

**U.S. Department of Health and Human Services
Centers for Disease Control and Prevention
Health Resources and Services Administration**



**Virtual Meeting of the
CDC/HRSA Advisory Committee on
HIV, Viral Hepatitis, and STD Prevention and Treatment
November 5 and 6, 2020**

Record of the Proceedings

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Executive Summary

The United States (U.S.) Department of Health and Human Services (HHS); the Centers for Disease Control and Prevention (CDC) National Center for HIV/AIDS, Viral Hepatitis, Sexually Transmitted Diseases (STDs), and Tuberculosis (TB) Prevention (NCHHSTP); and the Health Resources and Services Administration (HRSA) HIV/AIDS Bureau (HAB) convened a meeting of the CDC/HRSA Advisory Committee on HIV, Hepatitis, and STD Prevention and Treatment (CHAC). In response to the COVID-19 pandemic, the proceedings were held virtually via Zoom on November 5 and 6, 2020.

CHAC members discussed the **COVID-19 pandemic** and its impact on the workforce, clinics, and patients. Specifically, CDC/HRSA programs have worked to address and adapt to shifts in resources in response to the pandemic. There have been reduced opportunities face-to-face patient-provider interactions and falling rates of HIV and STI testing. Telemedicine and home-based testing may be viable alternatives to address these issues.

Presentations were made to update CHAC on workgroup activities. The **Perinatal Infectious Disease Workgroup** presented their recommendations to standardize and improve perinatal infection screening and health outcomes. The **HIV and Aging Workgroup** presented recommendations to improve clinical assessment for people with HIV as they age. The **Viral Hepatitis Workgroup** recommended a national strategy to develop hepatitis C virus (HCV) diagnostics. The **EHE Community Engagement Workgroup** recommended drafting a Community Engagement letter to CDC/HRSA to gather guidance for EHE Year 2.

Presentations were also made on two key issues related to the nation's response to HIV, STDs, and viral hepatitis. These key issues were:

Increased community engagement within the Ending the HIV Epidemic (EHE) initiative

Panelists discussed how collaboration with other community organizations will help address barriers, build or maintain strategic partnerships with new and existing community providers, develop opportunities for meaningful engagement among peers, and include people with HIV in implementation and decision-making. Panelists shared their experiences and the potential approaches that CDC/HRSA may use to support jurisdictions to engage people with HIV and community-based organizations.

Trauma and women with HIV

Panelists indicated that women with HIV have five times higher rates of post-traumatic stress disorder (PTSD) than the national average. Social and behavioral factors associated with trauma also increase the risk for HIV infection. HRSA has addressed the intersection of HIV and trauma in a 2015 expert panel and subsequent toolkit. Further strategies are needed to recognize and care for women with HIV who experience trauma. These strategies should be culturally sensitive and trauma-informed, given the high rates of intimate partner violence (IPV), siloes between IPV and sexually transmitted infection (STI) approaches, and the need for early prevention measures.

CHAC Action

CHAC members voted for an interim meeting in early 2021 to discuss a proposed workgroup to address home-based HCV testing.

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
HEALTH RESOURCES AND SERVICES ADMINISTRATION**

**CDC/HRSA Advisory Committee on
HIV, Viral Hepatitis, and STD Prevention and Treatment
November 5-6, 2020**

Minutes of the Meeting

The United States (U.S.) Department of Health and Human Services (HHS); the Centers for Disease Control and Prevention (CDC) National Center for HIV/AIDS, Viral Hepatitis, Sexually Transmitted Diseases (STDs), and Tuberculosis (TB) Prevention (NCHHSTP); and the Health Resources and Services Administration (HRSA) HIV/AIDS Bureau (HAB) convened a meeting of the CDC/HRSA Advisory Committee on HIV, Hepatitis, and STD Prevention and Treatment (CHAC). In response to the COVID-19 pandemic, the proceedings were held virtually via Zoom on November 5 and 6, 2020.

The CHAC is a committee chartered under the Federal Advisory Committee Act (FACA) to advise the Secretary of HHS, Director of CDC, and Administrator of HRSA on objectives, strategies, policies, and priorities for HIV, viral hepatitis, and STD prevention and treatment efforts for the nation.

Information for the public to attend the CHAC meeting virtually was published in the Federal Register, in accordance with FACA rules and regulations. All sessions of the meeting were open to the public. (See Appendix A for the Participant List.)

DFO Opening of the Meeting: Day 1

Laura Cheever, MD, ScM

Associate Administrator

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

Dr. Laura Cheever welcomed participants to the CHAC meeting and called the proceedings to order at 2:00 PM ET. She reminded participants that CHAC meetings are open to the public and that all comments made during the meeting are a matter of public record. Members of the public had an opportunity to provide comment later in the afternoon. Dr. Cheever asked CHAC members to be mindful of their potential conflicts of interest identified by the Committee Management Office and to recuse themselves from voting and participating in those discussions.

Dr. Cheever then conducted roll call and gathered conflict of interest disclosures from members in attendance during roll call on Day 1. She confirmed that 15 voting members were in attendance, thus constituting a quorum for CHAC to conduct its business on November 5, 2020.

Conflict of Interest Disclosures

CHAC Voting Member (Institution/Organization)	Disclosure of Conflict
Jean Anderson, MD (Chair) (Johns Hopkins Medical Institutions)	Recipient of funding from NIH, Ryan White, and Gilead funding; spouse has stock in Merck
Wendy Armstrong, MD (Emory University School of Medicine)	Recipient of funding from HRSA/Ryan White HIV/AIDS Program
Marvin Belzer, MD, FACP, FSAM (Children's Hospital Los Angeles)	Recipient of funding from NIH, HRSA, SAMHSA, and CDC
Demetre Daskalakis, MD, MPH (New York City Department of Health and Mental Hygiene)	Recipient of funding from HRSA/Ryan White HIV/AIDS Program and CDC
Jodie Dionne-Odem, MD (University of Alabama, Birmingham)	Recipient of funding from NICHD
Travis Gayles, MD, PhD (Montgomery County Department of Health and Human Services)	Recipient of funding from HRSA/Ryan White HIV/AIDS Program and CDC
Debra Hauser, MPH (Advocates for Youth)	Recipient of funding from CDC, ViiV, and Gilead
Venton Hill-Jones, MSHCAD, PMP (Southern Black Policy and Advocacy Network)	Recipient of funding from Gilead
Devin Hursey (The U.S. People Living with HIV Caucus)	No conflicts
Jennifer Kates, PhD (Kaiser Family Foundation)	No conflicts
Shruti Mehta, PhD, MPH (Johns Hopkins Bloomberg School of Public Health)	Recipient of funding from NIH and USAID; speaker fees from Gilead in last 18 months
Kneeshe Parkinson (Washington University/Project ARK)	Recipient of funding from HRSA/Ryan White HIV/AIDS Program
Michael Saag, MD (University of Alabama at Birmingham, School of Medicine)	Recipient of funding from NIH, Ryan White, Gilead, and Merck
Bradley Stoner, MD, PhD (Chair) (Washington University School of Medicine)	Recipient of funding from CDC and HRSA
Lynn Erica Taylor, MD, FAASLD(University of Rhode Island/CODAC Behavioral Healthcare)	Recipient of funding from CDC and NIH

Ex-Officio members in attendance included Dr. Pradip Akolkar of the Food and Drug Administration (FDA), Dr. Paul Gaist of the National Institutes of Health Office of AIDS Research, Dr. Neerja Gandotra of the Substance Abuse and Mental Health Services Administration (SAMHSA), Mr. Richard Haverkate of Indian Health Services (IHS), Ms. Kaye Hayes of HHS Office of HIV/AIDS and Infections Disease Policy, and Dr. Douglas Olsen for the Centers for Medicare and Medicaid Services (CMS). There was no one in attendance from the Agency for Healthcare Research and Quality (AHRQ). Also in attendance was liaison representative Mr. Carl Schmid of the Presidential Advisory Council on HIV/AIDS (PACHA).

Introductions, Welcome, and Adoption of Minutes

Jean Anderson, MD

CHAC Co-Chair, HRSA appointee

Bradley Stoner, MD, PhD

CHAC Co-Chair, CDC appointee

Chairs Dr. Jean Anderson and Dr. Bradley Stoner reviewed the day's agenda and the minutes of the July 2020 CHAC meeting.

CHAC Action

Dr. Anderson called a motion to accept the minutes. CHAC members unanimously accepted the minutes with no changes or further discussion.

DFO Welcoming Remarks

Laura Cheever, MD, ScM

Associate Administrator

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

Dr. Cheever provided an update on CHAC membership.

- Mr. Richard Aleshire, a CHAC member from 2016 to 2019, passed away in April 2020.
- Dr. Marvin Belzer, Mr. Devin Hursey, Dr. Jennifer Kates, and Dr. Michael Saag, terms will end before the next CHAC meeting.
- Dr. Douglas Olsen is a new ex-officio member from CMS; Dr. Richard Wild will remain the alternate for this position.
- Ms. Carla Holmes and Ms. Shalonda Collins, HAB staff members, recently joined the CHAC support team for HRSA.

