Hybrid Meeting of the
CDC/HRSA Advisory Committee on
FIV, Viral Hepatitis, and STD Prevention and Treatment

October 21–22, 2024

US Department of Health and Human Services
Centers for Disease Control and Prevention
Health Resources and Services Administration

Record of the Proceedings

Contents

Executive Summary

The United States (U.S.) Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC), and the Health Resources and Services Administration (HRSA) convened a meeting of the CDC/HRSA Advisory Committee on HIV, Hepatitis, and STD Prevention and Treatment (CHAC) on October 21–22, 2024, in Rockville, Maryland.

CHAC members heard presentations from HRSA and CDC focused on strategies and facilitators to engage people who are not consistently in care, including presentations on strategies to re-engage individuals with human immunodeficiency virus (HIV) who are out of care through data to care initiatives, expanding access to long-acting injectable (LAI) antiretroviral therapies for HIV treatment, and enhancing mental health services for people with HIV and sexually transmitted diseases (STD). These presentations highlighted the importance of involving individuals with lived experience to better inform program and policy development. Key topics focused on overcoming barriers to re-engage people with HIV into care, increasing access to innovative treatments like LAIs, and building supportive systems to re-engage patients with HIV out of care, particularly individuals facing substantial challenges in maintaining consistent care.

HRSA presented a federal update focusing on recent progress and ongoing efforts within HRSA's HIV/AIDS Bureau (HAB), Office of the Immediate Administrator, Bureau of Primary Health Care (BPHC), and the Bureau of Health Workforce (BHW) to advance comprehensive care. HRSA HAB's update covered initiatives under the Ryan White HIV/AIDS Program (RWHAP) which aim to improve health outcomes and reduce disparities, particularly in minority communities. HAB's Ryan White Program 2030 initiative aims to close viral suppression gaps by increasing focus on the out of care. Another initiative, Catalyzing Unity, Leadership, and Team-building through Individualized, Validating Approaches to Transformational Empowerment for people with HIV, or CULTIVATE, seeks to empower people with HIV as leaders within healthcare, enhancing their roles in planning. Updates from BPHC included efforts to expand access to care in federally qualified health centers, focusing on underserved communities with high rates of HIV and STDs. BHW highlighted initiatives to strengthen the HIV workforce through residency training programs and collaborations to integrate HIV education into primary care. These updates reflect HRSA's commitment to holistic HIV care that addresses social determinants of health, such as housing stability.

CDC presented a federal update covering recent advancements in diagnostics, recently published doxycycline post-exposure prophylaxis guidance, and CDC's syndemic approach to address interconnected health issues. Key initiatives included expanding pre-exposure prophylaxis (PrEP) access and developing new diagnostics for hepatitis C and B. CDC's update also discussed strategies to manage medication shortages for tuberculosis and syphilis, and CDC's efforts to reduce racial disparities in HIV and sexually transmitted infection (STI) rates, particularly in the Southern U.S. Notable achievements included a 12 percent decline in new HIV infections over four years and in the 50 Phase 1 Ending the HIV Epidemic in the U.S. (EHE) counties, HIV incidence decreased 21% in 2022 compared to the baseline 2017. However, further focused work is needed to address disparities among Black and Hispanic/Latino populations.

The Presidential Advisory Council on HIV/AIDS (PACHA) provided an update on the global response to HIV through PEPFAR (President's Emergency Plan for AIDS Relief), emphasizing the importance of bipartisan support for its reauthorization and the program's success in saving over 25 million lives worldwide. Discussions included strategies to increase equitable access to innovations such as long-

acting injectable PrEP, learning lessons from the RWHAP to guide PEPFAR's community planning, and addressing the challenges of transitioning programmatic and financial responsibility to individual countries. PACHA also highlighted the importance of fostering collaboration between domestic and global HIV initiatives to advance shared goals of ending the epidemic.

Four panels were held to provide CHAC members with an overview of:

1. Innovative strategies and data-driven initiatives aimed at re-engaging individuals with HIV who are out of care by leveraging diverse data sources, fostering interdepartmental collaboration, and addressing health equity. Emphasis was also placed on integrating holistic support systems while highlighting the importance of community engagement, privacy, and adaptability in public health responses.
2. Firsthand experiences from five individuals with lived experience using LAIs for HIV treatment. Discussions highlighted the challenges, benefits, and patient perspectives that can help guide more effective and personalized treatment strategies.
3. Current initiatives and challenges in expanding mental health care access for individuals with HIV and STDs, emphasizing the need for integrated, trauma-informed care models, addressing stigma, and exploring innovative approaches such as telehealth and collaborative care to improve patient outcomes.
4. Strategies and community-based models aimed at overcoming barriers to re-engaging individuals with HIV who are out of care, emphasizing the importance of personalized outreach, flexible care options, and integrated support services to improve retention and health outcomes.

The CHAC LAI Workgroup presented an update on their efforts to address access and reimbursement challenges for LAIs. Key considerations included advocating for standardized access across payers, reducing cost-sharing barriers, and clarifying whether LAIs should be reimbursed under pharmacy or medical benefits. The workgroup also emphasized the importance of incorporating people with lived experience to inform policy and improve care delivery.

CHAC Actions

During the meeting, CHAC members voted unanimously to:

- Sunset the CHAC Community Partnership Workgroup.
- Approve recommendations to CDC and HRSA to work with clinical partners to determine the preferred reimbursement mechanism for LAIs and consult with the Food and Drug Administration on labeling for viremic patients.
- Recommend a spring 2025 CHAC meeting scientific panel be held on LAIs for diseases beyond HIV, such as viral hepatitis and STIs.
- Approve and advance four recommendations for addressing the unique needs, health outcomes, and quality of life of lifetime HIV survivors.
- Establish a CHAC workgroup to focus on reimbursement for point-of-care and self-testing for STIs and viral hepatitis.
- Establish a CHAC workgroup to explore payer levers that can be used to support HIV and hepatitis C services not covered by RWHAP funding.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION/
HEALTH RESOURCES AND SERVICES ADMINISTRATION
Advisory Committee on
HIV, Viral Hepatitis, and STD Prevention and Treatment
October 21–22, 2024

Meeting Minutes

The United States (U.S.) Department of Health and Human Services (HHS), the Centers for Disease Control and Prevention (CDC), and the Health Resources and Services Administration (HRSA) convened a meeting of the CDC/HRSA Advisory Committee on HIV, Hepatitis, and STD Prevention and Treatment (CHAC) on October 21–22, 2024, in Rockville, MD.

The CHAC is a federal advisory committee chartered under the Federal Advisory Committee Act to advise the Secretary of HHS, Director of CDC, and Administrator of HRSA on objectives, strategies, policies, and priorities for HIV, viral hepatitis, and sexually transmitted disease (STD) prevention and treatment efforts for the nation. Information for the public to attend the CHAC meeting was published in the Federal Register, in accordance with Federal Advisory Committee Act rules and regulations. All sessions of the meeting were open to the public. Please see Appendix A for Membership Attendance.

Day 1: Opening of the Meeting and Welcome

Wendy Armstrong, MD
Professor
Emory University School of Medicine
CHAC Co-Chair

Dr. Armstrong called the proceedings to order at 9:00 a.m. Eastern Time (ET) and welcomed everyone to the October 21–22, 2024 CHAC meeting. Dr. Armstrong thanked CHAC members, federal officials, HRSA and CDC staff, and the public for their attendance. Dr. Armstrong reviewed the agenda for the meeting, which would include federal updates as well as four panels, including a panel of individuals with lived experience related to the use of long-lasting injectable (LAI) antiretroviral therapies (ART).

Designated Federal Official (DFO) Meeting Roll Call

Laura Cheever, MD, ScM
Associate Administrator
HRSA HIV/AIDS Bureau (HAB)

On behalf of CDC and HRSA, Dr. Cheever welcomed attendees and reminded everyone that CHAC meetings are open to the public and that all comments made during the proceedings are a matter of public record. Dr. Cheever stated that CHAC members should be mindful of potential conflicts of interest identified by the Committee Management Office and recuse themselves from voting or participating in any discussions for which they could be conflicted. Dr. Cheever then conducted a roll call to determine

quorum for the CHAC members and Ex-Officios in attendance. Dr. Cheever established quorum for the CHAC to conduct its business on October 21, 2024.

CHAC Member Conflict of Interest Disclosures

CHAC Member (Institution / Organization)	Disclosure of Conflict
Wendy Armstrong, MD (Co-Chair) Emory University School of Medicine	Works at an organization that receives RWHAP funding.
Marguerite Beiser, ANP-BC, AAHIVS Boston Health Care for the Homeless Program	Works at an organization that receives RWHAP funding.
Keiva Lei Cadena-Fulks Positive Women's Network	No conflicts.
Jorge Cestou, PhD, MBA Chicago Department of Health	Works at an organization that receives HRSA, RWHAP, and CDC HIV Prevention and Surveillance funding.
Shannon Brown Dowler, MD Mecklenburg County Health Department	Works at a clinic that receives RWHAP funding. Works as a sexually transmitted infection (STI) consultant with OIDP.
Daniel Driffin, DrPH, MPH D3 Consulting	No conflicts.
Grissel Granados, MSW Lifetime Survivors Network	No conflicts.
Meredith Greene, MD IU Health Physicians Geriatrics	Works for two organizations that receive RWHAP funding. Recipient of funding from NIH.
Vincent Guilamo-Ramos, PhD, MPH, LCSW, RN, ANP-BC, PMHNP-BC, FAAN Johns Hopkins School of Nursing	Recipient of funding from NIH, CDC, and SAMHSA.
Christine Markham, PhD University of Texas Houston	Recipient of funding from NIH, CDC, Office of Population Affairs, Office of Minority Health, and the Department of Defense.
Brigg Reilley, MPH Northwest Portland Area Indian Health Board	Works at an organization that receives funding from the Indian Health Service.
Robert Riester, PLWH Colorado Health Network	Recipient of funding from RWHAP and CDC.
Leandro Rodriguez, MBA Latino Commission on AIDS	Recipient of funding from CDC, SAMHSA, and RWHAP.
Renata Arrington Sanders, MD, MPH, SCM The Children's Hospital of Philadelphia	Works at an organization that receives funding from RWHAP and CDC. Recipient of funding from NIH.
Samuel So, MBBS, FACS Stanford University	Recipient of funding from CDC and NIH.
Maria Trent, MD, MPH Johns Hopkins University School of Medicine	Works at an institution that receives research supplies from a corporate entity through a material transfer agreement. Recipient of funding from NIH.

CHAC Ex-Officios and Liaisons in Attendance:

- Dr. Carolyn Deal, National Institutes of Health (NIH) National Institute of Allergy and Infectious Diseases (NIAID)
- Dr. Neerja Gandotra, Substance Abuse and Mental Health Services Administration (SAMHSA)
- Dr. Christopher Gordon, NIH National Institute of Mental Health (NIMH)
- Mr. Richard Haverkate, Indian Health Service (IHS)
- Ms. B. Kaye Hayes, HHS Office of Infectious Disease and HIV/AIDS Policy (OIDP)
- Dr. Julia Tait Lathrop, U.S. Food and Drug Administration (FDA), Office of Blood Research and Review
- Dr. Iris Marry-Hernandez, Agency for Healthcare Research and Quality (AHRQ)

- Dr. Sarah Read, NIH NIAID

Approval of Minutes

Wendy Armstrong, MD
Professor
Emory University School of Medicine
CHAC Co-Chair

Dr. Armstrong asked CHAC members to vote on the approval of the April 2024 CHAC meeting minutes.

CHAC Action
Dr. Christine Markham made a motion to approve the minutes from the April 9–10, 2024, CHAC meeting. Dr. Shannon Dowler seconded the motion. CHAC approved the minutes with 17 affirmative votes, 0 opposed, and 0 abstentions with no changes or further discussion.

DFO Welcoming Remarks

Laura Cheever, MD, ScM
Associate Administrator
HRSA HAB

Jonathan Mermin, MD, MPH
Rear Admiral, U.S. Public Health Service (USPHS) (Ret.)
Director
CDC National Center for HIV, Viral Hepatitis, STD, and Tuberculosis Prevention (NCHHSTP)

Dr. Cheever welcomed attendees to the October 2024 CHAC meeting, highlighting a comprehensive agenda shaped by members' input over the past year. Dr. Cheever stated the meeting will include federal updates and panels addressing critical issues, such as re-engaging individuals with HIV out of care through data to care (D2C) strategies and overcoming care barriers, the use of long-acting (LAI) ART for HIV care and treatment from people with lived experience, and increasing access to mental health services for people with HIV and STDs.

Dr. Mermin reflected on his experience with various advisory committees and expressed that he believed the CHAC had evolved into a vital platform for addressing critical issues collaboratively across multidisciplinary fields. Dr. Mermin highlighted key topics on the agenda, including D2C — utilizing data to improve lives, integrating mental health issues into programmatic work, and advancing the availability of LAIs to individuals in need. Dr. Mermin emphasized the importance of these innovative topics and looked forward to the insights participants would bring thanking everyone for their time and commitment to the discussions.

HRSA HAB Update

Laura Cheever, MD, ScM
Associate Administrator
HRSA HAB

Dr. Cheever discussed recent updates and initiatives aimed at advancing HIV care and treatment in the U.S. Dr. Cheever outlined HAB's vision to achieve optimal HIV care for all, particularly through the Ryan White HIV/AIDS Program (RWHAP), which provides leadership and funding to improve health outcomes and reduce disparities among people with HIV.

HAB's Ryan White Program 2030 initiative seeks to address gaps in viral suppression rates within jurisdictions, particularly among individuals diagnosed with HIV who are out of care. This approach integrates comprehensive care addressing multiple health and social challenges beyond just HIV. To advance this work, HAB has funded six cooperative agreements nationwide, along with an evaluation and technical assistance center to support and measure the program's impact. These efforts aim to leverage partnerships, focus interventions, and engage communities in identifying and addressing barriers to care.

Dr. Cheever also highlighted HAB's Catalyzing Unity, Leadership, and Team-building through Individualized, Validating Approaches to Transformational Empowerment for people with HIV, or CULTIVATE, initiative[1] designed to empower people with HIV as leaders within the healthcare system. This program will train individuals with lived experience to actively participate in RWHAP activities, including planning councils and decision-making bodies. By focusing on training-of-trainers models, CULTIVATE aims to enhance the diversity and representation of individuals with HIV engaged in healthcare planning, ensuring their perspectives are integrated into local and national HIV responses.

HAB is prioritizing the development of a new generation of HIV care providers. Dr. Cheever discussed the development of HIV clinical training tracks for primary care residents[2], focusing on integrating HIV care into the broader context of primary care services. These tracks aim to address the growing need for trained providers capable of reaching and caring for individuals living with HIV, especially those who are out of care or underserved.

Dr. Cheever also discussed several key policy updates that reflect HAB's responsiveness to community and stakeholder feedback:

- Expungement services: HAB issued a program letter clarifying that RWHAP funds can be used for legal services related to expunging criminal records.[3] This policy aims to reduce barriers to care by addressing the stigma and systemic challenges individuals face due to prior convictions.
- HAB issued a program letter stating it expanded the allowable uses of RWHAP funds to include security deposits.[4] The change was made possible through close collaboration with the U.S. Department of Housing and Urban Development to ensure that funds for security deposits could be reclaimed by grant recipients at the end of a lease, thus avoiding conflicts with statutory restrictions on direct cash payments to clients.
- HAB issued a program letter on CDC's clinical guidelines on the use of Doxycycline post-exposure prophylaxis (doxy PEP) for prevention of bacterial STIs.[5] HAB encourages RWHAP recipients to

[1] https://targethiv.org/cultivate.
[2] https://www.hrsa.gov/grants/find-funding/HRSA-24-109.
[3] https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/grants/hrsa-hab-expungement-program-letter.pdf.
[4] https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/grants/hrsa-hab-security-deposit-program-letter.pdf.
[5] https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/grants/hab-doxy-pep-clinical-guideline-bacterial-sti-prevention.pdf.

use RWHAP funds to purchase doxycycline for eligible RWHAP clients and for RWHAP Part B AIDS Drug Assistance Programs add doxycycline to their formularies to ensure access and coverage.
- HAB released guidance outlining how RWHAP funds may be used to support people who are aging with HIV across various RWHAP core medical and support services categories described in HAB Policy Clarification Notice #16-02.[6]

Dr. Cheever highlighted the success of the recent 2024 National Ryan White Conference, which featured over 160 concurrent sessions, 127 posters, and participation from more than 8,000 attendees, both in-person and virtually. The conference emphasized peer-to-peer technical assistance and practical, community-driven solutions to challenges in HIV care. Community engagement was a particular highlight, underscoring the importance of grassroots input in shaping the future of the RWHAP.

Dr. Cheever presented new data from the RWHAP and the Ending the HIV Epidemic in the U.S. (EHE) initiative. In 2022, EHE jurisdictions achieved notable success, with approximately 22,000 individuals new to care and 19,000 re-engaged in care, representing 15 percent of the total population individuals diagnosed in EHE jurisdictions who were out of care. This accomplishment doubled initial program goals,[7] showcasing the effectiveness of targeted interventions. Dr. Cheever also presented on the 2022 RWHAP AIDS Drug Assistance Program (ADAP) Annual Data Report. ADAPs serve 291,170 people with HIV. Dr. Cheever also mentioned that, on August 20, HRSA announced more than $1.4 billion to provide lifesaving HIV medications and health care services to individuals with HIV and low incomes. Additionally, HAB continues to make strides in addressing health disparities, particularly among populations disproportionately impacted by HIV, through culturally relevant care, stigma reduction, and expanded access to innovative treatments like long-acting injectables.

Dr. Cheever's update reflected HAB's commitment to innovation, collaboration, and community-driven solutions in its efforts to end the HIV epidemic in the U.S. by 2030. Through initiatives like Ryan White Program 2030, CULTIVATE, and EHE, HAB is addressing barriers to care while advancing policies and programs that promote health equity and improve outcomes for people with HIV.

HRSA Update

Jordan Grossman, JD
Deputy Administrator
HRSA

Mr. Grossman highlighted HRSA's mission and ongoing priorities and emphasized HAB's critical role within it. Mr. Grossman outlined HRSA's top priorities, including integrating behavioral health into primary care, growing and diversifying the healthcare workforce, and reducing health disparities, especially in maternal health. Mr. Grossman acknowledged the need for continuous improvement and emphasized the significance of expanding programs like RWHAP, which supports over 560,000 individuals with HIV. Mr. Grossman noted the importance of addressing social determinants of health, such as housing and stigma, which continue to hinder effective care for some individuals despite ongoing progress.

[6] https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/grants/oaltlt-program-letter.pdf.
[7] https://ryanwhite.hrsa.gov/data/reports.

Mr. Grossman discussed two significant challenges facing HRSA. First, he mentioned the structural issues in the 340B program, which provides essential financial support to lower drug costs for individuals with HIV. Second, Mr. Grossman emphasized more resources for RWHAP and EHE are crucial for sustaining and building upon recent advancements.

Mr. Grossman closed his remarks by expressing deep gratitude for the community's efforts over the years. Mr. Grossman recognized that progress in HIV care was not accidental but the result of dedicated work by professionals across the nation. Mr. Grossman assured the audience that HRSA values their contributions and is committed to supporting these critical public health efforts.

