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

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

October 24-25, 2023

Record of the Proceedings

Table of Contents

Executive Summary

The United States (U.S.) Department of Health and Human Services (HHS); the Centers for Disease Control and Prevention (CDC) National Center for HIV, Viral Hepatitis, Sexually Transmitted Diseases (STDs), and Tuberculosis (TB) Prevention (NCHHSTP); and the Health Resources and Services Administration's (HRSA) HIV/AIDS Bureau (HAB) convened a meeting of the CDC/HRSA Advisory Committee on HIV, Hepatitis, and STD Prevention and Treatment (CHAC) on October 24-25, 2023 in Rockville, Maryland.

CHAC members heard presentations from HRSA and CDC on key issues, including Ryan White HIV/AIDS Program (RWHAP) activities; Ending the HIV Epidemic in the U.S. (EHE) activities; coordination with the Presidential Advisory Council on HIV/AIDS (PACHA); program models to address congenital syphilis and increases in syphilis incidence at an urban hospital and among American Indian/Alaska Native; progress toward integrating whole-person syndemics; initiatives on social determinants of health; and quality of life approaches.

CHAC members heard a federal update from HRSA emphasizing the importance of holistic healthcare, considering factors such as environment, transportation, housing, and employment—stressing the need for data-driven storytelling to secure funding and support. CHAC members also heard a federal update from CDC highlighting leadership changes and updates on the progress on the Perinatal Infection and Telehealth recommendations made by the CHAC. CDC also provided updates on TB services for Ukrainian refugees, new perinatal hepatitis C screening recommendations, draft guidelines for DoxyPEP, and the 2023 HIV prevention priorities.

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

1. Key lessons from various initiatives on HIV and hepatitis C (HCV) co-infection highlighted the need to improve HCV surveillance systems, noting disparities in infection rates and treatment, especially among marginalized groups, and CDC's efforts to address these epidemics through enhanced funding, health department engagement, and capacity building, including integrating HCV testing in opioid treatment centers and data surveillance programs.
2. Two special presentations covering 1) congenital syphilis (which is experiencing a rise due to factors such as homelessness, substance use, and lack of prenatal care) and coordinating success, as well as 2) framework for operationalizing quality of life.
3. An initiative emphasizing braided funding for marginalized groups and addressing health-related social needs; the need for equity, policy development, and diversifying funding sources; and successful experiences with harm reduction and syringe exchange programs.

The CHAC Long-Acting Injectable Workgroup presented a report on the use of long-acting injectable pre-exposure prophylaxis (PrEP) for HIV prevention and treatment, discussions with healthcare professionals and tribal representatives about implementation challenges, and key issues related to medication coverage, PrEP guidelines, and viral suppression requirements. The CHAC Community Partnerships Workgroup reported on challenges and strategies in developing community partnerships for health equity, emphasizing the need for shared leadership, a syndemic approach, and braided funding. The Workforce Workgroup reported scheduling issues but had a scheduled meeting with a PACHA working group.

Throughout the two-day meeting, CHAC members highlighted three overarching themes: 1) Health Equity and Access Challenges, 2) Community Engagement and Partnerships, and 3) Policy and Guidelines Improvement.

CHAC Action Items

Motions were passed to:

- Accept the April 2023 CHAC meeting minutes with no changes or further discussion.
- Approve the continuation of the Long-Acting Injectable Workgroup with no further discussion.
- Accept the recommendation that CDC and HRSA work with the Centers for Medicare and Medicaid Services (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.
- Accept the recommendation that CDC and HRSA work and partner with Indian Health Service (IHS) to add long-acting injectables to the IHS formulary.
- Accept the recommendation that CDC and HRSA work with the HHS Adolescent and Adult Antiretroviral Treatment Guidelines committee.
- Approve the continuation of the Community Partnerships Workgroup with no further discussion.
- Approve the continuation of the Workforce Workgroup with no further discussion.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

CENTERS FOR DISEASE CONTROL AND PREVENTION
HEALTH RESOURCES AND SERVICES ADMINISTRATION

CDC/HRSA Advisory Committee on
HIV, Viral Hepatitis, and STD Prevention and Treatment
October 24-25, 2023

Minutes of the Meeting

The United States (U.S.) Department of Health and Human Services (HHS); the Centers for Disease Control and Prevention (CDC) National Center for HIV, Viral Hepatitis, Sexually Transmitted Diseases (STDs), and Tuberculosis (TB) Prevention (NCHHSTP); and the Health Resources and Services Administration's (HRSA) HIV/AIDS Bureau (HAB) convened a meeting of the CDC/HRSA Advisory Committee on HIV, Hepatitis, and STD Prevention and Treatment (CHAC) on October 24-25, 2023 in Rockville, Maryland.

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

Day 1: Chair 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 2023 CHAC meeting and reviewed the agenda. The first day included federal updates and two panel discussions on HIV/HCV syndemic and congenital syphilis and quality of life. The second day included a third panel on innovative payment models to address social determinants of health.

DFO Meeting Roll Call

Ms. Shalonda Collins, MPH, CHES
Public Health Analyst / CHAC LEAD
HAB
Division of Policy and Data
HRSA

Ms. Collins welcomed participants to the CHAC meeting, reviewed ground rules, and provided instructions for discussion periods.

Laura Cheever, MD, ScM
Associate Administrator
HAB
HRSA

Dr. Cheever welcomed participants on behalf of CDC and HRSA. She reminded participants that CHAC meetings are open to the public and that all comments made during the proceedings are a matter of public record. She asked CHAC members to be mindful of potential conflicts of interest identified by the Committee Management Office and to recuse themselves from voting or participating in those discussions. Dr. Cheever conducted roll call and gathered conflicts of interest disclosures from voting and *Ex-Officio* members in attendance, which established a quorum for the CHAC to conduct business.

Conflict of Interest Disclosures

CHAC Voting Member (Institution/Organization)	Disclosure of Conflict
Wendy Armstrong, MD (Co-Chair) Emory University School of Medicine	Recipient of funding from RWHAP
Keiva Lei Cadena-Fulks Kumukahi Health + Wellness	No conflicts
Jodie Dionne, MD, MSPH University of Alabama at Birmingham	Recipient of funding from RWHAP and NIH
Shannon Brown Dowler, MD North Carolina Medicaid	No conflicts
Daniel D. Driffin, MPH D3 Consulting	No conflicts
Grissel Granados, MSW The Well Project	No conflicts
Meredith Greene, MD IU Health Physicians Geriatrics	Recipient of funding from NIH; work at RWHAP-funded clinics
Vincent Guilamo-Ramos, PhD, MPH Duke University	Recipient of funding from NIH and CDC
Kali Lindsey Pyxis Partners	Recipient of funding from NIH
Christine Markham, PhD University of Texas Houston	Recipient of funding from NIH, CDC/HRSA, and ACF
Joanne Morne, MS, ED New York State Department of Health	Recipient of funding from NIH, CDC/HRSA, OMH, ACF
Robert Riester, PLWH Colorado Health Network	Recipient of funding from CDC and RWHAP

CHAC Voting Member (Institution/Organization)	Disclosure of Conflict
Leandro Rodriguez, MBA Latino Commission on AIDS	Recipient of funding from SAMHSA, CDC, RWHAP, Gilead, and ViiV
Renata Arrington Sanders, MD, MPH, SCM The Children's Hospital of Philadelphia	Recipient of funding from RWHAP, CDC, and NIH
Samuel So, MBBS, FACS Stanford University	Recipient of funding from NIH and CDC

Ex-Officio members in attendance included Dr. Pradip N. Akolkar of the Food and Drug Administration (FDA), Dr. Carolyn Deal from the National Institutes of Health (NIH) National Institute of Allergy and Infectious Disease (NIAID), Dr. Christopher Gordon from NIH's National Institutes of Health (NIMH), Mr. Richard Haverkate from IHS, Ms. Kaye Hayes from HHS's Office of Infectious Disease and HIV/AIDS Policy (OIDP), and Dr. Bill Kapogiannis from NIH's Office of AIDS Research (OAR).

DFO Welcoming Remarks

Laura Cheever, MD, ScM
Associate Administrator
HAB
HRSA

Jonathan Mermin, MD, MPH
RADM and Assistant Surgeon General USPHS
Director, NCHHSTP
CDC

Dr. Cheever provided an update on CHAC staff and membership, introducing Dr. Sanders, Ms. Granados, and Ms. Cadena as new HRSA-appointed CHAC members. Each of the new members introduced themselves. Dr. Cheever thanked both new and existing members for their continuing support.

Dr. Mermin emphasized the importance of the meeting and the new technologies and opportunities that were now available. Significant work was still needed to make a difference in infections. Dr. Mermin thanked participants for their ongoing work.

Adoption of Minutes

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

Dr. Armstrong asked voting members to vote on the approval of the April 2023 CHAC meeting minutes.

CHAC Action
Dr. Armstrong called for a motion to accept the April 2023 CHAC meeting minutes. CHAC members accepted the minutes with no changes or further discussion.

HRSA Update

Carole Johnson, MA
Administrator
HRSA

Administrator Johnson thanked Dr. Cheever and the team that worked throughout the pandemic to ensure that clients accessed the services they needed. She added that their work during the pandemic was applicable to all HRSA's activities. Additionally, the influx of new federal resources has helped address the critical needs of communities. For example, nearly 40,000 people were engaged or re-engaged in care in the past two years through the EHE Initiative.

Administrator Johnson stated that the RWHAP has demonstrated that what happens inside the clinic walls was critical but not the whole story. Lived environment, transportation, housing, and employment were also critical considerations toward meeting outcome goals. Administrator Johnson stated HRSA was currently focused on telling a full story through data, lived experience, and the people who work to continue building on successes.

Administrator Johnson talked about continuing resolutions for the discretionary federal budget. Budget uncertainties challenged the difference HRSA was able to make in people's lives. People care about supports such as the Supplemental Nutrition Assistance Program (SNAP) and housing support. She emphasized that these uncertainties should not be demoralizing but instead energizing through the progress that has already been made and what that progress means for the future.

Administrator Johnson highlighted several examples of this progress. For instance, leveraging funds from the EHE initiative enhanced partnerships and facilitated effective COVID-19 vaccine distribution through community health centers. HRSA supported other broad efforts, including rural health and workforce initiatives, with a notable shift from concerns about reimbursement levels to challenges to the workforce such as shortages, burnout, and provider strain. HRSA's Bureau of Health Workforce (BWH) was actively seeking solutions, such as scholarships, loan repayments, and specialized training to attract healthcare providers to rural and high-need areas, with recent efforts focusing on integrating mental health, language, and disability care into primary care residency programs. Administrator Johnson discussed other efforts to increase healthcare providers in rural and underserved communities through career advancement opportunities, with a focus on cultural sensitivity and behavioral health.

Maternal health, and especially the disparities in maternal health outcomes, was another primary concern at HRSA. Administrator Johnson highlighted the work being done by HRSA's Maternal and Child Health Bureau (MCHB) and efforts to improve health outcomes for pregnant individuals with HIV.

Administrator Johnson expressed gratitude toward the Committee for their contributions and leadership. She emphasized that her team paid close attention to leveraging discretionary funds

to advance President Biden's HIV agenda. HRSA continues to focus on addressing critical needs and service gaps; integrating comprehensive care within clinical settings and communities; and supporting physical, behavioral, and social service needs. She noted the importance of economic development in national health, which creates supportive employment environments for people living with HIV, and the necessity of collaboration with partners, such as CDC to enhance prevention, treatment, and quality of life.

CHAC Member Discussion with HRSA

- Dr. Greene inquired about HRSA's role in addressing long-term care needs within the RWHAP structure, which traditionally does not include long-term care in its funding or scope. Administrator Johnson acknowledged the need to work within the limits of the RWHAP and highlighted the strong partnership with CMS and HHS's Administration for Community Living (ACL), indicating that opportunities exist for broader conversations on long-term and community-based care, especially with President Biden's focus in this area.

- Mr. Driffin asked about additional protections that RWHAP could offer for people living with HIV in the South, particularly in response to the increasingly draconian practices in that region. Ms. Johnson reflected on implementation of the Affordable Care Act (ACA) and expressed concern about states that have not expanded Medicaid. She emphasized the need for more work in connecting diverse groups to care and addressing mental health and substance use disorders (SUD). She acknowledged the political and policy environments in different states, suggesting that the Committee could assist in identifying potential challenges and exploring how RWHAP could address them.

- Dr. Guilamo-Ramos asked for guidance on effectively communicating the importance and impact of their work in HIV, STIs, and viral hepatitis, particularly in the context of competing priorities and a diminishing commitment to HIV issues. Administrator Johnson suggested that demonstrating how the work in HIV, mental health, and SUDs saves long-term costs and resources in the healthcare system would be an effective approach for engaging policymakers during a shifting policy climate.

- Dr. Sanders asked about the commitment to protect healthcare providers who offer transgender and gender-affirming care, emphasizing that safeguarding these providers was crucial for addressing HIV and other intersectional health issues. Administrator Johnson expressed dismay at the challenges faced by healthcare providers involved in this critical work and stressed the need for more discussion on how to best support and protect these providers.

- Dr. Mermin asked for suggestions on the most effective federal action to reverse the rising epidemics of STIs such as gonorrhea, chlamydia, and syphilis. Administrator Johnson suggested integrating STI screening into primary care, implementing quality metrics, and learning from the COVID-19 response (i.e., a rapid investment in diagnostics and treatment). She acknowledged the challenge of funding these initiatives.

- Dr. Dowler highlighted the conflict between federal non-discrimination guidelines and state laws prohibiting the use of state funds for gender-affirming care, emphasizing the need for more federal guidance to help public payers navigate this challenging situation. Administrator Johnson acknowledged the challenge and noted that HRSA was in an

ongoing conversation on these issues in collaboration with CDC and HHS's Office of Civil Rights.

HRSA HIV/AIDS Bureau Update

Laura Cheever, MD, ScM
Associate Administrator
HAB
HRSA

Dr. Cheever began by emphasizing the HAB's commitment to EHE in the U.S., noting their role in providing both resources and leadership to reduce health disparities and improve outcomes for people with HIV and their communities. She announced the addition of two new staff members to their team: Mr. Michael Kharfen, the new director of HAB's Division of Policy and Data, and Dr. Andrea Jackson, Senior Advisor in charge of special projects in HAB's Office of the Associate Administrator. She expressed enthusiasm for their energy, experience, and expertise, particularly in light of the urgency of current work and the policy developments they have led in the past.

Dr. Cheever expressed excitement about a joint CDC/HRSA community engagement effort over the last two years. These community engagements were led by HRSA in 2021 with CDC participation, followed by CDC-led engagements in 2022. In 2023, the community engagements are going, conducted jointly by HRSA and CDC in each region. In November 2023, HRSA and CDC will conduct the New England/Northeast/Caribbean region listening sessions, featuring Spanish translation with one session for public health leadership and another directly with impacted community members.