Jonathan Mermin, MD, MPH

Director, CDC, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention

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

Dr. Jonathan Mermin said that the terms of two CDC-nominated CHAC members (Dr. Lynn Taylor and Dr. Bradley Stoner) will expire on November 30, 2020, or for up to 180 days until their replacements have been approved by the Office of White House Liaison (OWHL). CDC

submitted the 2020 CHAC draft nomination package to HHS in February 2020, but their replacements have not yet been approved.

HRSA Update

Brian LeClair, JD, MBA

Deputy Administrator, HRSA

Mr. Brian LeClair updated CHAC and members of the public about new and ongoing HRSA activities, including the HIV/AIDS Program and efforts to address the COVID-19 pandemic. HRSA's mission is to improve health outcomes and address health disparities through access to services, a skilled health workforce, and innovative high-value programs. HRSA is the primary federal agency responsible for improving access to quality services, particularly for underserved and vulnerable populations.

HRSA recognizes the profound impact of the COVID-19 pandemic on partnering organizations and grant recipients. Supplemental funding from partners in Congress has enabled HRSA to continue their commitment to a portfolio of more than 90 programs. Additionally, the Provider Relief Fund distributes \$177 billion through general and targeted distribution payments to pay claims for uninsured patient testing, reimbursing hospitals and frontline providers for COVID-related expenses or lost revenue attributable to the pandemic. As part of this effort, HRSA administers the COVID-19 Claims Reimbursement to healthcare providers and facilities for testing, treatment, and vaccines for uninsured patients. Healthcare providers who have provided COVID-related care to uninsured patients on or after February 14, 2020 can submit claims for reimbursement through the COVID-19 Uninsured Program Portal. As of October 21, HRSA has reimbursed more than \$1.6 billion in COVID testing and treatment claims for uninsured patients.

Dr. LeClair recognized the 30th anniversary of the Ryan White HIV/AIDS Program, one of the largest federal programs that provides HIV treatment, care, and services to low-income patients. Ryan White Program recipients and providers remain committed to improving the lives of all people living with HIV, particularly in the difficult context of the COVID-19 pandemic.

HRSA HAB Update

Laura Cheever, MD, ScM

Associate Administrator

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

Dr. Cheever provided updates from the HRSA HAB. In May 2020, the HAB was reorganized to improve responsiveness to Ending the HIV Epidemic (EHE) initiative. The HIV/AIDS Education, Training, and Technical Assistance Branch was moved under the Office of Program Support; the Special Projects of National Significance Branch was moved under the Division of Policy and Data; and an Eastern Branch and a Midwestern/Pacific Branch were added to the Division of Metropolitan HIV/AIDS Programs. HAB also hired new leadership to address and advise on EHE.

To address the pandemic crisis, HRSA HAB conducts monthly COVID-19 data reports comprising responses from more than 700 providers, who report that CARES Act funding has increased their capacity to deliver telehealth and conduct COVID-19 testing. HRSA HAB also released a COVID-19 Program Letter on September 16, which ensured that funded recipients

are assessing risks and benefits of their emergency response, implementing telehealth, adjusting services to protect client and staff safety, and monitoring HIV/AIDS. To maintain oversight and management activities, site visits are now conducted virtually.

HAB continues to update FAQs to clarify eligibility and recertification requirements, which are major barriers to care. HAB encourages recipients to remain flexible and to understand that some jurisdictions may state “requirements” that are not actually required by law or policy.

In March, HAB released grants to Ryan White Program Part A and B jurisdictions, technical assistance providers, systems coordination providers, and AIDS Education and Training Center (AETC) program for workforce capacity development. Health Departments had to prioritize COVID response over EHE implementation, although EHE activities are slowly resuming. The RWHAP has significantly increased the viral suppression rate from 69.5% in 2010 to 87.1% in 2018. These improvements have reduced some of the disparity gap in viral suppression among Black and transgender people, although some disparities remain and must be addressed. EHE supports this effort by leveraging lessons learned from COVID-19, such as medication refill extensions, self-testing, and telemedicine strategies.

The community requested HRSA develop a jurisdictional directory for EHE points of contact for community engagement, which is now available on the NASTAD website. In response to COVID-19, HRSA has shifted community engagement activities to a virtual platform. HRSA also increased communication channels, including “HAB You Heard” monthly webinars, radio media tours, biweekly newsletters, website updates, listservs, and other efforts.

Additionally, based on community input in 2019, HRSA HAB has developed a series of initiatives to support EHE in 2020. These include:

- Reducing Stigma at Systems, Organizational, and Individual Client Levels in the Ryan White HIV/AIDS Program;
- Building Capacity to Implement Rapid Antiretroviral (ART) Initiation for Improved Care Engagement;
- Improving Care and Treatment Coordination: Focusing on Black Women with HIV; and
- Enhancing Engagement of People with HIV through Organizational Capacity Development and Training.

HAB also has convened four technical expert panels (TEPs) in 2020:

- Part D Reimagine (April 2);
- Assessing Implementation and Impact of RHWAP Rapid Eligibility Determination and Six-Month Recertification Policies and Procedures (February 19-20; June 17-18);
- Dimensions of HIV Prevention and Care for Black Women (October 14, 21, and 28); and
- Aging with HIV (November 17-18).

HRSA BPHC Update

Jim Macrae, MA, MPP

Associate Administrator
Bureau of Primary Health Care (BPHC)

Mr. Jim Macrae reviewed information gathered by the Bureau of Primary Health Care (BPHC) in recent months. The EHE program has grown steadily from \$27 million in fiscal year 2017 to nearly \$30 million in fiscal year 2020. Concordantly, the program has increased the annual number of HIV tests conducted in participating health centers by 30% and serves a growing number of people with HIV (from 165,000 in fiscal year 2017 to 196,000 in fiscal year 2019). EHE has also changed their standard to link people to care within 90 days of diagnosis to within 30 days, aligning with the national standard.

BPHC plans to use the HRSA 340B program and new resources provided in February to link patients with pre-exposure prophylaxis (PrEP), particularly those living in targeted counties and cities. In the first five months of the \$54 million Primary Care HIV Prevention (PCHP) award, 65% of health centers have hired new staff, nearly 250,000 patients were tested for HIV, 1,512 patients newly diagnose with HIV received follow-up within 30 days, and 19,000 patients were prescribed PrEP.

To address the pandemic, health centers have administered nearly five million COVID-19 tests. More than 550,000 patients have tested positive, nearly 60% of whom are racial/ethnic minorities. More than 16,000 health center staff have tested positive, and the consequent mortalities and morbidities have significantly disrupted program function. In the latest weekly survey, 81% of health centers reported having COVID-19 walk-up or drive-up testing capacity, and about one in four visits are now conducted virtually. Health center visits are at 84% of pre-COVID volume. Health centers continue to hold webinars and other communication channels to advance prescribing practices for PrEP, self-testing, and HIV prevention practices during the pandemic.

CDC NCHHSTP Update

Jonathan Mermin, MD, MPH

Director, CDC, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP)
HIV/AIDS Bureau (HAB), Health Resources and Services Administration (HRSA)

Dr. Mermin provided an update on recent activities at CDC. To address COVID-19, the Center has deployed more than 600 staff, with 124 currently deployed and 31 to deploy soon. CDC recently supported and co-edited a supplement of 34 articles in the *Journal of Infectious Diseases* on topics related to infectious disease and injection drug use.

NCHHSTP has issued a health alert to notify the public about HIV outbreaks during COVID-19, especially among people who inject drugs. The center developed and published a manuscript of lessons learned during six large outbreaks among this population, recommending that, when combined, Syringe Services Programs (SSPs) and medications for opioid use disorder can reduce transmission of HIV and acute hepatitis C (HCV) by more than two-thirds. A new national harm reduction cooperative agreement has addressed these issues over the last year by developing survey instruments, expanding patient navigation tools, monitoring and evaluating SSPs, and surveilling injection drug use.

CDC has also awarded \$109 million to accelerate progress in EHE and has issued a Notice of Funding Opportunity (NOFO) for community-based organizations in eligible states and jurisdictions, which comprise 96% of HIV diagnoses as of 2018. Research from the 90 awardees will be released in summer 2021. CDC also issued a NOFO to address HCV, which will integrate previously siloed HCV surveillance and prevention funding to reduce Hepatitis C and B prevalence in vulnerable populations (including American Indians/Alaska Natives and people who inject drugs). The CDC Division of Viral Hepatitis recently released its 2025 Strategic Plan, which highlights similar goals to reduce morbidities and mortalities associated with viral hepatitis with a focus on disparities reduction.

