters. HRSA also funds the AETC National Coordinating Resource Center, which supports workforce capacity training and clinical consultation on PrEP for primary care providers.

Presentation: The Health Center Program: Expanding Access to PrEP

Angela Powell

Ms. Powell said that the HRSA Health Center Program supports 1,400 health centers, 12,000 care delivery sites, and 28 million patients nationally. Service delivery sites include all 50 States, Puerto Rico, the Virgin Islands, and nine Pacific Island jurisdictions. The program is the largest healthcare safety network in the United States, serving one in 12 people. The program serves more than 800,000 people at school-based health centers. About 4.5 million patients served live in or near a public housing system.

The care delivery model is integrated comprehensive care, including mental health care services. Uniform Data System reports indicate utilization of all types of services offered increased between 2016 and 2018.

Ms. Powell reviewed the EHE initiative Plan for America, which focuses on preventing new HIV transmissions. The Health Center Program's focus is to expand HIV prevention education, access to PrEP, and care coordination for people at substantial risk for acquiring HIV infection. The plan has identified priority jurisdictions. The Health Center Program aims to increase rates of HIV testing, link people to prevention and care, and ensure staff know how to work with people who are HIV positive and people who are at substantial risk for HIV. The program conducts more than 2.4 million tests annually. It provides medical services to more than 190,000 patients with HIV. More than 600 health centers purchase PrEP through the 340B program, which provides substantial discounts to HRSA-funded entities. Health Centers have identified several promising practices in diagnosis and prevention.

Stigma continues to be a challenge. Engaging the faith-based community, especially in the South, can be a challenge. Many RWHAP entities have been successful at this, but the Health Center Program has found it challenging. Health centers are learning how to create a welcoming environment for people who have or are at risk for HIV. Cost of care and access to insurance present challenges.

The Health Center's training and technical assistance work includes expansion of practice transformation activities in three AETCs from the Southeast, Midwest, and Pacific regions. The

expansions goals are to leverage lessons learned and to expand HIV testing, linkage to care, prevention coaching, and promising practice in the health centers. HRSA is providing supplemental funding to the National LGBT Health Education Center to provide technical assistance on HIV prevention and PrEP through Project ECHO, to develop a regional train-the-trainer course on PrEP and HIV prevention, and to implement a two-part PrEP and HIV prevention distance learning series. The center also works to combat homophobia.

Supplemental funding also supports HRSA's Health Information Technology Training and Technical Assistance Center in conducting training on integrating EHR and health information technology systems to inform HIV prevention and treatment, and in providing technical assistance on EHR data integration, health information technology optimization, and data collection. Ms. Powell said goals include developing EHRs that record accurate, relevant information that is easy to access. HRSA also wants to reduce reporting burden on RWHAP grantees.

Presentation: Integration of PrEP into Primary Care at Whitman-Walker Health

Megan Coleman

Whitman-Walker is an FQHC in Washington, DC, serving more than 20,000 patients at two clinical sites in areas with high prevalence of HIV. The center has been in operation for more than 40 years serving LGBTQIA communities and offering expertise in delivering integrated HIV primary care and prevention as well as hepatitis C, behavioral health, STI, and gender-affirming services. In 2012, Whitman-Walker extended its NIH-funded PrEP demonstration project to a PrEP program that is fully integrated into primary care delivery. This program currently serves more than 1,500 patients, with about 75 new patients monthly.

Patient demand for PrEP services increased during the demonstration phase, when Whitman-Walker was the only PrEP provider in Washington, DC. Organization leaders responded by commitment to rapid expansion and integration into primary care. Administrative support and commitment from the beginning was key to success. A PrEP champion who integrated all efforts in the organization also was important to program success. The program conducted outreach early in the implementation process. As the program grew, staff were hired for insurance navigation, access to the manufacturer's patient assistance program, adherence support, and pharmacy liaison responsibilities. PrEP specialists and advocates were hired to support ongoing adherence and persistence.

Prior to implementation, center staff analyzed the clinic's strengths and weaknesses then developed the infrastructure necessary to support growth. Existing HIV and STI testing and screening programs provided an initial foundation for the PrEP program. Program administrators worked with internal and external leaders to expand RWHAP programs. They leveraged existing expertise on adherence counseling and patient navigation. Administrators also cross-trained all personnel on PrEP. Screening questions and algorithms were built into EHRs. Community partners are critical infrastructure. They sometimes can reach populations who are vulnerable to HIV that the center could not engage on its own, and facilitate linking them to care at Whitman-Walker. The center also identified all entry points to the clinic and determined how to reduce barriers to entry for new patients.

An initial part of early program implementation was raising awareness of PrEP. Communications should be tailored to the audience. The team used existing resources such as CDC's 2014 PrEP guidance to begin implementation. They assessed implications of existing internal reporting requirements. For example, all new FQHC patients receive full health screenings. This policy resulted in long visits and a backlog of more than a month. Whitman-Walker addressed this by establishing blocks of time for new PrEP patients to see the primary care team and by hiring a PrEP navigator.

During the early stages of implementation, patients had difficulty obtaining prior authorizations, and encountered insurance denials and large co-payments. The program collaborated with the on-site FQHC pharmacy to support new PrEP starts. Pharmacists were trained on co-pay program enrollments. Program developers produced English- and Spanish-language informational materials about PrEP and HIV testing, and how to access them. Awareness and knowledge varied greatly in the priority audience. Materials were designed to meet diverse informational needs.

Initially, the center did not plan or implement evaluation because it was unprepared for rapid growth. Dr. Coleman said this was a missed opportunity. The program now conducts ongoing evaluations to assess PrEP initiations and persistence, and to identify which populations have not yet been engaged. The program aims to be flexible in addressing changing community needs. Evaluation results indicated that many gender-affirming patients were not getting PrEP. Stakeholder interviews indicated that offering a PrEP clinic in the evenings would lower a barrier to care for this population. Another recent expansion is to offer mobile PrEP.

Presentation: HIV Prevention: Sexual Health

Richard Elion

Dr. Elion said reaching multiple communities requires offering multiple points of entry to HIV care. Sexual health services are a key entry point. Many communities in need are not accessing PrEP services. Large proportions of eligible black and Latinx people and women are not receiving PrEP. In response to this, the DC Department of Health STI Center where Dr. Elion works added sexual history screening questions to EHRs and trained providers in PrEP delivery. However, providers were uncomfortable initiating discussions about sex with their patients. Sexual history screening is recommended primary care for all adult and adolescent patients. It took a lot of effort to get clinicians comfortable with this, and to get STI specialists to get comfortable conducting screens designed specifically for PrEP. Patients tend to have difficulty discussing their sexual history or accepting that their behaviors are risky. The clinical team is working with clinicians to address patients' denial. The clinic is called a wellness clinic rather than a sexual health center to facilitate patients' comfort and a perspective that sexual health is simply a component of health in general.

Treating HIV-negative patients requires a different approach from treating HIV-positive patients. People tend not to perceive their own behaviors as risky. Women and men have different risk profiles.

Same-day PrEP initiation is recommended for engaging patients with care. Clinic staff reviewed data from other clinics on reasons for unwillingness to use PrEP. The main reason is that large proportions of patients at high risk perceive that they are not at risk for HIV infection.