The 2024 National Ryan White Conference on HIV Care and Treatment is scheduled for August 20-23, 2024. The conference will be a hybrid format, combining in-person and virtual participation, with up to 3,500 attendees expected to join in person. The conference aims to provide program and policy updates, showcase innovative models, and offer training and assistance to RWHAP recipients, and emphasize practical and implementable strategies. The theme of the conference will be "Innovating to End the HIV Epidemic: Empowering Communities, Expanding Partnerships, Implementing Interventions," which reflects the advancements learned through RWHAP and the need for diverse partnerships and approaches to reach those who are out of care. Messages regarding in-person and virtual registration for the meeting have been sent, along with a call for abstracts. Dr. Cheever encouraged submissions from those doing notable work.

Dr. Cheever highlighted HAB's work on Medicaid continuous enrollment, particularly the unwinding process that began in March 2023, when states restarted Medicaid and Children's Health Insurance Program (CHIP) eligibility reviews—a process that was halted during the COVID-19 pandemic. She noted that 42 percent of renewals retained Medicaid or CHIP coverage. About 37 percent resulted in loss of coverage, of which 77 percent were due to procedural issues such as failing to return renewal forms. The remaining 20 percent of renewals were still in process.

Dr. Cheever discussed recent programmatic updates, including a Dear Colleague letter in collaboration with the Department of Housing and Urban Development (HUD) and CDC, addressing HIV outbreaks among those experiencing homelessness and housing instability. HAB also released a Program Letter emphasizing the inclusion of STI treatments in RWHAP

recipients' AIDS Drug Assistance Programs (ADAPs) and encouraged addressing STIs more broadly across RWHAP programs. In partnership with IHS, HAB released a Program Letter across all HRSA programs about the spike in congenital syphilis in Native American populations, focusing on increased testing for pregnant women and outreach to combat the epidemic, particularly in Indian Country.

Dr. Cheever discussed HAB's approach to gathering expert input through Technical Expert Panels, highlighting work with HAB's Division of State HIV/AIDS Program to streamline eligibility across RWHAP. She referenced a 2021 Policy Clarification Notice (PCN 21-02) focused on eligibility requirements, shifting from a six-month recertification requirement to a recipient set timeframe. She emphasized that ongoing work is occurring to improve these processes.

HAB launched a three-year initiative with Minority HIV/AIDS Funds to assist RWHAP Part A jurisdictions in developing, implementing, and evaluating status-neutral strategies. This initiative focused on a whole-person approach and aimed to enhance services for both HIV-positive and negative individuals through improved collaboration among existing care systems in the U.S. One Evaluation and Technical Assistance Provider (ETAP) and four implementation sites were funded for this initiative, which will provide a unified access point for individuals, regardless of HIV status, to reduce stigma and blur the lines between HIV clinics and testing centers.

Dr. Cheever reviewed RWHAP's Community of Practice within the RWHAP Part D program, which is focused on women, infants, children, and youth to promote topic areas such as preconception counseling, youth transition to adult services, and trauma-informed care. RWHAP has made significant progress in reducing health disparities through its Center for Quality Improvement and Innovation, which focuses on improving viral suppression among key populations. Additionally, HAB has initiated efforts such as the Creating HIV Awareness With Influencing Groups to End the HIV Epidemic (CHANGE) Initiative to engage communities more effectively in terms of raising HIV awareness, particularly in African American communities. These efforts have included participation in events such as Black Atlanta Pride, where HAB partnered with recipients to provide education, counseling, testing, and assistance in locating nearby providers, aiming to reach and impact a broader audience, including those indirectly affected by HIV.

HAB is modernizing the RWHAP AIDS Education and Training Centers (AETC) program, focusing on fostering partnerships, promoting better data utilization, identifying training needs and gaps, and enhancing program coordination and accessibility. Dr Cheever provided a brief RWHAP data update, including the enhancement of the RWHAP Compass Dashboard, the release of the 2021 RWHAP AETC Data Report, the 2021 ADAP Data Report, and the RWHAP 2023 Biennial Report. There have also been new publications from RWHAP Special Projects of National Significance (SPNS) initiatives, including the release of published data on HIV/HCV integration and the Black Women First initiatives.

Finally, HRSA announced that approximately $152 million was awarded through the RWHAP EHE initiative in 2023. EHE initiative funds have had impacts, with 22,413 people newly engaged in care and 15,318 reengaged in care in 2021. This represents about 20 percent of those undiagnosed or out of care in these areas, demonstrating the substantial effect of the funding.

CDC Update

Jonathan Mermin, MD, MPH

RADM and Assistant Surgeon General, USPHS
Director
NCHHSTP
CDC

Dr. Mermin provided an update on NCHHSTP's personnel changes. Dr. Demetre Daskalakis was named the Acting Director of the National Center for Immunization and Respiratory Diseases (NCIRD) and Dr. Leandro Mena retired from the directorship of the Division of STD Prevention (DSTDP). The Division of Adolescent and School Health (DASH) joined the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) in October 2023.

Dr. Mermin highlighted NCHHSTP's responses to CHAC's perinatal recommendations, including CDC recommendation for universal screening for HIV, hepatitis B, hepatitis C and syphilis in pregnancy and is working with societies, USPSTF, and states to improve consistency. The American College of Obstetricians and Gynecologists (ACOG) guidance is no consistent with CDC recommendations from Hepatitis B and C as well. CDC has worked with commercial laboratories for HCV screening in prenatal panels. There is now improved data linkage through the CDC publication on an innovative approach to monitor medication exposures and outcomes in pregnancy. CDC also responded to the recommendation to explore integration of existing case review boards across relevant perinatal infections with Notice of Funding Opportunity (NOFO) CDC-RFA-PS23-0013, *Assuring Comprehensive Perinatal, Maternal and Infant Health and the Elimination of Perinatal HIV in the United States*, which was recently awarded with an expanded scope to incorporate congenital syphilis prevention. NCHHSTP also responded to CHAC's telehealth recommendations on health equity, PrEP Guidance and virtual services with STI screening, by highlighting cooperative agreement CDC-RFA-PS-24-0026: *Implementation of Community Health Worker-Mediated Services for Re-Engagement to Care and Outreach for Persons with HIV in Rural Communities* for training community health workers in rural communities to re-engage people with HIV who have fallen out of care by providing services that may include telehealth. NCHHSTP supported the national technical assistance provider, NASTAD, to expand TelePrEP in EHE jurisdictions through online learning and collaboration, as well as the development of the Telehealth: Using Human Centered Design to Reach Underserved Communities initiative.

Dr. Mermin provided updates on the Division of TB Elimination (DTBE), which received about $27 million in supplemental funding to currently funded states, cities, and territories for the Uniting for Ukraine initiative to ensure Ukrainian refugees receive appropriate TB services upon arriving in the U.S. CDC conducted a needs assessment with arrivals and community-based organizations and used the findings to develop a toolkit encouraging arrivals to get tested for TB. Materials are available in Ukrainian and Russian. He also highlighted a multi-state TB outbreak linked to bone allografts that could be traced back to allografts from ViBone matrix material. The investigation revealed that the cadaver used for the allografts had undiagnosed TB, leading to the infection of recipients, including two fatalities and others who experienced severe TB. This prompted a review of FDA guidelines for allografts.

DASH is actively developing a new NOFO for large cooperative agreements CDC-RFA-PS-24-0006, *Improving Adolescent Health and Well-Being Through School-Based Surveillance and the What Works in Schools Program* set to be released in February 2024. They are also expanding their conceptual framework to include mental health, creating a resource action guide for K-12 school administrators to promote mental health by providing strategies, approaches, and practices that can positively influence students' mental health, with dissemination planned for later in 2023.

The Division of Viral Hepatitis (DVH) made progress towards the complete and comprehensive viral hepatitis surveillance with the publication of the 2021 Viral Hepatitis Surveillance Report and the 2023 Viral Hepatitis National Progress Report in August 2023. CDC published a report that suggests the majority of people with hepatitis C still have not been cured nearly a decade after Direct-Acting Antivirals (DAAs) were first approved in the United States.

The findings highlight the urgent need for a proposed national program that would end much of the suffering and death from hepatitis C by eliminating the disease in the United States. As the incidence of HCV continues to rise, efforts are being made to expand treatment in high-impact settings. This included supporting the NASTAD (HIV directors organization)/National Viral Hepatitis Roundtable (NVHR) convenings to discuss HCV testing and treatment models in various settings, establishing a partnership with the American Correctional Association, and releasing data from the national syringe service program (SSP) evaluation survey to support and learn from SSPs in the U.S. CDC released new recommendations for perinatal hepatis C screening in November 2023 which will introduce HCV testing of all perinatally exposed infants with a nucleic acid test (NAT) for detection of HCV ribonucleic acid (RNA) at age two to six months; and consultation with a health care provider with expertise in pediatric hepatitis C management for all infants and children with detectable HCV RNA. Additionally, leveraging the Independent Test Assessment Program (ITAP), efforts are underway to accelerate the development of a point-of-care HCV ribonucleic acid (RNA) diagnostic test to address the high dropout rates in follow-up testing and to support HCV testing with operational guidance. There are also efforts advocating for the FDA to downgrade the classification of hepatitis B diagnostics to facilitate the development of improved tests.

DSTDP awarded $12.5 million to 26 recipients through the Enhancing STI and Sexual Health Clinic Infrastructure NOFO in September 2023 to strengthen clinic infrastructure and expand access to comprehensive sexual health services. CDC's STI program broadened their partnerships through all five components of STOP STDs: Support Technical Assistance and Opportunities for Program, Policy, and Communications to Prevent STDs. CDC's STI program developed an STI Impact Research Consortium to support service delivery research, field-based prevention research, and research to develop, test, and implement STI diagnostic tools to increase the proportion of people tested and diagnosed. One project funded under the Consortium, titled "Egocentric Sexual Network Study to Inform HIV, Mpox, and other STI Syndemics" will be an egocentric network ascertainment from 12,000 people across 10 sites with varying levels of sexual activity to gather information about sexual activity patterns over time and health services use.

CDC's STI program continues to support the EHE initiative by leveraging the STD clinic setting to address the overlapping HIV and STI epidemics. From July of 2021 to December of 2022 26 there was a 36% increase in the proportion of the clinics that offer PrEP onsite, with 72% of clinics now offering this service. The next iteration of Component C is coming soon. This funding opportunity will continue to support the EHE initiative by scaling up HIV prevention and care services in sexual health clinics, including STI specialty clinics. The anticipated publication date is November 1, 2023, with applications due in January 2024 and awards going out June 2024.

Draft guidelines for doxycycline post-exposure prophylaxis (doxyPEP) to prevent STIs are now open for public comment in the Federal Register on October 2nd, 2023. STIs are pervasive and increasing rapidly in the U.S., and Doxy PEP has demonstrated substantial benefit in reducing new chlamydia, gonorrhea, and syphilis infections. Doxy PEP can benefit the health of some gay, bisexual, and other men who have sex with men, and transgender women who have

increased chances of getting an STI. The current recommendation in the draft guideline document is that Doxycycline 200mg taken once orally within 72 hours of oral, vaginal, or anal sex should be considered for gay, bisexual, and other men who have sex with men, and for transgender women, with a history of at least one bacterial STI (i.e., gonorrhea, chlamydia or syphilis) in the last 12 months. This was given an A1 recommendation. These guidelines currently focus on gay and bisexual men and transgender women because successful studies were limited to these groups. This highlights two major research gaps on the effectiveness of the intervention: 1) cisgender women and 2) all populations that have had an STI in the last 12 months to test it as a preventive intervention. This intervention is considered one of the most exciting in STI prevention since the HPV vaccine.

Dr. Mermin reviewed recent 2021 surveillance reports indicating a 12 percent reduction in new HIV infections over the past four years, marking the first significant decrease in nearly eight years, even amidst the COVID-19 pandemic. While 87 percent of people with HIV now know their status, efforts to expand testing are needed to reduce the 150,000 people who are unaware of their infection. Despite a significant increase in PrEP coverage, racial and ethnic disparities, particularly among African Americans, persist in accessing PrEP. In EHE counties where there has been extra focus, the HIV incidence has declined by 16 percent.

Finally, NCHHSTP released their 2023 HIV priorities, which include strengthening collaborations to ensure comprehensive care, prioritizing health equity with proven interventions, advancing whole person care approaches and strengthening collaborations that place HIV prevention and treatment in the context of other disease, and deepening and broadening our engagement with communities and people with lived experiences whose perspectives are needed to tailor solutions and increase the effectiveness of prevention and treatment efforts at the local level.

CHAC Member Discussion with CDC

- Mr. So thanked CDC and Dr. Mermin for the new recommendation for nationwide one-time hepatitis B screening, which is expected to significantly aid in eliminating hepatitis B in the U.S. This is a significant development considering the 1.6 million people living with chronic hepatitis B in the U.S.

- Ms. Cadena asked about preparations to ensure consistent supply of doxycycline post-exposure prophylaxis (DoxyPEP) and PrEP across the country, especially in rural areas. She also asked about data or research on the impact of the 57-jurisdiction initiative on HIV programming and case increases in locations that stopped receiving direct CDC funding nearly a decade ago. Dr. Mermin addressed concerns about the draft guidelines on doxy PEP, noting its affordability and availability, and emphasized that while a comprehensive implementation plan is in development, considerations for equitable access and community outreach are key. Regarding the EHE Initiative, he clarified that it was three years since the additional funding for the 57 jurisdictions with the highest HIV burden was given, noting that a nationwide reduction in HIV incidence occurred, but it is more pronounced in EHE areas. He also discussed the complexities in comparing HIV reductions across different jurisdictions and the ongoing analysis to understand these differences.

- Mr. Lindsey asked about CDC's plans to scale up access to HIV self-testing through mail orders, especially in rural communities and areas with limited testing accessibility, noting the effectiveness of this approach based on published data. CDC's self-testing initiative has distributed over 250,000 tests and will continue to expand annually despite the high cost of

being the only licensed test in the U.S. He highlighted the program's success in reaching individuals with risk behaviors including transgender women and African American and Latino gay and bisexual men, with linkages to care comparable to that from community health centers. However, he acknowledged that this method does not replace community-based outreach and testing, especially in areas where home delivery might not be confidential or feasible, and suggested supplementing this with providing tests to community-based organizations for distribution within their networks.

- Dr. Guilamo-Ramos expressed a desire for more discussion on inequities and the need to focus on areas where progress is lacking, suggesting a constructive approach towards addressing these 'hotspots'. Dr. Armstrong noted that RWHAP faces significant challenges not just with those in their services, but particularly with individuals not consistently engaged or outside their services, admitting a sense of uncertainty on how to address this gap despite efforts to learn from successful models and ideas.