Dr. Mermin reviewed recent data from the 2019 Youth Risk Behavior Survey Report, which shows that high-school age youth report less sexual activity, increased use of condoms and hormonal birth control, and less high-risk substance use. However, violence and bullying continue to increase, particularly among high school students in racial/ethnic and sexual minority groups. Adolescent mental health trends are also declining, with significant increases in depression, suicidality, and hopelessness among all students and particularly among sexual minority youth. Dr. Mermin highlighted that New York City schools that received CDC funding through the Division of Adolescent and School Health have improved many of these health indicators compared to schools that did not receive funding.

NCHHSTP recently conducted a 2020 STD Prevention Virtual Conference with a focus on the impacts of the COVID-19 pandemic on sexually transmitted infection (STI) trends. Reported cases of STIs decreased at the beginning of pandemic and have slowly increased since, although chlamydia cases had not yet returned to 2019 levels as of late June 2020. Dr. Mermin suggested that the decrease in STI diagnoses is likely due to a combination of physical distancing, decreased healthcare engagement, and delays in diagnosis and reporting during the COVID-19 pandemic.

CDC recently reported results from a landmark study to identify a safe, shorter-course treatment regimen for tuberculosis, finding that a new four-month regime is non-inferior to the standard six-month treatment and likely will become standard care. Telemedicine activities for monitoring tuberculosis treatment are underway and have accelerated during the pandemic. Electronic Direct Observed Therapy (eDOT) using timestamped or real-time video is an effective strategy to engage people in HIV treatment. Patients report preferring eDOT to standard treatment, and economic analysis has found that the platform is lower-cost than standard face-to-face visits.

Last, and of special interest to CHAC, the Food and Drug Administration (FDA) has issued a public comment requesting reclassification of certain HIV and HCV tests from Class III (premarket approval) to Class II (special controls). Reclassification will reduce regulatory burdens and costs associated with these devices.

CHAC Member Discussion with CDC and HRSA on Updates

Dr. Stoner asked for clarification about the fall in reported numbers of STI testing and wondered if there has been parallel decline in HIV diagnoses due to lost health system capacity during the COVID-19 pandemic. Dr. Mermin said preliminary data suggests that testing declined across infections because emergency department visits declined by 30% during the pandemic. COVID-19 also disrupted outreach efforts to encourage affected communities to seek testing. Screening and diagnosis for HIV and other STIs have returned to and persist at pre-pandemic levels.

Dr. Michael Saag noted that PrEP guideline development is complicated by constantly moving targets, such as long-term injectables. Dr. Mermin said the CDC will continue to keep guidelines up-to-date as new regimens become available. CDC has successfully produced interim guidance in the past and more recently a “Dear Colleague” letter that has adjusted and supported provision of PrEP, ensuring that patients can still enroll or receive their medication during the pandemic.

Dr. Lynn Taylor asked if the CDC has information on HCV incidence in American Indian populations in the lower states versus Alaska Native patients in the upper states, suggesting that the large geographic spread may necessitate splitting the current “American Indian/Alaska Native” population designation. Dr. Mermin said that CDC could gather this information at a later time.

Dr. Demetre Daskalakis asked if the mechanism of HIV transmission has changed among 13-to-24-year-olds in the Ryan White Program. He also asked which interventions have been most successful at increasing viral suppression in Black people and transgender people. Dr. Cheever stated that the Ryan White Program has collected these data about mechanisms of transmission, and she could share these with him later. She said that interventions using trans-centered care and culturally competent care at most successful at increasing viral suppression in these populations, respectively.

Dr. Anderson asked about the role of CHAC as advisors on the issue of home-based and point-of-care testing, which have become particularly salient during the COVID-19 pandemic. Dr. Mermin said that, from a procedural standpoint, CHAC has the potential to engage the FDA about device reclassification. He added that COVID-19 has caused collateral benefits to technological advancement; that is, public health labs have received large throughput machines for SARS-CoV-2 testing that can later be used for large-scale HCV screening.

Johanne Morne asked about EHE reviews in the context of accommodations for jurisdictions severely impacted by the COVID-19 pandemic. Dr. Cheever said EHE has prioritized virtual Site Visits for any jurisdiction that has requested assistance, is overdue for a Site Visit, or has a particular issue to address.

Ms. Morne underscored the importance of continuing or expanding partnerships with SAMHSA, especially given increasing mental health needs during the pandemic. She asked CHAC to reflect on a partnership with SAMHSA and to expand eligibility for SAMHSA funding.

Dr. Marvin Belzer added that, while unhealthy sexual activity and substance use have generally improved among adolescents over the last decade, mental health has substantially worsened. He noted that mental health and substance use prevention must be addressed in parallel, and he pointed out the potential value of HRSA directives and Screening, Brief Intervention, and Referral to Treatment (SBIRT) screenings in youth settings.

Dr. Macrae said that HRSA recognizes this need and prior to the pandemic invested \$550 million in health centers for behavioral health, mental health, and substance use disorder services.

Workgroup Reports: Part 1

NHAS/EHE Workgroup
Greg Millett and Jennifer Kates, Co-Chairs

Dr. Jennifer Kates provided a brief update on the recent activities of the National HIV/AIDS Strategy (NHAS)/EHE Workgroup. The workgroup decided to temporarily pause their work, given COVID-19-related delays and the launch of a new related workgroup to address EHE and community engagement. They expect to reconvene in early 2021.

Perinatal Infectious Diseases Workgroup
Jean Anderson, Chair

Dr. Anderson provided an update on the Perinatal Infectious Diseases Workgroup. The workgroup is charged to advise CDC/HRSA regarding prevention, screening, and diagnosis of perinatal infections with a focus on syphilis, HCV, hepatitis B virus (HBV), and HIV in pregnancy and in women of reproductive potential. Towards this goal, the workgroup identified and made recommendations on four focus areas: 1) standardizing laws and regulations; 2) linking obstetrical and pediatric records; 3) standardizing laboratory pregnancy panels; and 4) reducing siloes between perinatal infections. Dr. Anderson further explained each focus area.

Aligning perinatal infection screening guidelines, laws and regulations

The workgroup highlighted significant variation across jurisdictions and professional societies regarding laws and regulations for screening relevant perinatal infections. They proposed efforts to align recommendations among major societies to reduce confusion among providers. Standardization across state regulations, if possible, is an ultimate goal.

These regulations should support universal baseline screening for HIV, HBV, HCV, and syphilis in pregnancy, with attention to jurisdiction-specific controversy about repeated screening for these diseases during pregnancy. The workgroup emphasized that meaningful legislative changes would require buy-in from relevant professional societies, as professional organizations' advocacy arms may interact more effectively with legislators. To this end, CDC and HRSA may consider meeting with representatives of these societies to discuss and reach consensus on this issue.

Linking obstetrical and pediatric records

The workgroup identified a need to share maternal testing and screening results with the pediatrician to ensure proper screening and management for the baby. Currently, maternal and baby records are not linked in the electronic health record (EHR), and pediatricians lack access to important maternal screening results.

At this time, the Congressional Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) has also recommended improvements to improve medical record linkage, and the Task Force reported that support from CHAC would strengthen their recommendations. CHAC may consider collaborating with PRGLAC to advocate for EHR-based medical record linkage between obstetric and pediatric providers.

Standardizing laboratory pregnancy panels

The workgroup determined that lab reporting of pregnancy status for perinatal infection tests results are uneven and providers may be unaware of current recommendations for pregnancy screening and may order incorrect tests.

The workgroup recommended developing universal pregnancy panels (including components for exposed infants) to standardize lab ordering, serve as a prompt to remind providers of screening recommendations, and remove the risk of ordering the wrong test. CDC/HRSA may

consider working with professional societies and major commercial labs to support coordination of standard pregnancy panels and timing of testing in pregnancy and to support laboratory reporting of pregnancy status when reporting results of HIV, syphilis, HCV and HBV screening.

Reducing siloes between perinatal infections

The workgroup highlighted that the current vertical approach to perinatal infections causes duplicated efforts and ineffectively allocated funds. Members identified case review boards as a viable model to collapse siloes across infections. However, they noted that limited time, capacity, and resources pose barriers to these efforts. The workgroup recommended integrating case review boards across infections to efficiently pool resources, but members recognized significant challenges to organizing these boards at the state/regional levels and noted that a nationally integrated board is largely aspirational.

HIV and Aging Workgroup

Michael Saag, Chair

Dr. Saag reviewed activities of the HIV and Aging Workgroup, which is charged with determining needs for clinical assessment of HIV patients as they age and to convert this needs assessment into recommendations for implementation in Ryan White Clinics. The workgroup recommended the following assessments:

- Neurocognition assessments (every 2 years for patients aged 60 and older);
- Frailty/mobility assessments (yearly for patients aged 60 and older);
- Cardiovascular risk reduction panel (every visit for patients aged 45 and older);
- Cancer screening (varied frequency for patients aged 50 years and older);
- STI screening (at every visit for all ages);
- Nutrition assessment (every 6 months for all ages);
- Sleep assessment (every year for patients aged 50 and older);
- Polypharmacy assessment (every visit for all ages);
- Mental health assessment (every visit for patients aged 60 and older);
- Substance use assessment with referral for treatment (every visit for all ages);
- Activities of daily living assessment (every year for patients aged 60 and older);
- Home safety assessment (every year for patients aged 60 and older); and
- Domestic and interpersonal violence screening (every visit for patients aged 60 and older).