HRSA Bureau of Primary Health Care (BPHC) Update

Jim Macrae, MA, MPP
Associate Administrator
HRSA BPHC

Mr. Macrae described the challenges of high-level health administration as akin to a duck gliding on water, where smooth appearances mask intense effort beneath the surface. These challenges include managing various stakeholder perspectives and adapting to different administrative priorities.

Mr. Macrae discussed BPHC's efforts to end the HIV epidemic, outlining three primary goals of Primary Care HIV Prevention funding: increasing HIV testing, ensuring linkage to care for individuals diagnosed with HIV, and expanding HIV prevention by prescribing pre-exposure prophylaxis (PrEP).[8] Mr. Macrae highlighted BPHC's progress, noting that 411 health centers received funding to expand HIV prevention services and are supported by $157 million in funding annually. These health centers conducted nearly 4 million HIV tests and provided over 83,000 individuals with PrEP services.

Mr. Macrae underscored that health centers' work outpaced national averages, demonstrating the Health Center program's effectiveness. Mr. Macrae noted the integration of HIV prevention into primary care, indicating that nearly 16 percent of all PrEP users nationwide were served by health centers in 2023. Furthermore, the Health Center program aimed to make healthcare environments more inclusive and accessible, with improvements in addressing sexual health within primary care and creating welcoming settings.

Mr. Macrae concluded by inviting feedback to refine and expand the health center program's impact on ending the HIV epidemic, reiterating gratitude for collaborative efforts and emphasizing the importance of the broader partnership in achieving these goals.

HRSA Bureau of Health Workforce (BHW) Update

Candice Chen, MD, MPH
Acting Associate Administrator
HRSA BHW

[8] https://bphc.hrsa.gov/funding/funding-opportunities/primary-care-hiv-prevention/fy-2023-awards.

Dr. Chen discussed BHW's major initiatives and strategies for addressing healthcare workforce challenges, particularly in underserved areas. BHW's goals include increasing workforce supply, improving distribution, advancing health equity, promoting worker well-being, and amplifying HRSA's impact. Dr. Chen highlighted BHW's substantial investments across multiple programs, notably in training grants, scholarships, loan repayment programs, and graduate medical education. BHW's funding allocations for fiscal year 2024 included $775 million for training grants, $579 million for scholarships and loan repayment, and $565 million for graduate medical education.

She noted the projected shortfall of healthcare providers in areas including infectious disease, where there is estimated to be a 12 percent national deficit in infectious disease physicians by 2036, impacting 38 states. Addressing workforce shortages, BHW's programs, like the National Health Service Corps and Nurse Corps, provide financial support in exchange for service in underserved communities. The National Health Service Corps supports nearly 18,000 healthcare professionals, including 9,000 in mental health, aiming to alleviate critical provider shortages across rural and underserved areas.

Dr. Chen emphasized the importance of early intervention in training pipelines to recruit diverse candidates, with initiatives like the Teaching Health Center Graduate Medical Education program[9] embedding primary care residency in community-based settings. Behavioral health integration is also a focus, with fiscal year 2025 grants aimed at addiction medicine, psychology, and paraprofessional training to improve access to mental health services, particularly in areas heavily impacted by substance use disorders.

Finally, Dr. Chen highlighted HRSA's support for community health workers and peer support specialists, enhanced through federal funding to address behavioral health needs in underserved regions. This workforce expansion supports the integrated primary and behavioral healthcare models, contributing to better health outcomes and healthcare delivery equity.

CDC Update

Jonathan Mermin, MD, MPH
Rear Admiral, USPHS (Ret.)
Director
CDC NCHHSTP

Dr. Mermin announced the upcoming CHAC charter renewal for November 25, 2024. Dr. Mermin then reviewed CDC's advancements of the 2023 CHAC recommendations of STI self-testing and self-collection, including collaboration with industry and academia to collect safety and stability data for Chlamydia trachomatis and Neisseria gonorrhoeae NAAT testing and the ongoing development of rapid point-of-care (POC) syphilis test that allows detection of both treponemal and non- treponemal antigens and a new POC CT/NG test. Dr. Mermin also highlighted a new FDA-cleared syphilis self-test.

CDC staff updates included Dr. Bradley Stoner as the new Director of the Division of STD Prevention and Dr. Renata Ellington as Deputy Director for Operations, Communications, and Policy.

[9] https://bhw.hrsa.gov/funding/apply-grant/teaching-health-center-graduate-medical-education.

Dr. Mermin discussed NCHHSTP's modeling and syndemic approach updates, noting CDC awarded Stanford and Emory universities a new five-year National Epidemiologic and Economic Modeling Agreement (NEEMA) grant[10] to support epidemiologic and economic modeling. CDC continues to advance syndemic approaches, including through partnerships with academic institutions, to improve the cost-effectiveness of screening and intervention models.

The NCHHSTP Office of Health Equity's[11] new initiatives aimed at advancing health services for justice-involved individuals were highlighted, including a correctional health newsletter and a guide for implementation in correctional settings. The NCHHSTP Office of Science updates were also discussed noting key clearance metrics, the development of a Science Prioritization Framework which emphasizes importance of strategic planning, establishing specific objectives, and formulating formal learning agendas, and a scholarly impact assessment.

Dr. Mermin emphasized the work of the Tuberculosis (TB) Elimination Alliance[12], recently funded by a new cooperative agreement, a national partnership of community leaders dedicated to increasing knowledge, testing, and treatment of TB and latent TB infection among populations at risk for TB, including Asian American, Native Hawaiian, Pacific Islander, Hispanic and Latino and African-American communities, targeting high-risk communities and strengthening the response to outbreaks. CDC efforts for continual support of health departments with TB outbreak response and large contact investigations were discussed. In response to recent shortages of tuberculosis and syphilis drugs in the United States, the Association of State and Territorial Health Officials, in collaboration with NCHHSTP, the Division of STD Prevention and the Division of TB Elimination developed a policy toolkit to support contingency planning for drug shortages and other medication access challenges for critical medicines, particularly drugs used to treat TB and syphilis.

The Division of STD Prevention launched the Support and Scale-Up of HIV Prevention Services in Sexual Health Clinics, or SHIPS, NOFO, a five-year award that started in August. The program supports the EHE initiative by scaling up HIV prevention and care services in existing sexual health clinics. doxy PEP guidance was released in the June 6, 2024, Morbidity and Mortality Weekly Report (MMWR).[13] In addition to the doxy PEP guidelines, the National Syphilis and Congenital Syphilis Syndemic Federal Task Force released considerations for implementation of POC testing for syphilis. There are currently two FDA authorized POC tests, ChemBio DPP and syphilis health check, that a health professional must perform for syphilis that can provide rapid test results in about 15 minutes. This can help overcome barriers in our ability to timely diagnose patients in communities across the nation. And lastly, the Bicillin shortage that began last year is resolving.

Dr. Mermin reviewed CDC's HIV prevention achievements, reporting a 12 percent reduction in overall in new HIV infections in the past four years, with significant decreases among young adults. However, racial disparities remain, with high infection rates among Black and Hispanic/Latino communities, especially in the South. EHE counties had a larger decrease in HIV incidence. In the 50 Phase I EHE counties, HIV incidence decreased 21 percent in 2022 compared to the baseline 2017. In all other U.S. and Puerto Rico (PR) municipalities, HIV incidence decreased six percent (19,100 in 2017; 17,900 in 2022) during that period. This is the clearest evidence that EHE is working. Dr. Mermin discussed CDC's tailored messaging

[10] https://www.cdc.gov/neema/php/index.html.
[11] https://www.cdc.gov/health-equity/index.html.
[12] https://www.cdc.gov/tb/tuberculosis-elimination-alliance/index.html.
[13] https://www.cdc.gov/mmwr/volumes/73/rr/rr7302a1.htm.

for Black and Latino, gay, bisexual, same gender loving, and other men who have sex with men in the south and their providers and the expansion of PrEP programs. Community outreach was highlighted noting that starting in August 2023, the Division of HIV Prevention partnered with the National Association of County and City Health Officials, the Southern AIDS Coalition, and regional community conveners to host in-person engagement sessions with community-led and community-serving organizations in the Southeast United States. The sessions aimed to discuss barriers and opportunities to promote health equity, expand community engagement, and understand local programming around syndemic and whole-person approaches.

Dr. Mermin discussed the 2024 new hepatitis C prevalence estimates published by CDC's NEEMA partnership that found that an estimated 2.4 million people had hepatitis C in the United States from 2017 to 2020, and it could be as many as 4 million. CDC staff published a paper in July 2024 that assessed the association of Medicaid policies that restricted access to hepatitis C treatment with overall treatment initiation numbers among Medicaid recipients. The analysis showed significant percent decreases in the number of people who were prescribed hepatitis C treatment because the state did not expand Medicaid, limited treatment to those with advanced liver disease, or required a period of sobriety before treatment initiation. This analysis suggests that removing prior authorization requirements may increase the number of Medicaid recipients who are treated for hepatitis C. FDA in partnership with NIH and CDC announced market availability of a hepatitis C virus RNA POC test on June 30, 2024. CDC has shared implementation considerations[14] and a cost calculator tool to help health departments and other venues offering hepatitis C testing determine how best to incorporate this tool. Another exciting development in testing is that the CDC and NIH have collaborated to fund NIH's Rapid Acceleration of Diagnostics Independent Test Assessment Program to rapidly bring a POC hepatitis B surface antigen test to market,[15] similar to the recent effort for the POC HCV RNA test. The program announced a solicitation at the end of September. Further, the FDA posted their proposal to down classify hepatitis B virus diagnostics on the federal register on September 25, 2024.[16] Lastly, early analysis from the Congressional Budget Office regarding the budgetary impact of hepatitis C treatment in the Medicaid population, which is a focus population of the proposed hepatitis C elimination initiative, showed substantial cost savings. This concurs with other models that project substantial cost savings from a national hepatitis C elimination initiative.

Dr. Mermin concluded with an update on HIV PrEP access, noting a new Centers for Medicare & Medicaid Services (CMS) Nation Coverage Determination starting September 30, 2024, where Medicare will cover without cost-sharing, FDA-approved PrEP using antiretroviral drugs to prevent HIV in individuals at increased risk of acquiring HIV, including administration of injectable PrEP using antiretroviral drugs to prevent HIV, supply or dispensing the drug regardless of route of administration, as well as the other recommended services that are part of PrEP care.

CHAC Member Discussion with CDC and HRSA on Updates

The following questions, observations, and suggestions were raised:

[14] https://stacks.cdc.gov/view/cdc/164804.
[15] https://www.cimit.org/radx-tech-itap-for-hepatitis-b-virus-surface-antigen.
[16] https://www.federalregister.gov/documents/2024/09/25/2024-21932/microbiology-devices-reclassification-of-antigen-antibody-and-nucleic-acid-based-hepatitis-b-virus.

- Dr. Dowler raised three key points: first, she sought clarification on whether a CMS announcement on prior authorization for PrEP medication applied to all payers or just Medicare, which was confirmed to be only for Medicare. Second, she expressed mixed feelings about the 21 percent reduction in HIV cases in EHE jurisdictions, highlighting that while it shows progress, it falls short of expectations given the significant resources invested in ending the epidemic. Lastly, she voiced concerns regarding over-treatment of bacterial STIs, noting that empirical treatments often lead to excessive antibiotic use, especially as some clinicians prescribe broad treatments for STIs without confirmatory diagnostics. Dr. Mermin responded by acknowledging the complexity of achieving precise treatment approaches, stating that while new diagnostics could potentially enable more specific treatments, current STI treatments still rely on empirical methods due to resistance issues. Dr. Mermin stated that while improved diagnostics are desirable for the future, current guidelines were revised for antimicrobial stewardship, switching to monotherapy to reduce unnecessary antibiotic use, a change that has been positively received.

- Dr. Sanders expressed concerns about the shortage of primary care providers specializing in HIV and PrEP care, especially within internal medicine and pediatrics, where recent residency positions remained unfilled. Dr. Sanders questioned how to ensure that primary care and HIV care providers receive the necessary residency training given this issue. Dr. Chen acknowledged the ongoing primary care workforce shortage was in part due to pay imbalances favoring hospital-based medicine, as most graduate medical education funding is hospital-controlled through Medicare. Dr. Chen mentioned initiatives like the Teaching Health Center program, which redirects funding toward primary care, though it represents only about one percent of Medicare's graduate medical education funding. Dr. Chen also highlighted challenges specific to pediatrics, where infectious disease subspecialties offer limited financial returns, discouraging residency graduates from pursuing them. Dr. Chen noted that while loan repayment programs for pediatric specialties exist, the programs' limited funding and scope may not provide sufficient incentive for students to enter lower-paying fields, suggesting a need for more comprehensive systemic reforms.

- Dr. Sanders emphasized that, despite some progress, efforts to provide PrEP to the 1.2 million people in need in the U.S. are falling short, with significant disparities in access among Black gay, bisexual men, and Latinx transgender women in the South. Mr. Macrae agreed, acknowledging the limitations of current resources (about $400,000 per clinic) and discussed efforts to integrate PrEP into routine primary care and to reach underserved communities through community health workers and partnerships with tech communities. Dr. Mermin echoed Dr. Sanders' points, highlighting that while 500,000 PrEP prescriptions were issued last year, this still falls short of need. Finally, Dr. Cheever referenced CDC modeling that suggested the funding needed to meet year-five goals of the EHE initiative is significantly higher than current allocations, stressing the challenge of needing to reprioritize within limited funds.

- Ms. Cadena-Fulks expressed concern about the lack of protection for the health information of individuals with HIV who use Housing Opportunities for Persons With AIDS funding for rental deposits. Ms. Cadena-Fulks was apprehensive about safeguarding the residents' HIV status. In response, Dr. Cheever acknowledged that various recipients might employ different methods to address this issue but emphasized that maintaining the confidentiality of HIV status is indeed a priority as they move forward.

- Ms. Cadena-Fulks expressed concern over a lack of updated information on efforts addressing HIV's impact on the transgender community in a recent CDC report. Ms. Cadena-Fulks emphasized the

need for updates specifically on engagement and PrEP accessibility, as well as strategies for supporting transgender individuals, particularly in states with HIV criminalization laws. Dr. Mermin acknowledged her concerns, noting that there are targeted initiatives, including specific funding, to support transgender individuals with PrEP access, diagnosis, and treatment. Dr. Mermin suggested the topic could benefit from a dedicated, in-depth discussion at the next CHAC meeting. Dr. Mermin also highlighted ongoing internal considerations for a more standardized and comprehensive approach to addressing HIV prevention and care across multiple agencies, suggesting that a syndemic approach for both trans women and men might be more effective at a larger scale.

- Ms. Cadena-Fulks expressed concerns about the 340B program's impact on community-based organizations, particularly regarding their sustainability and its potential effects on RWHAP. Ms. Cadena-Fulks questioned how RWHAP-funded case management and recipients are being protected within the 340B framework, especially as community-based organizations may push to recruit more 340B patients to secure income. Dr. Cheever acknowledged the program's importance for RWHAP but noted criticisms that some hospitals benefiting significantly from 340B funds are not necessarily increasing services for high-need populations. Dr. Cheever stated that HRSA tracks 340B fund usage through site visits and data collection (e.g., RWHAP Services Report data), ensuring reinvestment into RWHAP services. Ms. Hauck added that HRSA supports the integrity of the 340B program through technical assistance efforts, partnering with organizations like National Alliance of State & Territorial AIDS Directors (NASTAD) to assist RWHAP Part B ADAPs. Dr. Cheever acknowledged the broader challenges within 340B that HRSA continues to monitor closely.

- Ms. Beiser raised concerns about barriers to implementing HIV and hepatitis treatments effectively, especially for vulnerable populations. Ms. Beiser highlighted the challenges health centers face due to CMS policies that classify certain medications as specialty drugs, requiring complex insurance navigation that diverts staff time from direct outreach to high-need patients, including individuals who use drugs. Ms. Beiser also expressed concern that forthcoming advancements in PrEP could face similar barriers. Mr. Macrae agreed, acknowledging similar issues with hepatitis C treatments in health centers and emphasizing the importance of sharing real-world experiences with CMS and other insurers. Mr. Macrae noted that these on-the-ground insights help drive internal advocacy for policy adjustments to ensure better access to critical treatments.

- Dr. Greene expressed gratitude for HRSA's August 2024 letter on services for older adults with HIV, emphasizing its impact on local planning and the importance of including long-term survivors to address diverse needs. Dr. Greene raised a broader issue about integrating HIV care with primary care. Dr. Greene noted her experience with different models and observed that patients and colleagues desire a unified service location. Dr. Cheever agreed, acknowledging that while HIV care has simplified, supportive and stigma-free environments remain essential. Dr. Cheever discussed efforts to bridge primary and HIV care through initiatives like practice transformation and fostering a team-based care approach. Mr. Macrae added that evolving health center involvement in HIV care, previously exclusive to RWHAP-funded clinics, now reflects a need for broad support and wraparound services fueled by targeted funding like the EHE initiative. Dr. Chen highlighted the role of specialized workforce programs, advocating for adaptable care models tailored to community needs and emphasizing collaboration among specialists, such as geriatricians, to enhance healthcare systems holistically.

- Dr. Driffin raised concerns about the racial and ethnic breakdown of PrEP data and highlighted gaps in HIV care at community health centers, particularly in Atlanta, Georgia, where some major centers

still do not address HIV. Dr. Driffin emphasized the need for a broader, holistic approach to HIV care involving public health practitioners alongside clinicians. Mr. Macrae acknowledged that detailed demographic data for PrEP use is still in progress. Mr. Macrae stated that the Uniform Data System+ would soon allow for patient-level data collection, covering aspects like race, ethnicity, and insurance status, which could improve targeted interventions. Mr. Macrae also noted that while many health centers are now participating in HIV care programs, some still resist, and further funding could help bring them on board. Dr. Chen agreed on the importance of a systems-based approach beyond clinical work, emphasizing the need for investment in public health workforce training. Dr. Chen mentioned existing but limited programs in preventive medicine and public health training, noting that funding and interest often fluctuate, as seen with temporary boosts during the COVID-19 pandemic.

- Dr. Armstrong noted a 21 percent improvement in health outcomes attributed to targeted direct health expenditure funding while acknowledging that the funding levels were still inadequate to meet the full scope of needs. Dr. Armstrong inquired if data by county could reveal disparities or best practices, given the varied impact across regions. Dr. Mermin confirmed that jurisdiction-specific data is available in CDC's surveillance report, although confidentiality limits some details. Dr. Mermin added that understanding what strategies worked or failed requires examining localized responses, resource allocation, and whether services are optimally located for target populations. Dr. Cheever contributed that HRSA's qualitative report details successful strategies across jurisdictions and highlighted the new inclusion of jurisdiction-specific data in the report, potentially shedding light on regional efficiency in funding use.

- Dr. Armstrong expressed concerns about workforce issues in infectious disease and HIV care, noting a shortage of professionals in primary care due in part to medical schools' portrayal of the field and the bureaucratic challenges faced by primary care doctors. Dr. Armstrong highlighted how working in supportive environments, like RWHAP clinics, can make primary care and HIV care more fulfilling, partly because of extended patient visit times. Dr. Armstrong challenged the accuracy of workforce analysis data, arguing that infectious disease physicians, particularly individuals providing HIV care, are overrepresented in projections, leading to a misconception of an adequate infectious disease workforce. In response, Dr. Chen acknowledged the limitations of workforce projections, noting that they are based on assumptions and can be inaccurate, as illustrated by past misprojections of geriatricians. Dr. Chen emphasized her openness to collaboration to improve these projections, inviting input from the infectious disease and HIV care fields to ensure the data reflects actual workforce needs.