The center screened 262 patients for PrEP between August 2016 and 2018. Patients were predominantly MSM, diverse with regard to race/ethnicity, with high rates of unstable housing (28%), low income (53% with annual income less than \$26,000), and lack of insurance (35%). Approximately 95 percent of patients screened were prescribed PrEP. After 3 months, 70 percent of those prescribed PrEP were still on it. This is high compared with other programs. Dr. Elion attributes this to the program creating a welcoming atmosphere.

Dr. Elion said that sexual health care should be linked to prevention and primary care and also to other emerging models of care, such as mobile healthcare delivery.

One of the biggest challenges the program has encountered is being able to hire enough navigators.

Panel 3 Discussion

Dr. Hines asked presenters to describe organizational challenges to implementing PrEP that they had encountered. Dr. Coleman said the biggest current challenge is accessing same-day medication, especially through the manufacturer's Patient Assistance Program, for patients who are not well-insured and for patients who have annual incomes higher than \$62,000 but no insurance. Her program can help these patients access medication, but not other care. Dr. Elion said sustainability planning is challenging. He also said his team has not been successful with engaging women. They have tried several approaches to outreach and hiring diverse providers, but have remained unsuccessful. Dr. Elion said his clinic has not yet developed satisfactory methods for tracking treatment adherence. It would be useful to track medication refills through EHRs, but not enough pharmacies are willing to participate in data collection. It would be useful to integrate dispensing data into EHRs, but his clinic does not have the resources to do this.

Dr. Hines said data presented by Drs. Coleman and Elion suggested that African Americans were less likely than others to take PrEP. She asked what practices they would recommend to address this disparity. Dr. Coleman said her team has noticed this trend. When Whitman-Walker first started offering PrEP, about 85 percent of patients were white MSM aged 25 to 45 years. Patients were aware of the clinic and PrEP and asked for the medication. No screening or outreach was required. Partner organizations are better at reaching and engaging other vulnerable, at-risk populations. As a result of partners' efforts, the average age of new PrEP patients is 29 years and more people of color are starting care. Offering care outside the clinic in settings people frequent, such as schools, would increase utilization. For example, Whitman-Walker opened an STI evening clinic. It would be useful for community organizations to offer PrEP, which might require additional infrastructure to support prescribing and billing.

Dr. Elion said integrating with school-based programs could facilitate reach to adolescents. He said agnostic payment acceptance has facilitated success. Diverse staff help patients feel comfortable. He pointed out that sexual health is important across racial and ethnic groups and the clinic where he works aims to make everyone feel comfortable approaching with sexual health needs.

Dr. Hines asked Dr. Elion how he recommends addressing providers' discomfort with sexual health screening and discussion, including with women who can benefit from counseling about preventing maternal transmission. Dr. Elion said it has been effective to engage patients who present for contraception services. This is an opportunity to give something the patient wants while asking for sensitive information. In addition, provider education should address sexual health care.

Whitman-Walker has helped providers become more comfortable by teaching them that not talking about sex with patients can lead them to become HIV-positive.

Dr. Coleman said it is critical to normalize conversations about sexual health. Providers need to understand their own biases about sexuality, then learn how to counter them. Providers need to learn how to avoid using stigmatizing terms such as “promiscuity.” Conversations must be respectful and empowering. The role of the provider is to inform patients of their choices then trust them to make their own decisions. Many patients are not aware of PrEP. It is the clinician’s job to inform them of this option.

Dr. Mermin said data across programs show a PrEP adherence rate of 50 to 70 percent. He asked Drs. Coleman and Elion if they think non-adherent patients have dropped out of care or have stopped risky behaviors. He asked if it would be feasible for EHRs to be used to routinize HIV testing at FQHCs and community health centers. He asked Ms. Powell how her center funds a syringe exchange program.

Dr. Coleman said she does not think risky behaviors change. People stop PrEP because of losing health insurance or because it is difficult to visit the clinic frequently. Dr. Elion said there is little literature on reasons for non-adherence. He noted that women tend to adhere to birth control pill regimens, which suggests non-adherence may be a choice, and due to understanding of risks. He encourages patients to assume the likelihood of risky behavior is high enough that they should continue to use PrEP.

Ms. Powell said health centers are independent non-profit or public entities. It is difficult to mandate that they do anything. She suggested providing technical assistance for setting up EHRs to prompt testing. Another potential approach is to have pharmacist EHRs prompt referrals to service.

Ms. Powell said that the services at her organization are funded by State and local agencies and private foundations. Federal funds cannot be used to purchase needles or syringes. Dr. Mermin asked if BPHC can fund infrastructure for syringe services. Ms. Powell said Federal funds have supported general infrastructure for the center. Ms. Morne said that her organization uses State funding to support syringe support programs.

Carl Schmid asked Dr. Smith if PrEP guidelines address frequency of bone density testing. He also asked why the guidelines refer to the HHS distribution program. He asked if the guidelines would refer to the USPSTF recommendation for no co-payment assistance for people with co-pay assistance. He asked if guidelines would discuss the generic medications expected to be approved next year. Finally, he asked whether guidelines would include information about best practices for encouraging PrEP adherence.

Dr. Smith said bone density testing is not recommended. She said the guidelines refer to the HHS distribution program because clinicians are often unaware of resources that can help patients to access medication. The guidelines list assistance programs to facilitate linkage to coverage. Dr. Smith said CMS and insurers made decisions regarding co-payment and USPSTF graded the policy. The grade does not mean the policy is recommended. CDC does not have enough information to discuss this in the guidelines. CDC is developing a section about best practices for adherence and retention.

Dr. Akolkar said providers often first meet women patients when they are already pregnant. The guidelines are permissive but not encouraging about considering PrEP during pregnancy. He said

the updated guidelines should do so. He asked Drs. Elion and Coleman if they have worked with OB/GYNs to reach pregnant women. Dr. Akolkar also asked how close the field is to being able to implement mobile PrEP.

Dr. Coleman says she partners with an OB/GYN who serves many of Whitman-Walker's patients who are HIV-positive. The center has a program that trains clinicians to engage more women with PrEP. The clinic needs to expand its OB/GYN service capacity. She said the mobile health van is used to offer health screening services in hot spots. Center staff would like to offer PrEP starter kits from the van, then link people to primary care.

Dr. Elion agreed with Dr. Akolkar that PrEP guidelines do not encourage use during pregnancy. He said that is an important point.

Dr. Saag said that given the degree to which teams of specialists and champions supported by Federal funding to implement best practices struggle to implement programs, he wonders if it is realistic to expect to end the HIV epidemic by 2030. Dr. Belzer said cost-effectiveness is an important consideration. He said that funding for social support services is a fraction of the funding for medication. He said this should be reversed. He also said primary care doctors are unlikely to offer PrEP in 15-minute visits. Dr. Belzer said social media communication is an effective way to reach and engage high-risk populations. Dr. Elion said that about one-third of PrEP prescriptions have been issued by primary care physicians. They are uniquely poised to reach patients and are necessary for successful dissemination of PrEP. Ms. Morley said she thinks stakeholders must consider whether interventions and strategies are scalable. Dr. Coleman said primary care providers are in contact with a broad range of the population and are likely important for increasing PrEP uptake.

Mr. Hursey said that community partners who facilitate engagement want something in return, such as funding. He asked Dr. Coleman to discuss Whitman-Walker's relationships with community outreach partners. Dr. Coleman said health centers have not always been good at compensating community partners. People should be compensated for their work. Whitman-Walker offers compensation and training opportunities. Dr. Elion said it is essential to compensate partners. RWHAP 340B allocates nearly \$3 billion for PrEP funding. Partners who facilitate grantees' PrEP work must be paid for their efforts. If grantees do not compensate partners, they will not engage communities or develop sustainable programs.