Additionally, the workgroup recommended that the Care of People Aging with HIV: Northeast/Caribbean AIDS Education and Training Centers (AETC) Toolkit may be a useful reference for the development and implementation of these assessments in Ryan White Clinics.

Business Session and Member Discussion on Workgroup Reports

Dr. Taylor commented on the importance of the new CDC recommendation to screen pregnant women for HCV. She highlighted Dr. Rachel Epstein's work to use disease screening as an

opportunity to engage pregnant women and their families in integrated care across conditions, including HCV, polysubstance use, and injection drug use.

Ms. Kneeshe Parkinson commented on the recommended assessments developed by the HIV and Aging Workgroup, pointing out that many of these assessments (especially those related to mental health) should be delivered prior to age 50 to capture people who begin experiencing these life changes during their mid-40s.

Dr. Stoner pointed out that CHAC wrote a letter to the HHS Secretary regarding the importance of HIV in youth populations and suggested writing a similar letter for aging populations. Dr. Saag added that a next step for the workgroup may be to convene a representative group of clinics and rate the relative value of implementing these assessments routinely versus time constraints and disruption to clinic flow. With consensus, the workgroup would recommend or mandate that clinics adopt the assessment schedule. He explained that electronic patient-reported outcomes may support Ryan White Clinics in implementing a routine screening and assessment that captures high-risk patients during the preclinical stage.

Dr. Cheever commented that CHAC plans to convene an expert technical panel meeting to address aging-related issues and suggested showing the HIV and Aging Workgroup slides presented by Dr. Saag during this meeting. Additionally, CHAC is working with the HHS Assistant Secretary for Planning and Analysis to examine Medicare data in people with HIV, the results of which will be published in *PLoS*.

In reference to the Perinatal Infections Workgroup, Dr. Stoner agreed that unstandardized screening recommendations and legal requirements remain a significant problem. He suggested that CHAC recommend greater coordination of (or a national policy for) evidence-based recommendations. Dr. Anderson replied that the workgroup chose to partner and reach consensus with professional organizations for this purpose, given that CDC's mandate does not encourage direct action with state legislatures.

Dr. Anderson proposed a workgroup to address home-based self-testing or point-of-care testing and said that the end product of the proposed workgroup would include recommendations to CHAC regarding advancing home-based testing and addressing its barriers. Dr. Taylor added that the work product also could include lessons learned from the COVID-19 pandemic, which has motivated development and authorization of a wide array of tests. A potential workgroup may support CDC or FDA by narrowing the pool of available tests to a smaller group of well-validated, high-accuracy tests.

Dr. Mermin asked if the workgroup would be open to discussing the issue of FDA reclassification, and Dr. Anderson confirmed that it would. Dr. Mermin further explained that HCV blood screening tests currently are classified as Class III diagnostic devices, mandating often prohibitively expensive applications and high test stringency requirements. Reclassification to Class II would remove or reduce some of these barriers. Based on FDA requirements, any input from CHAC should occur during a public meeting. Dr. Cheever supported the idea of a workgroup and expressed concern about the level of expertise within CHAC with regards to advising CDC and the FDA on complex testing-related issues.

CHAC Action

Dr. Anderson made a motion to form a workgroup to address home-based or point-of-care testing for HCV; Dr. Taylor seconded the motion. CHAC members proposed moving the discussion and a vote until the next meeting day.

Update from the Presidential Advisory Council on HIV/AIDS Liaison

Carl Schmid

Presidential Advisory Council on HIV/AIDS (PACHA)

Mr. Carl Schmid talked about how the COVID-19 pandemic has impacted the ability of the Presidential Advisory Council on HIV/AIDS (PACHA) to move forward with their work. PACHA talked to community members, states, and medical providers to better understand their experience with the pandemic and how they have adapted. They also heard from other government agencies, and especially thank CDC/HRSA for their flexibility and leadership to the grantees during the crisis. Overall, they heard consensus that there is a critical need to prepare for the long-term impact of the pandemic.

Based on these conversations, PACHA developed a lengthy resolution. This resolution addressed the need for continued funding, increased telehealth, HIV self-testing, and flexibility in the delivery of services. PACHA is particularly concerned about the HIV workforce, as they tend to be the same people who work with people with COVID-19. They also addressed the need for innovations in HIV prevention approaches such as delivery of condoms or syringes to reduce the need to travel for those supplies. The resolution also addressed the need to reduce health disparities, better data collection, and increased research for the intersection of HIV and COVID-19.

PACHA passed a second resolution encouraging the Secretary of Health and Human Services to not move forward with the rolling back the Affordable Care Act (ACA) protections against discrimination in healthcare, based on the Supreme Court's decision. Ultimately, the Secretary of Health and Human Services did move forward with this rollback. A final resolution was developed on the advice of Assistant Secretary for Health Admiral Brett Giroir to address ways to increase uptake to the Ready, Set, PrEP program. PACHA made several recommendations such as ensuring that lab tests are paid for and collecting data for outreach and providers, especially in uninsured areas or certain communities. Mr. Schmid concluded by thanking HHS for their actions in response to a number of PACHA recommendations, and that they will report on those at their next meeting on December 2.

Public Comment Session

Mr. Jules Levin is Executive Director of NATAP and a community representative to the AIDS Clinical Trials Group (ACTG) and the HIV Disease Research Agenda Committee. He thanked Dr. Saag for his presentation on HIV and Aging. He commented that the two booklets that were released, although well-written and comprehensive, have failed to pervade clinics. Older adults with HIV continue to fall through the cracks, and many are especially unhappy with the movement towards telehealth as a result of the pandemic. Mr. Levin expressed disappointment that CHAC has added topics to their agenda without making real change among aging adults living with HIV. He also expressed frustration that the U.S. ranks last in the world in HCV

elimination due to inconsistent or nonexistent screening, federal linkage to care programs, and other important components of a national HCV elimination strategy.

Dr. John Nelson is affiliated with Rutgers University and receives Ryan White Part F funding. He spoke about the need for laboratories to conduct validation studies for accepting self-collected nucleic acid testing (NAT) specimens for extragenital site gonorrhea and chlamydia. Currently, his team is working with HRSA HAB on a large study of nine clinics; they found that non-acceptance of self-collected specimens remains a significant barrier. Commercial labs also disallow self-collection, and patients receiving telehealth care for an extragenital site infection are unable to self-collect specimens and mail them to labs. Dr. Nelson has not observed any evidence that patient self-collected specimen samples for NAT in gonorrhea and chlamydia are inferior to provider-collected specimens. Policies also vary from lab to lab, and there are no conclusive data about self-collection procedures and policies at a national scale. Dr. Nelson emphasized the need for FDA approval for self-collection and urged CHAC to take action on this important issue.

Recap of Day 1

Jean Anderson, MD
CHAC Co-Chair, HRSA appointee

Bradley Stoner, MD, PhD
CHAC Co-Chair, CDC appointee

Dr. Stoner spoke of the innovations and ongoing challenges that have developed as a result of the COVID-19 pandemic, and how both the CDC workforce and health centers are adapting and re-focusing their efforts. He reviewed the two workgroup themes of aging and perinatal infection with HIV, suggesting that these are critical issues that need continued attention.

Dr. Anderson highlighted the youth risk behavior survey as another important issue that was discussed, and suggested that mental health has been an ongoing concern even prior to COVID-19. She adjourned Day 1 of the CHAC meeting at 2:56 PM ET.

DFO Opening of the Meeting: Day 2

Laura Cheever, MD, ScM
Associate Administrator
HIV/AIDS Bureau (HAB), Health Resources and Services Administration (HRSA)

Dr. Cheever welcomed participants to Day 2 of the CHAC meeting and called the proceedings to order at 2:00 PM ET. Dr. Cheever then conducted roll call and asked members to disclose any changes to conflict of interest. She confirmed that 16 voting members were in attendance, thus constituting a quorum for CHAC to conduct its business on November 6, 2020.

Panel 1: Community Engagement and the HIV Epidemic: Innovatively Engaging Communities

Moderator: Chrissy Abrahms-Woodland, HRSA HAB

Ms. Chrissy Abrahms-Woodland provided an overview of EHE. She explained that stay-at-home orders and organizational disruptions caused by the COVID-19 pandemic have impacted all aspects of their work, including staffing issues, changes in service delivery, and shifts in community engagement. EHE has leveraged these challenges into new opportunities to drive innovation, such as virtual engagement strategies. Furthermore, Ryan White/EHE has adopted telemedicine, extension of medication refills, self-testing, and reassessing processes for eligibility and recertification.