- Dr. Markham raised a question regarding HIV incidence rates and disparities among American Indian, Alaska Native, Native Hawaiian, and Pacific Islander communities, emphasizing the need for improved resources, testing, and access to preventive care. In response, Dr. Mermin acknowledged these disparities and highlighted the need for increased focused support and investment, though existing data does provide some insights into these populations. Mr. Reilley added that while IHS's healthcare system mirrors general rural healthcare challenges, it also benefits from non-clinical services that improve patient care outcomes despite limited ART programs. Mermin noted the specific challenges these communities face, particularly in rural areas where accessing services can be difficult. Dr. Mermin pointed to efforts in syphilis prevention as a model, such as expanding access to preventive treatments like doxy PEP and HIV self-tests, which could be delivered directly to people's homes to circumvent the need for clinic visits.

- Dr. Trent raised concerns about several issues:
  1. Workforce gaps in adolescent medicine, particularly for HIV care. Only about 30 new providers are trained annually. Dr. Trent suggested potential lobbying to increase training centers in collaboration with HRSA programs, as adolescent medicine physicians often handle HIV and PrEP services.
  2. Adolescent privacy within electronic health records (EHRs). Adolescents face barriers in receiving confidential care due to parental access to EHRs, which includes sensitive data related to STI, HIV, and pregnancy care, despite legal protections. Dr. Trent urged for governmental pressure to enforce privacy in adolescent health records.
  3. Overlooked issue of trichomonas. Data suggests high rates occurring among certain populations and its link to HIV and calling for targeted intervention strategies.

  In response, Mr. Macrae acknowledged the challenges around EHR privacy, noting that, while efforts are underway, parental access issues further complicate privacy efforts.

- Ms. Granados thanked CDC partners for including lifetime survivors in its report and highlighted a key finding: individuals with perinatally acquired HIV had higher rates of HIV-related deaths from 2018 to 2022. Ms. Granados emphasized the need to track this group separately in data. Additionally, she underscored the importance of adolescent HIV care specialists and noted workforce challenges, particularly the high turnover in case management, which disrupts patient care.

- Dr. Cestou expressed concern over negative data regarding Latinos and questioned what proactive or reactive steps the CHAC, along with the CDC and HRSA, planned to take in response. Dr. Cheever responded that recent HAB efforts have focused on improving language access, including translating materials into Spanish, and holding presentations in Spanish at national conferences. Dr. Cheever also mentioned ongoing discussions regarding initiatives to prioritize improved outcomes for Latino populations.

- Mr. Riester asked about the funding allocation and community involvement in workforce analysis processes. Dr. Chen stated that the National Center for Health Workforce Analysis receives around $5.6 million annually, supplemented by investments from agencies like CDC and SAMHSA. This funding supports various workforce initiatives, including National Health Workforce projections and specialized research centers for mental and behavioral health. Dr. Chen acknowledged the importance of community input, noting that while advisory committees exist to gather diverse perspectives, including patient representation, there is room for improvement in enhancing community engagement.

CHAC Workgroup Reports

LAI Workgroup

Shannon Brown Dowler, MD
North Carolina Medicaid
Chair

Dr. Dowler summarized the LAI workgroup's efforts and progress over the past year. Dr. Dowler stated that the workgroup met between the spring and fall of 2024 to finalize various items discussed in

previous meetings, including collaborating with HRSA to organize a panel featuring people with lived experience's perspectives on using LAIs for the fall 2024 CHAC meeting.

Dr. Dowler then reviewed several recommendations the workgroup developed and were deliberated and approved by the CHAC in fall 2023, such as standardizing access to LAIs across payers, collaborating with IHS to include LAIs in formularies, and encouraging flexibility in adolescent and adult ART guidelines to enable broader use of these injectables. In spring 2024, the workgroup refined these ideas and focused on issues like reimbursement and cost-sharing.

The workgroup addressed the need for more explicit policies regarding whether LAIs should be reimbursed under pharmacy or medical benefits, as inconsistent policies have created confusion and barriers for providers. Dr. Dowler mentioned the importance of eliminating co-pays for LAI treatments. Dr. Dowler also suggested sunsetting CHAC recommendations on studying LAIs, as research is already underway. Lastly, Dr. Dowler proposed revisiting the topic in the spring 2025 CHAC meeting with a scientific panel to discuss LAIs for HIV, STIs, TB, and hepatitis.

Dr. Dowler emphasized the workgroup's goal of creating supportive policy and payment structures to enable clinicians to deliver timely and effective patient care. This reflects the group's focus to eliminate barriers and empowering providers to "do the right thing" for patients.

Community Partnership Workgroup

Meredith Greene, MD
Indiana University School of Medicine
Chair

Dr. Greene noted that the workgroup had completed its work at the spring 2024 meeting, and there were no updates.

Workforce Workgroup
The Workforce Workgroup did not provide an update.

Panel 1: Data-to-Care Strategies to Re-Engage People with HIV Out of Care

Melanie Moore, PhD
Senior Health Scientist
HRSA HAB

Dr. Moore, the panel moderator, gave an overview of HAB's D2C strategies designed to re-engage people with HIV who are out of care. Dr. Moore highlighted several key RWHAP initiatives to enhance collaboration among health departments, HIV providers, and support services to improve the engagement and retention of individuals with HIV.

Dr. Moore stated that D2C optimizes existing data sources to identify people not currently receiving HIV care, helping reconnect them to essential services. D2C programs have facilitated stronger partnerships within the healthcare sector and shown promising results in retention and re-engagement rates.

HAB implemented the RWHAP Part F Special Projects of National Significance (SPNS) *Leveraging a Data to Care Approach to Cure Hepatitis C within the RWHAP* initiative from 2020 to 2022, which focused on using data integration to address both HIV and hepatitis C in the RWHAP. This project enrolled over 5,000 individuals, with more than 40 percent completing treatment and achieving viral suppression. Another RWHAP Part F SPNS initiative, *Improving RWHAP Outcomes Using a Tiered Technical Systems Approach to HIV-STI Data Linkages*, aimed to improve data-sharing practices among public health departments for better linkage between HIV and STI data. This initiative project offered technical support to public health departments to create integration plans and enhance interdepartmental collaboration.

Additionally, HAB implemented the RWHAP Part F SPNS *Building Capacity to Improve Collecting and Reporting Viral Suppression Data to the Medicaid Adult Core Set* initiative, which worked with state Medicaid programs to improve the reporting and collection of viral suppression data from the Medicaid Adult Core Set. This project provided resources and technical assistance to state HIV and Medicaid Programs for better data handling.

Dr. Moore concluded by discussing HAB's EHE initiative, which supports data-related workforce training, infrastructure improvements, and integration activities such as developing software, enabling data sharing, and automating data exchanges. These efforts are coupled with HAB's initiatives to cross-reference client lists to reach out-of-care individuals and advancements in data monitoring and evaluation.

Finally, Dr. Moore encouraged attendees to explore resources such as the RWHAP Compass Dashboard, which provides insights into the reach and impact of HRSA's programs at national and local levels. Dr. Moore introduced the panelists Patricia Sweeney, Julie Dombrowski, and Colin Flynn, who would further discuss D2C innovations and challenges.

Data to Care Strategies to Re-Engage People with HIV Who are Out of Care

Patricia Sweeney
Senior Epidemiologist
National Center for HIV, Viral Hepatitis, STD, and Tuberculosis Prevention
CDC Division of HIV Prevention

Ms. Sweeney presented an overview of D2C strategies, data sources, and D2C lessons learned from health departments. Ms. Sweeney stated that D2C is a public health approach that uses HIV surveillance and other data to identify individuals not in medical care, link them to healthcare services, and help them achieve and maintain viral suppression. This strategy involves collaboration between surveillance, prevention, and care programs and requires partnerships with healthcare providers.

Ms. Sweeney highlighted that D2C programs are essential for re-engaging individuals in HIV care. Various D2C strategies exist, such as using surveillance data to track individuals who may be out of care, linking them back to healthcare, and, in some cases, using pharmacy refill data to monitor prescription adherence. Health departments may also use different data sources, such as pharmacy refill records and health information exchanges, to improve their efficiency in identifying people out of care. However, access to these data sources varies by location due to local laws and policies impacting program implementation.

Ms. Sweeney reviewed the steps in a typical D2C program, which includes identifying individuals with HIV, linking them to care, and tracking viral suppression. Collaboration, data sharing, and community involvement were emphasized as critical components for program success. Ms. Sweeney noted that integrating multiple data sources, such as laboratory data and surveillance systems, enhances the accuracy of identifying individuals out of care. Studies have shown that D2C interventions improve re-engagement rates and viral suppression.

Ms. Sweeney also shared findings from a systematic review of D2C interventions and CDC reports, showing positive impacts on re-engagement and viral suppression. From January 2018 to September 2021, CDC data revealed that nearly 20 percent of identified cases were confirmed out of care, with 30 percent re-linked to care through D2C interventions and another 13 percent returning to care independently. Despite these successes, many individuals declined or could not be successfully re-engaged, highlighting the need to understand better the barriers faced by these individuals.

Finally, Ms. Sweeney acknowledged health departments' challenges, such as limited access to data sources and data-sharing issues. Ms. Sweeney mentioned the need for training and support on best practices, community engagement, and data management. CDC plans to provide further guidance, training, and tools to address these needs and enhance the effectiveness of D2C programs.

HIV Data to Care Strategies to Re-Engage People with HIV who are Out of Care

Julie Dombrowski, MD, MPH
Professor
University of Washington
Director
HIV Treatment Initiatives, Public Health – Seattle & King County

Dr. Dombrowski discussed the development and challenges of the D2C program aimed at identifying and re-engaging individuals with HIV who have fallen out of care or are virally unsuppressed. Dr. Dombrowski outlined the program's evolution from "version 1.0," where initial efforts relied on surveillance data, identifying individuals with HIV out of care based on gaps in lab records. However, this method often yielded inaccurate results, as many flagged individuals had simply moved away.

Dr. Dombrowski detailed two newer methods to improve accuracy: the Regional Inter-jurisdictional Duplicate Evaluation and Resolution, or RIDER, system, which flags duplicate cases for jurisdictional follow-up, and the Black Box System, developed at Georgetown University, which allows jurisdictions to securely match data without direct data sharing. These systems work more effectively when used together, automating a task previously done by health department staff.

Dr. Dombrowski emphasized the importance of expanding data sources to improve the identification of individuals with HIV out of care. Internally, health departments have leveraged RWHAP, RWHAP Part B ADAP, and STI partner services' data sources. Externally, they utilize emergency department, jail booking, pharmacy, and Medicaid records data. Studies in specific regions have shown that integrating hospital and emergency room data, such as individual-level data from projects in Georgia and Seattle, Washington, can help locate high-priority populations, though coverage remains incomplete.

Dr. Dombrowski highlighted the Jail Booking Link program, which integrates jail booking records with HIV surveillance data to identify individuals with HIV who are not in care. This approach, while useful,

showed only a modest increase in post-release viral suppression, revealing the need for more robust, more coordinated support systems within jails and communities.

Dr. Dombrowski also discussed a pilot program with pharmacy data to identify people with HIV who had not refilled their antiretroviral prescriptions, which helped reach individuals overlooked by other methods. However, many flagged cases were due to stockpiled medications or pharmacy changes.

Dr. Dombrowski concluded with offering insights on optimizing D2C initiatives. Dr. Dombrowski advocated prioritizing high-yield activities, such as focusing on individuals with recent viremia and integrating hospital and jail data with surveillance records. Dr. Dombrowski stressed the need for increased data sharing among relevant stakeholders (e.g., RWHAP clinics, pharmacies, and HIV surveillance) and encouraged better alignment between D2C initiatives and low-barrier, differentiated care models to enhance re-engagement effectiveness.

HIV Data to Care Activities in Maryland

Colin Flynn
Chief
Maryland Department of Health/Center for HIV Surveillance, Epidemiology, and Evaluation

Mr. Flynn discussed Maryland's approach to HIV care and prevention, sharing insights from the state's efforts and emphasizing health equity. The state has partnered with various organizations and clinics to integrate health equity into their initiatives, specifically within Maryland's HIV program under the Infectious Disease Prevention Health Services Bureau.

Since 2014, Maryland has implemented a CDC-funded program called Partnerships for Care, collaborating with federally qualified health centers to check and support HIV patients. This partnership involved matching clinic populations to the HIV registry, analyzing patient data, and holding regular meetings with clinics to discuss individual patient progress on the HIV care continuum. The program also worked to clarify roles between state and local agencies, clinics, and outreach teams in coordinating patient care.

The program revealed discrepancies in electronic health records, which sometimes incorrectly flagged patients as HIV-infected. Moreover, the program found that many clinics were unaware of their patient's HIV status due to a lack of coordination between general and specialized care providers. This led to increased efforts in patient re-engagement, HIV screening, and ensuring continuity of care across providers.

The state's data-centric approach integrates surveillance data with electronic health records for a more complete view of patient care. The state identified individuals disconnected from care through regular data matching and addressed barriers to care. Mr. Flynn highlighted a successful statewide continuum of care where 93 percent of people with HIV were diagnosed, with high viral suppression rates among individuals consistently receiving care. However, about 6,000 people remained unlinked to regular care, which the state aims to address by combining surveillance and partner data to support re-engagement.

Maryland has introduced various innovations, such as a mobile application for monitoring HIV viral loads, a system with the University of Maryland's School of Pharmacy to monitor prescription pickups, and the "Gift Act" mandating reporting of pregnancies in HIV-positive individuals to prevent transmission. The

state collaborates with the Medicaid program to monitor viral suppression rates across demographics and health plans.

The state also focuses on HIV cluster detection, a method of identifying localized surges in HIV cases which allows a focused response to ensure patients in these clusters receive necessary care and achieve viral suppression. Maryland detects about 10 clusters annually, often identified geospatially rather than molecularly.

Mr. Flynn emphasized Maryland's commitment to health equity, adapting programs to meet the needs of aging populations, expanding Medicaid, and attracting a significant portion of patients from other regions. Maryland has updated its planning frameworks to reflect a holistic wellness approach and revised funding and structural policies to better address these needs.

Mr. Flynn conveyed Maryland's dedication to using data-driven strategies and partnerships to improve HIV care, underscoring the ongoing need for adaptive, inclusive healthcare practices to achieve viral suppression and support health equity statewide.

Panel 1: Q&A with Speakers and Member Discussion

The following questions, observations, and suggestions were raised:

- Dr. Mermin praised the presentations and discussed the challenge of integrating HIV care into regular healthcare. Dr. Mermin highlighted the benefits and limitations of D2C initiatives for tracking patient care, suggesting that while it improves data accuracy, the process is often too slow. Dr. Mermin posed questions about developing a rapid, nationwide data system and using LAI treatments to support patients more effectively. Dr. Dombrowski and Mr. Flynn echoed support for these ideas, emphasizing the importance of cross-jurisdictional data-sharing tools, like the "Black Box," which have shown success in the District of Columbia area by improving data accuracy and care coordination across regions.

- Dr. Sanders raised concerns about the need for additional data to identify individuals not receiving care and questioned how to ensure data security, especially for marginalized populations, given the potential role of artificial intelligence (AI) and machine learning. Mr. Flynn responded that while data collection has increased significantly, legal protections have expanded to safeguard data against subpoenas or misuse in civil, criminal, or administrative cases. Dr. Dombrowski emphasized the importance of involving individuals with lived experience to build trust and transparency in data use, while Ms. Sweeney acknowledged the challenges health departments face in balancing data use with security. Ms. Sweeney suggested that a national solution could be beneficial but challenging in the current environment. Overall, participants agreed on the need for the involvement of communities to ensure responsible and accepted data use.

- Ms. Sweeney acknowledged the widespread use of the "Black Box" approach in various jurisdictions and highlighted the need for foundational groundwork to implement it as a national solution. Ms. Sweeney emphasized the importance of managing the data responsibly, following up with individuals, and integrating data within specific community programs. Ms. Sweeney also highlighted health departments' significant responsibility in protecting data in D2C activities and commended their efforts. Dr. Armstrong noted that while some people with lived experience are receptive to this approach, acceptance varies significantly across states due to differing local climates.

- Ms. Granados raised concerns about rising surveillance in the Latinx community, particularly regarding undocumented individuals and their fear of government tracking, highlighting the need for informed consent and patient education. Ms. Granados questioned the lack of standardized community engagement practices and asked how re-engagement strategies would differ from prior approaches to ensure sustained care, suggesting a more holistic support approach beyond just medical treatment. Mr. Flynn responded by explaining their organization's efforts to restructure around health equity, focusing on comprehensive support for individuals' overall wellness, including housing and job security. Dr. Dombrowski added that community engagement varies widely and emphasized that re-entry programs prioritize fundamental needs like housing and trust-building over medical interventions.

- Dr. Cheever reflected on an initiative in New York led by Chinazo Cunningham, where a team visited residents in single room occupancy hotels to offer medical care, particularly focusing on HIV care. Often, residents stated they were connected to care, could name their doctor but acknowledged they had not been seen in years and declined immediate care, despite having multiple diagnoses. Dr. Cheever emphasized the importance of understanding a patient's priorities and trust-building, noting that many people may not prioritize HIV care due to factors like internalized stigma. Dr. Cheever concluded that efforts to end the HIV epidemic must involve more inviting, patient-centered systems to address these complex needs and perspectives.

- Dr. Driffin raised two key points, first suggesting inclusive language by replacing "pregnant women and mothers" with "individuals who can bear children" to encompass transgender individuals with HIV raising children. Additionally, Dr. Driffin expressed concern about the lack of direct community engagement by some health departments in HIV care and suggested that communities initiate these conversations rather than wait for government bodies. In response, Mr. Riester shared that Colorado has a data-sharing task force to involve individuals with HIV. Ms. Sweeney added that health departments are increasingly recognizing the importance of community engagement in D2C and cluster response efforts, working to provide resources and foster community dialogue on these issues.

Panel 2: Use of LAIs for HIV Care and Treatment

Marlene Matosky, MPH, RN
Clinical and Quality Branch Chief
HRSA HAB

Ms. Matosky, the panel moderator, presented on an ongoing RWHAP Part F SPNS initiative, *Accelerating Implementation of LAIs*, focused on accelerating implementation of LAIs for HIV treatment. The RWHAP Part F SPNS initiative launched two years ago under a national initiative to explore and scale these treatments. The initiative, currently halfway through, is designed to enhance equitable access to LAI treatments. CHAC began addressing this issue proactively by examining patient experiences early in the rollout as part of the CHAC LAI Workgroup.

One key aspect of this initiative is utilizing an "equity-first" approach. This framework was implemented to avoid disparities previously seen in ART by incorporating equity considerations from the outset. In collaboration with Columbia University and eight diverse demonstration sites across the country, the

initiative sought to incorporate patient perspectives through community forums and an advisory committee, which included individuals with HIV. This setup allowed the project to anticipate barriers and create supportive resources and patient educational materials.

Ms. Matosky discussed challenges identified through the initiative, such as inconsistent access to LAI treatment due to healthcare coverage variations, including insurance and Medicaid limitations. Resource constraints were evident as clinics often struggled with the pre-authorization and procurement processes required for treatment. Additionally, some patients were hesitant about LAI treatment, given the need for regular clinic visits every two months, and both patient and provider enthusiasm for the program varied. Additionally, she noted that several clinics have extended this equity-first framework to other aspects of their practices, reflecting the project's broader impact.