Dr. Belzer said that creating a social norm of perceiving sexual health as positive and integral to general health is to teach young people this perspective. Youth need access to information and comprehensive sexual health services, including patient assistance programs. He said Federal public health agencies should educate State and local government agencies about the public health benefits of access for minors, without requiring adult permission.

Dr. Belzer noted that NIH is supporting many projects to develop mobile health technologies. He said these should be leveraged to increase national capacity for PrEP promotion and services, including support for adherence, for relatively little cost.

Richard Haverkate said that EHRs can deliver reminders and could be used to remind providers to recommend HIV testing at least once annually. He asked how a Federal agency could develop guidelines modules for the 10 most commonly used EHRs and connect these modules to the 10 most commonly used EHRs in FQHCs. Centers are unlikely to make this a priority unless there is Federal funding. Dr. Smith said that the CDC is working to get PrEP guidelines into EHRs. Their

informatics team is developing algorithms using key PrEP indicators. They will pilot test this with the National Association of Community Health Centers. Ms. Powell said that if FQHC Uniform Data System performance measures included using EHRs with PrEP guidelines, FQHCs would develop EHRs with these guidelines. Ms. Morne said it is

Mr. Haverkate asked how much control the Federal government has over how grantees spend RWHAP 240 funds. Ms. Powell said that fund usage is regulated, but fairly loosely.

Ms. Morne said providers need more information about PrEP so they can support patients in making informed decisions. She expressed concerns that information about potential adverse effects have resulted in disproportionate fear and that not enough information has been disseminated about PrEP benefits.

Mr. Hursey said some people learn about PrEP and decide not to use it. He asked what the field knows about this group and the reasons for their choice, as well as what strategies can be implemented in response. Dr. Coleman said it is providers' role to provide patients with information so they can make informed decisions. However, their decisions are not always what providers think is best. She appreciates when patients honestly report their choices rather than accept the prescription and disengage from treatment without discussion. It is important to ensure patients continue contact with the healthcare system. Sometimes patients change their minds and decide to take PrEP after previously declining, so providers should reinitiate discussion periodically. She said her patients who are cis women and decline PrEP have indicated preferring other prevention options. Trans women patients have not shared their reasons for declining PrEP. Ms. Powell said some trans women fear that PrEP and hormone therapy will interact to produce adverse results. She asked how Whitman-Walker is addressing this concern and what messaging about PrEP the trans community needs. Dr. Coleman said many of her patients have asked about hormone interactions with PrEP and that there should be clear and consistent messaging about this. Whitman-Walker solicited input from trans people regarding their messaging needs. Results showed that providers initiated discussion about PrEP when patients came to see them for something else. Providers did not initiate further discussion after these initial encounters. Engagement has increased since providers have started revisiting the topic of PrEP after first addressing the patients' presenting needs.

Public Comment

Dr. Cheever said that 15 minutes were allotted for all public comment and asked that each comment take no more than 3 minutes. She asked commenters to state their names and organizational affiliations for the record. She said that CHAC had received letters from THRIVE Support Services, the National Coalition of STI Directors, and Ryan White Clinics for 340B Access. These letters are attached as appendices to the minutes.

Lauren Canary from the National Viral Hepatitis Roundtable said the organization would like CHAC members to include people with lived experience with viral hepatitis. She expressed appreciation of health centers implementing prevention strategies. She said she would like to know more about HRSA's strategies for addressing co-occurring HIV and viral hepatitis.

Taryn Couture of the National Coalition of STD Directors said that CDC surveillance data show that prevalence of three notifiable STIs is at the highest it has ever been. The organization is concerned that official guidance about ending the HIV epidemic does not specifically recommend

engaging organizations that address STIs as partners. STI directors say that this has led to their being excluded from efforts to which they could contribute.

Panel 4: Models of Clinical Care and Workforce Issues

Moderator:

Marlene Matosky, MPH, RN, Chief, Clinical and Quality Branch, Division of Policy and Data, HAB, HRSA

Presenters:

Robertson Nash, PhD, ACNP, BC, Vanderbilt Comprehensive Care Clinic, PATHways Program

Johanne Morne

Ms. Matosky introduced the panelists and presentations.

Presentation: HIV/AIDS Bureau Workforce and Model of Clinical Care Activities

Marlene Matosky

RWHAP provides comprehensive HIV primary care, support services, and medication for low-income people with HIV who are uninsured and underserved. More than half of people who are diagnosed with HIV in the United States receive services through RWHAP. HAB works to extend and support the HIV workforce and to identify the most effective models of clinical care. Ms. Matosky described three HAB projects in this area.

The AETC program supports two national centers and a network of eight regional centers and more than 130 local affiliate sites across the country, with a FY 2019 budget of more than \$29 million. Centers provide locally-based, tailored education and technical assistance to healthcare teams of systems with the purpose of increasing HIV clinical workforce capacity and competence. Goals are to improve outcomes at all points of the care continuum in alignment with the National HIV/AIDS Strategic Plan and to reduce HIV incidence by increasing rates of viral suppression among people with HIV. The program has five components. The first is core training, which includes interactive presentations, communities of practice, clinical preceptorship, and clinical consultation. The second component is the Minority AIDS Initiative, which supports education, training, and technical assistance for providers serving patients with minority race/ethnicity backgrounds. The third and fourth components are practice transformation and practice transformation expansion, which are implemented with select RWHAP and Health Center grantees to build capacity for providing HIV care. The fifth component is the Interprofessional Education Project, which offers education for students, faculty, institutions, and health professionals. AETCs offer clinicians free access to six types of telephone and electronic consultation services covering topics related to HIV prevention and treatment, such as HIV and substance use; hepatitis screening and treatment; and HIV testing and care during pregnancy, labor, delivery, and postpartum. AETCs offer the National HIV Curriculum e-learning platform, which provides current information on prevention, diagnosis, and treatment for providers. Users can earn continuing medical education and pharmacology credits.

HAB supports a Models of Care program to determine which clinical care models and components lead to better outcomes for RWHAP clients. The project includes a mixed method study analyzing medical record, provider survey, provider interview, and client focus group data. Models of care were primary, specialty, and integrated. In the primary model, the care provider leads HIV and general medical care and refers patients out for care for other infectious diseases and other specialist services. In the specialty model of care, the provider is an HIV or infectious disease specialist who leads HIV and general medical care and refers patients out for other specialist services. In the integrated model of care, primary and specialty care providers collaborate in all aspects of patient care. The study addressed research questions about designing models of care, patient experiences, and clinical outcomes. Results reports are currently in development.

The final project Ms. Matosky described was the RWHAP Program Chart Abstraction project, the purpose of which is to collect relevant, accurate, complete data on the extent to which care provided through RWHAP is meeting HHS and USPSTF guidelines. Medical record data on core and supplemental variables will be collected from 50 RWHAP organizations beginning in 2020. Core data will be collected annually. Supplemental data on STI screening and treatment will be collected during Option Years 1 and 3. Hepatitis vaccination, screening, and treatment data and opioid dependence screening and treatment data will be collected during Option Year 2. Researchers will collect data on provider demographics, discipline, licensure and board certification, as well as on provider-to-patient ratio and whether the clinic is fully staffed. Data will be collected on patient demographics, comorbidities, and clinical care.