Ms. Abrahms-Woodland reviewed expectations set forth by HRSA HAB in their NOFO, which require that Ryan White funding recipients must:

- Work with their community and public health partners;
- Collaborate with other community organizations to address barriers;
- Build, expand on, and/or maintain effective strategic partnerships with new and existing community providers;
- Develop opportunities for meaningful engagement and learning among peers; and
- Include people with HIV in implementation and decision-making.

Ryan White/EHE recipients have access to abundant community engagement resources, including a Technical Assistance Provider and a Systems Coordination Provider. They also provide an Integrated HIV/AIDS Planning Technical Assistance Center, which supports Ryan White Part A and B recipients, CDC Division of HIV/AIDS Prevention (DHAP) funded grantees, and their respective planning bodies. Additionally, the Planning Community HIV/AIDS Technical Assistance and Training program builds the capacity of Ryan White Part A planning councils and planning bodies to fulfill their legislative responsibilities, strengthen consumer engagement, and increase involvement of community providers in HIV service delivery planning.

To conclude, Ms. Abrahms-Woodland proposed questions for CHAC to consider during this panel:

- How can CDC/HRSA continue to support jurisdictions to engage people with HIV and community-based organizations?
- What challenges and barriers are communities and jurisdictions facing when working to engage stakeholders in ending the HIV epidemic, especially in light of the COVID-19 pandemic?
- With COVID-19 impacting in-person communication, how can CDC/HRSA encourage virtual community engagement?

Community Engagement: Strategies and Approaches with Partners to Support EHE

Erica Dunbar, CDC NCHHSTP

Ms. Erica Dunbar reviewed ongoing EHE community engagement approaches at CDC. In August 2020, CDC awarded \$109 million to 32 state and local health departments, representing 57 EHE Phase 1 counties. Using this program funding, health departments must allocate 25% of their total funding to support EHE planning and implementation by community organizations. They also are required to establish a new or expand an existing EHE advisory group or

committee that is inclusive of representatives from Phase 1 counties. Critically, these planning bodies should include jurisdiction members who have not previously participated in the planning process.

In September 2019, CDC awarded \$12 million of HHS Minority HIV/AIDS funding to the same 32 state and local health departments to conduct rapid planning processes that engage local partners, community members, HIV planning bodies, providers, and other partners to develop community-tailored jurisdictional EHE plans. These plans are living documents, and updated plans are due to CDC by December 31, 2020.

Ms. Dunbar explained that, to support the four pillars of EHE (diagnosis, treatment, prevention, and response), increased and ongoing community engagement is critical. CDC has developed and released program guidance (available online) to aid jurisdictions in their efforts to bring new voices to the table. CDC expects that EHE planning will add to or enhance—not replace—previous planning efforts, and EHE plans will serve as a living blueprint for ongoing and upcoming implementation activities.

Alternative approaches are necessary to meet these requirements during the pandemic. Previous expectations remain in place; therefore jurisdictions still need to share their draft EHE plans and CDC feedback with community partners and provide local point-of-contact information to community stakeholders. Engagement activities must still include community partners even while the jurisdiction adapts to changing circumstances.

Finally, Ms. Dunbar reviewed technical assistance resources to support EHE planning and implementation, including Program Guidance in the EHE plan, at-a-glance resources for community stakeholders, capacity-building assistance services, technical assistance webinars, and virtual town hall sessions with local EHE communities.

EHE Activities at Tarrant County HIV Administrative Agency

Lisa Muttiah, Tarrant County, Texas

Ms. Lisa Muttiah provided an overview of first-year EHE activities in Tarrant County, Texas, an area which experiences significant challenges related to disparate impacts and outcomes in the Black population, as well as uneven testing and late diagnosis in the Latinx population. To address these issues, the Tarrant County HIV Administrative Agency embraced a community engagement approach that includes and centers communities of color.

Ms. Muttiah and her team conducted in-person listening sessions (and virtual sessions post-COVID-19) with providers and people living with HIV, learning that younger adults desired public awareness about HIV coupled with compassionate care delivered by reflective staff and peers. They also hosted a virtual town hall meeting to gather additional perspectives.

Their one-year strategy focused on enhancing social media to engage with the community, implementing an early intervention Strengths, Weaknesses, Opportunities, and Threats (SWOT) model, and investing in workforce development. The team rapidly rolled out social media initiatives due to concerns that information access would be limited during the pandemic. Social media posts focus on spreading awareness about available services (e.g., rental assistance, telehealth). All social media posts are available in English and Spanish.

The team also engages with a consumer advisory board called the Health Improvement Team (HIT), which met virtually during the COVID-19 pandemic. Based on perspectives gained from

HIT, they developed work products such as eight-step “road map” from HIV diagnosis to first appointment and a THRIVING Guide to improve access to care and other resources.

Going forward, the Tarrant County team aims to enhance their social media strategy by increasing awareness, reach, and engagement. They are working to develop a social media campaign that motivates action within key target populations in Tarrant County. In addition to listening sessions, the team has conducted in-depth virtual interviews and focus groups to learn more about popular social media platforms and preferred ways to access information. Early listening sessions indicated that people want to see publicly available information in highly visible areas among communities impacted by HIV. Accordingly, the team is exploring more out-of-home media as a strategy for visibility and community engagement.

Community Engagement Strategies from the Hudson County Transitional Grant Area (TGA) Planning Council

Chad Balodis, Hudson County HIV/AIDS Planning Council, New Jersey

Mr. Chad Balodis briefly reviewed the successes of the Hudson County Transitional Grant Area (TGA) Planning Council, which include high levels of consumer, provider, and stakeholder engagement. He explained that community engagement in this region is facilitated by the dense population, proximity to the original HIV epidemic, a robust public transportation system, and relatively small number of Ryan White providers. The TGA Council’s ongoing community engagement approaches include word-of-mouth, subrecipient engagement in the planning process, building value for non-Ryan White stakeholders, and extensive training initiatives. Mr. Balodis said that word-of-mouth has been one of their most effective strategies.

To increase consumer engagement, the TGA Council ensured that these key partners understood their ability to effect real change and meetings are a comfortable, safe space to ask questions. To engage stakeholders, the TGA Council provided data access on the HIV positive and low-income community and convened a sounding board of pertinent individuals and agencies.

Mr. Balodis pointed out that effective engagement approaches should also include retention efforts. He said that consumer retention improves when they see that their feedback effects real change and that their relationships with recipients are important. Conditions also improve when consumers are promoted into leadership and consumer champion roles. Stakeholder retention improves when stakeholders better understand available services, are able to troubleshoot internal processes, and can create “wins” for municipal leadership.

He reiterated that there is no “silver bullet” for engagement. He has found that consumer engagement is most powerful when consumers are trained, listened to, and elevated to become champions in the community. Effective engagement will ensure follow-through on issues most important to consumers and will work to make proposed changes a reality. Stakeholder engagement strategies must create real value for stakeholders and work towards mutually beneficial wins that will retain and attract partners.

Panel 1 Discussion

Dr. Anderson asked panelists and meeting members to comment on ways to holistically leverage opportunities to link other non-HIV-related services such as General Education Development (GED) Test classes, job training, and leadership training. Ms. Muttiah said that the

Tarrant County HIT HIV Committee uses a Building Leaders of Color Curriculum that builds leadership skills, job training, and educational opportunities. Mr. Balodis said that his team is working to build a satellite site with integrated services accessibly located in one building, recognizing that this community space will sustain efforts beyond EHE funding.

Dr. Taylor said that a significant barrier to community consumer engagement is that many vulnerable populations lack resources or access to cell phones and data plans, and she suggested leveraging local, state, or federal support to provide low-income people with cell phones and data plans that could improve their access to important resources.

Mr. Devin Hursey commented that many health departments view community members as an obstacle to funding rather than an asset and an integral component of the planning process. He felt that HRSA's requirement to involve "new voices" conflicted with Mr. Balodis' point that the most effective community engagement occurred among community members who were present at the beginning of the HIV epidemic. He added that experienced voices are important, and new advocates may not have the skills to hold health departments accountable. Mr. Balodis said that many advocates are already involved in their own projects, and his team leans on subrecipient networks to find new voices.

Ms. Muttiah commented that Tarrant County provides engagement incentives and focuses on treating community members as professionals by providing mutual respect for their time and capabilities. Their team also leverages existing trust among younger communities of color, who can bring members of their networks to the table.

Dr. Stoner asked panelists to comment on the role of syringe provider services. Mr. Balodis said that the Syringe Access Program in New Jersey is up and running a few days a week, and his team is working to educate policymakers about harm reduction and to change laws in New Jersey that require municipal approval to start a syringe access site. Dr. Taylor said that collaborating with law enforcement can be an effective way to increase acceptance of syringe provider services. Ms. Muttiah said that her team is working towards this within the confines of Texas law.