Ms. Matosky concluded by summarizing the CHAC LAI Workgroup's recent work, including its collaboration with HRSA, to facilitate a panel of people with lived experience to discuss their use of LAI treatments. Ms. Matosky then introduced the five panel members with lived experience, representing diverse professional and geographical backgrounds, to share their perspectives on the use of LAI treatment.

Panel Q&A

Ms. Matosky facilitated a panel discussion with five individuals who shared their personal experiences with LAI HIV treatments, offering insights into the impact and challenges of this approach from a patient perspective. The panelist questions and answers are summarized below.

How did you decide to start using LAI antiretroviral medications?

- Erick started LAI treatment to gain firsthand experience to help him better advise patients at his clinic. Erick also found that using LAIs reduced the stress of frequent pharmacy visits, especially around holidays.
- Mikayla started LAI treatment to align with her other injectable medications, simplifying her treatment. This was especially helpful due to her busy schedule, which sometimes caused her to forget her daily pills, ultimately improving her viral load management.
- Korey started LAI treatment to better understand and support the patient experience despite a dislike for needles. Korey's decision involved navigating complex insurance processes to secure authorization, which he felt was essential for his work.
- Janiqua initially resisted taking her medication but, after multiple hospitalizations, accepted LAI at her doctor's suggestion. Though initially hesitant about its side effects, she ultimately found the treatment beneficial.
- Brian began with oral HIV medications but joined an LAI trial in 2017. Brian appreciated how LAIs made managing his treatment feel simpler and more integrated into a "normal" routine, providing mental ease even though he had not found the pills inconvenient.

What is your experience with LAI antiretroviral medications?

- Mikayla had a positive experience with LAI treatment, overcoming initial pain by changing injection sites and building trust with her doctor.
- Korey faced severe discomfort initially but found relief by the fifth injection, appreciating the convenience and acknowledging his access to treatment at work.

- Brian experienced minor discomfort for a day after injections. Brian also noted past relationship impacts and stated he is now in a consistent relationship.
- Janiqua initially had severe pain and immobility but now actively participates in her healthcare and is enthusiastic about her appointments.
- Erick found LAI treatment liberating from daily HIV management, strengthening his relationship with his care team, and benefiting from regular screenings.
- Erick stated that LAI medication reduced time spent managing pharmacy logistics, which he saw as a significant benefit.
- Janiqua noted her progress with her weight gain from 79 to 110 pounds after starting treatment and a significant improvement in her health.

Can you speak about your experience about reaching viral suppression while on LAI antiretroviral medications?

- Janiqua shared that she began LAI treatment in March after initially being nervous about its effectiveness. Over the past seven months, Janiqua successfully became undetectable, which she described as a positive experience and encouraged others in similar situations to try it.
- Korey shared that LAIs helped four previously unsuppressed patients in his clinic reach undetectable levels. Korey also emphasized the need for improved access to LAI treatments for the uninsured, particularly Black and Brown communities.

What advice would you give health care providers about LAI treatment?

- Brian emphasized the importance of open and transparent communication between doctors and patients. This helps build comfort and trust and allows patients to share essential information for treatment decisions.
- Korey advised providers to listen to patients, educate the entire care team about LAIs, and be aware of insurance timelines and requirements to facilitate treatment access.
- Mikayla highlighted the importance of effective communication for scheduling, especially given the limited time windows for administering injections and the learning curve within new injection departments.
- Erick emphasized communication and understanding patients individually, advocating for proactively informing all patients about LAI options, and allowing them to initiate conversations about treatment when ready.
- Janiqua stressed that doctors should genuinely listen to patient preferences (mainly when patients express strong aversions to taking medication) and offer alternative treatment options accordingly.

What would you say to a patient who is apprehensive about using LAI antiretroviral medications?

- Korey advised people to “just do it” by trying the treatment to overcome doubt, knowing they can always return to their oral regimen if unsatisfied.
- Erick echoed Korey’s statement and encouraged people to try the injectable route for its convenience and time-saving benefits, emphasizing that switching back is easy if they do not like it.
- Brian suggested that individuals prioritize what is important in their lives when making treatment decisions.
- Mikayla recommended ensuring readiness and commitment before starting injectables. Returning to a previous regimen is not guaranteed if the injectable does not work out.

- Erick added that long-lasting injectables represent a promising advancement in HIV treatment and could become the standard moving forward.

After the conclusion of the patient panel, Ms. Matosky invited Dr. Jonathan Colasanti, a subject matter expert on LAIs, to offer remarks on the use of LAIs for HIV care and treatment.

Jonathan Colasanti, MD, MSPH
Associate Medical Director
Ponce de Leon Center at Grady Health

Dr. Colasanti described LAIs as transformative and having a profound impact on patients who face challenges with oral medications. Drawing on his clinical experience, Dr. Colasanti emphasized how these therapies allow individuals to stabilize their health, enabling them to address broader life challenges. Dr. Colasanti likened compared the impact of LAIs to the breakthrough treatments of 1996, highlighting the urgent need to overcome challenges like insurance barriers and staffing limitations in order to provide equitable patient access.

Panel 2: Q&A with Speakers and Member Discussion

The following questions, observations, and suggestions were raised:

Ms. Cadena-Fulks asked if each panelist noticed any physical changes or side effects when they first started LAI medication.

- Janiqua shared that before starting the medication, she felt constantly tired and unmotivated, but now feels happier, more active, and has noticed a clear improvement in her mobility.
- Brian noted an improvement in his sleep, as he now regularly gets around six to seven hours instead of operating on five hours.
- Erick stated that he had no changes in his body except for initial pain during the first injection, which has since lessened with each dose.
- Mikayla observed that when she was on pills, she often felt tired and had no appetite. Mikayla has not noticed these results with the injection.
- Korey stated that he experienced significant weight gain and some pain with the first few injections, but he has not experienced other side effects.

Ms. Granados asked if there were specific individuals for whom the LAI treatment might not be suitable and inquired about what "readiness" for the treatment would look like, as well as ways to support and mitigate potential issues.

- Mikayla suggested that one of the most critical areas for support was helping individuals learn proper scheduling and providing better counseling before starting the treatment.

Dr. Armstrong asked what kind of counseling the panelists wished they had received before starting LAI treatment.

- Mikayla shared that she wished she had been prepared for the potential mental effects associated with switching to an injectable.
- Erick highlighted the importance of having a backup plan for contacting patients who might miss appointments, as this could indicate that the treatment may not suit them.

- Korey expressed interest in seeing more options for individuals who struggle with adherence to oral medication, noting how starting the injectable could help them achieve viral suppression.

Dr. Driffin expressed gratitude for the opportunity to meet and emphasized the unique dedication of workers in the industry who prioritize community well-being. Dr. Driffin noted the importance of shifting from survival to thriving for quality of life and warned against unintentionally reinforcing a "viral divide" while promoting undetectable equals untransmittable (U=U). Dr. Driffin also highlighted the need to overcome provider reticence towards LAIs, underscoring that people with HIV are equally important as experts in their own lives.

- Korey shared that disclosure practices differ by state laws but emphasized the personal responsibility to disclose one's status and educate others on U=U, noting his experience that disclosure rarely leads to rejection.
- Erick expressed that being on LAI treatment has not changed his approach to disclosure, as he would still disclose his status if asked or if he chose to.
- Brian discussed the importance of individual self-realization and complete transparency in intimate relationships, emphasizing that respect for the other person's decision following disclosure is crucial.
- Dr. Colasanti noted that qualitative data indicates that some long-term survivors felt more confident in the U=U concept with injectables, while others preferred daily oral medication for the reassurance it provided in managing their undetectable status.

Dr. Mermin asked if the FDA would consider changing the labeling requirements for cabotegravir to allow its use in individuals who have not been virally suppressed, given the evidence of its effectiveness in this group. Dr. Mermin also inquired about the kind of data—such as randomized trials or cohort studies—that might be required for such a change, as well as whether the FDA might proactively engage with industry on this issue.

- Dr. Lathrop stated that, although FDA's Center for Biologics Evaluation and Research regulates HIV testing rather than drug approvals, the FDA is generally open to labeling changes if supported by data, especially real-world data. Innovative trial designs, rather than full clinical trials, could be feasible for evaluating accessibility.
- Dr. Cheever noted that HHS treatment guidelines have historically influenced insurance coverage decisions and that the recent expansion of LAIs for people not fully suppressed in these guidelines might drive coverage.

Dr. Dowler asked whether providers in communities and networks consistently offer LAIs to everyone or if patients must request them and how accessible these treatments are overall.

- Brian shared that he participated in clinical trials for LAIs which entailed a rigorous six-week preparatory process with repeated assessments. Brian found it gratifying that the treatment is now widely available without such trials.
- Janiqua stated that not everyone in her community knows about the injectable option, noting that some people, including a friend, were unaware of it. Janiqua felt it was especially relevant for individuals who dislike pills.
- Erick said that within his personal networks, people are actively discussing the injectable treatment and frequently asking each other if they have heard about it or spoken to their doctors.

- Mikayla stated that in her transgender community, injectables are not widely discussed. Many individuals avoid HIV testing due to concerns about being forced to disclose their gender identity to healthcare providers.
- Korey observed that while patients are interested in LAIs, many private providers in Dallas, Texas, hesitate to offer them due to the complexities of approval, limiting overall accessibility despite medication availability.

Dr. Sanders asked about the barriers to providing injectable treatments to individuals in need and how to address them and the "ideal" scenario, which considers options like six-month injectables and long-lasting oral medications to better meet patients' needs and offer them more choices.

- Erick shared that making clinic visits accessible and building personal connections with patients, such as discussing their lives and providing snacks, encouraged trust and attendance for injections.
- Brian expressed that an ideal scenario would involve a yearly injection, similar to the flu shot. A six-month option would be acceptable, though yearly would be optimal.

Dr. Cestou asked if the panelists had considered a different modality, such as an at-home injection, and whether it would be useful to them, given that some individuals already had access to LAIs in clinics.

- Janiqua expressed that she loved receiving injections at home with a nurse visit.
- Erick shared that he preferred receiving care in a clinical setting, where he could also get STI testing and other services, rather than doing injections at home due to concerns about mistakes.
- Dr. Cestou reflected on the potential benefits of clinicians visiting clients at home, noting that while it may seem old-fashioned, many patients in areas like Chicago, Illinois, have shown interest in this approach.

Ms. Cadena-Fulks asked if there had been times when the panelists were unable to make their injection appointments and how their providers ensured they stayed within the required time frame for adherence to the injectable.

- Brian stated that he had a two-week grace period for his injection timing, which was helpful when he realized he was on vacation during his scheduled date.
- Mikayla noted that while there is a two-week grace period, her doctor is available only one day a week, which requires her to carefully coordinate time off work to meet that specific day.
- Brian shared that early morning appointments before 8 a.m. were generally feasible and accommodating in New York. Evening appointments after 6 p.m. posed more challenges.
- Erick stated that he typically did not experience issues with his target appointment dates, but he wished the 40-minute process for injection appointments could be shortened.

Dr. Driffin acknowledged that the previous comment about medical providers avoiding the injection conversation might have been overlooked and suggested revisiting the panel's discussion to consider Erick's point on timelines. Dr. Driffin also emphasized the need to identify a regional "sweet spot" in terms of optimal implementation and access to LAIs and expressed gratitude for what he considered one of the best CHAC panels held to date.

Business Session: Part 1

Wendy Armstrong, MD
Professor

Emory University School of Medicine
CHAC Co-Chair

Dr. Armstrong stated that the Business Session would address several items of business and engage in discussion to reflect on the presentation content and consider areas in which CHAC might be able to make a difference.

Business Item 1: Community Partnership Workgroup

The Community Partnership Workgroup has completed its tasks and, with consensus among members, will be sunset without requiring a formal vote.

CHAC Action
CHAC members reached a consensus to sunset the Community Partnership Workgroup.

Business Item 2: Workforce Workgroup

The Workforce Workgroup update was not presented during the meeting. There is uncertainty about whether the workgroup is ready to conclude, as discussions are still ongoing with PACHA regarding a potential joint statement.

Business Item 3: LAI Workgroup

Dr. Dowler summarized the status of the LAI Workgroup, suggesting it might be time to sunset the workgroup after completing its original objectives. Dr. Armstrong and CHAC concurred with this decision.

Members stated concerns about issues such as provider and location variability in access. Members discussed recommendations regarding determining reimbursement mechanisms, consulting the FDA on labeling for viremic patients and organizing a scientific panel for the spring 2025 CHAC Meeting to discuss LAIs for additional diseases. These recommendations were then formalized into a motion for a vote.

CHAC Action
Dr. Dowler made a motion to approve the following recommendations:

1. Ask CDC and HRSA to work with partners in clinical practice to seek feedback on the preferred mechanism for reimbursement of LAIs (pharmacy vs. medical benefit) for best patient access and to communicate this preference to the appropriate parties to seek standardization of LAIs under exclusively pharmacy or medical benefit and to eliminate cost sharing/co-pays.
2. Requesting CDC and HRSA to work with the FDA on potential labeling changes for LAIs to include viremic patients in alignment with current guidelines

Additionally, CHAC members recommended the CHAC include a scientific panel discussion at the spring 2025 CHAC meeting on LAIs for other diseases beyond HIV, including viral hepatitis and STIs.

Dr. Cestou seconded the motion. CHAC approved the recommendations with 17 affirmative votes, 0 opposed, and 0 abstentions with no changes or further discussion.

Business Item 4: Lifetime Survivors Letter

CHAC members discussed specific recommendations for supporting lifetime HIV survivors from the draft CHAC Lifetime Survivors letter. Dr. Armstrong introduced revised recommendations, noting the importance of more detailed guidelines to assist agencies like CDC and HRSA. The recommendations included:

1. Include lifetime survivors in all HIV-related programming (e.g., HRSA-funded RWHAP and recipients, the Secretary's HIV/AIDS Fund, PACHA) and in the development of action plans, initiatives, and advisory committees of HHS.
2. Address long-term health outcomes for survivors (e.g., increased HIV mortalities, metabolic outcomes, mental health, fatigue, cancer, etc.) and include lifetime survivors as a separate category in studies and surveillance, including in NIH-sponsored research and the RWHAP.
3. Establish different models of care and provider resource needs within HRSA-funded recipients that shares best practices, develops centers of excellence, and hubs of expertise; and
4. Develop a strategic plan, including specific goals and action steps within HHS, to address the unique needs, health outcomes, and quality of life of lifetime survivors of HIV.

CHAC members clarified the recommendation language, added "unique needs" to the fourth recommendation, and emphasized including "increased HIV-related mortality" in the second recommendation.

CHAC Action

Dr. Meredith Greene made a motion to approve the four recommendations for addressing the needs of lifetime HIV survivors, as presented with the inclusion of "increased HIV-related mortality" in the second recommendation. Dr. Driffin seconded the motion. CHAC approved the recommendations with 16 affirmative votes, 0 opposed, and 0 abstentions, with no changes or further discussion.

Business Item 5: Viral Hepatitis and Access Barriers

Ms. Beiser raised concerns about viral hepatitis, noting that the prevalence of hepatitis C has grown significantly and now impacts four times as many people as HIV. Ms. Beiser highlighted the lack of infrastructure to effectively tackle this issue, particularly in implementing high-impact testing with newly approved POC tests. Ms. Beiser expressed concern over how CMS regulations impact access to medications classified as "specialty medications," such as medications for individuals with hepatitis and LAIs for individuals with HIV. Ms. Beiser suggested that the CHAC consider strategies for better collaboration with CMS to address these systemic barriers.

Business Item 6: Self-Testing and Coverage for STIs

Dr. Sanders advocated for increased access to self-testing for STIs, including HIV and viral hepatitis. Dr. Sanders emphasized the need for insurance coverage for testing and treatment options, including doxy PEP. Dr. Sanders noted recent changes in World Health Organization guidelines that stress making post-exposure options readily available, underscoring a gap in U.S. guidelines which have not been updated

since 2018. Dr. Sanders also stressed the importance of modernizing approaches to make testing and treatment more accessible.

Business Item 7: Addressing HIV and Hepatitis Care in Rural Areas

Ms. Cadena-Fulks highlighted the challenges of providing HIV and hepatitis care in rural areas and emphasized the diverse definitions of "rural" across regions. Ms. Cadena-Fulks noted that barriers to care differ widely based on geography and demographics, from Alaska to the Midwest. Ms. Cadena-Fulks also pointed to the lack of tailored services for women with HIV, emphasizing that current services are often modified for women rather than created with their unique needs in mind. Dr. Armstrong supported this concern, highlighting the shortage of infectious disease providers in rural areas and the southeastern U.S. and the resulting lack of HIV and hepatitis services in these "desert" regions.

Business Item 8: Barriers to HIV and Hepatitis Care in Underserved Communities

Mr. Reilley and Ms. Cadena-Fulks emphasized that clinics in rural areas face significant administrative hurdles, particularly staff shortages, which deter them from taking advantage of available drug programs due to the overwhelming paperwork. A lack of community involvement further exacerbates this burden, as small community settings make disclosure and privacy difficult for individuals seeking HIV and hepatitis care. This issue hinders the meaningful involvement of people with lived experiences in care and advocacy processes.

Business Item 9: Latino HIV Rates and Outreach Efforts

Dr. Cestou and Ms. Granados discussed the increasing rates of HIV among Latino gay and bisexual men who have sex with men. Ms. Granados noted that the Latino community is not a monolith, and outreach efforts must consider generational and cultural differences within Latino populations. Materials intended for newly immigrated individuals may not resonate with second or third-generation Latinos with different cultural and linguistic needs. Both highlighted the need for a strategic, tailored approach that reflects the diversity within the Latino community.

Business Item 10: Privacy and Data Security Concerns

Dr. Trent expressed concerns about privacy and data security, particularly for individuals in high-risk groups like transgender individuals and young people. Dr. Trent referenced a recent case where an individual was denied life insurance due to their PrEP usage being noted in their health record, underscoring the need for more stringent privacy measures. Dr. Trent also highlighted that young people are a vital population needing specific prevention and care approaches, especially regarding HIV and STIs.

Business Item 11: Trichomonas Testing and Gender-Affirming Care

Dr. Dowler noted the under-discussed issue of trichomonas, an STI with persistent and often untreated infections especially in men who have sex with women. Dr. Dowler advocated for broader testing and coverage for this infection.

Business Item 12: Medicaid Coverage for the Incarcerated

Ms. Beiser highlighted the potential implications of the Section 1115 waiver for HIV and hepatitis care for incarcerated individuals, which enables Medicaid coverage three months prior to release. While this waiver could improve post-release care continuity, she emphasized that it may unfold unpredictably and requires further discussion to maximize its positive impact on the carceral population.

Recap of Day 1 / Review of Day 2

Wendy Armstrong, MD
Professor
Emory University School of Medicine
CHAC Co-Chair

Dr. Armstrong expressed gratitude for everyone's participation and noted the first meeting day was productive. Rather than providing a detailed recap, she emphasized her plan to synthesize insights from both meeting days. Dr. Armstrong noted the topics for Day 2 would complement the first day's discussions. The focus would remain on advancing the Ryan White Program 2030 initiative's goals, particularly by enhancing strategies to engage individuals currently out of care. Dr. Armstrong acknowledged the impactful discussion with individuals who shared lived experiences with LAI and thanked federal partners for their valuable updates.