Presentation: The PATHways Program at the Vanderbilt Comprehensive Care Clinic: An Innovative Approach to Reach Traumatized, Marginalized People with HIV Otherwise Not Engaged in Care

Robertson Nash

Dr. Nash said the PATHways program is part of the Vanderbilt Comprehensive Care Clinic, which currently serves more than 4,000 active patients, is the largest HIV clinic in the Southeast United States, and is a Ryan White excellence clinic. It is funded by RWHAP Part B, the Tennessee Center for AIDS Research, and the Southeast AETC. The PATHways program is designed to serve people who do not respond well to care provided in 15-minute clinical visits. Some patients respond well to annual visits to check laboratory results, while others do not. The PATHways program was developed to serve the latter. The program serves people who have adhered to ART, are socially marginalized and traumatized, have untreated mental illness, have active addictions, or who experience poverty or poor education. Dr. Nash pointed out that no one has only one of these problems. The majority (58%) of PATHways patients are people of color. Most are male (70%) and most are aged 25 to 44 years (66%). Patients' age range is 22 to 70 years.

PATHways patients are identified through a validated screening process or internal referral. The screening process identifies patients who are not virally suppressed and missed their last clinical appointment. It identifies about 90 patients per quarter. Patient assessments identify their strengths and risks in the domains of mental health, clinical care, physical environment, social environment, and education. Assessments take about 20 minutes to complete using an iPad. Results support patients in developing their own individualized care plans. Discussions always start with strengths.

The clinic also assesses patients' history of adverse child events, which are associated with HIV treatment adherence and outcomes. A majority (61.1%) of PATHways patients report having experienced four or more adverse childhood events. A PATHways study found that these patients were eight times more likely to miss their next appointment compared to those with a history of no more than two adverse childhood events. They were twice as likely than patients with a history of no more than two adverse childhood events to have a viral load greater than 200 copies per milliliter. Results have been accepted for publication in *Journal of the Association of Nurses in AIDS Care*.

Dr. Nash presented data on viral load between intake and most recent test for 28 active patients. Viral load has decreased for 21 of these patients. Large proportions of PATHways patients are achieving and maintaining viral suppression or significant declines in viral load. In the sample of 28 patients, fewer than 10 percent were virally suppressed at intake. More than 70 percent had achieved viral suppression by their first lab draw. These rates of suppression have been maintained, in some cases for more than 2 years.

PATHways aims to keep patients in care because they believe this is better for people who have been traumatized or marginalized than referring them elsewhere after 6 to 12 months.

PATHways uses a nursing paradigm of care. In the nursing model, an interdisciplinary team with case managers and an advanced practice nurse meet weekly to discuss cases and approaches. The lead clinical provider meets with the patients for an hour once per month. Each patient sees a licensed social worker monthly. Validated screening tools inform all aspects of care, including behavioral health. Behavioral health approaches are dialectical behavior therapy and behavioral activation, which teach self-efficacy. Dr. Nash said the social environment in the Southern United States is often hostile to HIV patients' survival and well-being. The clinic cannot fix this, but it can teach skills for coping with that environment.

Dr. Nash said PATHways is not appropriate for patients who refuse to engage in HIV care or behavioral health care, who have a history of missing appointments and do not respond to reminder calls from the clinic, or who are unmotivated to even consider freedom from addictions. Lessons learned from implementation include necessity of patient-centered care, the need to integrate AIDS service organizations into clinical care, and the need to provide care in community-based settings.

A key factor in the PATHways Program's success is hiring nurses with experience with HIV and similar patient populations. Another key factor is team members working together in the same office space where they can support each other to avoid burnout. In addition, team roles are interdependent.

Presentation: Ending the Epidemic

Johanne Morne

Ms. Morne said that understanding health equity issues is foundational to AIDS Institute work. She said that discourse about ending the HIV epidemic did not begin with government but with community. Community members can leverage their history of achieving to reduce or eliminate HIV occurrence. In New York State, community activists were able to gain political and other resources. Implementation strategies reflect community input. New York's goal is to reduce the number of new HIV diagnoses by 55 percent by the end of 2020. Ms. Morne noted that metrics

about whether that goal has been achieved will not be available until 2021. In New York, new diagnoses decreased 18 percent between 2013 and 2017.

In 2017, about 50 percent of eligible people in New York State had been tested for HIV at least once, according to self-reports. Government officials and community members considered how to improve this. New York State mandates physicians to offer HIV testing to all patients aged 13 years or older. Primary care providers are vital for success. Community members said they wanted home testing. New York City Department of Health and Mental Hygiene and the State Department of Health AIDS Institute collaborated to implement a pilot project to assess the effects of home testing. Researchers gave free home test kits to participants. Researchers prioritized recruitment of MSM and trans people. The effort was successful and led to a statewide initiative. More than 40 percent of participants had never before been tested for HIV.

Between 2013 and 2017, viral suppression among people in New York State diagnosed with HIV and in care increased 6 percent. The State health department's goal is 95 percent viral suppression in this population by the end of 2020. This will require helping patients to make informed decisions, using resources available through CDC's U+U (Undetectable=Untransmittable) campaign, and developing effective, tailored messages for communities in need. Efforts must be based on community input. Providers must inform patients of the benefits of viral suppression. Success requires reducing stigma. The AIDS institute currently has 32,000 patients who have a PrEP prescription. Their goal is to increase this to 65,000 patients by the end of 2020.

AIDS Institute personnel are discussing the potential risks and benefits of rapid ART initiation, introducing patients to the option of medicine at the time of diagnosis. The team has developed a guideline for rapid ART initiation. The guideline presents a definition of rapid ART initiation and how to implement it. Clinicians are responsible for helping patients understand the impact of their decisions.

AIDS Institute outcomes reflect success for all demographic groups. However, disparities continue to affect communities of color and men who identify as bisexual and other MSM. The organization endorses trauma-informed care. They are conducting a pilot test to study the impact of integrating trauma-informed care into all treatment services.

The Department of Health developed HIV Special Needs Plans, a managed care option for people living with or at-risk for HIV. People who are homeless and HIV-negative and trans people who are HIV-negative are eligible. The program supports clients in addressing social determinants of health, STIs, and general wellness.

The AIDS institute had worked with a community advisory group for 2 years to develop a peer certification program that focuses on HIV, hepatitis C, harm reduction, and PrEP. Empire State College awards 28 to 32 credits at no cost to program graduates. The program was to support students in qualifying for meaningful work and livable wages.

The AIDS Institute developed the Clinical Education Initiative, which is implemented in partnership with the regional AETC to give care providers access to current information about care and guidelines through an "Ask an Expert" call line.

The AIDS Institute worked with a 53-member task force representing diverse community stakeholders to develop a plan for ending the HIV epidemic in New York State. Advisory groups were formed to develop strategies for priority communities. The task force will hold the health department accountable for implementing the strategies in the plan.

Ms. Morne said that, while a “one-stop-shop” approach is a priority in developing plans to end the HIV epidemic, it is important to understand why that can be challenging. The main focus should be to ensure that all community members have input and authority to achieve change, and that providers respond to community needs.

Ms. Morne acknowledged that some plan components will be successful while others will not. All performance data must be shared so that jurisdictions can learn from each other’s experiences.