- Dr. Sanders asked when CDC would provide more granular data on PrEP access, highlighting the significant disparities in usage among different age groups, particularly the low rates in adolescents aged 16 to 24, and the lack of detailed information for older populations because current data groups everyone over age 55 together. Dr. Mermin confirmed CDC could provide more precisely stratified age group data on PrEP usage, which will be publicly available for analysis once it is included in Atlas. He noted there are significant gaps in PrEP usage, especially among younger adolescents, and stressed the importance of not delaying work in this area while waiting for those detailed data. The age stratifications were available on Atlas Plus up to the first quarter of 2023 for national, state, and some local jurisdictions, although the stratifications might be broader for local areas.

- Dr. Dionne expressed appreciation for CDC incorporating recommendations to include congenital syphilis into the HIV perinatal groups, noting the significant reduction in HIV cases and the increase in congenital syphilis, with both conditions sharing similar risk factors and underlying issues, and highlighted this integration as a major advancement.

Update from the Presidential Advisory Council on HIV/AIDS

Vincent Guilamo-Ramos, PhD, MD
Dean and Professor
School of Nursing
Duke University

Dr. Guilamo-Ramos provided an overview of the 78th PACHA meeting. The meeting took place in West Virginia and focused on Appalachia; a region often overlooked in these discussions. Dr. Guilamo-Ramos emphasized the importance of correctly understanding and representing the region's unique challenges. A key observation from the meeting was the pronounced impact of polysubstance use, especially opioids, on the HIV epidemic in West Virginia.

During their visit to West Virginia, a state where 97 percent of the population is white, the team observed the significant impact of substance use, particularly opioids, on rural communities and their HIV challenges. Despite the demographic majority, the 3 percent non-white population faced even more pronounced inequities, highlighting an ecological crisis in terms of social determinants of health. They were struck by the stark public health needs in certain areas of the country.

Significant changes in PACHA occurred with the swearing-in of new PACHA members and when two actions were taken: 1) a letter to the Secretary addressing concerns about global and domestic HIV funding and 2) a resolution to remove the upper age limit on CDC's HIV testing guidelines in response to epidemiological data demonstrating a significant number of infections and late diagnoses among older individuals. These actions aimed to broaden the scope of HIV testing and address funding issues.

CHAC Member Discussion about the PACHA update

- Dr. Greene stated she works with older adults and often sees severe AIDS-related conditions misdiagnosed as Alzheimer's disease. She thanked PACHA for addressing the need for upper age HIV screening.

- Dr. Dowler emphasized the need to challenge ageism in sexual health, appreciating the new recommendation addressing older adults, and suggested that it should be one of many such future recommendations.

- Ms. Granados asked what RWHAP was doing to support the community of around 10,000 individuals in the U.S. who acquired HIV perinatally, highlighting the challenges of isolation, mental health, adherence, and quality of life due to their small and diminishing numbers. Dr. Armstrong acknowledged that while they have not given much thought to the social aspects, such as quality of life and isolation for those with perinatal HIV, they have considered care models and expert support for pediatric HIV, recognizing the need to think more about the unique needs of long-term survivors who acquired HIV perinatally.

- Mr. Driffin questioned whether the right questions were being asked and the right people were involved in addressing racial biases in HIV prevention and care, noting that despite efforts, disparities persist (such as the 94 percent prescription rate of PrEP among eligible white people). He emphasized the need to include HUD's Office of HIV Housing in these discussions due to the significant impact of housing on HIV prevention and care.

- Dr. Sanders asked Dr. Cheever how to ensure comprehensive coverage for individuals living with HIV, especially those with multi-drug resistant strains, citing a case in which a patient lost health insurance and access to a long-acting injectable. The case highlighted the challenges of providing treatment continuity despite insurance gaps and limitations. Dr. Cheever acknowledged the challenges posed by the U.S. healthcare system, especially when a patient loses access to medication due to insurance issues. She mentioned measures such as the same day start of antiretrovirals and policy clarifications to provide flexibility in drug access. She also discussed the importance of long-acting injectables for those with pill fatigue and efforts to make these treatments more accessible in RWHAP Clinics, especially for those who might struggle to obtain them without such assistance. Despite these efforts, challenges with insurance coverage and medication access persist, and she encouraged the Committee to consider specific recommendations to improve the situation.

HRSA Bureau of Primary Health Care Updates

Jim Macrae, MA, MPP
Associate Administrator

Bureau of Primary Health Care (BPHC)
HRSA

Mr. Macrae provided updates on BPHC's work with community health centers for HIV prevention, highlighting the differences in outcomes between EHE funded and non-funded organizations. Over 400 health centers were funded with a focus on making HIV prevention a routine part of primary care, with specific goals to increase HIV counseling and testing, PrEP prescriptions, and rapid connection to care for newly diagnosed patients. Initially focusing on organizations with RWHAP funding and experience in HIV care, the initiative successfully expanded to include centers with varying levels of experience, supporting them with funding of $157 million.

This effort resulted in a slight increase in patients served, from about 28.6 million to 30.5 million, and a significant rise in HIV testing, with almost a million tests conducted in the last three years. The number of patients living with HIV served at health centers remained around 200,000, with 82 percent connected to care within 30 days and approximately 85,000 patients receiving PrEP management services.

The data showed that funded organizations had increases in the overall effectiveness of HIV work. A significant increase occurred in the number of patients tested and those receiving their first HIV diagnosis in funded health centers compared to non-funded health centers. However, the number of individuals provided with PrEP decreased in non-funded organizations, highlighting the importance of funding to improve PrEP access.

Health centers identified four key areas critical for success in HIV prevention: prescribing, outreach, counseling and testing, and workforce development. Emphasis was placed on making organizations more welcoming, building relationships, and implementing routine HIV prevention work, including opt-out testing. During COVID-19, telehealth visits increased from less than 1 percent to about 16 percent, highlighting its importance in ongoing HIV prevention work.

CHAC Member Discussion about BPHC

- Dr. Mermin asked about the method used to adequately compensate community health workers and how the expansion of their numbers was achieved. Mr. Macrae noted that BPHC learned that grant funding could be used to support community health workers and other providers. Health centers received an average of $400,000 in grants, enabling them to support at least one or two community health workers.

- Mr. Driffin asked about the initial reservations community health centers had when they started implementing HIV services. Mr. Macrae noted that the availability of funding for health centers to support HIV-related activities made a significant difference despite initial hesitations from the centers about providing such services. Federal leadership and the initiative to make HIV prevention a priority pushed health centers to expand their services, leading to an increase in opt-out testing and counseling. Despite ongoing issues with stigma and workforce challenges, efforts continue to encourage all health centers to make HIV prevention a routine part of primary healthcare.

- Dr. Dionne asked how to upscale and routinize the process of identifying those who could benefit from PrEP, specifically pregnant women, in areas where the PrEP-to-need ratio needs improvement. Mr. Macrae noted that efforts were being made to collect and analyze

data on the prescription of PrEP across various states, and a team is investigating why these numbers were not as high as anticipated. The process was integrated into the electronic health record (EHR) system, and health centers were paired up to learn from each other's experiences. A small cohort of health centers in high-need areas was funded to focus on maternal mortality and morbidity, including HIV, to understand how to better incorporate these aspects into their work.

- Dr. Sanders expressed appreciation for a presentation on telehealth services, mentioning the creation of the Virtual Online Integrated Sexual Health Services (VOISES) program in Baltimore to enhance adolescents' access to virtual sexual health and education services. She raised two main concerns: strategies for increasing virtual access in regions lacking electronic access for youth and managing state restrictions on telehealth services, as well as the operationalization and support for long-acting injectable PrEP. Mr. Macrae addressed the question regarding adolescent and teen telehealth services, describing significant investments in optimizing virtual care in primary care settings, particularly in behavioral health. He highlighted the expansion of school-based health center sites, with a focus on behavioral health as a gateway to addressing adolescent issues, including sexuality. Regarding long-acting injectable PrEP, he noted challenges in access and reimbursement, emphasizing efforts to integrate these options into patient care and the ongoing work to address training and availability issues.

- Dr. Cheever asked about the applicability of lessons learned from prescribing PrEP and addressing sexual health and stigma in primary care, specifically about the support necessary for primary care providers to comfortably treat less complicated HIV patients and those with other comorbidities. Mr. Macrae acknowledged that, despite no significant increase in HIV patients treated in health centers, challenges such as clinician familiarity with treatments and reimbursement issues were not insurmountable. He emphasized the importance of resources, telehealth opportunities, and partnerships with specialists while also addressing the broader challenge of expanding primary care's role in various health initiatives. He also highlighted the need for a larger conversation about flexible funding and value-based care to support a broader range of services.

Panel 1: Reducing Barriers and Improving Outcomes in HIV and HVC Co-Infection

Moderator:
Demetrios Psihopaidas, PhD, MA
HAB
HRSA

Dr. Psihopaidas reviewed HRSA HAB's past SPNS initiatives related to HIV/HCV co-infection. For example, the HCV Treatment Expansion Initiative was an effort spanning 2010 to 2014 in which 29 sites implemented their choice of one of four HCV treatments. Although more than 5,000 patients initially enrolled in the study, only 239 initiated treatments. At the time, there was concern about potential HIV/HCV drug interactions, but the high number of eligible patients indicated a need for expanded HCV treatment. Another initiative was the Jurisdictional Approach to Curing HCV among HIV/HCV Co-infected People of Color, which spanned from 2016 to 2019 and funded five RWHAP Parts A and B jurisdictions to implement HIV/HCV screening, care, and treatment. HAB also created a curriculum for RWHAP Part F AETCs, which resulted in several lessons learned such as the need to strengthen data surveillance

systems. The Curing HCV among People of Color Living with HIV Initiative was a recent three-year initiative that supported the expansion of HCV prevention, testing, care, and treatment capacity. Finally, the Leveraging a Data to Care Approach to Cure HCV within the RWHAP Initiative, which ended in 2023, created HCV clearance cascades to support surveillance and treatment initiation.

Dr. Psihopaidas reviewed lessons learned from these initiatives, which included the need for strengthened surveillance systems and new strategies to improve care linkages due to the complexity of clearance cascades.

Reducing Barriers and Improving Outcomes in HIV and HCV Co-infection

Neil Gupta, MD, MPH
Chief, Epidemiology & Surveillance Branch
CDC

Dr. Gupta provided a high-level overview of HCV epidemiology and its overlap with HIV, reporting that acute HCV cases have increased nearly 300 percent from 2011 to 2021, with over 5,000 cases reported in 2021 (estimated at 70,000 after adjusting for underreporting). The highest rates were observed among 20- to 39-year-olds, with a notable recent decline in the 20 to 29 age group potentially linked to changes in drug use patterns and higher rates generally in Eastern U.S., particularly around Appalachia.

The most recent estimate indicates about 2.2 million people were living with HCV in the U.S. before the COVID-19 pandemic—a number largely unchanged from 2.1 million during 2013-2016 despite the availability of lifesaving direct-acting antivirals. HCV mortality rates showed initial declines from 2014 with the wider availability of these antivirals, but the declines have stalled recently. Substantial disparities exist by race, particularly among American Indian/Alaska Native and non-Hispanic Black persons.

Recent analyses have shown that insufficient numbers of people, even among insured adults, are being treated for HCV with lifesaving medications, as evidenced by decreasing national treatment numbers and low rates of timely treatment within one year of diagnosis. Additionally, an analysis of lab data revealed that among one million people, only 34 percent diagnosed with HCV had evidence of viral clearance, with even lower rates among those without health insurance or under the age of 40.

Dr. Gupta highlighted the critical importance of understanding and addressing the overlapping epidemics of HCV and HIV, noting the accelerated progression of liver injury and higher rates of co-infection among people who inject drugs. HCV diagnoses often precede HIV diagnoses, suggesting that HCV prevalence could indicate HIV risk among people who inject drugs. Dr. Gupta also discussed the benefits of medication for opioid use disorder and SSPs in reducing HIV and HCV transmission and outlined the Integrated Viral Hepatitis Surveillance and Prevention Cooperative Agreement, which is the core funding for health departments focusing on surveillance, prevention, and enhancing services for people who inject drugs.

Dr. Gupta emphasized addressing gaps in HCV surveillance infrastructure, noting that funding expanded from 14 to 59 jurisdictions in 2021, enabling health departments to hire dedicated epidemiologists, build databases, and transmit data to CDC for the first time. They highlighted a collaboration between Yale University and the Connecticut Department of Health, which involved matching HIV and HCV registries. These matched registries estimated that the

proportion of people with co-infection cleared of HCV was about 39 percent. This project, which was a part of CDC's capacity building work and a SPNS grant from HRSA, revealed significant challenges related to poor HCV surveillance infrastructure and difficulties in data sharing and applying these data effectively in health systems.

One component of the cooperative agreement provided funding to health departments for improving access to services for people who inject drugs, especially in areas disproportionately affected by drug use (through the development of a people who inject drugs service bundle, which lists services designed to prevent, reduce, or treat infectious disease complications of drug use). The expected outcomes of this effort included increased access to needle syringe exchange, linkage to SUD treatment, and enhanced testing for hepatitis B, HCV, and HIV. Health departments expressed appreciation for the flexibility in funding to meet specific population needs rather than focusing solely on a particular pathogen.

Dr. Gupta reviewed cooperative agreement 2208, which aims to strengthen SSPs in the U.S., increase access to harm reduction services, and reduce complications from injection drug use (IDU). The agreement, which is the first dedicated funding opportunity from CDC to directly fund SSPs, supports and expands these programs across 31 jurisdictions and aims to increase access to services and supplies; testing for hepatitis B, HCV, and HIV; and prevention and treatment of infections.

Accelerated progress is urgently needed to meet national viral hepatitis elimination goals, with critical infrastructure and policy gaps relating to information systems, human resources, reporting policies, and data sharing that need to be addressed to tackle HIV/HCV co-infection. Focusing efforts on key populations, rather than just pathogens, supports the study of health outcomes and service gaps, provides holistic services, reduces stigma, and improves the efficiency and cost-effectiveness of interventions.

Professional Learning Communities: A Model to Support Integrating HCV, HIV, and STD Services into Opioid Treatment Programs

Kelly Reinhardt
Senior Research Associate
University of Missouri-Kansas City

Ms. Reinhardt talked about the Collaborative to Advance Health Services team’s work on a project to integrate HCV testing and treatment in opioid treatment programs funded by the Substance Abuse and Mental Health Services Administration (SAMHSA). The project kicked off in February 2018 and is part of the Addiction Technology Transfer Center (ATTC) network, a long-standing grant program at the university. The Opioid Response Network, funded by SAMHSA in 2018 and partnered with the American Association of Addiction Psychiatry, uses this network to provide training and technical assistance to organizations and individuals across the country to address the opioid epidemic.

SAMHSA provided supplemental funding to the ATTC Network grant to develop tools and resources for publicly funded opioid treatment programs (OTPs) to integrate HCV testing and treatment. This initiative recognizes the close link between the HCV and opioid epidemics, particularly among vulnerable populations treated by OTPs. OTPs serve as a single point of entry to address the holistic needs of these clients, effectively dealing with multiple issues through one door.