Recess

Wendy Armstrong, MD
Professor
Emory University School of Medicine
CHAC Co-Chair

Dr. Armstrong stated that the meeting was on recess for the evening and would begin the next day at 9:00 am ET. Dr. Armstrong reminded virtual CHAC members to log in at least 10 minutes prior to the meeting to ensure that they could start on time.

Day 2: DFO Meeting and Roll Call

Laura Cheever, MD, ScM
Associate Administrator
HRSA HAB

Dr. Cheever welcomed participants to the second day of the CHAC meeting. Dr. Cheever conducted a roll call and asked CHAC members to disclose any new conflicts of interest. CHAC members did not disclose new conflicts. Dr. Cheever established quorum for the CHAC to conduct its business on October 22, 2024.

Objectives

Wendy Armstrong, MD
Professor
Emory University School of Medicine
CHAC Co-Chair

Dr. Armstrong thanked everyone for returning for Day 2, noting the success of Day 1 and expressing anticipation for two panels on increasing access to mental health services and addressing barriers to re-engage individuals with HIV out of care. Dr. Armstrong encouraged attendees to consider future discussion topics and potential recommendations for the end-of-day business session.

Presidential Advisory Council on HIV/AIDS (PACHA) Update

Hansel Tookes III, MD, MPH
CHAC PACHA Liaison

Dr. Tookes discussed the recent PACHA meeting in August, which was held online. The meeting focused on global HIV responses, emphasizing that progress has been uneven, particularly due to stigma and discrimination. During the PACHA meeting, Dr. Sullivan, a PACHA member, underscored the importance of improving access to testing, highlighting barriers like CDC's "Take Me Home" campaign and the value of fostering a two-way learning relationship.

Dr. Tookes' update focused on the President's Emergency Plan for AIDS Relief (PEPFAR). Dr. Tookes highlighted a presentation at the PEPFAR meeting by Mark Dybul, PEPFAR's architect, who discussed the program's inception under President George W. Bush in 2003, its bipartisan foundation, and continued support from the faith community and private sector. PEPFAR has adopted a data-driven approach, setting targets and adjusting operations based on real-world data rather than spending estimates. During the PEPFAR meeting, Dr. Dybul emphasized that restoring bipartisan support for PEPFAR would require more in-person engagement among lawmakers.

Dr. Tookes also highlighted PEPFAR's achievements, including saving an estimated 25 million lives, preventing HIV in 5.5 million newborns, and reducing the number of children orphaned due to AIDS. Dr. Tookes noted challenges posed by hostile governments, such as Uganda's anti-homosexuality laws, which complicate efforts to ensure safe, accessible care for people with HIV. PEPFAR has significantly expanded its investment in PrEP, with initiatives like the Lenacapavir trials doubling oral PrEP uptake to nearly two million people and setting the stage for innovations such as LAI PrEP.

Additionally, PEPFAR has drawn valuable lessons from the RWHAP, emphasizing community engagement in planning processes. CDC has committed to embedding U=U into its initiatives, a concept further reinforced through collaborative learning between PEPFAR and RWHAP.

Looking forward, PEPFAR aims to establish a smooth transition for countries to sustainably take ownership of their HIV programs, focusing on handover and empowering countries to develop programs that meet their unique needs. PEPFAR will continue tracking progress toward the 95-95-95 targets (95 percent of people with HIV diagnosed, 95 percent on treatment, and 95 percent of people with HIV on treatment being virally suppressed).

Dr. Tookes also shared updates from Francisco Ruiz on the White House Office on National AIDS Policy's priorities and new HIV/AIDS strategies. A panel by Tori Cooper and DeAndre Moore on U=U during the PEPFAR meeting was highlighted as especially impactful. Dr. Tookes concluded with expressing gratitude for PACHA's collaborative spirit and expressed enthusiasm for future meetings, including an upcoming December PEPFAR meeting in Alabama.

PACHA Update: Q&A with CHAC PACHA Liaison and Member Discussion

The following questions, observations, and suggestions were raised:

- Dr. Armstrong asked whether recent PACHA meetings addressed ways to support or collaborate on PEPFAR advocacy, including engaging with legislators. Dr. Tookes reflected on the bipartisan origins of PEPFAR and stressed the importance of educating legislators on the program's global impact, describing it as one of the United States' most successful diplomatic efforts. Dr. Tookes expressed disappointment over the recent reauthorization and emphasized the need for sustained advocacy. Dr. Armstrong echoed the importance of maintaining support for PEPFAR, especially as the program seeks sustainable transitions to in-country management, a point Dr. Tookes underscored as essential for PEPFAR's long-term viability amid current political dynamics.

- Dr. Trent discussed the idea of incorporating a homeland security perspective and partnering with other agencies to promote global health and ensure safe international travel, considering the interconnectedness of today's world and the presence of the U.S. military abroad. Dr. Tookes responded positively, noting the strategic value of appealing to legislators by framing arguments to align with their interests, especially regarding public health initiatives like PEPFAR. Both agreed that tailored arguments addressing bipartisan concerns could be impactful, with Dr. Tookes appreciating the innovative approach of linking infectious disease prevention to homeland security.

- Dr. Sanders expressed concern about PEPFAR's original goal of transitioning HIV/AIDS program management to host countries, particularly in places like Uganda, where legal and social challenges around Lesbian, Gay, Bisexual, Transgender, Questioning, Intersexual, Asexual, Plus (LGBTQIA+) rights and criminalization could increase vulnerability. Dr. Sanders also highlighted the importance of continued industry pressure to make LAI HIV treatments accessible and affordable. Dr. Tookes acknowledged these concerns, noting the safety risks for LGBTQIA+ people in Uganda and the potential loss of PEPFAR's influence in policy areas if financial support were withdrawn. Dr. Tookes cited examples like Vietnam, where PEPFAR funds helped advance harm reduction initiatives. Dr. Tookes emphasized that this transitional phase represents a critical test of commitment from the U.S., industry, and partner nations to truly end the HIV epidemic.

Panel 3: Increasing Access to Mental Health Services for People with HIV and STDs

Britt Gayle, MD, MPH, AAHIVS
Clinical Advisor
HRSA HAB

Dr. Gayle, the panel moderator, presented an overview of RWHAP initiatives to address mental and behavioral health for people with HIV. Dr. Gayle discussed CDC's Medical Monitoring Project from 2022, which highlighted the prevalence of mental health issues among people with HIV, notably a 17 percent prevalence of depression and 20 percent for anxiety for people with HIV. Dr. Gayle emphasized the connection between mental health, physical health, and self-perception, showing that depression and anxiety significantly impact individuals' perceived health, even more than traditional risk factors like low

CD4 cell count or housing insecurity. Furthermore, depression was identified as a common reason for individuals with HIV missing ART doses due to its effects on memory, motivation, and daily functioning.

Dr. Gayle also reviewed data on mental health service utilization among RWHAP clients, noting a gap where 11 percent of individuals in need were unable to access necessary mental health services. To bridge these gaps, RWHAP supports RWHAP Part F AIDS Education and Training Centers (AETCs) to provide training to healthcare professionals on mental health and HIV care across the U.S. RWHAP AETCs offer resources like the National HIV Curriculum, guidance on integrating behavioral health in clinical settings, and tools like an application for ART and psychiatric medication interactions.

Dr. Gayle highlighted the regional AETCs' initiatives that focus on a range of mental health topics, including motivational interviewing and peer support. Training events extend to the entire HIV care team, addressing stigma and discrimination's role in exacerbating mental health conditions.

Dr. Gayle also discussed the RWHAP Part F SPNS Evidence-Informed Interventions initiatives. One initiative is the collaborative care management model, where psychiatric consultants support the primary care team. After 12 months, this model showed improvements in ART adherence, retention in care, and viral suppression. Another initiative using cognitive processing therapy for trauma showed a 17 percent improvement in care retention among participants.

Dr. Gayle concluded with a brief overview of the ongoing and upcoming educational initiatives within the RWHAP, which aims to continue support for mental and behavioral health care for individuals with HIV.

Mental Health and HIV Research at the NIMH Division of AIDS Research

Teri Senn, PhD
Scientific Program Officer
Division of AIDS Research
NIH NIMH

Dr. Senn presented on the intersection of mental health and HIV, emphasizing the significant mental health challenges faced by people with HIV and the resulting impact on their overall health and HIV care outcomes. Dr. Senn outlined NIMH's current research efforts, including initiatives to enhance mental health care access, such as telehealth, collaborative care models, and task-shifting interventions. Dr. Senn also highlighted challenges related to both patient and provider barriers in accessing mental health services, including limited provider availability, lack of time, stigma, transportation difficulties, and competing life demands.

Dr. Senn discussed several studies funded by NIMH that aim to overcome these barriers. For instance, Dr. Ellen Eaton's research in Alabama utilizes telemedicine to deliver mental health and substance use services in rural areas, addressing provider shortages and patient access issues. Similarly, Dr. Dombrowski's study piloted a collaborative care model in a clinic, integrating a behavioral care manager to support patients directly, which led to improved mental health engagement. Modifications, such as hiring a full-time manager and removing the screening requirement, significantly increased patient participation.

Other funded projects include mobile health interventions, such as a peer-navigation program for transgender women with HIV, which showed improvements in mental health outcomes, though not in

HIV suppression, as the participants faced compounded barriers like homelessness and stigma. Dr. Senn also mentioned Dr. Brian Pence's study, which adapted a transdiagnostic mental health intervention for a range of mental health issues and substance use, showing promising improvements in mental health and HIV care engagement.

Dr. Senn concluded with an overview of ongoing efforts to innovate mental health care for HIV populations, such as using AI-driven chatbots for dialectical behavior therapy, which can provide support outside of clinic hours with minimal staffing. Dr. Senn highlighted an upcoming initiative to streamline mental health interventions for youth with HIV, aiming to develop shorter, resource-efficient treatments with meaningful impacts.

Dr. Senn emphasized that while effective interventions exist, significant barriers persist in delivering mental health care to people with HIV. NIMH continues to explore and fund novel strategies to improve mental health outcomes and HIV care, although further innovation is needed to increase engagement and overcome existing challenges.

Increasing Mental Health Access for People with HIV and STDs

Cristina Lopez, PhD
Clinical Psychologist
Medical University of South Carolina

Stephanie Amaya, PhD
Post-Doctoral Fellow
Medical University of South Carolina

Dr. Lopez described the high rates of trauma and post-traumatic stress disorder (PTSD) among people with HIV, which often serve as barriers to engagement in HIV care. Dr. Lopez highlighted that PTSD symptoms, such as intolerance of uncertainty and difficulties in establishing new relationships, often hinder patients from engaging in treatment, forming trust with providers, and adhering to ART. To address this, the Medical University of South Carolina developed the Resiliency, Engagement, and Accessibility for Comorbid HIV Populations, or REACH, program, which delivers evidence-based, time-limited interventions for PTSD and co-occurring substance use, often utilizing community partnerships and telehealth.

Dr. Lopez also discussed their adaptation of cognitive processing therapy, a gold-standard PTSD treatment, combined with Life Steps adherence counseling. This combined approach, called cognitive processing therapy with life steps adherence, aims to address both PTSD symptoms and the specific challenges related to HIV stigma. It incorporates activities and worksheets to reinforce empowering messages on safety, trust, power, control, esteem, and intimacy—areas commonly affected by trauma and stigma.

Dr. Amaya discussed the significance of reducing stigma within HIV care. Dr. Amaya stated that societal stigma and biases remain significant barriers for people with HIV despite progress in medical care. Dr. Amaya presented a trauma-informed care guide organized around themes of safety, trust, power, control, esteem, and intimacy. For example, Dr. Amaya explained how hypervigilance in PTSD might translate into beliefs about being a threat to others due to HIV status, which can lead to isolation. Dr.

Amaya recommended that providers adopt a trauma-informed approach by validating patient experiences, providing relatable language, and encouraging empowerment through self-determination.

In discussing trust, Dr. Amaya advised providers to validate patients' vulnerability rather than dismiss their fears and to guide them in making empowered decisions regarding disclosure. For power and control, Dr. Amaya suggested emphasizing patient autonomy, involving them in care decisions, and using mental health partnerships to support patients in finding treatment options that align with their values.

Dr. Amaya also addressed the impact of intersecting stigmas, noting that LGBTQIA+ patients might perceive HIV as a punishment and fear being outed. The guide includes ways to challenge such beliefs and promote an understanding that HIV is not a moral failing. For intimacy, Dr. Amaya recommended using empowering messages, such as U=U, and working with local activists to deliver HIV-related messages in a relatable manner.

The speakers concluded by emphasizing that a stigma-free, trauma-informed approach at every level of care is essential to improve HIV outcomes. They highlighted testimonials from patients who completed the Cognitive Processing Therapy with Life Steps adherence treatment, which underscored the value of integrating mental health support in HIV care to foster hope, resilience, and healing.

Addressing the Mental Healthcare Needs of People with HIV in RWHAP Clinics

Katie Catanzarite, PsyD
Psychology Fellow
Louisiana State University Health Sciences Center

Dr. Catanzarite discussed the HIV Outpatient Program at University Medical Center in New Orleans, Louisiana, emphasizing its co-located, comprehensive care model for HIV patients. Established in 1987, the HIV Outpatient Program clinic aimed to provide a safe, non-judgmental space for patients, particularly as HIV patients frequently face stigma and discrimination. The HIV Outpatient Program clinic integrates multiple services—primary care, dental care, mental health services (including psychiatry, psychology, and social work), dietitian support, hepatitis C treatment, PrEP, and other infectious disease services—within one location to improve access and reduce patient attrition.

Dr. Catanzarite highlighted the demographics of the clinic's patients (mainly Black men over 45, most of whom live below the poverty line) and face additional barriers to care, such as transportation and financial instability. The clinic's location is in New Orleans, a city with one of the highest rates of new HIV cases. The clinic also services surrounding rural and suburban areas, bringing a diverse range of cultural, linguistic, and socioeconomic backgrounds into the patient population. This diversity requires providers to be culturally responsive, flexible, and sensitive to each patient's unique challenges regarding medication adherence and engagement in care.

Behavioral health care is a key focus, as the clinic aims to integrate mental health assessments into all HIV care services. Patients are routinely referred to psychology services upon entering the clinic to normalize mental health as part of comprehensive HIV care. This broad approach helps to avoid singling out individuals, instead offering support as a routine aspect of HIV treatment. Referrals for mental health support can also occur at any stage of treatment, and patients are encouraged to initiate these services themselves when they are needed. The mental health team includes psychiatrists, psychologists, and social workers, coordinating to provide therapy, financial aid, and crisis support. This collaborative

approach ensures patients have access to immediate support for needs such as same-day mental health crises.

Psychological evaluations are another distinctive offering at the HIV Outpatient Program. These evaluations address cognitive concerns, particularly related to HIV-associated neurocognitive disorders, and can facilitate referrals to neurology. The co-location of services, including imaging, facilitates efficient, coordinated care, and minimizes patient disruptions.

Dr. Catanzarite emphasized the importance of cultural responsiveness and bi-directional communication among providers, which helps prevent patients from "falling through the cracks." The HIV Outpatient Program clinic sees high patient engagement and satisfaction by focusing on patient comfort and continuity. While the clinic already provides trauma-informed care, it continues to expand its trauma services through collaborations to meet evolving patient needs.

Panel 3: Q&A with Speakers and Member Discussion

The following questions, observations, and suggestions were raised:

- Ms. Beiser expressed gratitude for the presentations and highlighted the importance of incorporating neuropsychiatric evaluations, especially in the context of aging populations where memory, fatigue, mood disorders, and substance use intersect. Ms. Beiser questioned the panel about including neurocognitive considerations in patient care. Dr. Catanzarite responded that neuropsychological evaluations are integral to their clinic's approach, supported by trained psychologists and ongoing training led by a neuropsychologist. This integration helps differentiate neurocognitive issues from mental health conditions, leading to targeted treatment options and appropriate referrals, such as neurology or psychiatry, to improve patient care for aging individuals with HIV.

- Mr. Riester expressed the importance of considering patients' HIV medication histories, especially for aging long-term survivors, to address both physical and mental side effects from older drugs, such as dideoxyinosine. Mr. Riester highlighted the emotional impact of PTSD diagnoses, noting that for him, the term felt particularly stigmatizing due to its military associations. Dr. Amaya affirmed that medication history is explored during therapy sessions to understand any barriers and address concerns related to past side effects. Dr. Amaya also emphasized the importance of trauma-informed approaches to discussing PTSD and validating symptoms while aiming to reduce stigma. Mr. Riester supported the idea of a visual drug chart for elderly clients who might struggle to recall specific medications, as it can aid in memory and reduce the stigma surrounding past treatments. Dr. Amaya appreciated this suggestion and indicated an interest in incorporating such resources.

- Dr. Greene discussed the integration of mental health services in HIV clinics, particularly the value of embedded neuropsychology services and the necessity of expertise in HIV for accurate neuropsychological assessments. Dr. Greene expressed concern over the lack of HIV context in some neuropsychology reports, especially for patients with complex mental health histories. Dr. Lopez and Dr. Cheever highlighted the trauma experienced by long-term HIV survivors, noting that trauma-informed care should address the unique experiences of individuals diagnosed in the 1980s and 1990s. Dr. Cheever also discussed HRSA's efforts to support this population. Dr. Gayle noted that HRSA includes training on HIV history using testimonials from individuals with lived experience to enhance provider understanding.

- Dr. Driffin inquired if there was information on the race, ethnicity, and sexual orientation of the principal investigators funded by the initiative. Dr. Senn responded that while the identities of funded principal investigators can be looked up, the program side did not have access to specific demographic data.

- Dr. Driffin asked if panelists were observing a reduction in stigma as patients shifted from daily oral medication to LAI treatments and about involving individuals with HIV in program development and implementation. Dr. Amaya responded that, due to the current duration of treatment (6–13 weeks), they lacked sufficient data to determine any changes in stigma linked to medication type, emphasizing that addressing core beliefs was more effective in reducing stigma. Dr. Lopez added that preliminary, unpublished data indicated a significant stigma reduction over their 12-session program and highlighted that people with lived HIV experience were actively involved through a community advisory board, informing content development and contributing as peer advocates within the program's design and execution.

- Dr. Mermin expressed appreciation for the presentation and raised concerns about the dual needs of mental health and access to medication for people with HIV. Dr. Mermin highlighted the importance of integrating both behavioral interventions and medication for conditions like schizophrenia, suggesting HRSA consider compiling effective intervention options for both approaches to improve outcomes. Dr. Gayle responded by emphasizing the collaborative care model, which supports primary providers in prescribing psychiatric medications with specialist consultation to enhance access. Dr. Gayle also noted that some HRSA initiatives had successfully improved viral suppression and highlighted the usefulness of resources on the Target HIV website, where providers can find best practices and guidance for implementing evidence-based models suited to their specific settings.

- Ms. Cadena-Fulks expressed gratitude for the discussion, shared personal connections to the issues, and asked about the role and background of peer navigators in supporting transgender women of color. Dr. Senn explained that the peer navigators were carefully chosen and trained in motivational interviewing to encourage engagement in mental health and substance use services, though challenges remained in fully reaching participants. Ms. Cadena-Fulks also asked about the integration of gender-affirming services in HIV care, especially in New Orleans, Louisiana. Dr. Catanzarite responded that while their organization does not offer gender-affirming care, they are able to refer patients to Crescent Care, a local clinic that provides comprehensive gender-affirming services for the community.