Panel 4 Discussion

Dr. Taylor asked how to ensure that best practices and models of care are implemented in diverse settings. Hoping people will become aware of them then implement them is not enough. Many clinical sites are administered by medical corporations. How can best practices be incentivized? Possible ways include making funding contingent upon implementing best practices and basing grades or audits on best practice implementation. Without incentives, plan developers are only hoping optimal models will be adopted. Dr. Nash said his experience is that it is hard to obtain funding to expand best practices. State policymakers can be barriers. It would be helpful to have a State department of innovative clinical practices that provides funding and dissemination support. Ms. Morne said policymakers must be flexible regarding how plans can be implemented. Implementers have to be willing to change in response to lessons learned. They must get approval and support from key stakeholders. Dr. Cheever said a goal of the current initiative is to explore different models of care. She said incentivizing must encourage not just overall increased viral suppression but also decreases in disparities. She said RWHAP includes requirements for the types of services grantees deliver. Ms. Morne added that best practice implementation can be facilitated by care teams being flexible about their roles and practices.

Dr. Anderson asked if PATHways has incorporated screening instruments into EHRs. She asked if patients completed their own assessments and, if so, how program staff address patients with literacy challenges. She asked Ms. Morne how the peer education certification program was developed and if certification is linked to job opportunities. She asked how potential participants become aware of the program, what the application process is, and how it links with community health workers.

Dr. Nash said the screens are not yet integrated into EHRs. Paper copies of screen results are shared with care providers before patients’ initial appointments. He said some patients are not literate and cannot complete the screen. Patients with unmanaged delusional disorders also cannot complete the screen. He added that the screen has only been validated in English. Currently, the screen can only be used with literate English-speaking patients.

Ms. Morne said that about 300 people have graduated from the peer certification program. About 180 people are enrolled currently. Self-reports indicate that about 45 percent of graduates have become employed. Her agency also disseminates information about job opportunities through a listserv, which peer certification program graduates can use. The agency is exploring possible partnerships with employers. Ms. Morne said the advisory board comprises people with lived experience in priority areas. They determine who is accepted into the program and who graduates. Graduates report they have meaningful wages and purposeful work. Ms. Morne pointed out that some people receive HIV care coverage benefits contingent on income limits. This is a consideration when seeking employment.

Dr. Mermin said New York data presented seem to indicate success is plateauing. He said this could be due to increased testing and diagnosis or to plateauing incidence. He asked if Ms. Morne knew which, if trends vary by region, and, if so, does this mean response should vary by region. He asked presenters what they would ask their governors for if they could ask for just one thing over the next 3 years. Ms. Morne said she expects that when 2018 data are released they will show a continuing trend toward decreasing HIV incidence. She said the Ending the Epidemic initiative has provided consistent goals and objectives and amplified annual reductions in incidence. She does not think declines are leveling off. But stakeholders must continue to address disparities, including prevention needs among priority communities, such as people who use drugs. Ms. Morne said different regions have different needs to consider in planning. State regions and New York City boroughs have their own steering committees that develop their own priorities, goals, and objectives.

Dr. Nash said he would ask the governor for housing. Tennessee has dire need, with 20,000 people on the waitlist. He also perceives a need for harm reduction. Also, systems need to support community-based care. He is unable to provide it because Vanderbilt perceives it to be too risky. He does not know how to change this. Ms. Morne said she would ask the governor for continued support of current efforts.

Dr. Gayles asked if PATHways served HIV-negative clients and, if so, what the results had been. Dr. Nash said a person has to be HIV-positive. The clinic provides PrEP for PATHways patients' partners and for patients who are insured. He believes HIV-negative people who are eligible for PrEP would benefit from an intervention such as PATHways.

Mr. Hursey noted that patients' successes are often attributed to interventions while poor outcomes tend to be attributed to patient choices. He asked Dr. Nash to elaborate on eligibility requirements that disallow patients who refuse to engage in HIV or behavioral healthcare. He noted that Dr. Nash had referred to skin color rather than race. He also said that racism is traumatizing and he would have preferred for it to be addressed in Dr. Nash's presentation. Dr. Nash agreed that racism is traumatic. He said he does not believe race is a biological factor with meaningful categories. He said it is useful to talk about race, that the topic is not discussed often enough, and this makes it more difficult to discuss. Dr. Nash said program staff are working to identify people who do not want the PATHways model of care but also need more than the 15-minute clinical visit model. They are working to develop PATHways so that it meets those people's needs, and to reach out to them and work with community AIDS service organizations.

Ms. Morne said that momentum toward change begins with people feeling energized. She said that conversation about ending the epidemic began in 2013. A blueprint was produced in 2015, followed by resources to support the blueprint. Implementation programming began in 2016. Data on 2018 progress will be presented a few weeks after the current CHAC meeting. Initial momentum started before funding became available. Small things such as developing and displaying a logo can motivate people to act. When people wonder how to make progress, they should consider that there are many opportunities to do so.

Guidance for CHAC Resolutions and Recommendations

Antigone Dempsey

Ms. Dempsey provided guidance for CHAC resolutions and recommendations. She explained that resolutions describe a position, whereas recommendations are for taking specific action. She said that members who want to discuss a recommendation or resolution should raise their hands during the business meeting to indicate this. The group then deliberates and, if someone makes a motion, votes. If the motion passes, a workgroup or ad hoc group with the initiating CHAC member develops text, which the co-chair must approve. HRSA provides technical assistance for developing text. In some cases, a workgroup works on developing a concept before the CHAC votes.

Update on the Recency Assay-Based Incidence Estimation Pilot Project

John Brooks, MD, Medical Epidemiologist, CDC, National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention, Division of HIV/AIDS Prevention

Dr. Brooks presented a CDC director proposal to consider assessing assay-based recency testing to determine how recently a patient was infected with HIV. Dr. Brooks explained that new efforts to test and diagnose can lead to an increase in total diagnoses. This may be due to new infections or to old infections that are being discovered as a result of increased testing and diagnostic efforts. CDC thinks the latter is likely. They need to state this with authority, which recency assays would allow. The test is currently being used in other countries. It assesses how tightly HIV antibodies bind to a detector. The longer a person lives with HIV, the more tightly their antibodies bond to substrates. Tightness of bond is referred to as “avidity.” Low avidity indicates new infection. CDC has used these assays in the past. Agency staff have discussed difficulties differentiating true new infections from existing infections that are newly diagnosed. They developed a recency testing algorithm that would support this distinction in incidence assessments using the results of recency assay testing. They are considering launching a pilot test of the method with health departments. The estimated pilot project cost is about \$10 million. Assays would be performed at CDC’s central laboratory to avoid burden on other laboratories and the costs of training, technical assistance, and monitoring. Recency testing would be conducted in parallel with existing incidence estimation efforts. Analysts would compare results of both approaches.

The assay is conducted with an antibody-reactive specimen, which is sent to a laboratory and analyzed using commercially available assay Bio-Rad that has been amended slightly by CDC to determine avidity. Avidity of at least 30 percent indicates the infection occurred at least 6 months prior. If avidity is less than 30 percent, the infection would be classified as recent. To distinguish new infections from established infections associated with low avidity due to ART use (an infected person who has been on long-term ART), the specimen is analyzed for the presence of ARV drugs or viral load assessment.