SAMHSA also commissioned the development of tools and resources to aid OTPs, including a guide for integrating HCV testing and treatment, with a focus on partnership building and memorandums of agreement to compensate for the lack of onsite testing and treatment capabilities in many OTPs. A 2023 supplement was added to reflect changes in treatment guidelines due to the COVID-19 pandemic, and a learning community was launched in 2020 to provide OTPs with a nine-month training and technical assistance program on implementing the guide's steps. The learning communities provide intensive, ongoing technical assistance to OTPs, with participants learning from both subject matter experts and each other over nine months without any financial incentives.

Ms. Reinhardt stated that the first cohort of the learning community, which was shifted to a virtual format due to the pandemic, had three OTPs withdraw due to the increased workload from COVID-19 changes, leaving seven OTPs to complete the program. The second cohort was larger and used a simplified process to reduce the data collection process. Anticipated barriers to the project included patient retention and engagement, funding and reimbursement for HCV testing and treatment, staffing at OTPs, and differences in medical records and record keeping in an OTP setting.

In October, the project will expand from testing only for HCV to other infectious diseases, including HIV, and will include a complete rewrite of the guide and an expansion of the learning community. To scale the work, members from the regional ATCs will train 15 facilitators of learning communities. The team plans pilot test these materials with OTPs while also exploring other treatment settings. They will also include certified community behavioral health centers in their pilot to seek feedback on the utility of their materials in different treatment settings and anticipate creating new materials and training products for these new settings in 2023-2024.

Addressing Gaps in Public Health HCV Surveillance Data Systems

Kelsa Lowe, MPH
HCV Epidemiologist
Wisconsin Department of Health Services

Ms. Lowe discussed a public health gap in HCV surveillance from the perspective of a RWHAP recipient. She highlighted the Wisconsin Electronic Disease Surveillance System's (WEDSS) role in managing HCV data in Wisconsin. WEDSS is adaptable for disease-specific reporting and quality assurance. Automation is a key feature of WEDSS to enhance public health workforce capacity for disease follow-up and surveillance. A team of informaticists and the Wisconsin State Lab of Hygiene were also essential in improving laboratory communication and reporting within the HCV data surveillance system.

Ms. Lowe detailed the collaboration between HIV and HCV programs in Wisconsin, explaining how HIV lab data was integrated into WEDSS since 2018 and is used for analyses to identify upticks in cases and potential clusters. WEDSS provides near real-time identification of HIV/HCV co-infections, with monthly updates to aid patient services coordination and care management. WEDSS also has a dashboard of de-identified data for monitoring exposure factors and detecting co-infection clusters. These data had identified 111 co-infection cases in Wisconsin from 2019 to 2023, primarily among adult males who have sex with males and those who engage in IDU.

Between 2020 and 2022, notable variations in care cascades existed for HCV and HIV/HCV co-infection. The lab data showed 10,279 positive HCV cases and 54 co-infection cases, with the

cascades focusing on RNA testing to determine current infection and subsequent infection clearance. Among the 10,279 individuals with positive HCV, approximately 85 percent underwent RNA testing, which is similar to the percentage of those with co-infection who underwent RNA testing. In contrast, less than half of those with HCV had a positive RNA result in contrast to the 100 percent of those with co-infection with a positive RNA result. This suggested that those with co-infection were more engaged with accessing care services.

Between March 2020 and the time of the report, only three individuals co-diagnosed with HCV and on ADAP had filled their HCV prescriptions. This indicates that despite increased care access for co-infected clients, much progress is left to be made. In 2019, Wisconsin expanded its ADAP formulary to include all HCV treatments, along with options for conditions like opioid use disorder and mental health issues, with a note that each state's ADAP formulary differs.

Ms. Lowe concluded by discussing successes and limitations in the integration of HIV and HCV data systems in Wisconsin. Ms. Low highlighted the ease of linking HCV and HIV data, the co-location of STI, HIV, and HCV programs, and the existence of a community-based harm reduction response team, all contributing to a more effective approach to managing these conditions. However, a major challenge remained capturing treatment data, which required reliance on other data sources, such as Medicaid, to track treatment initiation and patient care journeys. This data is often not available in real time.

Implementing STIRR-IT Among Vulnerable Individuals at High Risk for HCV & HIV: Results from two SAMHSA Programs

Seth S. Himelhoch, MD, MPH
Professor and Chair
University of Kentucky

Wendy Potts, MS
Program Director
University of Maryland

Dr. Himelhoch and Ms. Potts reviewed the implementation of STIRR-IT. STIRR-IT is an intervention developed for people with serious mental illness who are at high risk for HCV and HIV. It is a four-session intervention delivered over six months by a registered nurse. The acronym STIRR-IT stands for Screening for risk level, Testing for HIV and HCV, Immunization for Hepatitis B and A, and Risk Reduction Counseling and includes personalized education and distribution of safety items such as condoms.

The research team developed a modified STIRR-IT model for implementation at a single site in Baltimore, Maryland. The modified STIRR-IT included on-site blood drawing, vaccine storage and delivery, and a shared medical record system—which were integrated into the site's usual clinical workflow. From 2013 to 2018, the program recruited 270 participants, who were predominantly African American, with an average age of 53. Over 70 percent of participants were diagnosed with serious mental illness, and most also had a history of SUD.

Of the participants who completed the intervention, 25 percent were diagnosed with HCV (often a new diagnosis) and 8 percent were diagnosed with HIV (the majority of whom were aware of their HIV status). Of the participants referred for HCV treatment, 75 percent received treatment and 47 percent achieved virological suppression, with sobriety requirements and insurance coverage challenges identified as major barriers.

Following the success of STIRR-IT in a mental health clinic, the program received SAMHSA funding to implement an updated version of the intervention at a methadone assistance treatment program for women in Baltimore City. The program was designed in collaboration with the women and included sections for recording personal health information relevant to HCV, HIV, and other women-specific diagnoses. This program currently includes 181 participants, predominantly African American, with an average age of 54, over half diagnosed with mental illness, and all with a history of substance abuse. Despite COVID-19 challenges, which reduced session attendance from 80 percent to 66 percent, 14 percent of participants tested positive for HCV and six percent tested positive for HIV, and all participants were referred to care. The services, including blood draws and vaccines, were conveniently provided at the methadone clinic where the women were already receiving treatment, fostering rapport and trust. The program's goal was to reach over 200 patients before the end of the project.

CHAC Member Discussion on Panel 1

- Mr. Driffin asked if any panelists could address racial and ethnic disparities in the incidence or diagnosis of the epidemic. Dr. Gupta acknowledged the existence of racial and ethnic disparities in HCV, noting higher mortality rates among American Indian/Alaska Native persons, and higher prevalence among non-Hispanic white and Black persons, with the latter group experiencing higher mortality rates. This indicated potential gaps in treatment access. Mr. Driffin asked for further information about the HCV cure. Dr. Gupta also noted disparities by race and ethnicity.

- Dr. So asked whether nationwide data reflected that the care continuum for patients co-infected with HCV and HIV was better than for those with HCV mono-infection, as suggested by the data presented from Wisconsin. Dr. Gupta acknowledged that people co-infected with HIV and HCV might have better access to HCV medications and care continuum if they already engaged in HIV services but noted the lack of national level data describing the HIV-HCV care continuum. Obtaining accurate data on co-infection rates and characteristics was challenging due to the varied and often poor surveillance infrastructure for HCV across the U.S. Dr. Gupta suggested the potential use of commercial lab data and referenced a recent paper and a MMWR publication about the HCV national care cascade.

- Mr. Riester asked Ms. Lowe whether there was buy-in to the ADAP formulary changes via a work group or planning body. Ms. Lowe acknowledged the absence of a current planning body but mentioned that it was a work in progress and offered to involve an HIV subject matter expert for further inquiries about the ADAP formulary. Mr. Riester asked how often the formulary was updated. Ms. Lowe stated the formulary was updated every time a new medication was released.

- Dr. Mermin noted the low rate of HIV among people diagnosed with HCV in Wisconsin and a higher rate of HCV among people with HIV. He inquired if efforts exist to universalize screening and treatment for HCV, particularly in clinics treating a significant number of HIV patients—an approach similar to that used by the VA for veterans. Ms. Lowe agreed with this approach and noted the advantage of already having the attention of case managers and patient services in these areas. Dr. Gupta highlighted the discrepancy between the prevalence of HIV among people with HCV and the higher prevalence of HCV among those with HIV, especially in IDU-associated cases and emphasized the need for health systems and HIV clinics to focus on understanding and addressing the HCV status and care

continuum for their patients. Dr. Armstrong emphasized the crucial first step in managing HIV and HCV cases, which involved clinics and states collaborating to develop and maintain patient lists to effectively understand and address patient care needs. Ms. Lowe discussed a recent collaborative Medicaid analysis revealing that, despite lifting restrictions on HCV treatment in 2017, treatment initiation among Medicaid-enrolled persons decreased by 35 percent compared to 2015-2018 data. This indicated a significant challenge in increasing access to treatment services in the HCV community.

Panel 2: Special Presentations

Congenital Syphilis: An Opportunity to Innovate Perinatal Health Services in San Francisco

Dominika Seidman, MD, MAS
Assistant Professor
University of California, San Francisco

Dr. Seidman began by discussing congenital syphilis cases in San Francisco, which experienced significant challenges with homelessness and fentanyl and methamphetamine crises. She expressed concern about the significant nationwide increase in congenital syphilis, referencing a CDC MMWR report that outlined the congenital syphilis prevention cascade, starting with prenatal care and syphilis testing and treatment before birth. The report highlighted regional disparities in the U.S., with the West primarily affected by a lack of prenatal care, the Northeast by missed seroconversions during pregnancy, and the Southeast by missed opportunities for syphilis treatment. The Midwest showed a combination of these issues.

In San Francisco, there has been a dramatic rise in syphilis cases among females, leading to a corresponding increase in congenital syphilis cases, particularly striking after decades without any cases. This increase began around 2018 and coincided with a housing crisis, the introduction of fentanyl, and a surge in methamphetamine use. Key themes involved in congenital syphilis cases in San Francisco included homelessness, methamphetamine and opioid use disorders, and a significant number of patients with prior child removals. Fear of further child removal emerged as a major barrier to seeking care.

In the clinic, there were concerns about people engaging in prenatal care. Despite people interacting with the healthcare system through urgent care and emergency rooms, these places were not counted as prenatal care settings, leading to limited or no prenatal care. Dr. Seidman advocated for systems change to provide prenatal care anywhere, send labs anywhere, and connect syphilis labs with other prenatal labs whenever a positive urine pregnancy test occurs.

In San Francisco, providing care to people diagnosed with syphilis was challenging due to the high proportion of unsheltered individuals, with the state caring for over half of the country's unsheltered population. These individuals, including many diagnosed with syphilis in pregnancy, faced significant barriers to care due to various forms of trauma, violence, post-traumatic stress disorder, and the lingering impact of prior child removal, which greatly affected their willingness and ability to engage in healthcare services.

At San Francisco General Hospital, a safety net hospital, an increase in individuals presenting for birth without prenatal care in 2018 coincided with rising syphilis and congenital syphilis rates.

This led to the creation of Team Lily, a multidisciplinary perinatal care program providing low-barrier, open-access services for pregnant individuals facing significant challenges, including SUDs, mental illness, homelessness, and partner violence. The program's mission was to offer a dignified, autonomous, and supportive pregnancy, birth, abortion, and postpartum experience, with a focus on addressing barriers such as history of child removal. The program is now fundable through California's Medi-Cal benefits, enhancing its reproducibility statewide.

About one-third of Team Lily clients were unsheltered, half of whom had a history of child removal, 80 percent with SUDs, and 10 percent diagnosed with syphilis during pregnancy. The program uncovered a highly siloed health system, prompting the creation of the congenital syphilis prevention task force in 2018, which improved cross-departmental coordination and care, leading to initiatives such as syphilis case review boards, increased screening in emergency rooms, and point-of-care testing for pregnant individuals.

San Francisco General Hospital utilizes its EHR system, Epic, to facilitate syphilis screening and treatment to ensure patients receive necessary care across various healthcare settings. Additionally, they used a key intervention using a weekly, brief, and focused 30-minute call to coordinate care for pregnant individuals at risk of or diagnosed with syphilis, emphasizing engagement in pregnancy care. This intervention had successfully attracted diverse stakeholders due to its efficiency.

In 2021, the team conducted a pregnancy lost to follow-up call, discussing 36 patients in San Francisco, two-thirds of whom needed syphilis testing and one-third were diagnosed. Many of these patients faced multiple care barriers. Around 60 percent of these patients were treated, highlighting the critical need for care coordination and a multidisciplinary approach for pregnant individuals with syphilis, who often confront intersecting barriers to care. Their current efforts were focused on integrating reproductive health services into street outreach programs, including pregnancy testing alongside other services, such as administering Narcan and buprenorphine, to better identify pregnancies early and connect individuals to appropriate care.

Dr. Seidman concluded that the shift from siloed public health divisions to collaborative efforts between community organizations and public health departments in San Francisco had facilitated coordinated patient outreach, increased adoption of screening recommendations, and demonstrated that addressing congenital syphilis required a multidisciplinary approach that focused on access to housing, substance use treatment, mental health services, and person-centered support for parenting goals—an approach that was exemplified by Team Lily.

Congenital Syphilis Perspective from IHS/Tribal/Urban Clinics

Brigg Reilley, MPH
Clinical Programs Epidemiologist
Northwest Portland Area Indian Health Board

Mr. Reilley highlighted the significant impact of the SUD epidemic on Indian Country, with primary and secondary syphilis rates among American Indian/Alaska Native now the highest among all ethnicities, having increased over 300 percent in the past five years. Syphilis rates among women in this group have risen 140 percent, five times the national average. Moreover, the rate of congenital syphilis among American Indian/Alaska Native in 2021 was alarmingly high, with about one case per 260 live births, leading to infant deaths and other negative lifelong consequences.

Mr. Reilley provided an overview of IHS, which encompassed a network of 170 IHS, tribal, and urban service units. He noted that a slight majority of people in IHS received care in tribally-run, rather than federally run facilities, covering a catchment area of over two and a half million American Indian/Alaska Native persons. The geographical distribution is primarily west of the Mississippi due to historical forced displacement, with significant facilities in Oklahoma, Alaska, and in the Southwest—including the Navajo Nation and the Hopi Reservation.

IHS records indicate about 13 million outpatient visits and 40,000 inpatient admissions annually, but faces significant under-resourcing, with per-user expenditure falling far below the national average. There are challenges in recruitment and retention, especially in remote areas with high syphilis rates. Despite these challenges, IHS and its tribal partners have initiated successful educational campaigns to enhance knowledge of syphilis among clinicians, who often lack experience with the disease. This effort included the creation of resources like stopsyphilis.org, offering various educational materials tailored for native communities.