- Mr. Rodriguez highlighted the challenges of retaining peer navigators and Latino mental health providers, noting that burnout and exposure to trauma often deter professionals from clinical roles despite rigorous training and certification programs. Mr. Rodriguez emphasized the scarcity of Latino providers and the need for better support to retain new interns, who often opt for less trauma-exposed roles. Dr. Lopez responded by stressing the importance of trauma-focused training (like Components for Enhancing Clinician Engagement and Reducing Trauma, or CE-CERT) to help mitigate secondary stress. Dr. Catanzarite also recommended ongoing clinical supervision as a vital support for reducing burnout and maintaining treatment fidelity among mental health providers.

- Dr. Cheever highlighted HRSA's efforts to improve coordination between SAMHSA-funded behavioral health programs and RWHAP. Dr. Cheever noted that SAMHSA grants often operate separately from

RWHAP, leading to unmet needs, especially in mental health. Dr. Lopez supported this integration, mentioning that SAMHSA requires a memorandum of understanding with a RWHAP facility, reinforcing the importance of collaboration between the two entities.

Panel 4: Overcoming Barriers to Re-Engage People with HIV Out of Care

Paul Mandsager, MSPH
Senior Advisor
HRSA HAB

Mr. Mandsager, the panel moderator, highlighted strategies to engage and re-engage individuals with HIV into care. Mr. Mandsager noted the progress in HIV viral suppression rates but highlighted ongoing disparities in rates between states and communities. While moving from a 69 percent to an 89 percent reduction in viral load was significant, the challenge now lies in achieving full suppression across all demographics.

Mr. Mandsager discussed the need to reach individuals with HIV who are currently in care to further improve their viral suppression and reduce disparities. Mr. Mandsager emphasized the importance of linking newly diagnosed individuals to care and re-engaging individuals who had dropped out of care to enhance retention rates.

To address these disparities, Mr. Mandsager stressed the need for better insights into barriers faced by people with HIV, expanded clinic outreach, evidence-based interventions, supportive policy development, and increased workforce capacity in HIV care. Mr. Mandsager cited 2022 EHE data showing that RWHAP EHE jurisdictions served over 22,000 clients new to care, representing 15 percent of individuals in specific jurisdictions who were undiagnosed or out of care. Although early, the data suggested potential positive trends in reaching underserved populations.

Mr. Mandsager concluded by reaffirming RWHAP's vision of providing optimal HIV care to all individuals as part of efforts to end the HIV epidemic. Mr. Mandsager stressed the importance of partnerships, targeted interventions, and community engagement to reach individuals out of care.

The MORE Program at Whitman-Walker Health

Bobby Bangert, LICSW
Senior Manager of Care Navigation
Whitman-Walker Health

Mr. Bangert outlined the services provided by Whitman-Walker Health, a federally qualified health center in the District of Columbia with a particular focus on care for the LGBTQIA+ community and individuals with HIV. Mr. Bangert described the organization's extensive range of medical, dental, behavioral health, legal, and supportive services, emphasizing his team's work to re-engage HIV-positive individuals with healthcare and retain them in treatment.

Mr. Bangert focused on the Mobile Outreach, Retention, and Engagement (MORE) program. This program is a collaborative effort between Whitman-Walker's care navigation team and Whitman-Walker's medical services to deliver home-based care for people facing significant barriers to visiting

clinics. The program combines medical home care with enhanced care coordination, allowing the team to meet patients with complex needs where they are and tailor support to each individual. Care navigators work closely with clients to assess barriers, which may include transportation, lack of technology for telehealth, or stigma related to HIV care. Clients are referred through providers, self-reports, and proactive outreach based on internal data.

The program offers flexible engagement options, with services including home visits, care coordination, assistance with applications, and connections to community resources. Mr. Bangert highlighted the program's flexibility, allowing services to scale up or down as clients' needs evolve. A notable feature of the MORE program is its ability to conduct outreach and engagement using mobile technology, such as texting, which has improved patient communication.

The team led by Mr. Bangert behind the MORE program includes a mobile advanced practice provider and two mobile care navigators who conduct needs assessments and help clients establish health goals, focusing on holistic well-being. The navigators assist with appointment scheduling, social service connections, and pharmacy navigation, enhancing clients' adherence to treatment.

Mr. Bangert also provided insights into the structure of home visits. The visits are longer than typical clinic visits and include services such as vitals monitoring, medication management, and specimen collection, with samples processed directly at Whitman-Walker's clinic.

The MORE program collaborates with Whitman-Walker's research department to assess its effectiveness. The program began with research to determine if home-based care could improve retention rates. Data suggested that MORE participants were often cisgender women, transgender women, Black, non-Hispanic, heterosexual, and Medicaid-insured, representing demographics with historically limited access to healthcare.

Looking to the future, Mr. Bangert discussed the MORE program's new initiative to deliver LAI treatments at home, marking its evolution over nearly a decade. Since 2021, Whitman-Walker has offered LAIs, with about 250 patients now enrolled, 54 of whom receive these treatments at home through MORE. This initiative, seen as an equity measure, aims to provide innovative care options to communities traditionally underserved by healthcare systems. Mr. Bangert noted the success of the LAI program, with clients consistently receiving injections on schedule and maintaining undetectable viral loads, demonstrating the program's effectiveness.

Community-based Approaches to Linkage, Engagement, and Retention in HIV Care

June Gipson, PhD
President
My Brother's Keeper, Inc.

Dr. Gipson discussed community-based approaches to HIV care, focusing on innovative strategies for engagement and retention. Dr. Gipson's organization operates Open Arms Health Care Center, a holistic clinic emphasizing preventive and mental health services for underserved, underrepresented, and uninsured populations, particularly in the LGBTQIA+ community. With locations across Mississippi and a mobile clinic offering screenings, Open Arms provides comprehensive healthcare, including women's health, transgender care, and wellness services integrated with HIV care.

Dr. Gipson highlighted Open Arms' efforts to make healthcare affordable and accessible through a model that integrates clinical care with community-based support, emphasizing disease prevention, health education, and patient-centered care. Since beginning HIV care in 2013, Open Arms has served approximately 4,500 patients, including about 130 individuals with HIV. Despite challenges like high poverty and lack of Medicaid expansion in Mississippi, the organization has developed a successful integrated HIV service model, showing notable improvements in viral suppression, adherence to therapy, and retention rates over a two-year study.

The integrated model includes six components: case management, HIV care, behavioral health, adherence counseling, support services, and wellness. Case managers serve as the first point of contact and support, helping patients navigate healthcare services and address barriers to care. The HIV care component focuses on close patient-provider partnerships, including regular screenings for individuals over the age of 50. Behavioral health care, which includes mandatory mental health assessments, addresses the mental wellness crucial to successful treatment adherence.

The wellness program, a highlight of the model, was expanded in 2020 to address the needs of HIV-positive patients over the age of 50. This program promotes physical, social, and mental wellness through personalized services, including digital engagement tools, group outings, nutrition counseling, fitness classes, medication delivery, and lifestyle support. Participants reported high satisfaction, with 88 percent noting increased happiness and 76 percent reporting enhanced social engagement and healthcare utilization.

Dr. Gipson expressed pride in the program's impact, noting its ability to foster community and support for an aging HIV population. Dr. Gipson concluded that this holistic and community-focused approach to healthcare has been a significant and rewarding highlight of his career.

Overcoming Barriers to Re-engage People with HIV who are Out of Care

Everlyne Sawyer, MA
Unit Administrator and RWHAP Manager
University of Virginia Health

Veronica Ross
Retention in Care Coordinator
University of Virginia Health

Ms. Sawyer presented on the University of Virginia Health's program, a RWHAP recipient, which provides comprehensive HIV care and is supported by various federal and state funding sources. Ms. Sawyer described the program's extensive services, including primary and mental healthcare, case management, community health support, and specialized care for incarcerated patients transitioning back into society. The program operates within the University of Virginia's academic medical center, allowing access to many resources that enhance patient support.

Ms. Sawyer outlined the demographics of their patient population—mostly male, with significant representation from Black and rural communities, and many individuals below the federal poverty line. Ms. Sawyer's presentation focused on the University of Virginia's initiatives to improve HIV care retention and reduce "no-shows" in appointments. Ms. Sawyer shared that the team identified key barriers for patients, such as housing instability, transportation, mental health issues, substance abuse,

food insecurity, and lack of childcare. In response, the team implemented immediate support mechanisms. For instance, they connected patients in real-time to case managers or provided transportation and food assistance. These actions built trust and fostered patient engagement, allowing the team to address patients' challenges actively and increase appointment attendance, ultimately improving health outcomes.

Additionally, Ms. Sawyer highlighted the program's engagement with patients through support groups, a client advisory board, and monthly quality meetings to integrate patient feedback into care delivery.

Ms. Ross then discussed her role as a retention coordinator. Ms. Ross explained how the team monitors patients categorized as "inactive" due to missed appointments. Ms. Ross reaches out through various methods, including phone calls and letters, to address barriers to care and re-engage patients. Ms. Ross emphasized the importance of continuity in communication, especially for rural patients facing confidentiality concerns at local pharmacies. Solutions included discreet medication delivery and offering a mobile application that enhances patient involvement in their care while providing a communication tool and small phone credits.

Overall, the presentation underscored how the University of Virginia's program leveraged dedicated funding and personalized outreach to foster community trust, reduce barriers, and support patient retention and viral suppression.

Panel 4: Q&A with Speakers and Member Discussion

The following questions, observations, and suggestions were raised:

- Dr. Driffin thanked Ms. Ross for the presentation slides and asked if the phone credit mentioned was linked to maintaining service or part of a gamification model. Ms. Ross clarified that the credit aimed to help participants keep their phones active to ensure continuous communication, contingent on their eligibility.

- Dr. Sanders praised the presentation on an HIV-focused project, expressing enthusiasm for its innovation and questioning funding and confidentiality in community settings for people with HIV. Dr. Gipson responded that the program was shaped by participants' preferences, focusing on a community model for people over the age of 50 rather than an HIV-specific support group, which maintains confidentiality and inclusivity by not advertising it as an HIV program. Funding is sourced from Gilead, 340B program funds, and grants to expand the program clinic-wide in the coming years, including cost-benefit analysis, health monitoring, and integrating AI for additional support.

- Dr. Armstrong asked about the effectiveness and challenges of administering LAIs through a mobile unit, particularly regarding patients' initial virologic status, adherence challenges, and difficulties in consistently reaching patients. Mr. Bangert shared that many patients initially had high viral loads and faced barriers to regular clinic visits, making the mobile services crucial for adherence. Mr. Bangert described successful cases, including a long-term patient who, for the first time, achieved viral suppression through LAIs. Building relationships, setting expectations, and offering flexible communication options with mobile care navigators were key strategies in overcoming adherence obstacles. Mr. Bangert also noted the program's current goal is to serve 60 patients, with 54 enrolled so far, indicating positive outcomes and plans for growth.

- Dr. Dowler sought clarity on which services, besides routine office visits and medications, are covered by payers like Medicaid, Medicare, and commercial insurers. Mr. Bangert shared that most of their community services, particularly through the MORE program at Whitman-Walker, are funded primarily by RWHAP grants, with limited ability to bill other payers as the services are not covered by them, which restricts capacity and service expansion. Dr. Gipson added that wellness services, like chiropractic care, face challenges in reimbursement due to clinic licensing issues, leading to reliance on grants for support. Ms. Sawyer noted that their program's services are largely funded by RWHAP, with additional state funding from Virginia specifically for their Charlie program, which provides testing for incarcerated patients.

- Mr. Reilley commented on the challenges of care integration within rural health systems, noting a high patient backlog for hepatitis C treatment and emphasizing the importance of linking patients to services. Mr. Reilley inquired if hepatitis C patients were covered in the discussed services and treatment initiation rates. Dr. Gipson responded that hepatitis C screenings were included in the "Becoming a Healthier You" program, though they found only a few hepatitis C cases despite extensive screenings. Ms. Sawyer added that the University of Virginia Medical Center program integrates hepatitis C care within their infectious disease clinic, facilitating seamless collaboration between hepatitis C and HIV care providers.

- Dr. Cestou expressed appreciation for the presentations and highlighted concerns about the premature aging effects of long-term HIV medication on patients as young as 35. Dr. Cestou suggested a reconsideration of what constitutes aging in the HIV population. Dr. Cestou asked Dr. Gipson if her wellness program could be extended to individuals under the age of 50. Dr. Gipson confirmed plans to expand the program to all patients after testing its effectiveness, aiming to incorporate deeper assessments like autonomic testing and DNA profiling while ensuring the program meets patients' needs and preferences.

Public Comment

Carie Harter
FVP, Government Relations & Advocacy
ViiV Healthcare

Ms. Harter advocated for CHAC extending the LAI Workgroup by at least one year to support ongoing examination and best practice sharing among HIV stakeholders. Representing ViiV's commitment to advancing HIV treatment and prevention, particularly with LAIs, Ms. Harter highlighted the challenges facing LAI adoption, such as cost-sharing and benefit transitions, and emphasized the importance of policy support from federal entities like CHAC, especially given pending litigation that may affect cost-sharing protections. Ms. Harter stressed the value of RWHAP Part B ADAP coverage for LAIs, citing benefits over oral treatments, including improved adherence, treatment satisfaction, viral suppression rates, and support for patients' psychological well-being. Ms. Harter affirmed ViiV's dedication to collaborating with the CHAC to enhance HIV treatment outcomes and support patients in focusing on other critical areas of life, such as employment and stable housing.

Charles (Charlie) Peterson
Director of Business Development
Neelyx Labs

Mr. Peterson discussed critical healthcare challenges for vulnerable populations, emphasizing AIDS Foundation Chicago's work in HIV care with 8,000 clients and 1,200 housing units and Howard Brown Health's services for over 40,000 LGBTQIA+ clients in the Midwest. Honoring the Nacotchtank and Piscataway ancestral lands, Mr. Peterson highlighted underserved communities he relates to Latinx and Hispanic immigrants facing language and insurance barriers, LGBTQIA+ individuals, and transgender and gender nonbinary people, especially transgender men, transmasculine individuals, and rural indigenous populations dealing with high treatable disease rates due to healthcare underfunding. While commending CDC and HRSA for health equity efforts, Mr. Peterson called for more funding for Spanish-speaking clinicians with cultural competency, pathways for Latinx, indigenous, and transgender and gender non-binary individuals to join healthcare fields, and expanded decentralized, community-based healthcare and integrated services for HIV, STIs, behavioral health, and harm reduction to meet the complex needs of underserved communities.

Shyam Saladi, PhD
Scientist
Neelyx Labs

Dr. Saladi discussed the barriers preventing the widespread availability of home-use diagnostic tests for STIs and infectious diseases. Despite industry efforts and available technology, Dr. Saladi argued that slow federal bureaucracy hinders timely access to these tests. Dr. Saladi cited three examples: First, California Senate Bill 306 mandated insurers to cover home-use tests but required a billing code from CMS, which typically takes seven to nine months; however, even after three years, no code exists. Dr. Saladi noted that during the COVID-19 pandemic, CMS expedited a billing code in days, suggesting similar urgency could be applied to STI tests. Secondly, Dr. Saladi noted that the FDA's 70-day response time to data inquiries delays test development, posing a challenge to quick patient access. Finally, Dr. Saladi pointed to CDC's efforts in developing test validation protocols, though these protocols remain inaccessible to industry, limiting broader test availability. Dr. Saladi urged federal entities such as CHAC, CMS, FDA, and CDC to prioritize STIs, HIV, viral hepatitis, and TB tests, emphasizing that quicker access could prevent numerous cases of congenital syphilis and improve patient outcomes.

Business Session: Part 2 and Suggestions for Future Agenda Items

Wendy Armstrong, MD
Professor
Emory University School of Medicine
CHAC Co-Chair

The CHAC took a moment to formally recognize and honor Dr. Laura Cheever for her exceptional contributions as the DFO on the committee and her impactful leadership at the HAB. As Dr. Cheever prepares to retire from federal service, members expressed deep gratitude for her dedication to advancing HIV care and treatment, applauding her legacy in improving health equity and achieving remarkable outcomes within the RWHAP.

Business Item 13: CHAC Workgroups on Self-Testing and Payer Support

CHAC members discussed various gaps and challenges in addressing sexual health, HIV, STIs, and viral hepatitis care, with a focus on funding, accessibility, and payer involvement.

Dr. Markham initiated the conversation by highlighting the youth's transition challenges from pediatric to adult care. Dr. Markham noted that the system lost many young patients during this transition and emphasized the need for models of care that better support youth.

Dr. Dowler proposed creating a CHAC workgroup to examine how payers could leverage resources more effectively in sexual health, specifically regarding payment for ancillary services such as community health workers and clinical pharmacists. Dr. Dowler made the point that payers could play a critical role in supporting home and POC testing, an area that saw progress during the COVID-19 pandemic but regressed afterward.

Dr. Greene and Dr. Armstrong questioned CHAC's role in addressing payer-related issues and discussed whether CHAC or agencies like CDC and HRSA should communicate recommendations to CMS. Dr. Cheever suggested that a letter to the HHS Secretary, rather than directly to CMS, might more effectively influence CMS policy.

CHAC members expressed support for a broad scope in the payer-related workgroup, noting that addressing viral hepatitis and other sexual health considerations could fall under this umbrella. Dr. Trent and other members raised concerns about how self-testing results would link to care, particularly for vulnerable age groups. The importance of connecting self-testing to appropriate care and public health tracking was emphasized.

Dr. Mermin and other CHAC members discussed the need for clarity and scope definition for any proposed workgroup. Dr. Mermin suggested focusing on top priorities, while Ms. Beiser advocated for addressing non-RWHAP-funded support services for linkage and navigation in viral hepatitis and STI treatment, particularly in communities lacking sustainable funding streams.

Dr. Sanders proposed creating two separate CHAC workgroups: one on self-testing and POC testing for STIs and viral hepatitis and another on payer levers for funding support services. After deliberation, Dr. Armstrong presented a refined summary of each group's focus.

CHAC Action

Dr. Sanders made a motion to establish a CHAC workgroup focused on self-testing and POC testing, particularly as it pertains to STIs and viral hepatitis. The workgroup will focus on reimbursement of POC tests and self-tests for STIs and viral hepatitis. Dr. Dowler proposed a friendly amendment to include POC tests in the scope which was accepted. Ms. Beiser seconded the motion. CHAC approved the motion with 17 affirmative votes, 0 opposed, and 0 abstentions.

CHAC Action

Dr. Dowler made a motion to create a CHAC workgroup focused on payer levers that can be utilized to support HIV and hepatitis C services not covered by RWHAP funding. The workgroup will investigate potential payer strategies for linkage, navigation, and other support services. Dr. Armstrong seconded the motion. CHAC approved the motion with 16 affirmative votes, 0 opposed, and 0 abstentions.

Business Item 14: LAI Treatments for Viremic Patients

Dr. Driffin raised the topic of LAIs being used with viremic patients to help them achieve undetectable viral levels, although this usage is not yet formalized in treatment protocols. Dr. Driffin emphasized the need for more data on the benefits of this approach. Dr. Armstrong added that guidelines now include provisions for starting viremic patients on LAI treatments in specific cases. Dr. Armstrong also highlighted ongoing discussions with the FDA to consider an official indication for this use, which could expand patient access and reimbursement.