Dr. Belzer commented that COVID-19 has reduced access to cell phones, internet, and other important social connections among adolescents and young adults. He pointed out that disparities in telehealth access likely will deepen the existing gap in healthcare access. Mr. Balodis said that a promising model may be health kiosks, small locations in cities that provide free Wi-Fi and other health resources for homeless people and people with limited access to internet or telehealth platforms.

Dr. Mermin posed two questions to the panelists. First, he asked them to make one priority recommendation for jurisdictional planning committees on best practices for engaging communities. Second, he asked how they are addressing conflicts of interest, such as challenges to ensuring that all activities are maximally beneficial for the HIV community rather than beneficial for financially involved stakeholders.

Ms. Muttiah answered that one of her team's activities was to address these potentially competing interests. They aim to ensure that energy is allocated to serving clients' needs rather than tracking funding and organizational interests. She added the need to balance input so that people with lived experience have an equal or greater voice than professionals.

Mr. Hursey said he is encouraging the Missouri Health Department to allow community members to workshop plans according to their own priorities and the priorities of the HIV Decriminalization Coalition to develop a plan that serves community interests.

Dr. Cheever commented on the issue of conflicting interests. In her experience, consumers are not any more or less conflicted or biased than other members (such as professionals) during the planning process. Mr. Venton Hill-Jones agreed and highlighted this concept in the context of local planning councils, some service providers feel that conflicts of interest are weaponized to minimize their involvement. He said this is unfair to providers, who have a unique perspective on this work, and emphasized the need for opportunities to promote mutual respect among these diverse roles and relationships.

Dr. Kates asked CHAC to consider potential mechanisms to intersect national EHE planning efforts with the ongoing national efforts to distribute a COVID-19 vaccine.

Panel 2: Women, HIV, and Trauma in the Current Healthcare Environment

Moderator: **Dana Hines**, HRSA HAB

Dr. Dana Hines introduced the second panel, which focuses on the intersecting challenges of HIV and trauma among women living with HIV. Rates of post-traumatic stress disorder (PTSD) among women with HIV are five times higher than the national average, and rates of intimate partner violence (IPV) and childhood sexual or physical abuse among this population are more than twice the national average. Race plays an intersecting role, as Black women comprise 58% of new HIV diagnoses in women, despite representing only 13% of the female population.

Other trauma-associated social and behavioral factors create and reinforce conditions that increase HIV risk and transmission. For example, social determinants of health such housing instability, substance use disorder, stigma and discrimination, and geographic region play a complex role in HIV risk and must be addressed to improve HIV-related health outcomes among vulnerable populations.

Dr. Hines reviewed several HRSA HAB programs and initiatives to address the intersection of HIV and trauma in women, including a technical expert panel in 2015, a National Alliance of State and Territorial AIDS Directors (which led to the creation of a trauma-informed approaches toolkit), and the Special Projects of National Significance (SPNS) Program.

To conclude, Dr. Hines reviewed questions for CHAC to consider during this panel:

- What can CDC and HRSA do to better address the healthcare needs of women with or at risk for HIV, including those who have experienced trauma?
- How can CDC and HRSA address trauma and trauma-informed care in their programs to improve HIV treatment and prevention for women?
- How can CDC and HRSA better utilize IPV resources and strategies to improve HIV prevention and care services for women?
- How can CDC and HRSA improve PrEP uptake among women?

San Diego Mother Child Adolescent HIV Program
Nicole Pepper, University of California

Ms. Nicole Pepper reviewed the Mother Child Adolescent HIV Program at the University of California, San Diego. She highlighted that trauma impacts every stage of the HIV care continuum, including increased risk of HIV acquisition and transmission, delayed linkage to and decreased retention in care, and lower adherence to antiretroviral treatment.

Given these challenges, she underscored the need to create a trauma-informed care environment for his vulnerable population. She recommended that organizations serving women with HIV do the work to ensure that all services and care environments are trauma-informed. Critically, trauma-informed care is not a “box to be checked,” it is a client-informed culture that includes racial justice and requires training and support inclusive of all members—from front desk staff to clinicians. A successful trauma-informed care environment should include universal screening for trauma, supervision and care for providers (to treat vicarious trauma and burnout), and continuous quality improvement.

Ms. Pepper explained that, with support from HRSA, her program has implemented an evidence-informed intervention for trauma called Seeking Safety. This one-on-one or group intervention can be administered in-person or virtually by a wide array of individuals, including mental health providers, peers, community health workers, and case managers. It uses a present-focused model to teach safe coping skills to people impacted by trauma and/or substance use. Importantly, the intervention is informed by client input and does not require participants to retell their traumatic experiences.

She pointed out a number considerations when caring for women with HIV. These women often are responsible for financially supporting a multi-person household while managing stigma, transportation issues, limited childcare, complex healthcare systems, and unstable housing. Successful trauma-informed interventions must consider these barriers to care.

Engaging Community **Dottie Rains-Dowdell**

Ms. Dottie Rains-Dowdell shared an anecdote from her work to provide sexual health education in South Africa. She found that the South African women knew what HIV is and how to prevent it, but some women have unique risk factors and cultural considerations (i.e., a married monogamous woman whose husband has unprotected sex with other people). As a result, there is a need for culturally-responsive community engagement to successfully engage Black and Latina women in HIV prevention and treatment.

She highlighted the importance of William Madsen’s concept of cultural curiosity, which shifts providers’ role from teacher to learner. That is, the provider should express genuine curiosity, convey respect, show a true desire to learn from others, and admit not knowing about a particular problem. Ms. Rains-Dowdell reviewed three areas in which HIV providers can demonstrate cultural curiosity:

- *Awareness and self-reflection:* Providers should demonstrate an understanding of their own cultural biases, be prepared to serve Black and Latina women, participate in cultural immersion experiences, and participate in cultural responsiveness trainings.
- *Knowledge:* Providers should stay informed on relevant evidence; critically evaluate the cultural appropriateness and sensitivity of an intervention for a target population; and

guide choice-making based on the beliefs, values, and practices of Black and Latinx communities.

- *Skills:* Providers should engage in relationship building and communication skills, become skilled at working with translators in Spanish, engage and work with the whole family unit, ask questions and practice active listening, and partner with traditional and spiritual leaders to maximize impact.

Last, Ms. Rains-Dowdell pointed out that organizations can demonstrate their commitment to diversity, equity, and inclusion by incorporating culturally sensitive and responsive practices across policy, procedure, practice, and accountability structures.

Addressing Violence and Trauma in HIV Prevention and Care

Michele Decker

Dr. Michele Decker provided information about the intersections of IPV and HIV. Approximately one in three women in the U.S. experience IPV, and extensive evidence has linked IPV with increased risk of STIs and HIV—that is, data indicate that IPV is significantly more frequent and severe among HIV-positive women.

She explained that both IPV and HIV are associated with limited control over sex with a high-risk partner, compromised sexual and condom negotiation, coerced and forced sex (often unprotected), partner notification of diagnosis status as a context for fear and abuse, and higher risk-taking behaviors among male violence perpetrators (who are more likely to engage in sexual risk behaviors and are more likely to live with HIV).

Furthermore, IPV and trauma often impede HIV-related care. For example, abusive partners may use HIV status as a tactic for abuse and control, directly interfering with their partner's access to care and medication adherence. Mental health disorders commonly associated with IPV (such as PTSD and depression) are correlated with low care and medication adherence, and other stressful life events can cause poorer immune function and inhibited viral response.

Dr. Decker briefly reviewed the work of a 2012 Federal Interagency Working Group that articulated and addressed the intersection of HIV/AIDS, violence against women and girls, and gender-related health disparities. The Working Group recommended screening for IPV as a part of routine HIV care, which has since been integrated into the National HIV/AIDS Strategy.

She explained that IPV screening and response must be conducted sensitively and privately, must be accompanied by links to supports and services, should recognize barriers to disclosure, and should link survivors to care without attempting to advise or resolve the situation.

Dr. Decker concluded by providing resources on violence and trauma, including an [HIV/IPV factsheet](#) and [patient and provider resources](#) for addressing violence, trauma, and HIV.

PrEP and Cisgender Women

Ann Namkung Lee, NIAID Division of AIDS

Ms. Ann Namkung Lee discussed strategies to help cisgender heterosexual women learn about PrEP, decide whether to not to use PrEP, and access and sustain use of PrEP. These projects are funded by National Institutes of Health (NIH) as part of their role in the EHE initiative.