IHS provides frictionless access to resources for clinicians through its website, offering materials for syphilis education and prevention, but faces challenges in implementing new guidelines due to human resource constraints. Facility-level challenges include shortages in first-line syphilis treatments, the need for more intensive case management for second-line treatments, and limited staff availability, leading to dramatic increases in untreated syphilis cases especially in areas with some of the highest syphilis rates in the U.S.

Federal policies sometimes hinder effective patient care within IHS, such as the inability to text patients due to archiving requirements. This leads to inefficient follow-up, especially since many patients lack consistent phone access or data plans. Patients often have multiple health and social issues, which underscores the complexity of care coordination within IHS. Even though syphilis testing is conducted, various barriers, such as delayed test results and difficulties in contacting patients, complicate treatment. This results in patients often needing external referrals for additional care needs, which further complicates the care pathway due to poor linkage and the use of different providers.

Prenatal SUD treatment faces challenges such as transportation, wait times, and a lack of female- and family-friendly support, with much of the behavioral help being geared towards men with alcohol issues. As services expanded, it became difficult to maintain an overview of the situation, leading to concerns about the potential for public health nurses to be overwhelmed.

Mr. Reilley stated that going forward, IHS plans to continue collaborating with state health departments to provide extensive support for partner services. Additionally, IHS intends to focus on expanding data access, particularly with syphilis databases, to streamline patient care and improve management of increased caseloads. IHS often finds that the best practices emerge from field experiences, learning from sites where innovative solutions are developed, then replicating and sharing these successful workflows. While the aim is to expand the workforce, current limitations, data sharing challenges, and the sensitive nature of syphilis diagnoses pose additional obstacles.

Quality of Life in the RWHAP: Individualized, Self-perceived, Time-specific

LaQuanta Smalley, MPH, RN
Senior Public Health Analyst
Division of Policy and Data
HAB

HRSA

Via a prerecorded video presentation, Ms. Smalley reviewed HRSA HAB's recent efforts to enhance the quality of life for individuals in RWHAP. This focus emerged from listening sessions with various stakeholder groups, including older people, youth, women, and community partners. The overwhelming consensus was that quality of life was critical to well-being and needed more explicit attention within the program. To address this, an internal work group was formed to create a framework to demonstrate how the program inherently contributes to improving clients' quality of life.

This newly developed HAB Quality of Life Framework is a comprehensive model that centers on the lived experiences of people with HIV. At its core, it acknowledges that an individual's perception of their quality of life is shaped by various influencing factors, priorities, and values. The framework consists of five key domains: physical, emotional, social, environmental, and structural, each surrounding and impacting the individual. These domains are specifically tailored to RWHAP and related services, and are supported by medical and support services, special projects of national significance, and other resources. This framework is not meant to be an exhaustive representation of all services, but rather a flexible tool to adapt to the varied needs and encounters of their clients.

The physical domain addresses aspects such as mobility, independence, pain management, and overall physical capacity, which are central to a client's daily life and medical care. The emotional domain encompasses mental health, self-esteem, and cognitive functions, acknowledging the deep interconnection between mental and physical health. The social domain focuses on interpersonal relationships, financial stability, and community engagement, recognizing the importance of a supportive network in improving life quality. The environmental domain addresses factors such as housing, safety, and community amenities, highlighting the need for a stable and secure living environment. Lastly, the structural domain draws attention to systemic issues like housing quality, employment opportunities, and access to nutritious food, acknowledging the impact of larger societal structures on individual health and well-being.

Projects and initiatives under these domains demonstrate HRSA HAB's commitment to a holistic approach. For example, the use of peer navigators and trauma-informed care training under the social and emotional domains respectively, shows an understanding of the complexities of HIV patients' lives. Similarly, initiatives such as the Homeless Health Outreach Mobile Engagement (HOME) project in the environmental domain illustrate innovative approaches to providing care to those most in need. These projects are not just about medical treatment, they are also about addressing the myriad of challenges that people with HIV face in their everyday lives.

Ms. Smalley stated that the development of the HRSA HAB Quality of Life Framework was a significant step towards a more integrated and comprehensive approach to HIV care. It invited stakeholders and federal partners to collaborate and continue the dialogue around improving the quality of life for those affected by HIV. This framework also served as a reminder that the battle against the HIV epidemic is not just about managing a medical condition, but about ensuring a life of dignity, support, and fulfillment for those impacted.

CHAC Member Discussion on Panel 2

- Dr. Dionne asked Dr. Seidman about the implementation and effectiveness of partner services in the perinatal syphilis program in San Francisco and whether there were strategies to get partners into treatment and any success stories related to these efforts. Dr.

Seidman highlighted successful strategies in partner treatment, including facilitating simultaneous treatment for partners at the Women's Health Center, providing syphilis treatment and testing in the community for both partners, and recent efforts to involve social workers to focus on partners (particularly fathers) to address the broader needs beyond syphilis treatment.

- Dr. Dionne asked Mr. Reilley whether the main factors affecting health in the discussed communities were like those in San Francisco, such as access to care, substance use, and other drivers beyond personnel challenges. Mr. Reilley confirmed that the drivers of health issues in the discussed communities were almost entirely like those in San Francisco, including policies that might deter women from seeking care and the use of incentives in tribal health programs to encourage clinic visits and medication adherence.

- Mr. Driffin thanked Dr. Seidman for acknowledging the role of fathers in healthcare responses, highlighting that fathers, whether in chosen or biological families, contribute significantly to the quality of care. Mr. Driffin also touched upon a recent interaction with men working in the HIV workforce, discussing how viral load can affect perceptions of desirability and value in social contexts, an aspect that should be considered when thinking about quality of life for RWHAP clients.

- Ms. Cadena talked about the significant presence of syphilis and congenital syphilis in the Native Hawaiian and Pacific Islander communities, focusing on challenges such as cultural barriers in discussing sexual health, particularly within the Federated States of Micronesia and COFA communities. She asked whether similar cultural barriers were addressed in areas such as San Francisco with substantial Pacific Islander populations. Dr. Seidman acknowledged the presence of a small but disproportionately affected group of Pacific Islanders in San Francisco, particularly noting their high rates of pre-term birth, a condition often overlapping with congenital syphilis. To engage these communities, the city and local programs employed doulas for culturally and racially concordant outreach, finding this approach to be tremendously successful in bridging the gap between healthcare services and Pacific Islander communities. This strategy emphasized the importance of culturally relevant and language concordant partners in community health initiatives. Ms. Cadena emphasized the importance of cultural humility in addressing the significant impact of sexual health issues, particularly syphilis and congenital syphilis, among American Indian/Alaska Native and Native Hawaiians, viewing this as an opportunity to also address disparities in access to healthcare for conditions such as HIV and HCV.

- Ms. Granados asked Dr. Seidman for further explanation on how the speaker's program addressed fears linked to prior Child Protective Services (CPS) to encourage pregnant individuals to engage with prenatal care and other health services. Dr. Seidman emphasized the importance of providing pathways to parenting for everyone, focusing on offering housing, SUD treatment, and mental health treatments during and after pregnancy. In San Francisco, this is achieved through residential treatment, which many patients need. However, a significant gap exists in treatment options for fathers, which is crucial for family building. Engagement with patients is prioritized as early as possible, focusing on what the patient sees as their primary need, which is often housing and SUD treatment. She highlighted the importance of being transparent about different pathways, including interactions with CPS and recognizing the strength in engaging in care regardless of current circumstances. The goal was to expand treatment options, extend the duration of residential

treatments, and provide more varied paths into treatment to better support individuals' parenting goals.

- Mr. Riester expressed gratitude for presentation on quality of life, particularly in geriatric care and the inclusion of financial status in the social domain and comorbidities in the physical domain.

- Dr. Dowler commented on the challenge of congenital syphilis and how health systems in San Francisco may differ from the perspective in the Southeast. She noted a critical need to change how emergency departments and urgent care facilities operate, highlighting a bias for testing for conditions with immediate results, such as chlamydia and gonorrhea, versus tests that do not have immediate results, such as syphilis and HIV. This leads to missed opportunities for early identification and resource provision for those at risk. She also emphasized the importance of providing pregnancy care and testing beyond prenatal visits, criticizing policies that restrict syphilis and HIV testing in urgent care due to delayed results. Hospitals have a need to retain mothers and babies until test results are obtained. Dr. Seidman stated that San Francisco had switched to reverse sequence testing for syphilis, now running tests every two hours, which made it feasible to have HIV and syphilis tests results before a patient left. She recommended that those with barriers to care should stay until results were available and emphasized the need for more widespread availability of point-of-care testing for syphilis.

- Dr. Mermin referred to a CDC-funded initiative aimed at obtaining FDA approval for treponemal and non-treponemal point-of-care syphilis testing, as such tests exist in other countries. He asked how this test could be effectively used or make a difference in the current syphilis management situations if it were available within about a year and a half. Mr. Reilley indicated that a point-of-care syphilis test would indeed be very impactful, especially if accompanied by clear guidance on how to act on positive results. The guidance would need to include considerations for treating with the first line drugs despite shortages and managing potential penicillin allergies, which would be particularly relevant for field treatments. Dr. Seidman highlighted that point-of-care syphilis testing should be used with clear intent to treat based on the results, noting that its current use was primarily for those further along in pregnancy who failed initial serum collection. However, the test was less helpful for those with a history of syphilis, and its significant potential would be in aiding the treatment of partners who were difficult to reach and had limited health history available.

- Dr. Deal asked for clarification on the follow-up care for the one in 260 live births with congenital syphilis within IHS and whether any cost analyses were conducted comparing the cost of caring for these infants versus the cost of preventing the infection. Mr. Reilley was unaware of any cost-benefit analysis for congenital syphilis treatment, expressing concern that such an analysis might face similar challenges to HCV treatment, in which the long-term savings of treating the disease were overshadowed by immediate budget constraints. Dr. Deal asked about follow-up on the infant. Mr. Reilley explained that most care for congenital syphilis often gets referred out due to limited hospital capacities at most sites, leading to more disjointed care and complexity in determining who bears the cost for these outcomes.

- Dr. Greene inquired about the existing infrastructure for Team Lily and what would be needed start similar cross-discipline work in other areas. She also asked about workforce development needs and shortages that could be supported by HRSA and CDC. Mr. Reilley

suggested two potential paths: 1) the federal expansion of the workforce, even temporarily (a lesson learned from the pandemic), and 2) allowing temporary data sharing policies so that tribal and other partners could assist with syphilis follow-up (currently hindered by restrictions on showing patient data). Dr. Seidman discussed the challenge of transferring existing HIV infrastructure to congenital syphilis prevention, noting that while the structures exist, the funding had historically been directed towards HIV. It would be difficult to shift resources. In San Francisco hospitals, a cultural barrier exists towards patients affected by substance use, mental illness, and homelessness, which was a contrast to the proactive approach taken for perinatal HIV. This highlighted the need for a cultural shift in healthcare to address congenital syphilis as an emergency, particularly in emergency rooms and labor delivery contexts, reluctance exists to engage with this patient population.

- Dr. Armstrong asked about the integration of open access clinics and street medicine, whether individuals who were brought in from the streets came voluntarily, how the services were funded, and whether there were any other unique care delivery models being used. Dr. Seidman explained that their open access clinic operated differently from urgent care, with patients consistently seeing the same provider and coming in primarily through street outreach workers and public health nurses—an approach that resulted in a significant drop in no-show rates. The clinic's funding came from Medi-Cal through enhanced care management, which substantially improved their ability to provide care. It was a shift from being grant-funded to being supported by the Department of Public Health with reimbursements for navigation service.

Day 1 Recap

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

Dr. Armstrong elected to forgo the Day 1 Recap.

Adjourn

Dr. Cheever adjourned Day 1 of the October 2023 meeting and CHAC stood in recess until 9:00 a.m. ET on October 25, 2023.

Day 2: DFO Meeting and Roll Call

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

Dr. Cheever welcomed participants to the second day of the CHAC meeting, reviewed ground rules, and conducted roll call, which established a quorum for the CHAC to conduct business. She indicated that public comments would be accepted at the 9:20 A.M. session but would not be accepted at any other point during the meeting.

Dr. Cheever thanked three outgoing members: Dr. Jean Anderson, Ms. Kneeshe Parkinson, and Mr. Venton Hill-Jones.

Recap of Day 1 and Objectives/Process

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

Dr. Armstrong outlined the agenda for the day, which included a public comment period, a third panel on innovative payment models, workgroup reports, and a business discussion.

Public Comment

Terri Wilder, MSW
HIV/Aging Policy Advocate
SAGE

Ms. Terri Wilder spoke about the critical need to remove the upper age limit from CDC's HIV testing guidelines, which currently recommended testing for individuals aged 13 to 64. She pointed out that this policy created a false sense of security among older individuals and their healthcare providers, leading to delayed diagnoses and a lack of timely HIV prevention services. Ms. Wilder cited an article emphasizing the growing number of older adults with HIV, challenges related to sexual activity in older age, and the misconception among primary care physicians about the low risk of HIV in this group. She advocated for updated CDC guidelines, funding for HIV prevention campaigns targeted at older people, and better education for medical providers on HIV testing and care for older populations. Ms. Wilder stressed the importance of including insights from older individuals recently diagnosed with advanced HIV in developing guidelines and prevention programs to avoid perpetuating disability and loss of life in this demographic.

Emily Blaiklock, PharmD
Vice President of Pharmacy
Positive Impact Health Centers

Dr. Blaiklock highlighted that Ryan White Clinics for 340B Access (RWC-340B), a national organization of RWHAP clinics participating in the 340B program, achieves significantly better

patient care outcomes compared to clinics without RWHAP funding. These outcomes included higher rates of viral suppression, better retention in care, and more comprehensive services such as care coordination and mental health services, largely due to the savings from the 340B program. Dr. Blakelock emphasized the role of the 340B program in reducing demographic disparities in viral suppression rates and urged CHAC to recognize the program's importance in successful clinical outcomes for people living with HIV. She concluded by stating the indispensability of the 340B program for the continued operation of RWHAP clinics.

Jawanna Henry, MPH, MCHES
Branch Chief for Interoperability
Office of Policy
Office of the National Coordinator for Health Information Technology (ONC)

Ms. Henry discussed ONC's focus on advancing the use and interoperability of social determinants of health (SDOH) data, aligning with its mission to improve health through data access, exchange, and use. In 2021, ONC convened a panel of experts to guide the interoperability and implementation of SDOH Information Exchange in communities, leading to the development of the SDOH Information Exchange Toolkit and learning forum sessions. This toolkit, released in 2022, serves as a practical guide for various stakeholders in the health IT community, offering resources for the collection and use of SDOH information, including aspects like community engagement, IT standards, and governance. The toolkit's framework, consisting of interrelated foundational elements, is adaptable for different stakeholders and not a one-size-fits-all solution. Rather, it aims to guide the planning, design, implementation, and evaluation of SDOH information exchange initiatives. Ms. Henry noted that the toolkit and recordings of the forum sessions were available on the ONC website under the health equity resources section.