Business Item 15: Workgroups and Future Discussion Topics

Dr. Cheever clarified that the LAI Workgroup completed all intended tasks as planned. However, she suggested that similar initiatives could be proposed if there was continued interest in related topics. Dr. Greene proposed additional areas for future discussion, such as alternative delivery models like mobile and home care, which could reach underserved populations. Dr. Greene also recommended focusing on a comprehensive, sustainable approach to care, particularly for patients with complex needs and underscored the role of AI in healthcare and its potential impacts on healthcare disparities.

Business Item 16: Life Course Perspective and Care Transitions

Dr. Armstrong and Dr. Greene discussed the importance of a life course approach to healthcare that addresses care transitions at different life stages. They recognized the challenges of retaining patients in care as they age and transition between healthcare settings. Dr. Greene and Dr. Armstrong advocated for an ongoing focus on older adults and adolescents, particularly regarding mental health and prevention across the lifespan.

Business Item 17: Alternative Delivery Models and Peer Navigation

Dr. Armstrong expressed interest in alternative care models, including mobile units, street medicine, and home care, especially for individuals with substance use disorders or struggle with adherence to oral medication. Dr. Armstrong shared insights from a study that achieved high retention by focusing on personalized care and accessibility. Ms. Cadena-Fulks suggested exploring CHAC workgroups on peer navigation and linkage, emphasizing the benefits of well-trained peer navigators for patient support, especially in managing complex cases. Dr. Armstrong noted that peer navigators need training and support to sustain their roles effectively.

Business Item 18: Data Privacy and Sharing Concerns

CHAC members discussed data privacy, particularly for patients with HIV. Dr. Sanders and Mr. Reilley expressed concerns over ambiguous data-sharing regulations, especially across state lines. There was a shared sense of caution regarding data used for healthcare purposes and the risk of privacy violations. CHAC members discussed convening a panel focused on data sharing and privacy, especially given the specific challenges for individuals affected by privacy-sensitive health conditions, such as HIV and care for transgender individuals.

Business Item 19: Transparency in Data Use

Ms. Granados emphasized the importance of transparent data practices, advocating for clear expectations in community engagement, especially with data-to-care strategies. Dr. Trent expressed worry about young people's understanding of data use and the potential harm of insufficiently protected

health data. Dr. Trent also highlighted cases where personal data remained on health records, sometimes inadvertently revealing sensitive information.

Business Item 20: EHRs and Privacy Concerns

Dr. Armstrong and Dr. Trent discussed current EHR practices' limitations and potential risks. Dr. Trent highlighted that EHR systems, like Epic, may inadvertently disclose sensitive information, such as maternal HIV status, raising concerns over patients' lack of control over their data. Dr. Trent urged the CHAC to engage with EHR developers to explore improvements in privacy protections, especially for vulnerable populations.

Business Item 21: Program Updates and Recommendations for Future Meetings

CHAC members proposed potential agenda items for the spring 2025 CHAC meeting, including health systems and coverage gaps, alternative delivery models, and workforce diversity. Dr. Armstrong suggested topics related to self-testing, waiver implications for formerly incarcerated individuals, and AI in healthcare. Ms. Hayes also provided an update on the "Ready, Set, Prep" program, indicating that while new enrollments have paused, current patients will continue receiving support.

Recap and Wrap-Up

Wendy Armstrong, MD
Professor
Emory University School of Medicine
CHAC Co-Chair

Jonathan Mermin, MD, MPH
Rear Admiral, USPHS (Ret.)
Director
CDC NCHHSTP

Laura Cheever, MD, ScM
Associate Administrator
HRSA HAB

Dr. Armstrong concluded the meeting by expressing gratitude for the participants' engagement and energy. Dr. Armstrong highlighted that the discussions over the past two days were inspiring and informative, reinforcing the team's strong collaborative spirit. Dr. Armstrong noted that the presentations provided valuable insights for the Ryan White Program 2030 initiative, especially focusing on how to connect the approximately 15 percent of people not currently engaged in care and recognize successful strategies within the community.

Dr. Armstrong noted the potential of D2C strategies, acknowledging concerns about data usage while recognizing its powerful role in identifying individuals out of care to improve retention. Dr. Armstrong highlighted promising developments in viral suppression and enhancing quality of life, particularly through LAI treatments. Dr. Armstrong also discussed the impact of the success stories, including the Whitman-Walker model and similar alternative care approaches.

Mental health care was emphasized as essential for engaging patients and enhancing wellness, with re-engagement strategies and LAIs discussed as promising tools for viral suppression and overall quality of life improvement.

Two new CHAC workgroups were launched to explore expanded care models, such as self-testing POC testing, and integrating wraparound services with funding sources. Dr. Armstrong noted the significant progress and the need to adapt to evolving landscapes, particularly in anticipation of upcoming developments with PEPFAR and other initiatives to end the epidemic.

Dr. Mermin announced that the proposed dates for the spring meeting would be April 1 and 2, 2025. Dr. Mermin appreciated the opportunity to meet with everyone, listen to the presentations, and participate in the discussions. Dr. Mermin also extended a special thank you to Dr. Cheever for being an outstanding collaborator in their efforts to improve the lives of people with HIV and reduce infection rates nationwide. Dr. Mermin acknowledged the challenges of working within the federal government but praised Dr. Cheever's ability to navigate bureaucracy efficiently while maintaining a strong focus on health improvement.

Dr. Cheever thanked everyone present and acknowledged their dedication to the work. Dr. Cheever highlighted that one reason RWHAP functions so effectively is due to the exceptional commitment of its participants. While Dr. Cheever noted that this level of commitment is unsustainable and should be addressed, this dedication allows clients and patients to receive such high-quality care. Dr. Cheever also acknowledged the additional time and focus everyone invests in workgroups between meetings, which she deeply appreciated. Dr. Cheever concluded by thanking everyone again and adjourning the meeting.

Adjourn

Laura Cheever, MD, ScM
Associate Administrator
HRSA HAB

With no further business raised or questions/comments posed, Dr. Cheever officially adjourned this meeting.

Certification

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

Wendy Armstrong, MD — Date
CHAC Co-Chair

Attachment A: Participant List

CHAC Members Present
Wendy Armstrong, MD (Co-Chair)
Marguerite Beiser, ANP-BC, AAHIVS
Keiva Lei Cadena-Fulks
Jorge Cestou, PhD, MBA
Shannon Brown Dowler, MD
Daniel Driffin, DrPH, MPH
Grissel Granados, MSW
Meredith Greene, MD
Vincent Guilamo-Ramos, PhD, MPH, LCSW, RN, ANP-BC, PMHNP-BC, FAAN
Christine Markham, PhD
Brigg Reilley, MPH
Robert Riester, PLWH
Leandro Rodriguez, MBA
Renata Arrington Sanders, MD, MPH, ScM
Samuel So, MBBS, FACS
Maria Trent, MD, MPH

CHAC Ex-Officio Members Present
Carolyn Deal, PhD
NIH NIAID

Neerja Gandotra, MD
SAMHSA

Christopher Gordon, PhD
NIH NIMH

Richard Haverkate, MPH
IHS

B. Kaye Hayes, MPA
HHS OIDP

Julia Tait Lathrop, PhD
FDA

Aditi Mallick, MD
CMS

Iris Marry-Hernandez, MD, MPH
AHRQ

CHAC Liaison Representatives Present
Hansel Emory Tookes, III, MD, MPH
PACHA

CHAC Designated Federal Officers
Laura Cheever, MD, ScM
HRSA HAB

Jonathan Mermin, MD, MPH
CDC NCHHSTP

Federal Agency Attendees
Jordan Grossman, JD
HRSA

James Macrae, MA, MPP
HRSA BPHC

Candice Chen, MD, MPH
HRSA BHW

Heather Hauck, MSW
HRSA HAB

Michael Kharfen
HRSA HAB

Seta Hovagimian
HRSA HAB

Breana Alsworth
HRSA HAB

Sarah Read, MD, MHS
NIH NIAID

Ervin Simmons
HRSA HAB

Dominick Black
HRSA HAB

Marah Condit, MS
CDC NCHHSTP

Presenters
Stephanie Amaya, PhD
Medical University of South Carolina

Bobby Bangert, LICSW
Whitman-Walker Health

Katilyn (Katie) Catanzarite, PsyD
Louisiana State University Health Sciences Center

Jonathan Colasanti, MD, MSPH
Ponce de Leon Center at Grady Health

Julie Dombrowski, MD, MPH
University of Washington
HIV Treatment Initiatives, Public Health – Seattle & King County

Colin Flynn, ScM
Maryland Department of Health/Center for HIV Surveillance, Epidemiology, and Evaluation

Britt Gayle, MD, MPH, AAHIVS
HRSA HAB

June Gipson, PhD
My Brother's Keeper, Inc.

Cristina Lopez, PhD
Medical University of South Carolina

Paul Mandsager, MSPH
HRSA HAB

Marlene Matosky, MPH, RN
HRSA HAB

Melanie Moore, PhD
HRSA HAB

Veronica Ross
University of Virginia Health

Everlyne Sawyer, MA
University of Virginia Health

Presenters (cont.)
Teri Senn, PhD
NIH NIMH

Patricia Sweeney, MPH
CDC NCHHSTP

Panel of Individuals with Lived Experience
Bryan
Erick
Janiqua
Korey
Mikayla

Public Comments
Carie Harter
ViiV Healthcare

Charlie Peterson
Neelyx Labs

Shyam Saladi, PhD
Neelyx Labs

Attachment B: List of Acronyms

ADAP	AIDS Drug Assistance Program
AETC	AIDS Education and Training Center
AHRQ	Agency for Healthcare Research and Quality
AI	Artificial Intelligence
AIDS	Acquired immunodeficiency syndrome
ART	Antiretroviral Therapy
BPHC	Bureau of Primary Health Care
BHW	Bureau of Health Workforce
CDC	Centers for Disease Control and Prevention
CHAC	CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment
CMS	Centers for Medicare & Medicaid Services
D2C	Data to Care
DFO	Designated Federal Official
Doxy PEP	Doxycycline Post-Exposure Prophylaxis
EHE	Ending the HIV Epidemic in the U.S.
EHR	Electronic health record
ET	Eastern Time
FDA	Food and Drug Administration
HAB	HIV/AIDS Bureau
HHS	U.S. Department of Health and Human Services
HIV	Human immunodeficiency virus
HRSA	Health Resources and Services Administration
IHS	Indian Health Service
LAI	Long-acting injectable
LGBTQIA+	Lesbian, Gay, Bisexual, Transgender, Questioning, Intersexual, Asexual, Plus
MMWR	Morbidity and Mortality Weekly Report
MORE	Mobile Outreach, Retention, and Engagement
NASTAD	National Alliance of State & Territorial AIDS Directors
NCHHSTP	National Center for HIV, Viral Hepatitis, Sexually Transmitted Diseases, and Tuberculosis Prevention
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
NIMH	National Institute of Mental Health
OIDP	Office of HIV/AIDS and Infectious Disease Policy
PACHA	Presidential Advisory Council on HIV/AIDS
PEPFAR	President's Emergency Plan for AIDS Relief
POC	Point-of-care
PrEP	Pre-Exposure Prophylaxis
PTSD	Post-traumatic stress disorder
RWHAP	Ryan White HIV/AIDS Program
SAMHSA	Substance Abuse and Mental Health Services Administration
SPNS	Special Projects of National Significance
STD	Sexually transmitted disease

STI	Sexually transmitted infection
TB	Tuberculosis
U=U	Undetectable equals untransmittable
U.S.	United States
USPHS	United States Public Health Service

Attachment C: Syringe Service Program Letter

CDC/HRSA ADVISORY COMMITTEE

on HIV, Viral Hepatitis and STD Prevention and Treatment

October 3, 2024

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Becerra,

Thank you for your support and leadership in the continuing work to improve public health among all U.S. individuals. The Centers for Disease Control and Prevention (CDC)/Health Resources and Services Administration (HRSA) Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHAC) met in Atlanta on April 9-10, 2024, where we discussed recent actions taken by elected officials across the country to defund, close, or preemptively ban syringe service programs (SSPs) and other evidence-based interventions developed to support and improve the health of people who use drugs. *CHAC passed a resolution and wishes to express its strong support for SSPs and other harm reduction interventions which have a track record of success.*

Background Evidence for SSPs

SSPs, as well as a broad range of harm reduction services, are core elements of HIV and viral hepatitis prevention and are supported by nearly 30 years of evidence-based research. The Substance Abuse and Mental Health Services Administration, CDC, and U.S. Department of Health and Human Services (HHS) have long-recognized that comprehensive SSPs are safe, effective, cost-saving, do not increase illegal drug use or crime, and play a critical role in decreasing transmission of viral hepatitis, HIV, and other infections.[1,2,3,4] The White House Office of National Drug Control Policy offers a model law[5], the Model Syringe Services Program Act, for states to expand access to SSPs.

It explicitly authorizes the establishment of comprehensive SSPs, which are associated with a decrease in bloodborne infectious disease diagnoses as well as the number of needlestick injuries to first responders and others.

SSPs provide care far beyond prevention of HIV and viral hepatitis. SSPs flexibly respond to the needs of their clients to provide overdose prevention, facilitation of safe disposal of used needles and syringes, and drug checking as well as material resource support (food, clothing, housing services, etc.). Some SSPs have also integrated critical medical services, such as connection to HIV care and curative hepatitis C virus (HCV) treatment, medication treatment for substance use disorders, and care for skin and soft tissue infections through on-site, mobile, and telehealth models. SSPs additionally afford people who use drugs, who are highly marginalized in our society and health care environments, a place to engage safely with people who respect and support them.

Despite the efforts of 39 states to expand access for SSPs in the last decade, data suggest that these life-saving programs are not sufficiently reaching the people who need them. In fact, local jurisdictions[6,7,8,9,10,11] across the nation have increasingly sought to sanction, defund, and close SSPs despite state-level expansion for services.

Even where SSPs are permitted, policy restrictions in many areas limit their ability to meet the comprehensive needs of people who need sterile syringes. Common restrictions include the requirement of one-for-one exchanges (one new needle for each needle returned); limiting access to pick up supplies; proof of residency in the county of the SSP; special approval by local government or law enforcement; and specific services in order to operate. Additionally, many SSPs exist in environments where local law enforcement maintains and enforces criminal laws prohibiting the possession of syringes. For SSPs to protect communities and provide meaningful reduction in the risk of transmission of HIV and hepatitis C, syringes and equipment related to injection drug use must be available in large quantities, without restriction. The World Health Organization recommends increasing the distribution of syringes/person/year to 300/person/year to eliminate hepatitis C.[12]

In addition to variation of restriction and services in SSPs at the local and state level, most SSPs are inadequately funded. An analysis of SSP programs[13] demonstrated that the median SSP annual budget was $100,000 (interquartile range of $20,159–$290,000), far below the estimated costs for running a comprehensive SSP, which ranges from U.S. $400,000 for a small rural SSP (serving 250 clients) to $1.8 million for a large urban SSP (serving 2500 clients).

The United States is experiencing an addiction and overdose crisis. In 2021, there were 107,000 unintentional drug overdose deaths in the United States. In the last two decades the number of deaths attributed to unintentional overdose has increased by 500%. Studies suggest that the increasingly toxic and unpredictable illicit drug supply is worsening the epidemic. Racial and ethnic minoritized communities, and communities already experiencing health inequities (e.g., lack of housing, low employment, limited access), are disproportionately impacted. Alongside these emergencies, we are witnessing a startling uptick in HIV[14,15,16] and HCV infections.[17] Outbreaks of HIV among people who inject drugs have been described in both urban and rural environments. Hepatitis C incidence, which decreased by 48.2% from 2001 to 2010[18], has more

recently increased every year from 2015-2021.[19] CDC analysis determined that of the 220, mostly rural, counties they identified as vulnerable to HIV and/or HCV outbreaks[20], only 8% of them were covered by SSP services.[21]

The public health and infectious disease prevention efforts of our collective agencies are inextricably linked to the availability of SSP services. As such, efforts to sanction, defund, or close SSPs are harmful to our mission, and we must reinforce and support SSPs to the best of our ability.

Conclusion

The CHAC wishes to reiterate its **support for SSPs and harm reduction services for people who use drugs**. Efforts to defund, repeal or ban SSPs are harmful and contradictory to public health strategies that we know work.

Thank you for your consideration of these significant concerns and the recommendations of this Committee. Please let us know if you have questions or if we can provide additional information.

Regards,

/Wendy Armstong/

Wendy S. Armstrong, MD
CHAC Co-Chair

cc:
Dr. Laura Cheever, Associate Administrator, HRSA
Dr. Jonathan Mermin, Director NCHHSTP, CDC
CHAC Members

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Attachment D: Public Comment

Letter from Chera Mattox

Hello

My name is Chera Mattox. I am the Director of HIV Prevention and Education at Park DuValle Community Health Center. I had a question regarding PrEP access. I work at a FQHC that is a sub recipient of EHE funds. I have been working in the HIV space for a long time, but I have only been in a FQ setting for about a year. I am proud to say that we have been able to significantly increase our HIV testing and have better PrEP participation. When I arrived, I immediately started asking questions about PrEP access (especially for our patients who do not have access to Kentucky's expanded Medicaid program). As you know, Kentucky has been identified as a priority state and is on the top 10 list of states with H-2A workers. I am interested in hearing your thoughts about making the pharmacies at FQHCs Ready, Set, PrEP sites. I believe this would assist not only in the number of scripts written but in accessibility and adherence. I was informed that the Ready, Set, PrEP program is no longer accepting applications for enrollment. Do you feel that utilizing FQHC pharmacies would be a viable option for PrEP to reach underserved and priority populations?

Thank you for your time and attention.

Sincerely,

Chera H. Mattox, MPH

Letter from ViiV

October 31, 2024

Submitted via online form - https://chacfallmeeting.org/public-comment/

Wendy Armstrong, MD, FIDSA, FACP
Co-Chair
CDC/HRSA Advisory Committee on
HIV, Viral Hepatitis and STD Prevention and Treatment

RE: CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment Meeting – October 21-22, 2024

Dear Dr. Armstrong:

ViiV Healthcare Company ("ViiV") writes to the CDC / HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment ("CHAC") to provide comments related to CHAC's Long-Acting Injectable Workgroup (LAIW). Specifically, ViiV writes to:

- Request an extension of the LAIW for at least one additional year. to examine emerging issues and encourage best practice sharing among HIV treatment and prevention stakeholders;
- Request the CHAC continue to identify and preserve protections and guidance to address coverage-related issues that hinder access to LAIs for HIV treatment and prevention;
- Emphasize the benefits of AIDS Drug Assistance Programs ("ADAPs") covering LAI HIV treatments and request CHAC continue to provide TA and best practices; and
- Encourage the LAIW to continue to explore the impact LAIs have on the ability of patients and providers to address social determinants of health ("SDOH").

ViiV is the only independent, global specialist company devoted exclusively to delivering advancements in HIV treatment and prevention to support the needs of people with HIV and those vulnerable to HIV. ViiV remains singularly focused on improving the health and quality of life of people affected by HIV and has worked to address unmet needs in care and treatment. In collaboration with the HIV community, ViiV is committed to developing meaningful treatment advances, improving access to its HIV medicines, and supporting the HIV community to facilitate enhanced care and treatment.