The NIH Centers for AIDS Research and National Institute of Mental Health (NIMH) AIDS Research Centers have been conducting implementation science research to serve EHE. In fiscal year 2019, the majority of PrEP-related projects focused on men who have sex with men (MSM) and transgender women, while very few applications focused on cisgender heterosexual women. To address this gap, they released an EHE solicitation that specifically requested applications to meet the unique needs of cisgender heterosexual women and PrEP use and accessibility. Seven of these projects were selected for funding. Ms. Namkung Lee provided high-level overviews for each of these ongoing projects:

- **Novel Strategies for Reducing Barriers to HIV Testing and Increasing Access to PrEP for Cisgender Women:** This project aims to develop and pilot an innovative strategy to increase and normalize HIV testing, PrEP awareness, and PrEP access among cis women by expanding and enhancing New York City's HIV home-testing program.
- **Addressing Unmet PrEP Needs Among Diverse Black Women:** This project aims to incorporate PrEP access into a mobile HIV/STI community outreach intervention and will determine feasibility and accessibility of PrEP access through this intervention among African Americans, African immigrants, and Caribbean immigrant women in Suffolk County, Massachusetts.
- **Optimizing PrEP Engagement Among Cisgender Heterosexual Women and Their Partners** This project aims to address ongoing disparities in access to and uptake of PrEP among cisgender women and their sexual and injection partners in Baltimore, Maryland.
- **SEPA-PrEP: A Promising HIV Prevention Strategy for Cisgender Hispanic Heterosexual Women to Access, Initiate, and Sustain Use of PrEP:** This project aims to identify barriers to PrEP acceptance and strategies in rural cisgender heterosexual Hispanic women in Florida at risk for HIV.
- **Exploring PrEP Implementation Strategies Tailored for African American Cisgender Women Living in Mississippi:** This project aims to examine barriers and facilitators to PrEP use to reduce HIV incidence among cisgender heterosexual African American Women living in Mississippi HIV hotspots.
- **Telehealth to Optimize PrEP Care Continuum Outcomes among Cisgender Black and Latina Heterosexual Women:** This project aims to implement a telehealth PrEP intervention within the setting of two community-based agencies that do not provide clinical services.
- **Implementing PrEP into Non-Title X Clinic Settings to Reduce HIV Disparities among African Women:** This project aims to increase providers' PrEP knowledge and self-efficacy to prescribe PrEP to increase access among African American women in the Atlanta area.

Panel 2 Discussion

Dr. Anderson said that increased at-home virtual HIV and IPV screening during the COVID-19 pandemic poses significant challenges for women's safety and privacy, given that one in three women with HIV screen positive for IPV. Telehealth screening in the home may put women at risk or miss women who are unable to respond truthfully due to IPV-related safety concerns. She also noted issues related to PrEP in pregnancy, particularly among pregnant cisgender women. Although screening for HIV in pregnant women is robust, many providers do not engage their partners to receive screening as well.

Dr. Daskalakis pointed out the need to integrate IPV and PrEP care, which are currently siloed. He noted that STIs are a good indicator for HIV risk, therefore IPV may also act as a good indicator for STI and HIV risk. He suggested a strategy in which IPV screening includes an implementation stage that offers PrEP or some other HIV-targeted intervention.

Ms. Parkinson added that disclosure is an important component of this work and noted the need to develop infrastructure to bridge women who have disclosed their status to the next stages of care. She agreed with Dr. Anderson that safe housing is a barrier; many women lack a safe space in which to privately discuss IPV and HIV. Furthermore, the police system is poorly equipped to handle crisis interventions and mental health scenarios.

Dr. Decker said that providers need to ask questions about the partner dynamic to determine if the relationship will pose risks to a woman's ability to seek and sustain care. In some cases, strategies will need to be secretive or hidden to keep women safe. During COVID-19, privacy screenings have become even more critical; providers should begin the conversation by asking if they are in a safe space to discuss sensitive questions.

Dr. Jodie Dionne-Odom said that she is often impressed by the way that many of her female patients are still experiencing trauma from events that occurred decades ago, particularly instances of sexual violence. She pointed out the need to create prevention opportunities, including early sexual health education curricula that teach consent and leverage community health partners to prevent early traumas from occurring. Ms. Parkinson said that schools limit access to this information and organizations, especially at the elementary grade levels. This poses a significant barrier for many states and communities.

Ms. Debra Hauser said that her organization, Advocates for Youth, has developed national sex education standards. Unfortunately, some of the most complicated, controversial topics are those related to child physical and sexual abuse. For example, research indicate that it is critical to teach children the proper names of their body parts by second grade or earlier, but parents push back against this movement. Ms. Hauser suggested using the internet to reach and directly educate young people without requiring their parents' input but, in most states, PrEP is not available to youth without parental consent.

Mr. Hursey said that, in his experience, sexual assault in adolescence is an extension of bullying. He asked to what extent researchers are using a race-based lens to consider the social positioning of women of color that leaves them especially vulnerable to this kind of abuse. Dr. Decker agreed and noted the importance of developing bystander interventions to reduce bullying.

Workgroup Reports: Part 2

Viral Hepatitis Workgroup Lynn Taylor, Chair

Dr. Taylor provided an update on the activities of the Viral Hepatitis Workgroup, which is charged to assist in the development of feasible guidance related to enhanced HCV diagnostics. They aim to prioritize national leadership to accelerate development and implementation of rapid point-of-care HCV ribonucleic (RNA) diagnostic testing, as well as partnerships to guide rapid HCV diagnosis across the nation. The development of short-duration, pan-genotypic

direct-acting antivirals offered new hope to people with HCV, but two-step venous-puncture diagnostic tests for HCV are a significant barrier to treatment.

The workgroup has identified rapid point-of-care finger-prick RNA testing as a viable alternative to two-step diagnostic testing. The workgroup highlighted that ideal diagnostic testing should be rapid (i.e., results in 1 hour or less), simple (requiring minimal equipment and training), cost-effective, sensitive, specific, and minimally invasive. They cited a promising point-of-care test, the Xpert® HCV Viral Load Fingerstick, which detects and quantifies HCV RNA from 100µL with comparable performance to other available HCV RNA assays. An alternative option is dried blood spot (DBS) testing, which is easy and inexpensive to collect, but does not yield immediate results.

To conclude, the workgroup asked CHAC to consider recommending a national HCV testing strategy using systematic one-step HCV RNA-based testing as the pillar of the HCV elimination effort. This will require a national, coordinated, efficient approach to development of optimal HCV diagnostics, involving interagency collaborations among CDC/HRSA, the FDA, and manufacturers. The workgroup recommended that CHAC prioritize development, validation, and regulatory approval of point-of-care molecular fingerstick and DBS testing. Last, the workgroup urged CHAC not to delay these efforts due to the COVID-19 pandemic.

EHE Community Engagement Workgroup **Venton Hill-Jones, Chair**

Mr. Hill-Jones provided an update on the EHE Community Engagement Workgroup, which was charged to review and consider the effectiveness of community engagement in EHE jurisdictional plans, to identify innovative strategies that have successfully engaged community stakeholders during the pandemic, to identify innovations for replication in other jurisdictions, and to meet with key stakeholders to inform recommendations. To do so, in October 2020, the workgroup conducted an information-gathering webinar framed by four key focus areas, including 1) Planning and Design, 2) Implementation, 3) Evaluation, and 4) Technical Assistance. Mr. Hill-Jones provided more information on each focus area.

Planning and Design

The workgroup recommended implementing full transparency after the December deadline for revised plans, including clear expectation and specific documentation of community roles in the planning process, particularly in rural jurisdictions. Workgroup members highlighted the importance of visibility and early community engagement in every project, including intentional efforts to engage networks of people living with HIV. Last, EHE should remain the standard vision among the entire HIV workforce.

Implementation

The workgroup identified a need to create guidance to ensure effective allocation of EHE community resources and coalitions of people living with HIV, with flexibility to changing landscapes and needs. The workgroup recommended CDC/HRSA can proactively respond to problems by setting a federal point-of-contact for community members who are unable to access information at the jurisdictional level.

Evaluation

The workgroup recommended that CDC work to improve PrEP access and uptake among vulnerable populations, such as Black communities, women, and gender/sexual minorities. Members emphasized that funding allocation must be transparent but remain aligned with

current evaluation techniques. Last, data collection should be participatory, affording communities' authority over collection processes. Researchers should collect all data with nuanced attention to specific cultural groups and populations.

Technical Assistance

The workgroup recommended that technical assistance funds should be allocated after discussing specific community engagement work plans with each jurisdiction.

Next Steps for CHAC

The workgroup noted that further clarification is needed from CDC/HRSA regarding EHE Year 2 Guidance and the CDC/HRSA Integrated Plan. Members also recommended that CHAC write a Community Engagement letter to CDC/HRSA detailing ongoing activities, considerations, and recommendations related EHE community engagement efforts. Mr. Hill-Jones said that the letter is currently in drafting stages.

Business Session and Member Discussion on Workgroup Reports – Part 2

Dr. Stoner opened the Business Session by reminding members to discuss the proposed new wkgroup for HCV testing from Day 1. Dr. Taylor summarized that the HCV Workgroup made three specific recommendations to CHAC about supporting, promoting, and recommending a national approach to single-step HCV testing. She asked CHAC to think about the best way to frame these recommendations (e.g., a letter, an advisory group, etc.) to optimize diagnostics for STIs and HCV. Dr. Anderson reiterated her idea to create an HCV testing Workgroup and pointed out that diagnostics cross-cut over several existing workgroup recommendations. She emphasized that this work should not be delayed by waiting for authorization of a new workgroup. Dr. Cheever encouraged CHAC members to develop specific charges or recommendations for the new Workgroup offline, at an interim business meeting, or the next regular meeting in spring 2021.