Panel 3: Innovative Payment Models/Pathways to Addressing Social Determinants of Health

Moderator:
Andrea Jackson, DrPH, MPH
HAB
HRSA

Dr. Jackson began the panel by providing an overview of how SDOH are addressed within RWHAP. SDOH include factors such as housing, economic stability, food security, access to reliable transportation, and access to healthcare. Although significant progress has been made in viral suppression among priority populations in RWHAP, there are persistent inequities. Much of the inequity in viral suppression is correlated with disparities across certain populations such as those who fall at or below the federal poverty level, those with no healthcare coverage, and those with unstable housing. New RWHAP efforts to address these disparities include the 2021 Policy Clarification Notice (PCN) 22-01 that streamlines the process of requesting a waiver for medical services expenditures, the Supportive Replication of Housing Interventions (SURE) Housing SPNS initiative, the Innovative Intervention Strategies (2iS) SPNS initiative to facilitate the rapid implementation and evaluation of seven innovative interventions, and the Black Women First SPNS initiative to improve care coordination among black women with HIV.

Dr. Jackson summarized that although inequities in SDOH are significant drivers to HIV health disparities, RWHAP was implementing initiatives to address these disparities in at-risk populations.

Braiding EHE Funding to Address Social Determinants of Health

Rebecca Hutcheson, MSW, MS
EHE Program Manager
Public Health – Seattle & King County

Ms. Hutcheson presented on the EHE Initiative in King County, focusing on braided funding to support EHE services, particularly for low barrier services. In King County, approximately 7,000 people live with HIV, half of whom receive services through RWHAP Part A program. The county's HIV prevention and care system was effective for most, but not all. Specifically, it was not effective for a small, but significant group, called the “last 10 percent” or “10, 10, 10”, consisting of people not yet diagnosed, not virally suppressed, and persistently not virally suppressed. This subgroup, primarily affected by racism and other SDOH, often faced immense challenges, such as unstable housing and untreated substance use, making access to traditional HIV prevention and care extremely difficult. The focus of EHE in King County was to address the needs of this specific group, recognizing their unique challenges in accessing healthcare.

Despite numerous initiatives within the existing RWHAP Part A program and prevention system to better serve a particular population in King County, SDOH, widened economic disparities, and the legacy of racism had led to the displacement of this subgroup to North Seattle and South King County—areas that were more affordable but that had less access to HIV prevention and care systems. These systems remain concentrated in central Seattle, originally developed to meet the needs of a predominantly white men who have sex with men population from earlier in the epidemic.

The planning body in King County recognized barriers to HIV care engagement as systemic rather than individual issues and saw the EHE Initiative as an opportunity to develop new infrastructure to serve a specific subgroup. They adopted the Max Clinic model, a successful walk-in approach for HIV care with incentives and intensive wraparound services, as the core strategy for expanding HIV care access, especially in areas lacking such services. This model was adapted to be status-neutral to reduce HIV-related stigma and to support both individuals with HIV and those at risk, addressing the needs of a dispersed population across the county. The process of implementing this model and integrating various funding sources and services was ongoing with support from federal, state, and local partners.

Ms. Hutcheson talked about the planning process for addressing HIV in King County, which started with a clear mission and a specific population and adopted a holistic approach to serve those at risk for HIV and those living with HIV—especially the subgroup struggling to engage with traditional care systems. The team embraced innovative thinking to develop a plan that suited the population's needs, but challenges arose when integrating this plan into existing structures. This situation led to expansive thinking without the constraints of existing structures or predefined funding limits, but it also took a few years to align the innovative approaches with the practical aspects of implementation and funding.

They initially adopted a status-neutral approach for funding allocation, dividing services between those reaching people with HIV (funded by HRSA) and those either HIV-negative or of unknown status (funded by CDC). This division initially seemed practical, with most interventions being status-neutral, leading to subrecipients receiving both HRSA and CDC funding. However, this approach soon became administratively challenging, particularly for smaller, new organizations

inexperienced in managing federal awards, as they struggled to meet the complex data reporting requirements and to operationalize the services.

As a newly directly funded prevention entity under the EHE initiative, Seattle and King County faced challenges with their small staff and developing infrastructure, making the initial approach of braided funding for subrecipients untenable. Consequently, they shifted to a strategy of unbraided funds, assigning subrecipients to either HRSA or CDC funding based on the majority of clients they served, simplifying management and compliance. This change aligned with a growing understanding of existing policies within RWHAP and CDC. This evolution in strategy also included aligning services with HRSA funding for all diagnosed with HIV, while addressing specific challenges such as organizations reluctant to participate due to philosophical differences with client-level data collection requirements.

Around 15 individuals in King County's HIV program were not initially captured in HRSA data systems and could only be engaged through CDC funding, but this was being resolved. The primary focus of funding had shifted to individuals with unknown HIV status, involving a complex alignment of services—such as clinical, social, and housing support—within the constraints of what was permissible under HRSA and CDC funding. This approach, part of a broader systems change and infrastructure intervention, was expected to evolve over time, particularly as the program-built trust within the community and integrated more people with HIV into its services.

In King County's HIV program, outreach efforts for individuals not yet diagnosed with HIV were primarily funded through HRSA, while CDC funds engagement efforts were aimed at building trust for testing and engagement in HIV care and prevention services. This complex braiding of funds was challenging to operationalize, especially for partner organizations accustomed to different funding mechanisms such as RWHAP Part A, B, or C. This led to an active search for additional funding sources to enhance service delivery in clinics. These clinics are co-located within community-based organizations in North Seattle and South King County, adding a third dimension to their funding strategy and leveraging existing trust within the community.

The clinics in King County's HIV program have leveraged their unique resources and community links to enhance service provision, with some offering shelters, housing, outreach programs, and mental health services, which are easily accessible to patients. Additionally, these clinics have tapped into alternative funding sources, such as SAMHSA for opioid treatment, vouchers dedicated to this specific population, and a Medicaid initiative for HCV, enabling them to address broader public health needs such as syphilis outbreak response. This approach enabled efficiencies in the use of both HIV- and non-HIV-related funds.

Addressing Health-Related Social Needs in Section 1115 Demonstrations

Jessica Lee, MD, MSHP
Acting Chief Medical Officer
CMS

Dr. Lee addressed health-related social needs (HRSN) in the context of Section 1115 demonstrations, highlighting the importance of partnerships and the challenges associated with braiding funding streams, particularly for those new to these demonstrations. She talked about technical assistance and sharing best practices to help new entities prepare for using Medicaid funding, acknowledging the challenges associated with new funding authorities. She also referenced a state health officials' letter that outlined opportunities to address SDOH through Medicaid, CHIP, and other waivers and focused on three main areas: care delivery, quality

measurements, and coverage of HRSN interventions. Several states are integrating these services into their programs using various authorities, demonstrating a growing commitment to addressing these social needs in healthcare.

States have utilized Section 1115 demonstration to cover specific evidence-based services addressing health-related social needs, enabling a more nuanced approach in defining target populations than other authorities allow. There are additional requirements and guardrails related to these services, including aspects of budget neutrality. HRSN refers to unmet adverse social conditions contributing to poor health, such as food insecurity, housing instability, and lack of reliable transportation. These needs, driven by underlying SDOH, are significant in creating health disparities across demographic groups.

Extensive research indicates that health outcomes are significantly influenced by HRSN and SDOH, presenting a crucial opportunity for state Medicaid programs to help beneficiaries maintain coverage and access essential health services. The framework for HRSN services in Section 1115 demonstrations encompasses four tiers: 1) covered services, 2) service delivery, 3) fiscal policy, and 4) related requirements, focusing mainly on housing and nutrition supports but also other needs. Specific guidelines cover housing supports, nutrition supports, case management, and service delivery requirements, with fiscal policies and related requirements acting as important guardrails. Nutrition supports are categorized into four broad interventions, including nutrition counseling and education, meal delivery, pantry stocking, and medically tailored meals, which were approved under seven different Section 1115 demonstrations.

Under Section 1115 demonstrations, specific guidelines for nutritional supports include time-limited interventions such as meals or pantry stocking, tailored for individuals who are pregnant and households, as well as food and vegetable prescriptions or protein boxes. These services are designed to supplement, not replace, existing nutritional support, ensuring that beneficiaries experiencing food insecurity are connected to programs such as SNAP and Women, Infants, and Children (WIC). Additionally, identified housing supports in these demonstrations allow for rent or temporary housing assistance for up to six months, targeting individuals transitioning from institutional care or congregate settings, those who are homeless or at risk of homelessness, and those moving out of emergency shelters.

Additional housing support opportunities include traditional respite services, day rehabilitation, pre-tenancy and tenancy supports, and housing transition navigation. Additionally, one-time transition and moving costs, medically necessary home accessibility modifications, and environmental modifications are supported. Coordination with HUD ensures integration with existing supports, promoting partnerships for rental assistance, housing navigation services, and short-term housing transitions. States were encouraged to partner with state housing finance agencies, public housing authorities, municipal and county government housing agencies, and Continuums of Care providers, to integrate these services with existing housing funds and address the housing needs of Medicaid beneficiaries.

Timing and collaboration are crucial for food and housing support under Section 1115 demonstrations. Housing and homeless service agencies often face resource scarcity and need to coordinate with local housing authorities and state programs for seamless beneficiary experiences. Housing agencies typically cannot prioritize individuals based on diagnosis or disability. Short-term housing assistance covered by Medicaid should align with existing long-term rental assistance, resembling housing choice vouchers. Effective communication and collaboration at local, state, and federal levels were necessary for success, requiring ongoing investments of time and effort. Additional services beyond those specifically outlined may be

approved on a case-by-case basis, with budget neutrality considerations unique to this framework. States were encouraged to consult with their project officers to explore opportunities.

Under Section 1115 demonstrations, all HRSN services must be medically appropriate, as determined by state-defined clinical and social risk criteria, and the individual must have a documented need in their care plan or medical record. Beneficiaries have the choice to opt out of HRSN services at any time, and states or managed care plans cannot make Medicaid coverage conditional on the receipt of these services. Furthermore, these services do not relieve the state or managed care plan of their responsibility to provide other medically necessary services. States must also establish partnerships to appropriately use this funding.

Additionally, HRSN services have specific fiscal policies and requirements. First, HRSA expenditure spending caps cannot exceed 3 percent of the total Medicaid spending in states. States must also maintain baseline state funding for social services related to approved HRSN services, based on pre-1115 funding levels. Additionally, states must ensure provider reimbursement rates are sufficient to ensure access to basic Medicaid services, with specific requirements for Medicaid to Medicare ratios and rate increases in certain categories. Finally, systematic monitoring and evaluation is required and should focus on the implementation process, service utilization, quality, and health outcomes in order to maintain program integrity and identify best practices.

CMS has identified a set of measures for states to report on, aiming to align these with existing quality measures to avoid adding extra burdens. Currently, two CMS programs involve screening for SDOH: the Merit-Based Incentive Payment System at the provider level and the Inpatient Quality Reporting Program for facilities. These screenings help assess the frequency and need for such screenings. Additionally, an appendix provides resources related to housing and nutritional agencies that are useful for state partners.

Rethinking Health Equity: Braiding Funding and Innovative Practices for Sustainable Change in New York State

Johanne Morne, MS
Director
New York State Department of Health

Ms. Morne discussed New York state's health initiatives, emphasizing the need to advance equity and eliminate health disparities by rethinking the approach to addressing *determinants of health*—a term that she opted to use over the term SDOH. She highlighted the need to focus on political will, policy development, and diversified funding sources to support innovative practices.

Ms. Morne also pointed out that funding these practices is a challenge due to the lack of established evidence, emphasizing the need for flexibility in funding mechanisms. Specifically, challenges were inherent to short-term, five-year funding cycles, especially in the post-COVID-19 era, in which the workforce has significantly changed and has become more dependent on each funding cycle. Ms. Morne suggested that sustainable change required moving beyond these short-term funding cycles, possibly through exploring braided funding approaches.

She highlighted successes in New York State's approach to EHE, which included setting statewide goals, focusing on regional priorities, and involving multiple sectors to address diverse needs. New York focused on increasing access to quality care by considering the roles of

various state agencies essential for effecting and maintaining change. Additionally, the state revised its strategic frameworks, such as the New York State Prevention Agenda, to address health determinants and health equity more intentionally. Additionally, the New York State Master Plan for Aging was designed to provide quality services not just for seniors but for individuals at all stages of aging, thereby ensuring access to the determinants of health needed for overall health and wellness.

Ms. Morne also discussed advantages of the Section 1115 waiver in promoting health equity, especially for marginalized communities in New York State. This waiver enables the creation of a resilient and integrated care delivery system through essential services such as housing and independent living support. The emphasis of the Section 1115 waiver was to build comprehensive care networks not only in large healthcare facilities, but also vital community-based organizations known for their effective engagement and safe, trustworthy environments. These networks were crucial for applying braided funding strategies and achieving optimal health outcomes.

New York State has a long history of harm reduction work. For example, a controversial syringe exchange programs in the 1990s led to a significant reduction in HIV and HCV diagnoses. In 2018, a state plan amendment allowed for reimbursement for harm reduction services for eligible recipients within Medicaid managed care plans or fee-for-service Medicaid, diversifying funding streams. This shift from grant funding allowed Medicaid to become a payer for harm reduction services, offering opportunities for reimbursement for various aspects of care. Ms. Morne highlighted the importance of innovative practices to address determinants of health, citing harm reduction services and access to syringe exchange programs as examples. In closing, Ms. Morne emphasized the need for innovation in funding allocation, the potential for expansion based on scientific advancements and community development, and the transformative impact of COVID-19. She suggested that facing the current crisis required dialogue about sustainable funding approaches that could impact sustainable change.

CHAC Member Discussion on Public Comment and Panel 3

- Dr. Cheever expressed appreciation for the strategic and innovative work done by the panelists, acknowledging their use of data, understanding of politics, and ability to navigate legislative requirements. She expressed concern about potential limitations given constraints of various statutes and appreciating their ability to make the most of existing resources.

- Dr. Armstrong asked whether the innovative advances discussed were made possible because of existing political will or if that will have to be generated. She also asked if there were strategies that could be successful in less progressive areas such as the South. Ms. Morne stated that political will exists in New York, attributing the progress to stakeholders and community advocates who effectively brought attention to community needs with evidence and data. She emphasized that political will must be backed by resources and action to create impactful policies and build momentum. Dr. Lee added that their work was evidence-based, focused on improving health, and supported by decades of work from various stakeholders to provide comprehensive services and supports for health. Ms. Hutcheson highlighted the challenges of expanding services into areas with less HIV experience and more political charge, particularly in conservative, faith-based settings. She emphasized the importance of finding partners with solid political relationships and acknowledged the difficulties of implementing interventions in such contexts.