The CHAC Should Extend the LAIW for a Period of at Least One Year

As the CHAC considers the future of treating and preventing HIV, the scope of the LAIW is and will remain an integral part of the Committee's mandate.[i] Over the next several years, innovations in LAI treatment and prevention are likely to continue, introducing more options that require fewer administrations to maintain viral suppression or prevent new HIV infections. Accordingly, ViiV urges the CHAC to maintain an active LAIW for at least one year.

In establishing the LAIW, the CHAC charged it with "providing input to the CHAC for consideration and deliberation on addressing current and emerging issues related to use of LAI PrEP and treatment, including identification of system and clinic-level barriers and opportunities (including cost and access issues) and

identification of best practices and potential models of care."[ii] ViiV applauds the CHAC for forming the LAIW to identify issues and solutions across the continuum of care for HIV treatment and prevention.

LAIs Remain Novel and the Full Scope of Challenges Remains Unknown

While the workgroup has rapidly identified many of the critical challenges facing LAIs, these products remain very new to market. The U.S. Food and Drug Administration approved, the first LAI treatment for HIV-1 and the first LAI PrEP drug in 2021.

As the CHAC is likely aware, it can take many years for stakeholders across the continuum of care to adopt, understand, and implement innovative treatment and prevention tools, particularly in medically underserved areas. Patients, care delivery systems, and public and private payers alike are still navigating implementation of LAI options for people living with HIV and people who could benefit from PrEP.

As the LAIW has previously identified, a need remains to "standardize the provision of LAIs across payers for HIV prevention and treatment and to increase access for all populations."[iii] Most recently, a major milestone in standardization was reached with the issuance of a National Coverage Determination (NCD) from the Centers for Medicare and Medicaid Services (CMS). Under the NCD, both oral and LAI PrEP and ancillary services are now covered under Medicare Part B with $0 cost sharing for Medicare beneficiaries. This significant change in coverage, which transitions all PrEP modalities to a medical benefit, is likely to present new challenges for providers, pharmacies, patients, and payers while benefitting patients with $0 cost. ViiV believes the LAIW is uniquely positioned to identify any challenges and offer viable solutions that could be implemented across payers.

We also applaud the guidance issued this week by the Departments of Health and Human Services, Labor, and Treasury ("tri-agencies) which mandates all non-grandfathered plans cover both daily oral PrEP and long-acting PrEP without cost-sharing, and prohibits the use of medical management techniques that would direct individuals to utilize one formulation over another.[iv] The FAQ also reiterates decisions for HIV prevention should be made between a provider and the patient, without intrusion from an insurer, and includes billing and coding information to make its intention clear that PrEP must be covered at zero cost share. The LAIW can play a critical role in sharing communications with CMS if plans do not follow this guidance.

Likewise, as pioneers in LAI PrEP and treatment for HIV, we continue to hear from local, state, and national advocacy partners and providers that since LAIs are a new modality, challenges remain. Advocates are presently contending with issues such as the inclusion of LAI treatments on state ADAP formularies, legislative authorization for pharmacists to prescribe and administer LAI PrEP, and utilizing Ryan White funding to purchase premium assistance for ADAP clients as a cost-effective alternative to direct drug purchasing. Accordingly, ViiV strongly encourages the CHAC maintain the LAIW to continue to examine current and emerging issues and make recommendations related to policy and access barriers.

The LAIW Provides a Critical Forum for Best Practice Sharing

As noted above, in addition to its responsibility to provide input on current and emerging LAI issues, the LAIW is also charged with identifying best practices and potential models of care. Given the novelty and

continued innovation in LAIs for HIV treatment and prevention, best practices are still emerging, and the need for an interagency forum for identifying and analyzing these practices remains critical.

ViiV urges the CHAC to extend the LAIW for a period of at least one year. This helps ensure patient and provider advocacy groups that support people living with HIV and people who could benefit from PrEP have a sustained and predictable opportunity to engage with public health agencies at the federal level.

Patients Continue to Experience Coverage Issues Related to Cost-Sharing, Medical Benefit Challenges, and Utilization Management (UM) Measures

As the LAIW has previously identified, cost and access barriers related to payer behaviors remain a major challenge for people who could benefit from LAI treatment or PrEP.[v] ViiV urges the LAIW to address plans that are not implementing $0 cost sharing for preventive services related to PrEP; to analyze and recommend best practices related to the transition of PrEP to a medical benefit; and to examine how UM practices hinder access to LAI and perpetuate the HIV epidemic.

The Affordable Care Act Mandates $0 Cost-Sharing for Preventive Services in the Commercial Market

In 2023, the USPSTF under the authority of the ACA assigned a "Grade A" rating to PrEP as a highly effective preventive intervention which requires plans to cover PrEP with $0 cost sharing.[vi] Additionally, on October 21, 2024, the Departments of Treasury, Labor, and Health and Human Services issued comprehensive coverage guidance directing non-grandfathered health plans to cover all forms of PrEP, including LAIs.[vii]

Notwithstanding the ACA's mandate and recent guidance, patients are sometimes burdened with impermissible cost-sharing requirements for PrEP and ancillary services, which may include denials of coverage despite current USPSTF PrEP recommendations. Coverage denials can result in treatment delays, which may leave people who could benefit from PrEP without prescribed medication and faced with lengthy appeals processes. According to the HIV+HEP Policy Institute, financial obligations as low as $10 can lead to prescription abandonment for preventive drugs.[viii] ViiV urges the LAIW to examine these barriers and develop recommendations for enforcement action to ensure payers are fully compliant with the law in covering LAI PrEP and related services. In addition, we encourage the LAIW to explore whether plans or insurers limit networks to impede access to PrEP since guidance requires $0 cost sharing only if the provider is "in-network". It is critical, especially in rural areas and PrEP "deserts" that providers are provided with technical assistance to ensure they remain in network with plans that serve these areas.

Streamlined Coverage of LAI Treatment and PrEP is Essential to Ending the HIV Epidemic

LAI innovations offer significant advantages for certain people living with HIV or who could benefit from PrEP. ViiV urges the LAIW to continue identifying challenges and best practices in coverage to ensure unimpeded access by patients who decide, in consultation with their provider, that an LAI option is appropriate. Specifically, ViiV suggests policy solutions that encourage all payers to adopt, at minimum, the scope of coverage established by the recently finalized PrEP NCD and FAQ issued by the tri-agencies.

ViiV recognizes transitions in coverage often necessitate changes to benefit design and billing processes at the site of service. ViiV encourages the LAIW to convene key stakeholders to identify ways to address barriers, such as streamlining the process to receive LAI medications, ensuring Medicaid pharmacy benefit

coverage and adequate reimbursement for "buy and bill" products, and reducing administrative burden. Future innovation in both HIV treatment and prevention will continue to shift care delivery models to

physician-administered products and create more accessible and durable options for HIV viral suppression and transmission suppression.

All ADAPs Should Include LAI HIV Treatment on Formularies

In the early days of HIV treatment, patients were burdened by complex dosing regimens with high pill burdens.[ix] For over 20 years, those living with HIV have benefitted from scientific advances that offered effective HIV treatment in co-formulated tablets reducing the number of pills taken per day.[x] Despite progress, all complete HIV treatment regimens still required taking daily pills. With the availability of LAI treatment, appropriate patients no longer need to take a pill every day, with an effective long-acting treatment option with dosing as few as 6 times per year.[xi] The SOLAR trial showed that despite achieving viral suppression on oral therapy, 47% of patients reported psychological challenges with daily oral ART at the time of study entry.[xii] Across several clinical trials as well as real-world cohorts, CABENUVA has been associated with significant improvements in treatment satisfaction and strong patient preference.[xiii,xiv,xv] Finally, switching from oral ART to CABENUVA was associated with improvements in psychological challenges.[xvi]

LAI treatment may have additional benefits for people living with HIV. In a claims database study among US people with HIV on stable oral ART, switching to LAI ART resulted in significantly higher adherence and persistence compared to those continuing on oral ART.[xvii] Most recently, the LAI treatment CABENUVA has been shown to help improve outcomes for people with HIV with adherence challenges. In an interim analysis of a Phase III study (ACTG 5359, LATITUDE), considering all endpoints together, CAB + RPV LA (cabotegravir + ripilvirine long-acting) showed superior efficacy when compared to daily oral standard of care ART in people with HIV who face barriers to adherence.[xviii] The potential virologic benefits of CABENUVA in patients with adherence challenges, many of whom struggle with mental health or substance abuse, have also been observed in US real-world cohorts including a safety net clinic.[xix]

Currently, only six states (Texas, Missouri, Kentucky, Louisiana, Oklahoma, and South Dakota) do not cover LAI treatment through their HIV medication programs. Given the demonstrated benefits of LAI treatment for patients who have difficulty with the current oral standard of care, an LAI option can support state strategies in alignment with the End the HIV Epidemic (EHE) initiative. In addition, for people who move between Medicaid and ADAP, ensuring continued access to LAIs is critical to prevent treatment disruption. Lastly, ADAPs not including LAI as an option creates a health disparity for the most vulnerable patient populations, a thought difficult to comprehend since one of the program's goals is to serve as a safety net for those not eligible for other insurance.

Accordingly, the LAIW should examine disparities between states that do an do not include an LAI modality in their ADAP formularies and make recommendations based on these findings. We specifically urge the LAIW to issue findings on how LAI treatment for HIV can help communities identified by EHE increase viral suppression and potentially reduce the total cost of care for treating new and existing cases of HIV.

LAI PrEP and HIV Treatment Can Allow Patients and Providers to Address SDOH and Social Risk Factors

As demonstrated by the SOLAR trial discussed above, for certain populations, daily oral treatment and PrEP can pose a logistical and psychological burden that may be reduced significantly by LAIs. Social risk factors, such as access to affordable care, housing stability, and stigma associated with a positive HIV status, can impact an individual's ability to be adherent to a daily oral ART.

For individuals experiencing these challenges, LAI treatment has been shown to be clinically superior to oral treatment in achieving viral suppression, which is critical to improving overall health and reducing new incidence of HIV.[xx] With LAI options, treatment and prevention can be successful with as few as six physician office visits annually. With the burden of daily oral regimens eliminated, individuals facing social risk factors may be able to devote more time and resources to priorities like finding stable housing and employment and achieving consistent access to health care.

ViiV encourages the LAIW to continue efforts to hear the experience of people living with HIV and people who could benefit from PrEP who are using an LAI option, particularly with respect to how LAIs empower them to improve SDOH outcomes.

###

Thank you for the opportunity to provide comments, feedback, and recommendations. ViiV looks forward to being a dedicated partner in the continued efforts to end the HIV epidemic and improve outcomes for people living with HIV and for people who could benefit from PrEP. If you have any questions, please contact Carie Harter at carie.a.harter@viivhealthcare.com.

Sincerely,

Carie Harter

Carie Harter
Senior Director, ViiV Government Relations
ViiV Healthcare

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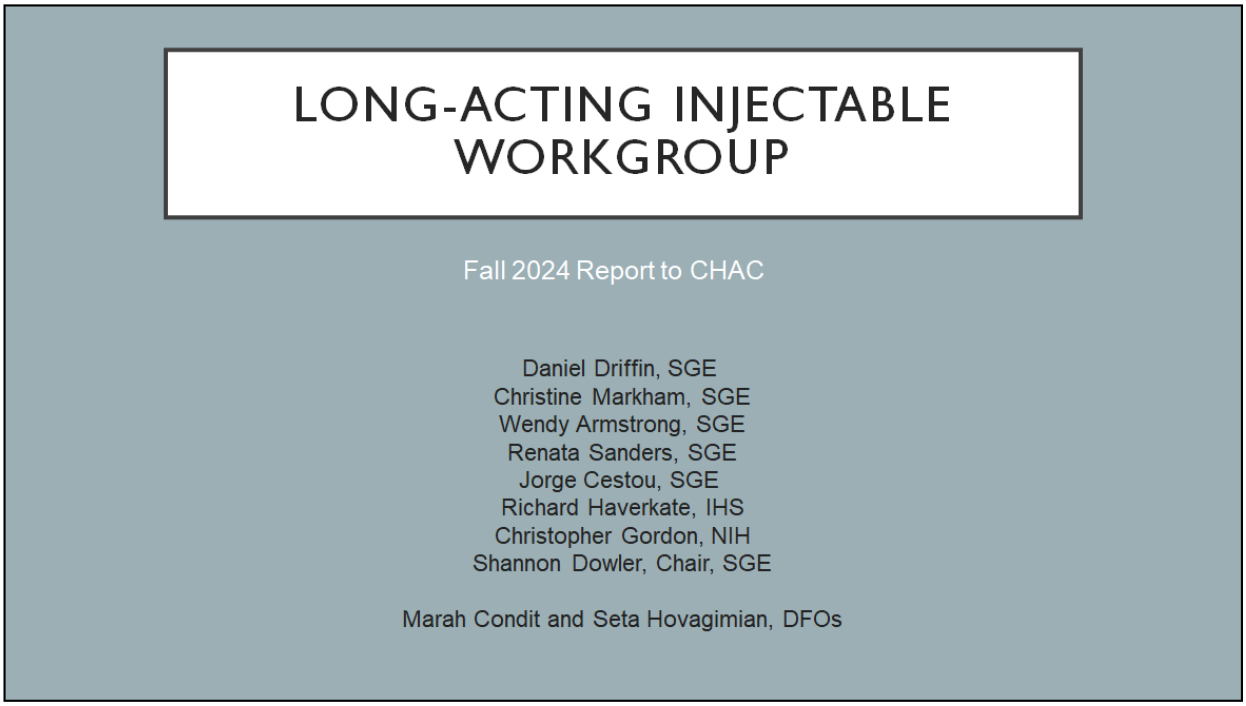
Attachment E: Workgroup Reports



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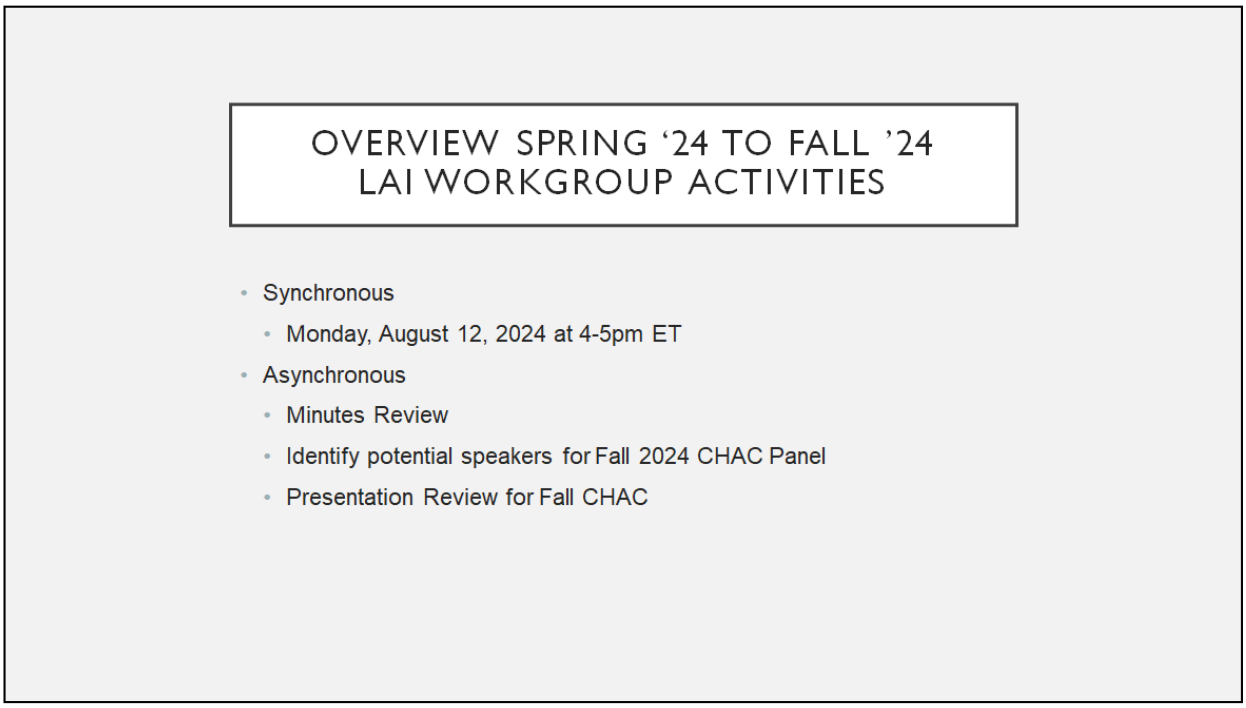

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OVERVIEW FALL '23 RECOMMENDATIONS

- **CHAC recommendations following the fall 2023 meeting included:**
  - CDC and HRSA work with CMS to investigate how to standardize the provision of long-acting injectables across payers for HIV prevention and treatment and to increase access for all populations.
  - CDC and HRSA work and partner with IHS to add long-acting injectables to the IHS formulary.
  - CDC and HRSA work with the HHS Adolescent and Adult Antiretroviral Treatment Guidelines Committee on two items: 1) evaluating the emergence of new data that will allow people living with HIV to access direct to inject broadly and in settings of non-viral suppression; and 2) reevaluating the long-acting injectable PrEP guidelines to include permissive utilization in unique circumstances.

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FOLLOW UP ACTION FROM APRIL 2024

- **RESOLVED with CHAC Fall Panel Discussion:**
  - Ask the CDC/HRSA to work with partners, such as NIH and Ryan White programs, to request current grantees working in the LAI space to share the current state of their learnings from 2022-present.
  - Ask CDC/HRSA to convene existing advisory boards of people with lived experience to discuss the current barriers to access and uptake of LAI(for HIV treatment and prevention)(for instance in 8/24 Ryan White Conference).
  - Ask CDC/HRSA to partner with CBOs specifically related to populations demonstrating rising risk, such as women and young adults, to increase uptake of LAI.
- **BRING BACK TO CHAC FOR DISCUSSION:**
  - Ask the CDC/HRSA to work with partners in clinical practice to seek feedback on preferred mechanism for reimbursement of LAI(pharmacy vs. medical benefit) for best patient access.
  - Request CHAC to consider revisiting the fall 2023 recommendation to more explicitly ask CDC/HRSA to seek standardization of LAI under exclusively pharmacy or medical benefit and to eliminate cost sharing/co-pays.
- **SUNSET THIS REQUEST:**
  - Request CHAC to consider revisiting the fall 2023 recommendation to more explicitly ask CDC/HRSA to drive study and recommendations related to increasing inter-injection intervals, decrease the burden of additional labs, and allow direct to treat when clinically appropriate.
- **BRING BACK TO CHAC WITH MODIFICAITON:**
  - *Request CHAC consider modifying scope of LAI WG and extending to include: tracking the emergence of new LAI for other conditions, driving ongoing study to evaluate and eliminate barriers for access to LAI* CHANGE TO
  - Ask for a scientific panel discussion at the spring 2025 CHAC on all LAI and long acting non-injectable drugs for viral hepatitis, STI's and HIV in development

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ITEMS FOR FOLLOW UP DISCUSSION

- Ask the CDC/HRSA to work with partners in clinical practice to seek feedback on preferred mechanism for reimbursement of LAI(pharmacy vs. medical benefit) for best patient access.
- Request CHAC to consider revisiting the fall 2023 recommendation to more explicitly ask CDC/HRSA to seek standardization of LAI under exclusively pharmacy or medical benefit and to eliminate cost sharing/co-pays.
- Ask for a scientific panel discussion at the spring 2025 CHAC on all LAI and long-acting non-injectable drugs for viral hepatitis, STI's and HIV in development

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