To conduct assays, CDC must assure confidentiality and protect data from law enforcement. New testing requires Office of Management and Budget (OMB) authorization. CDC will need to have a memorandum of understanding with the Food and Drug Administration (FDA) or obtain an Investigational Device Exemption for use of a non-FDA-approved assay for surveillance. Laboratory workflows would change, including storage and shipping of specimens. Data collection will include a complete HIV testing history. The research team needs Institutional Review Board (IRB) approval for using assays to detect HIV and to collect ARV history.

Samples would be collected at local laboratories, then shipped to public health repository laboratories. Health departments would identify specimens eligible for recency testing and ship them to the CDC laboratory, which returns results to health departments. Health departments would then submit results to the National HIV Surveillance System. Specimens would be discarded at some time (TBD) after analysis.

Dr. Stoner asked if recent diagnoses would be recorded in existing databases. Dr. Havens said reviewing clinical charts is expensive and time consuming. He asked if the study can be done without this. Dr. Brooks said reasons for avidity cannot be determined from the assay alone.

Ms. Morne said that incidence is an estimation whereas diagnosis is factual. She asked why CDC is proposing this type of estimation. She said direct diagnosis and measures of social determinants of health support practical work in the field.

Mr. Hursey asked what the test's utility would be. He said implementation could have harmful consequences to people affected by criminalization. He consulted the community he services, which expressed these concerns. Dr. Brooks said the assay has become more sensitive and can estimate incidence better than previously. Mr. Hursey said it would not change what practitioners can do in the field.

National HIV/AIDS Strategy (NHAS)/EHE Workgroup Report

Greg Millett, MPH, Vice President, Director of Public Policy, amfAR, Foundation for AIDS Research

Dr. Brooks invited Mr. Millett to present the NHAS/EHE Workgroup report on the proposed pilot study. Mr. Millett reminded participants that the workgroup was established in April. He and Jennifer Kates are co-chairs. The group's purpose is to provide input to the CHAC regarding updating NHAS and to address implications of EHE vis-à-vis NHAS. The workgroup includes members who represent EHE sites and who are not members of CHAC. The group has drafted and approved terms of reference. It has shared information about EHE planning and meetings with agency principals responsible for EHE. The workgroup discussed input on the EHE sites' amfAR database, and has discussed and provided recommendations about the proposed CDC pilot project. Mr. Millett said the group also thought the study could present concerns for communities. In addition, the workgroup is concerned about study cost and effect on lab work flows. They gathered input from three panels, each representing one of three constituencies: health department officials, laboratory/surveillance officials, and community advocates with experience and understanding of HIV surveillance. The workgroup asked panelists to answer three questions:

- 1) How will the proposed pilot project serve to improve U.S. efforts to estimate incidence of HIV infection, reduce new HIV infections, and advance national and health department efforts to end the U.S. HIV epidemic?
- 2) Will findings of the proposed project be adequately generalizable to allow for expansion of the technology nationally?
- 3) What vulnerabilities should CDC anticipate as a result of this pilot project, and how could these be addressed?

Health department officials were concerned about the relative benefits of recency assay testing compared to the existing CD4 testing method. Many participants said the new method costs substantially more. Participants expressed concern about feasibility of adhering to the proposed project timeline given the requirements for OMB and FDA authorization, disruptions to laboratory workflow, and potential community concerns regarding phylogenetic testing. Participants also reported that recency testing has been helpful in responding to opioid-related outbreaks.

Community member call participants also expressed concerns about cost, relative value, and privacy. They expressed concerns about using results to prosecute individuals for having a recent HIV infection. Participants said CDC should engage with the community more before implementing the project.

Laboratory and surveillance officials asked why CDC would return to using a method that has been discontinued for a current method they understand to be better than the proposed approach. Participants said it would be a burden to change data reporting procedures. They also said that ART and PrEP could result in invalid data.

The workgroup asked CDC determine whether other products are available. CDC responded that the proposed assay is the only one that could get FDA approval within the proposed timeframe. The workgroup said CDC should specify what information the pilot study is expected to produce. The workgroup recommends reviewing available evidence about recency testing and other methods for estimating incidence. It also recommends evaluation of costs associated with the proposed new testing approach, including need for authorization, laboratory workflow changes, and shipping requirements.

If the pilot study is implemented, the workgroup recommends establishing a process to support ongoing community involvement, such as community advisory boards. The group recommends conducting a process evaluation that would identify the advantages and disadvantages of the new testing approach. The workgroup also recommends that CDC provide support for health departments and laboratories for transitioning to the new testing method. Finally, the workgroup recommends that, if the pilot test is implemented, it should evaluate the testing technology in terms of cost, feasibility, and accuracy.

Mr. Millett said the workgroup welcomed input from CHAC regarding the pilot project and whether it should be implemented.

Recency Assay-Based Incidence Estimation Project and the NHAS/EHE Workgroup Report: Discussion

Dr. Mermin asked if participants who work in State health departments have observed increases in diagnoses following increased testing efforts. Dr. Philip said this happened in San Francisco. She asked if CD4 testing and results of most recent HIV test could provide the same information as the proposed recency assay. She said that, in anticipation of increased diagnoses, the health department made statements to policymakers explaining that this this would happen and why. Dr. Gayles said that when the Maryland Department of Health increased testing they notified policymakers that this would likely increase diagnosis. Dr. Saag said CD4 counts are not very precise, while viral load of less than 200 with a new HIV diagnosis can be assumed to indicate a

history of ART. Dr. Brooks pointed out that PrEP alters antibody and antigen responses. Dr. Saag suggested asking patients if they have taken PrEP.

Dr. Akolkar suggested using a nucleic acid test for recency, since CDC requires this test. Dr. Brooks said the incidence assay allows a larger timeframe for testing (i.e, a larger window of time for a person to be “recent”). Dr. Akolkar asked how the test would benefit patients. Dr. Brooks said the benefit is improved surveillance.

Dr. Havens asked if individuals would ever have access to their own data. Dr. Brooks said an IRB would have to decide that. Dr. Havens asked if it is standard to report results of tests that have not been FDA approved. Dr. Brooks said they could be reported depending on the circumstances and ethical review of the project but the test and study intents must be explained clearly.

Mr. Hursey asked if data would be collected when patients are starting laboratory work. Dr. Brooks said data collection occurs immediately after HIV testing.

Ms. Morne asked if there are other surveillance data collection efforts in which results are not provided to individual participants and do not have clinical impact. Dr. Brooks said he was not aware of any. Dr. Mermin said this is the case with some other CDC studies.

Dr. Stoner expressed concern that data could be used to prosecute people for recently transmitting an infection in States with HIV criminalization laws. This is especially important given the stigma associated with HIV. Dr. Brooks says CDC does its best to maintain confidentiality. The project’s terms of confidentiality state that law enforcement cannot access specimens. He said current biogenetic testing done for surveillance cannot be used to infer directionality. With recency testing, if one member of a dyad has a more recent HIV-positive test than the other, someone might want to interpret that to mean that the person who tested positive earlier had infected the other. Mr. Millett said this question was raised frequently during panel discussions with the workgroup. Mr. Millett said that, if the pilot test is implemented, there should be evaluation of adverse effects of the testing.

Dr. Belzer asked if pilot test results could provide information that would allow future estimates of incidence to be made without ongoing primary data collection. Dr. Brooks said this may be possible.