- Dr. Mermin asked panelists how they chose interventions or activities to implement, given that some may be more effective or cost-effective than others. He also asked whether any efforts occurred to understand what works best for health outcomes or if a need exists to develop structures to allow grantee success. Dr. Lee talked about establishing a flexible framework that allowed states to identify suitable populations and interventions. She acknowledged the importance of using information from formal evaluations and informal discussions to disseminate best practices and to generate new evidence from these demonstrations to inform other states. Ms. Morne emphasized the importance of stakeholder input in creating practical models and the need to communicate outcomes back to the community for continued engagement and trust-building. Ms. Hutcheson discussed leveraging the Multicenter AIDS Cohort Study (MACS) model and NIH grant supplements to adapt HIV care strategies for different demographics, focusing on evidence-based practices for testing and prevention and integrating these into innovative strategies.

- Mr. Rodriguez expressed excitement about SDOH manifested in requests for proposals at city, state, and federal levels. However, he also expressed frustration about the disconnect in operationalizing this intention due to stagnant funding levels, which were insufficient to truly impact SDOH. He called for continued advocacy to ensure funding reflects the needs of addressing these determinants.

- Dr. Gordon asked whether consideration was made for structural racism in these discussions, specifically in terms of law enforcement, politics, and community groups. Ms. Morne acknowledged the importance of addressing structural racism in public health work, citing efforts, such as the establishment of the Office of Health Equity and Human Rights in New York, the state's declaration of racism as a crisis, and the inclusion of equity discussions in funding applications as steps towards achieving health equity and diversity. Ms. Hutcheson talked about their robust discussions during their planning process and their choice of strategies with immediate impact on reducing HIV incidents. She also emphasized the need to engage with other systems, such as housing and policing, especially for the unhoused. Despite delays in these efforts, they remained interested in implementing more system-level strategies. Dr. Lee expressed gratitude for the insightful comments, emphasized the importance of equity in all policy conversations and work at CMS, and highlighted their responsibility to identify ways to advance equity in all aspects, including quality reporting, mobile crisis opportunities, and transitions from incarceration settings.

- Dr. Dowler highlighted the challenges of balancing high-level design goals with on-the-ground realities, noting that over-engineering and excessive guardrails limited access and increased implementation difficulties for providers. She emphasized the need for collaboration between different stakeholders to ensure practical and implementable designs.

- Dr. Guilamo-Ramos expressed appreciation for the panel's commitment and innovation and raised concerns about the persistence of health inequities despite addressing SDOH. He expressed concern over tackling structural racism and the cost and efficacy of SDOH projects, suggesting a need to blend of blue- and white-collar perspectives in decision-making. Ms. Morne agreed and emphasized the need to be flexible, especially programs that may not have achieved their intended outcomes, to move forward and expand in different ways.

- Dr. Cheever discussed how NIH changed the approach for Centers for AIDS Research (CFAR) grants from funding research at academic medical centers to working closely with HRSA and CDC to fund health department recipients—an approach that produced impactful results in EHE work. She highlighted the challenge of retooling old funding and the difference new funding can make.

- Dr. Greene asked for advice about actions CDC and HRSA could take to make the process easier for recipients of new braided funding, particularly in overcoming administrative and bureaucratic hurdles. Ms. Hutcheson suggested that aligning federal awards and combining data systems could improve reporting and implementation of status-neutral approaches but acknowledged the complexity of linking administrative structures of different programs. She also emphasized the need for more flexibility and clarity early on in new initiatives, as well as the importance of integrating administrative structures for such initiatives to ease the burden on ground-level workers. Dr. Cheever explained that HAB designed the EHE and RWHAP with built-in structural elements for future integration despite constraints and the uncertainty of program reauthorization. Ms. Hutcheson found the EHE services category useful but faced challenges in fitting many things into it due to its restrictions. She suggested that it could be more beneficial during the infrastructure development period and expressing a desire for further discussion on its potential uses.

- Dr. Sanders emphasized the complexity of operationalizing data on the ground due to multiple funding sources and the need for streamlined processes to help programs that lack the capacity to manage these intricacies. She also advocated for more collaborative funding across different entities to address SDOH and structural racism, highlighting the need for a unified approach to data and implementation at the site level.

- Dr. Armstrong suggested that technical assistance and sharing of evidence-based success stories would be beneficial for states seeking to obtain Section 1115 waivers.

CHAC Workgroup Reports

Long-Acting Injectable Workgroup

Workgroup Members:
Shannon Dowler, Co-Chair
Kneeshe Parkinson, Co-Chair
Wendy Armstrong
Daniel Driffin
Christine Markham
Richard Haverkate
Christopher Gordon

Dr. Dowler reviewed efforts from the Long-Acting Injectable Workgroup, which was charged with researching current and emerging issues related to use of long-acting injectable 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.

The Workgroup first established that their discussions needed to be evidence-based. They reviewed the literature and confirmed the efficacy and consumer satisfaction of PrEP for

preventing HIV infection and its effectiveness in treatment. They then held two external sessions with experts to address challenges in healthcare. One was a productive discussion with IHS and federally recognized tribes about incorporating long-acting injectables into their formulary for tribal members. This discussion focused on logistical challenges, such as refrigeration and staffing, along with the potential for tribes to subsidize medication costs. The second session included a panel of physicians and pharmacists and focused discussions on the provision of long-acting injectable treatments. They identified major challenges, notably in securing commercial insurance coverage for these treatments as compared to public payers, as well operational issues due to varying coverage policies. Despite these challenges, a unanimous positive outlook exists on the impact of long-acting injectables, although resource constraints were a significant barrier to broader implementation. Dr. Dowler stated that they had also hoped to include a panel of individuals with lived experience but were unable to organize it in time for the meeting.

The Workgroup identified three key topics to address. The first topic is the confusion between medications covered as a pharmacy benefit versus those considered a medical benefit, particularly in terms of long-acting injectables. This distinction leads to administrative challenges, frequent changes in payer requirements, and issues with reimbursement for clinics. The second topic is focused on long-acting injectable PrEP, for which current guidelines created barriers due to increased visits, transportation costs, and staffing requirements. They also discussed the high costs and disruptions caused by viral load requirements, questioning whether the theoretical risk of missing early infections outweighed the benefits of providing PrEP. The third topic is the viral suppression requirement for long-acting injectable treatments, with emerging studies suggesting the efficacy and safety of direct-to-inject methods. They emphasized the potential for updated guidelines or permissive utilization in certain cases as a significant opportunity.

The Workgroup requested an extension to increase the Workgroup's duration to incorporate lived experience perspectives.

Community Partnerships Workgroup

Workgroup Members:
Kali Lindsey, Chair
Meredith Green
Johanne Morne

Mr. Lindsey reviewed efforts by the Community Partnerships Workgroup, which was charged with providing research on the best strategies for and consistent barriers encountered in the development, capacity, and retention of community partnerships that increase health equity by identifying and eliminating disparities.

The Workgroup encountered an initial challenge in defining the difference between community partnership and community engagement, as these terms were often used interchangeably. This confusion, along with the power dynamics and mistrust inherent in serving communities, highlighted the need for continuous community involvement, as discussed in CDC and HRSA contexts, especially regarding EHE initiatives. For instance, CDC outlined a community engagement continuum, for which the current focus was often on early phases such as outreach or consultation for community input. However, the ultimate goal should be shared leadership, with the community contributing equally alongside funding partners such as federal, state, or academic entities. This approach was exemplified in their Workgroup, which included diverse perspectives from research, academia, state health departments, and community-based

organizations, highlighting the need for more equitable sharing and less hierarchical structures in community partnerships.

The Workgroup also discussed how community organizations, already burdened by the increased pressures of COVID-19, were struggling to cope, particularly in communities that repeatedly faced challenges. These same communities grappled with issues such as housing, food insecurity, and structural racism, with parallels drawn between the ongoing struggles with HIV and the recent COVID-19 pandemic. The Workgroup highlighted the need for syndemic approaches to address the root causes affecting these communities, as they are also disproportionately impacted by HIV, STIs, hepatitis, substance use, and other health challenges. The Workgroup also identified the need for braided funding to break down silos.

The Workgroup acknowledged that while CDC and HRSA were making efforts, the effectiveness of these efforts went beyond content; rather, it was important to understand the context within communities. They recognized the abundance of data on healthcare utilization and epidemic response but emphasized the need to address the 'noise' in communities, such as misinformation and misconceptions about health interventions such as vaccinations and HIV prevention. The challenge was bridging the gap between evidence-based content and the real-world context, ensuring effective community engagement and decision-making amidst widespread misinformation.

The Workgroup appreciated CDC and HRSA organizing a community conversation on November 3, 2023, but noted that an hour and a half was insufficient for community members to fully express their needs and propose solutions for better health equity and outcomes. The community sought to be an equal stakeholder. The lack of coordination on the ground was a disruptive factor, despite HRSA's support for community planning groups. The Workgroup emphasized the need for more than listening sessions, advocating for engagement methods that integrated the community as partners in public health decision-making. They questioned why effective strategies employed during the COVID-19 emergency response were being discarded in normal times.

The Workgroup also discussed how to prepare communities and public health systems for future outbreaks and highlighted the need to reconsider information collection and research utilization, especially in the context of the impact of opioid and fentanyl crises on healthcare systems and community behaviors. They discussed the need for the inclusion of community-based organizations in expanding health literacy and response to epidemics, noting that these organizations wanted to be equal stakeholders but had seen their role eroded in favor of a more medical model. Additionally, the Workgroup acknowledged the emotional and financial strain on communities constantly responding to various health crises with limited resources, urging a focus on equipping both clinics and community partners to effectively respond to public health challenges.

The Workgroup noted the NIH’s All of Us research program, a precision medicine initiative, as an example of developing community partnerships with underrepresented populations to enhance participation in healthcare research. Additionally, the Community Partnership Gateway Initiative was another example that involved more than a hundred organizations in healthcare discussions. The Workgroup identified the need to move beyond the episodic and transactional approach of current initiatives such as HRSA's CHANGE initiative, emphasizing the importance of sustainable, ongoing strategies for community education and partnerships.

The Workgroup expressed hope that community-based organizations would be deeply integrated into meaningful, sustainable partnerships with research, academia, and government agencies, going beyond mere advisory roles to actively contribute to the public health response.

Workforce Workgroup

Workgroup Members:
Vincent Guilamo-Ramos, Chair
Wendy Armstrong
Daniel Driffin
Kali Lindsey
Robert Riester

Dr. Guilamo-Ramos stated that the Workforce Workgroup update was brief. The Workgroup will continue conversations with PACHA and work toward a joint effort between CHAC and PACHA. They have scheduled an upcoming meeting in which a PACHA working group would address CHAC's recommendations.

Business Session CHAC Member Discussion on Workgroup Reports and Suggestions for Future Agenda Items

The Business Session focused on discussions from the Workgroup presentations, with special attention paid to advice requested from CHAC and specific requests to be voted on.

- Dr. Dowler suggested the consideration of three requests: 1) extending the work group to include voices of lived experience, 2) investigating with CMS on how to standardize the provision of long-acting injectables across payers, and 3) partnering with IHS to add these injectables to the formulary. Additionally, she recommended that CDC and HRSA work with HHS to revise HIV treatment guidelines, considering direct inject access for people living with HIV based on emerging data and reevaluating the guidelines for long-acting injectable PrEP for more permissive utilization in certain cases.
    - Dr. Dionne sought clarification about the mechanism to support making long-acting injectables as a pharmacy benefit instead of a medical benefit. Dr. Dowler acknowledged the request for clarification, explaining that the first or second recommendation involved CDC and HRSA working with CMS to investigate standardizing whether long-acting injectables should be classified as a medical or pharmacy benefit across different payers.
    - Dr. Sanders suggested considering how the request from the Long-Acting Injectable Workgroup would apply to individuals with HIV and multi-drug resistance, particularly the complexities of crafting regimens that include multiple long-acting injectables and the challenges in getting such regimens approved.
    - Dr. Dionne favored a motion to put forward specific Workgroup requests immediately, regardless of whether the Workgroups continue to meet.

- Dr. Armstrong sought to clarify the discussion about working with CDC, HRSA, and HHS regarding guidelines for direct-to-inject treatments, emphasizing that the focus was not just on direct-to-inject, but specifically in the context of non-viral suppression.

- Dr. Sanders expressed her appreciation for the earlier presentation on the community partnership group and her interest in hearing if the group had specific requests to advance syndemic approaches that integrate the community at all levels.

CHAC Action
Dr. Guilamo-Ramos called for a motion to extend the Long-Acting Injectable Workgroup to include the voices of people with lived experience to further develop our understanding of long active injectables. CHAC members unanimously approved the request with no changes or further discussion.

CHAC Action
Dr. Guilamo-Ramos called for a motion to approve that 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. CHAC members approved the request with no changes or further discussion.

CHAC Action
Dr. Guilamo-Ramos called for a motion to approve that CDC and HRSA work and partner with IHS to add long-acting injectables to the IHS formulary. CHAC members unanimously approved the request with no changes or further discussion.

CHAC Action
Dr. Guilamo-Ramos called for a motion to approve that 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. CHAC members approved the request with no changes or further discussion.

CHAC Action
Mr. Lindsey called for a motion to extend the Community Partnerships Workgroup to allow for certain initiatives and activities to gather more information. CHAC members unanimously approved the request with no changes or further discussion.

CHAC Action
Dr. Guilamo-Ramos called for a motion to extend the Workforce Workgroup to allow for collaboration with PACHA. CHAC members unanimously approved the request with no changes or further discussion.

Suggestions for Future Agenda Items

- Dr. Greene suggested that both CDC and HRSA consider implementing a lifespan approach to public health, particularly in infection prevention across different age groups, including targeted campaigns for older populations in HIV, HCV, and other infections. Additionally, Dr. Greene highlighted the unique needs of perinatally infected populations, often overlooked

yet significant, emphasizing the potential benefits of tailoring services to this group for broader learning and application in treating people living with HIV and other infections.

- Mr. Driffin emphasized the importance of using non-stigmatizing, inclusive language in future discussions, noting instances during their two-day meeting where terminology could be improved, particularly in reference to childbearing, to acknowledge that women are not the only individuals capable of childbirth, and to be mindful of all communities, including those living with HIV.

- Dr. Dowler suggested organizing a panel of providers to discuss experiences and challenges with Doxy-PrEP and another panel involving payers to address coverage issues related to HCV and HIV treatments. The idea included possibly having a two-part panel to explore providers' experiences with payers or a direct discussion to highlight how payers significantly influence the implementation of guidelines and evidence-based practices.