Dr. Pradip Akolkar added that the FDA is discussing these issues in an open public forum and considering innovative processes to meet regulatory legal requirements. He said that CDC may take an advisory role in accelerate this process. Dr. Stoner asked if CHAC should recommend that CDC advise manufacturers to expedite their activities.

Dr. Taylor said that there is precedent for pharmaceutical companies to work with the government, citing Gilead's work to manufacture remdesivir for COVID-19. She said that opportunities for CDC and FDA collaboration are available, but largely unleveraged. Dr. Mermin agreed that CDC/HRSA should convene to determine best methods for advancing specific diagnostics, including supports for standards and frameworks across a variety of infections.

Dr. Mermin suggested making available online the upcoming plans for community engagement. Mr. Hill-Jones replied that this would be an important way to increase transparency and parallel engagement. He also pointed out the value of including community members in a conversation with federal stakeholders about the EHE Year 2 guidance before it is released and finalized. Dr. Cheever said that this would be possible, as HRSA has posted Integrated Plans online in the past with permission from those involved. (Addendum/correction: Technical assistance provider posted examples in the past, not fully integrated plans)

Dr. Cheever returned the discussion to HCV diagnostic testing, pointing out that at-home self-collection poses a number of regulatory and structural barriers. Dr. Stoner noted that although the literature suggests that self-collection is feasible, many labs refuse to run self-collected

tests. Dr. Mermin noted that many of the ideas raised about an HCV testing Workgroup need further detailed discussion before proceeding. He suggested that CHAC take time to delineate potential next steps towards this Workgroup.

Dr. Taylor said that the HCV Workgroup has already finalized their recommendations, which include asking CHAC to advise CDC on adoption of a national HCV testing strategy based on single-step RNA based testing; creation of a coordinated, efficient, CDC-led approach to development of these diagnostics rather than relying on leadership from pharmaceutical; and immediate progress despite the ongoing pandemic.

Ms. Gloria Searson added that the HCV Workgroup aims to leverage ongoing mobilization of rapid COVID-19 testing. Dr. Wendy Armstrong asked if there is advantage to finger-prick antibody testing followed by reflexive polymerase chain reaction (PCR) testing, and Dr. Mermin replied that they have considered eliminating antibody testing altogether.

Dr. Anderson recommended that CHAC convene an interim meeting to discuss recommendations from the other Workgroups. Dr. Stoner and Dr. Dionne-Odom agreed. CHAC members agreed to delay voting on the HCV testing Workgroup until such a time that members have more fully discussed and detailed the purpose, role, and logistics of the Workgroup.

CHAC Action

Dr. Anderson and Dr. Stoner made a motion to accept the recommendations posed by the HCV Workgroup. CHAC members used the virtual chat function to second the motion. The CHAC decided to address the issue in an interim business meeting in February 2021.

Adjournment

Dr. Cheever thanked HRSA and CDC for hosting the CHAC, the participants for their robust involvement and commitment to CHAC, and the Day 2 panelists for their presentations on community engagement and issues related to women's health. She reminded participants that there would be an interim business meeting to discuss the proposal to form a new Workgroup. She asked participants to provide input on a draft letter and set of recommendations before the meeting.

Dr. Cheever adjourned the meeting at 5:15 PM ET.

CHAC Co-Chairs' Certification

I hereby certify that, to the best of my knowledge, the foregoing Minutes of the proceedings are accurate and complete.

Jean R. Anderson, MD, Co-Chair
CDC/HRSA Advisory Committee on HIV,
Viral Hepatitis, and STD Prevention
and Treatment

Date

Bradley Stoner, MD, PhD, Co-Chair
CDC/HRSA Advisory Committee on HIV,

Date

Viral Hepatitis, and STD Prevention
and Treatment

Attachment A: Participant List

CHAC Members Present

Dr. Jean Anderson (Chair)
Dr. Bradley Stoner (Chair)

Dr. Wendy Armstrong
Dr. Marvin Belzer
Dr. Demetre Daskalakis
Dr. Jodie Dionne-Odem
Dr. Travis Andre Gayles
Ms. Debra Hauser
Mr. Venton Hill-Jones
Mr. Devin Hursey
Dr. Jennifer Kates
Dr. Shruti Mehta
Ms. Kneeshe Parkinson
Dr. Michael Saag
Ms. Gloria Searson
Dr. Lynn Erica Taylor

CHAC Members Absent

Mr. Gregorio A. Millett
Ms. Joanne Morne

CHAC Ex-Officio Members Present

Dr. Pradip N. Akolkar
U.S. Food and Drug Administration

Dr. Paul Gaist
National Institutes of Health

Dr. Neerja Gandotra
Substance Abuse and Mental Health
Services Administration

Mr. Richard Haverkate
Indian Health Service

Ms. Kaye Hayes
U.S. Department of Health and Human
Services

CHAC Ex-Officio Members Absent

Dr. Iris Mabry-Hernandez
Agency for Healthcare Research and
Quality

Dr. Douglas Olsen
Centers for Medicare and Medicaid
Services

Dr. Richard Wild (Alternate)
Centers for Medicare and Medicaid
Services

CHAC Liaison Representative

Mr. Carl E. Schmid
Presidential Advisory Council on HIV/AIDS

CHAC Designated Federal Officers

Dr. Laura Cheever
Health Resources & Services Administration
HIV/AIDS Bureau Associate Administrator

Dr. Jonathan Mermin
Centers for Disease Control and Prevention
National Center for HIV, Viral Hepatitis, STD
and TB Prevention Director

Federal Agency Attendees

Guest Presenters

Brian LeClair
Health Resources & Services Administration

James Macrae
Health Resources & Services Administration
Bureau of Primary Health Care

Chrissy Abrahms Woodland
Health Resources & Services Administration
HIV/AIDS Bureau

Erica Dunbar
Centers for Disease Control and Prevention
National Center for HIV, Viral Hepatitis, STD
and TB Prevention

Lisa Muttiah
Tarrant County, Texas

Chad Balodis

Hudson County HIV/AIDS Planning Council,
New Jersey

Dana Hines
Health Resources & Services Administration
HIV/AIDS Bureau

Nicole Pepper
University of California, San Diego

Dottie Rains-Dowdell
Creative Training and Development

Michele Decker
Johns Hopkins Bloomberg School of Public
Health

Ann Namkung Lee
National Institutes of Health
National Institute of Allergy and Infectious
Diseases

Attachment B: List of Acronyms

ACA	Affordable Care Act
ACOG	American College of Obstetricians and Gynecologists
ACTG	AIDS Clinical Trials Group
AETC	AIDS Education and Training Center
AHRQ	Agency for Healthcare Research and Quality
AIDS	Acquired Immunodeficiency Syndrome
BPHC	Bureau of Primary Health Care
CDC	Centers for Disease Control and Prevention
CDC DHAP	CDC Division of HIV/AIDS Prevention
CHAC	CDC/HRSA Advisory Committee on HIV, Hepatitis, and STD Prevention and Treatment
CMS	Centers for Medicare and Medicaid Service
COVID-19	Corona Virus Disease 2019
DFO	Designated Federal Officer
EHE	Ending the HIV Epidemic
eDOT	Electronic Direct Observed Therapy
FACA	Federal Advisory Committee Act
FDA	Food and Drug Administration
GED	General Education Development Test
HAB	HIV/AIDS Bureau
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HHS	Department of Health and Human Services
HIT	Health Improvement Team
HIV	Human Immunodeficiency Virus
HRSA	Health Resources and Services Administration
IHS	Indian Health Services
IPV	Intimate Partner Violence
MSM	Men Who Have Sex With Men
NAT	Nucleic Acid Testing
NCHHSTP	National Center for HIV/AIDS, Viral Hepatitis, Sexually Transmitted Diseases and Tuberculosis Prevention
NHAS	National HIV/AIDS Strategy
NICHD	National Institute for Child Health and Human Development
NIH	National Institutes of Health
NIMH	National Institute of Mental Health
NOFO	Notice of Funding Opportunity
PACHA	Presidential Advisory Council on HIV/AIDS
PTSD	Post-Traumatic Stress Disorder
PrEP	Pre-exposure Prophylaxis
RNA	Ribonucleic Acid
SAMHSA	Substance Abuse and Mental Health Services Administration
SARS-CoV-2	Disease caused by COVID-19
SBIRT	Screening, Brief Intervention, and Referral to Treatment
SPNS	Special Projects of National Significance Program
SSP	Syringe Services Program
STD	Sexually Transmitted Disease
STI	Sexually Transmitted Infection

SUD	Substance Use Disorder
SWOT	Strengths, Weaknesses, Opportunities, and Threats
TB	Tuberculosis
TGA	Transitional Grant Area
USAID	United States Agency for International Development