Mr. Millett asked if any CHAC members requested changes to the workgroup’s letter to CDC. Dr. Belzer asked if the workgroup had consulted an expert on how well data would be protected. Mr. Millett said the workgroup had discussed with Catherine Hansen, an attorney at HIV Law Project, what the possible implications of implementing the test would be in States with HIV criminalization laws. Ms. Hansen expressed concerns about the consequences of prosecutors gaining access to data. Mr. Millett invited participants to recommend other attorneys for consultation on this issue.

Ms. Parkinson agreed that the pilot should only proceed if it includes robust community engagement. She said the CHAC should provide guidance on what that would mean, possibly within a recommendation letter. Ms. Hauser said she was concerned that the risk of undermining community trust by implementing the pilot test could outweigh the benefits. She asked if CHAC was against implementing the pilot test or in favor of it, conditional on following CHAC recommendations. Ms. Parkinson said CHAC should consider whether to recommend project implementation; not just CDC should implement the project. Ms. Parkinson said existing technologies could yield the same data as the proposed project; that project financial and labor

costs are exorbitant; and that the project could undermine community trust, especially in States that criminalize HIV. She reiterated that the project would not have clinical benefits.

Mr. Hursey asked Dr. Brooks if he would appear as a defense witness and explain the data when people are prosecuted for exposing a partner to HIV based on evidence generated from recency testing. Dr. Brooks said he does commit to explaining the data and that CDC has provided consultation for people in this situation. He said he would share and explain information with local doctors and experts and pointed out that support of Federal law enforcement can sometimes be disadvantageous in court.

Dr. Saag said that the study would involve evaluation. He thinks it is important to know the reason for spikes in positive HIV tests. The test would be useful for this purpose and is at least worth exploring. Dr. Havens said that the problem of spikes could be addressed with anticipatory guidance and asking patients directly about their history at a cost of less than \$10 million. He said intent to keep data private may not be enough to protect privacy. Dr. Brooks agreed that these points are important, but a severe critic could also say that increased diagnoses mean increased incidence and that CHAC may want to consider this when developing a recommendation.

Dr. Anderson asked if CHAC wanted to recommend that CDC address CHAC concerns before proceeding with the pilot study.

Dr. Akolkar said that he did not see how the new method of estimation would be different. Dr. Brooks said the algorithm and follow-up test for ARV were new. Dr. Akolkar said that viral load spikes just after infection, which would need to be explained. Dr. Brooks said he understands that CHAC would need CDC to clearly present the value of the pilot test before they can recommend it. It is a recurring theme from the panelists who participated in discussions with the workgroup.

Mr. Millett asked if other CHAC members thought the workgroup's recommendations were strong enough. Dr. Anderson said the group had three options: to recommend for pilot study implementation, to recommend against implementation, or to recommend implementation conditional on addressing concerns in the workgroup's letter. Dr. Havens asked if CHAC could motion for CDC to review the letter then discuss it with CHAC, without implying an endorsement of the pilot study. The letter could emphasize the necessity of addressing community concerns. Mr. Hursey said the process of considering the study had to be done properly to avoid serious consequences. Key community stakeholders must be included in the discussion.

Dr. Havens moved that CDC consider CHAC concerns raised in the workgroup's letter and present responses to CHAC prior to proceeding with the pilot. Ms. Morne seconded the motion. She asked if the pilot would require IRB approval. Dr. Mermin said surveillance projects are not subject to IRB approval as research projects are, but the group would seek expert consultation on ethics. Dr. Saag said this would delay project timelines. He said the pilot would yield information to inform policy. He said he did not think it was necessary to delay implementation 6 months. Mr. Millett said he was unsure whether the pilot study should be implemented. Dr. Cheever said that timing issues could be addressed through convening a brief (approximately 30 minutes) phone meeting to address the topic as needed. Dr. Philip said that, based on her experiences explaining increases in diagnosis following increased testing, she does not think the pilot test is necessary. Dr. Hauck said she did not think the test would have benefits. Dr. Saag said that results would support identification of hotspots of recent infection in microenvironments, allowing focused, tailored intervention.

Dr. Stoner asked the committee to vote on Dr. Havens's motion. Mr. Millett said he was more in favor of voting against pilot project implementation. The motion carried.

Ms. Hauser moved for CHAC to recommend against implementing the pilot study. Mr. Millett seconded. Dr. Saag said he opposed the motion. He thought the study had potential to yield important public health information and it would be a mistake to end it without gathering additional information. The motion did not carry.

Perinatal Infectious Disease Workgroup Report

Jean Anderson, Peter Havens Co-Chairs

Dr. Anderson said the workgroup was suggested during the May CHAC meeting. The workgroup had to revise terms of reference and have a CHAC vote of approval before proceeding with work. Dr. Anderson referred CHAC members to the terms in its report. The workgroup proposed that it will advise CDC and HRSA regarding prevention, screening, and diagnosis of perinatal infections, focusing on syphilis, hepatitis B virus, hepatitis C virus, and HIV during pregnancy and among women with reproductive potential. This may include advising in: provision of guidance for practitioners regarding the significance of these infections in women of childbearing potential and pregnancy and current recommendations for screening; improving linkage between primary care, pediatrics, and obstetrics regarding prevention and screening of these infections; and alignment of programmatic objectives and activities between different perinatal infections. Dr. Anderson asked if there was any discussion on the terms of reference. Dr. Anderson requested a motion to accept these terms of reference. Dr. Saag so moved. Several members seconded. The motion passed unanimously.

HIV and Aging Workgroup Report

Michael Saag, Chair

Dr. Saag said the meeting had not conducted more work since its most recent presentation. He asked members to submit ideas for workgroup activities

The co-chair recently resigned. Dr. Saag asked for volunteers to replace the co-chair. Ms. Searson volunteered.

Hepatitis Workgroup

Lynn Taylor, Chair

Dr. Taylor said the committee was proposed at the last meeting. One reason for this is that the two-step hepatitis C diagnostic process is a major barrier to eliminating the disease. Other countries are effectively implementing one-step hepatitis C virus RNA testing technologies. Phlebotomy may be a barrier for people who inject drugs, people without stable housing, and people without ready access to healthcare. Fingerprick sampling can facilitate access and rapidly scale-up diagnosis. Development, validation, and regulatory approval of fingerstick technology must be a priority. The other reason for forming the workgroup is that in 2019, CDC reported that less than one-third of U.S. adults at high-risk for hepatitis B virus were protected despite development of a safe and effective vaccine more than 40 years ago. This leaves 64 million high-risk adults susceptible. Strategies for increasing vaccination rates are needed.

The workgroup proposes to provide guidance to CDC and HRSA regarding gaps in systems-level enhancements to accelerate elimination in the United States. Guidance would focus on:

- 1) Increased public and provider awareness and knowledge regarding viral hepatitis disease, prevention, testing, and treatment;
- 2) Increased access to and use of viral hepatitis prevention services;
- 3) Accelerated implementation of viral hepatitis testing recommendations and rapid linkage to care;
- 4) Expanded healthcare provider capacity to treat viral hepatitis;
- 5) Identification of strategies ensuring access to elimination efforts to all populations; and
- 6) Conducting research and surveillance to improve the detection and monitoring of viral hepatitis.

Dr. Taylor said she would add that the services in the second focus area should include opiate agonist therapy, methadone, and harm reduction—with the goal of ensuring each individual has a brand new syringe for every injection. She recommended that focus area three refer to screening rather than testing recommendations. Dr. Taylor said that focus area 3 should specify linkage to care is typically effective for vulnerable populations when services are co-located and conveniently located. She said that area four refers to expansion of co-located embedded care for viral hepatitis in diverse and accessible settings. She recommended that the description of area 5 should say “expansion of strategies ensuring access to elimination efforts to all populations.”

Dr. Anderson moved to approve the hepatitis workgroup’s expanded charge. Ms. Searson seconded. Ms. Searson said she thought the workgroup should recommend dedicated funding for hepatitis C. She said that provider cultural bias is probably the largest barrier to treating the disease. She also said Medicaid should be expanded. Dr. Taylor concurred with these points. She also said she concurred with the recommendation for the workgroup to include someone with lived experience with viral hepatitis.

Dr. Anderson asked CHAC to vote on the motion. The motion passed unanimously.

Update from the Presidential Advisory Council on HIV/AIDS (PACHA) Liaison

Carl Schmid

Mr. Schmid said PACHA currently has 11 members and would like to add more, especially women living with HIV and trans people. HUD and CMS participated in the last PACHA meeting. Meetings are webcast and are reaching hundreds of people. PACHA has held three meetings this year. The first was with the Secretary and HHS agency directors. The Council has focused on the EHE initiative. PACHA encourages people to voice their concerns to the council. The meeting was held in Jackson, MS, with a focus of HIV among African Americans in the rural South. The meeting included listening to community concerns as well as a site visit to a community-based organization. Field meetings have greater attendance than those held in Washington, DC, with robust public comment and interaction among participants. The second meeting was convened in Miami, FL, with a focus on the Latinx community in Florida and Puerto Rico and HIV. Participants included people from Puerto Rico.

At this meeting, the PACHA passed three resolutions. One was to ensure meaningful community input at all levels of the EHE plan. The second was to support innovation to end the epidemic, to break down barriers. Innovations include telehealth, mobile vans, and flexible clinic hours. The third resolution was to encourage the Secretary to ensure increased funding for programs to end the epidemic. The budget is small after being divided by 57 jurisdictions. Scaling up activities will require increased funding. The resolution also stated there should be no reductions to HIV program budgets. PACHA expressed concern about the administration working to reduce the protections specified in Affordable Care Act Section 1557. Assistant Secretary Giroir responded by meeting with members of PACHA, including CDC Director Robert Redfield, who stated that reducing protections increases stigma. Dr. Redfield issued a letter stating that CDC does not allow discrimination based on HIV status. PACHA advocates positive support for people most vulnerable to HIV. The next meeting will likely be in February in Washington, DC. PACHA hopes this will be after the next Federal budget is released so that they can discuss the budget at their meeting.

Mr. Schmid said he and his co-chair were invited to serve on President's Emergency Plan for AIDS Relief scientific advisory boards and to benefit from lessons learned internationally.

Update from the Presidential Advisory Council on HIV/AIDS (PACHA) Liaison: Discussion

A CHAC member asked if everyone on PACHA had resigned and been reappointed. Mr. Schmid said this is standard when a new President of the United States is elected. He said it took effort to get new members appointed, but there has never been an effort to eliminate PACHA.

Business Section

Dr. Anderson opened the floor.

Mr. Hill-Jones recommended that program guidance for PS 19-1906 state more clearly how grantees are expected to engage with communities. He asked how to encourage CDC to establish a workgroup on community engagement in EHE planning and to establish expectations for community engagement in plans due December 31. Mr. Hill-Jones said that State plans should include local plans that were revised after implementing community engagement guidelines along with letters from community stakeholders verifying the engagement. Guidance should clarify what types of activities constitute community engagement. Current guidance refers only to attendance, not developing meaningful strategies. Finally, Mr. Hill-Jones said community engagement should be defined to include the HIV workforce community. Dr. Anderson asked which of these recommendations was most urgent. Mr. Hill-Jones said that only establishing the workgroup was not urgent. All other recommendations are urgent because they are regarding the community engagement for local planning guidance for implementing grants funded under mechanism PS 19-1906. Dr. Stoner suggested creating a workgroup that would develop a document for CHAC to consider. Mr. Hill-Jones said the issue was urgent since it impacts deliverables due December 31. Dr. Dempsey said CHAC could write a letter as long as it was in response to an approved motion. Mr. Hill-Jones said he would share a draft of the letter that he was already developing. Dr. Brooks pointed out that plans can be developed iteratively and guidance can be as well. Mr. Hill-Jones said communities may not be involved at all in initial plan drafts and it is urgent to convey the importance of community engagement to grantees immediately. Dr. Havens asked how soon CHAC had to act to support this. Dr. Brooks said it was too late to affect drafts due December 31, but that CHAC could have meaningful impact if it acted in the next 4 to 6 months. Dr. Brooks confirmed to Mr. Hill-Jones that communities are to create their own plans.

Mr. Hursey requested that Catherine Hansen and Jeanette Oxford be added to the workgroup on EHE and recency testing. He also requested a panel to discuss community engagement.

Dr. Taylor requested that the next meeting agenda include an opportunity for CHAC to speak with a CMS representative. It is the 5-year anniversary of the CMS letter stating that Medicaid beneficiaries should have access to direct acting antiviral therapies for hepatitis C cure. However, many State Medicaid programs restrict access. Dr. Taylor would like CDC to discuss why they (CMS) have not been enforcing regulations and their letter, and how CHAC can help. She also requested a presentation from FDA about the status of improving hepatitis C diagnostic testing. If this is not possible, she would like a presentation from practitioners who are applying innovative technology about how they are doing it and how others can replicate their successes.

Mr. Hill-Jones moved to adopt a CHAC workgroup on community engagement. It passed unanimously. Mr. Hill-Jones volunteered to chair the committee. Ms. Parkinson agreed to co-chair. Mr. Millett recommended referring to the NHAS/EHE workgroup report to develop the scope of the new workgroup.

Ms. Hauser said she sent materials requesting a CHAC recommendation that Federal partners should include young people in planning. She said the recommendation includes suggestions such as including young people in developing guidance for PrEP. Ms. Hauser pointed out that people ages 13 to 24 years are least likely to engage in care rapidly and least likely to be virally suppressed. She said there is a need to counter the requirement of parental consent to access PrEP. She said barriers affect young people substantially more than others and that this is especially true for young

people who are bisexual, trans people, and trans people of color. She recommended rescinding actions to expand religious exemptions for service providers and to limit confidentiality for young people seeking healthcare. She asked CHAC to request Federal partner support for CDC programs that offer sex education about PrEP and routine HIV testing at a cost of about \$10 per person. Dr. Anderson said a quorum was no longer available. She requested Ms. Hauser write a draft letter and distribute it to CHAC members for comment. Discussion and voting would be at the next meeting. Dr. Gayles said the discussion should address best practices for engaging young people. Ms. Parkinson said the meeting could include a panel discussion, with a panel that includes young women and new mothers.

Dr. Gayles expressed interest in discussing how best to increase use of non-biomedical prevention efforts. He thinks it would be useful to apply the PATHways approach presented by Dr. Nash to prevention. He added that there are commonalities in planning to address chronic diseases and suggested discussion about how to leverage best practices and resources to efficiency.

Ms. Parkinson suggested that the next meeting agenda should include discussing how to connect black women aged 35 years and older with PrEP.

Dr. Cheever thanked participants for their work and adjourned the meeting at 2:50 p.m.