- Dr. Sanders expressed interest in discussing successful integrated service delivery models that address the coexisting impacts of substance use, mental health, HIV care and prevention, housing instability, and food insecurity, emphasizing the value of understanding how these models work and can be replicated. Additionally, she highlighted the need to continually address intersectionality and the importance of recognizing structural racism, advocating against categorizing people solely based on their identities.

- Dr. Armstrong suggested examining hepatitis B, focusing on the challenges and strategies to improve screening, especially considering the significant disparity in incidence among Asians and black people. She also pointed out a specific obstacle in screening for hepatitis B, which required entering both a screening encounter code and a problematic diagnosis code related to lifestyle. She expressed eagerness for a session dedicated to hepatitis B.

- Ms. Cadena expressed a desire to discuss practices for post-COVID-19 restrictions, noting the inconsistencies observed in reopening services among local community-based organizations in their area, which led to barriers in testing, recertifications, and treatment, and a spike in HIV, syphilis, and gonorrhea cases. She emphasized the need to provide guidance and support to small grassroots organizations on reopening strategies, as there had been a lack of such discussions at the local level. Dr. Armstrong observed a concerning trend in their region where innovative COVID-era practices such as self-testing and longer medication supplies were backsliding to pre-COVID's more restrictive policies.

- Dr. Greene suggested discussing how current data reflects the national quality of life in relation to HRSA and NIH definitions, with a focus on operationalizing the assessment of quality of life in the context of the National HIV/AIDS Strategy.

Recap and Wrap-up

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

- Ms. Hayes expressed satisfaction with the two days of discussion, announcing that PACHA will have a one-day virtual meeting on December 6, 2023, with plans to physically meet in

Houston in early 2024. She also mentioned the formation of a new subcommittee focused on aging with HIV. Dr. Cheever suggested examining maternal health models, emphasizing the importance of continuous health support over the lifespan to ensure better outcomes for pregnant individuals rather than focusing solely on the period of pregnancy.

- Dr. Armstrong stated she was impressed by the innovative models discussed but also expressed concern about the funding climate, particularly regarding the future of RWHAP funds, the EHE Initiative, and U.S. President's Emergency Plan for AIDS Relief (PEPFAR). She emphasized the need for everyone, from community members to medical professionals, to demonstrate the positive outcomes achieved with these funds to support their continued authorization.

- Dr. Guilamo-Ramos expressed curiosity about the financial aspects of healthcare initiatives, questioning the availability and presentation of financial data, and suggested a meeting topic focused on the economic implications of discontinuing or maintaining these initiatives, as told by various experts.
    - Dr. Armstrong agreed that making a case for the value of infectious disease prevention is challenging and essential, suggesting that those with more expertise could help in formulating this argument.
    - Dr. Guilamo-Ramos suggested Dr. Armstrong consider insights from Jay Bot, a Deloitte physician who has written papers on the monetary cost of inequities in chronic conditions, although not specifically HIV.
    - Dr. Cheever mentioned that there are models of HIV prevention services at the state level allowing people to input their state approaches and analyze modeled impact on outcomes.

Dr. Cheever thanked everyone for their active participation in the group, which boasted a diverse range of expertise. Special appreciation was extended to Dr. Armstrong, who not only co-chaired for the first time but effectively served as the sole chair for the meeting, and gratitude was also expressed to the contracting staff, as well as CDC and HRSA staff for their contributions to the success of the meeting.

Adjournment

Dr. Cheever adjourned Day 2 of the October 2023 CHAC meeting and thanked everybody for their work.

CHAC Co-Chairs' Certification
I hereby certify that, to the best of my knowledge, the foregoing minutes of the proceedings are accurate and complete.

Wendy Armstrong, Co-Chair CHAC — Date

Attachment A: Participant List

CHAC Members Present
Dr. Wendy Armstrong (Co-Chair)
Ms. Keiva Lei Cadena
Dr. Jodie Dionne
Dr. Shannon Dowler
Mr. Daniel Driffin
Ms. Grissel Granados
Dr. Meredith Greene
Dr. Vincent Guilamo-Ramos
Mr. Kali Lindsey
Dr. Christine Markham
Ms. Johanne Morne
Mr. Robert Riester
Mr. Leandro Rodriquez
Dr. Renata Arrington Sanders
Mr. Samuel So

CHAC Members Absent
No CHAC member was absent.

CHAC Ex-Officio Members Present
Dr. Pradip N. Akolkar
FDA

Dr. Carolyn Deal
NIH/NIAID

Dr. Christopher Gordon
NIH/NIMH

Mr. Richard Haverkate
IHS

Ms. Kaye Hayes
HHS

Dr. Bill Kapogiannis
NIH/ AIDS Research

Dr. Richard Wild (alternate)
CMS

CHAC *Ex-Officio* Members Absent
Dr. Neeraj Gandotra
SAMHSA

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

CHAC *Ex-Officio* Members Absent (cont.)
Dr. Aditi Mallick
CMS

PACHA Liaison Representative
Vacant

CHAC Designated Federal Officers
Dr. Laura Cheever
Associate Administrator
HRSA/HAB

Dr. Jonathan Mermin
Director
NCHHSTP
CDC

Federal Agency Attendees
Ms. Shalonda Collins
Public Health Analyst
HRSA/HAB
Division of Policy and Data

Ms. Breana Alsworth
Public Health Analyst
HRSA/HAB
Division of Policy and Data

Ms. Seta Hovagimian
Senior Public Health Analyst
HRSA/HAB
Division of Policy and Data

Ms. Marah Condit
Public Health Analyst
NCHHSTP
CDC

Dr. Carl Dieffenbach
NIH/NIAID

Presenters

Dr. Neil Gupta
Chief, Epidemiology & Surveillance Branch
CDC

Ms. Kelly Reinhardt
Senior Research Associate
University of Missouri-Kansas City

Ms. Kelsa Lowe
HCV Epidemiologist
Wisconsin Department of Health Services

Dr. Seth S. Himelhoch
Professor and Chair
University of Kentucky

Ms. Wendy Potts
Program Director
University of Maryland

Dr. Dominika Seidman, MD, MAS
Assistant Professor
University of California, San Francisco

Mr. Brigg Reilley
Clinical Programs Epidemiologist
Northwest Portland Area Indian Health Board

Ms. LaQuanta Smalley
Senior Public Health Analyst
Division of Policy and Data
HRSA/HAB

Ms. Rebecca Hutcheson
EHE Program Manager
Public Health – Seattle & King County

Dr. Jessica Lee
Acting Chief Medical Officer
CMS

Ms. Johanne Morne
Director
New York State Department of Health

Dr. Andrea Jackson
Senior Advisor
Office of the Associate Administrator
HRSA/HAB

Dr. Demetrios Psihopaidas
Supervisory Health Scientist
HRSA/HAB

Attachment B: List of Acronyms

ACF	Association for Children and Families
ACL	Administration for Community Living
ACOG	American College of Obstetricians and Gynecologists
ADAP	AIDS Drug Assistance Programs
AETC	AIDS Education and Training Centers
AI/AN	Alaska Native/American Indian
AIDS	Acquired immunodeficiency syndrome
ATTC	Addiction Technology Transfer Center
BPHC	Bureau of Primary Health Care
CDC	Centers for Disease Control and Prevention
CFAR	Center for AIDS Research
CHAC	CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment
CHANGE	Creating HIV Awareness With Influencing Groups to End the HIV Epidemic
CHIP	Children's Health Insurance Program
CMS	Centers for Medicare & Medicaid Services
COVID	Coronavirus disease
CPS	Child Protective Services
DASH	Division of Adolescent and School Health
DFO	Designated Federal Official
DVH	Division of Viral Hepatitis
Doxy-PrEP	Doxycycline pre-exposure prophylaxis
DSTDP	Division of STD Prevention
DTBE	Division of Tuberculosis Elimination
EHE	Ending the HIV Epidemic in the U.S.
EHR	Electronic Health Record
ET	Eastern time
FACA	Federal Advisory Committee Act
FDA	Food and Drug Administration
HAB	HIV/AIDS Bureau
HCV	Hepatitis C Virus
HHS	U.S. Department of Health and Human Services
HIV	Human immunodeficiency virus
HOME	Homeless Outreach & Mobile Engagement
HRSA	Health Resources and Services Administration
HRSN	Health-related social needs
HUD	Housing and Urban Development
IDU	Injection drug use
IHS	Indian Health Service
IT	Internet Technology
ITAP	Implementation and Technical Assistance Provider
MACS	Multicenter AIDS Cohort Study
MCHB	Maternal and Child Health Bureau
MMWR	Morbidity and Mortality Weekly Report
NASTAD	National Alliance of State and Territorial AIDS Directors
NCCDPHP	National Center for Chronic Disease Prevention and Health Promotion
NCHHSTP	National Center for HIV/AIDS, Viral Hepatitis, Sexually Transmitted Diseases, and Tuberculosis Prevention
NIAID	National Institute of Allergy and Infectious Diseases

NIH	National Institutes of Health
NOFO	Notice of Funding Opportunity
NVHR	National Viral Hepatitis Roundtable
OAR	Office of AIDS Research
OIDP	Office of Infectious Disease and HIV/AIDS Policy
OMH	Office of Minority Health
ONC	Office of the National Coordinator for Health Information Technology
OTP	Opioid treatment program
PACHA	Presidential Advisory Council on HIV/AIDS
PEP	Post-exposure prophylaxis
PrEP	Pre-exposure prophylaxis
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
RADM	Rear Admiral
RNA	Ribonucleic acid
RWHAP	Ryan White HIV/AIDS Program
SAMHSA	Substance Abuse and Mental Health Services Administration
SDOH	Social Determinants of Health
STOP STD	Support Technical Assistance and Opportunities for Program, Policy, and Communications to Prevent STDs
SURE	Supportive Replication of Housing Interventions
SNAP	Supplemental Nutrition Assistance Program
SPNS	Special Project of National Significance
SSP	Syringe service program
STD	Sexually transmitted disease
STI	Sexually transmitted infection
STIRR-IT	Screening & Testing for HIV/HCV, Immunization for Hepatitis A & B, Risk Reduction Counseling linked to Integrated HV Treatment
SUD	Substance use disorder
TB	Tuberculosis
US	United States
USPHS	United States Public Health Service
VOISES	Virtual Online Integrated Sexual Health Services
WEDSS	Wisconsin Electronic Disease Surveillance System
WIC	Women, Infants, and Children

Attachment C: Written Public Comments

Northeast Caribbean AIDS Education and Training Center, Francine Cournos, M.D.

This is Francine Cournos, M.D. I'm writing in my role as Co-Principal Investigator of the Northeast Caribbean AIDS Education and Training Center (NECA AETC). I listened to the November 2 presentation and panel discussion of the AETC programs at the Fall 2022 CHAC meeting. I'm writing to help clarify the full range of Regional AETCs activities.

I think it's important to know that our regional AETC (the NECA AETC) trains all health care providers, not just those with advanced professional degrees. The workforce has changed dramatically, and we reach out to the entire care system and team, including, for example, receptionists, peers, community health workers, patient navigators, social workers, etc. We know that every health care worker in every role matters.

Our regional AETC does in fact provide extensive training about managing mental illness and substance use among people with or at risk of HIV. We teach about harm reduction and do our best to address the social determinants of health of vulnerable populations. Our agility to do this work allowed us, for example, to mount immediate extensive training efforts in response the distress of HIV care providers and their patients during the COVID-19 pandemic.
One of the panelists asked: "If you build it, will they come?" Regional AETCs reach out to local providers to ensure that yes, they will come. We are powerful implementers at the local level. We see "the elephant in the room", and we try to help programs find the best possible workarounds.

I was impressed that your panelists were very aware of just how much work is involved in implementation and just how many barriers can get in the way. I want to make sure CHAC knows how much Regional AETCs strive to improve what happens on the ground.

Francine Cournos, M.D.
Professor of Clinical Psychiatry, Columbia University
Co-Principal Investigator, Northeast Caribbean AETC
fc15@cumc.columbia.edu
Cell: 917-232-8902

Northeast/Caribbean AIDS Education & Training Center, Daria Boccher-Lattimore, DrPH MPH

I appreciate the opportunity to provide a written comment to CHAC. I was unable to attend the final day when there was an opportunity for oral public comment.

My colleagues' presented on some of the specific programs within the larger AETC program. In light of the questions and workforce concerns expressed by the CHAC members, I wanted to expand on the role the Regional AETCs play in addressing those concerns. I am the Director and PI of the Northeast/Caribbean AETC.

The successes of the Regional AETC program can be, at least in part, attributed to its unique infrastructure, bringing leading experts across the country to community providers, health profession schools and HIV and primary care settings. Each Regional AETC partners with regional performance sites who have expertise in HIV, as well as HIV comorbidities, social determinants of health and knowledge of the local communities they serve. We partner with leading academic medical centers, peer networks, HSIs, HBCU, departments of health, professional associations/organizations, implementation science researchers, and other federally funded training centers. Our work includes translating the latest in scientific advances in HV prevention, treatment and care, as well as that which impacts the HIV care continuum, morbidity, mortality and quality of life into care, which includes those concerns raised by the CHAC membership --behavioral health, stigma and aging, to name a few. While we work with health profession schools to integrate HIV into their curriculum to address pipeline issues, there is a large and continuous need for ongoing training and support of the existing workforce and health care settings due to everchanging clinical and behavioral science, challenges in HIV management, emerging best practices, turnover, etc.

Because of the unique infrastructure of the program, a presence in our communities and access to diverse expertise, we are able to identify needs of the HIV workforce and care settings as they evolve and rapidly mobilize to address them. Such was evident in our robust responses to both COVID 19 and Mpox. In the Northeast/Caribbean region alone we conducted 225 training and technical assistance programs reaching 8,506 participants between March 1, 2020 and March 30, 2022 addressing COVID-19 diagnosis, testing, treatment, vaccines, behavioral health and workforce challenges, health care disparities and best practices in telehealth.

This role of the AETCs as disseminators and implementers has been recognized by others and called upon time and time again. Such as in our partnerships with the following to aide them in their TA and/or program implementation: SAMHSA's Opioid Response TA Network; CDC's CBA for HIV Prevention program and Prevention Training Centers; HRSA HABs national TA centers, e.g., TAP-IN, Midwest Integration of the National HIV Curriculum program, and SPNs programs; NIMH's AIDS Research Centers, NIH's CFARs. They have reached out to us for collaboration due to our presence and reach in highly impacted communities and the recognition that national programs need to be implemented locally.

The members of CHAC also expressed interest in training and support for the non-clinical workforce. The AETC program no longer focuses solely on clinical providers. We train nonclinical providers in a variety of formats, by training the health care team as a whole but also by working directly with our Departments of Health on specific programs for case managers, community health workers, etc. In addition, we work to insure the peer perspective is integrated into our trainings.

Finally, I did want to reiterate that the AETC program trains on all four pillars of EHE. I particularly want to highlight for CHAC the work we are doing on PrEP. Our training and TA include training providers on the science behind PrEP and on implementation and outreach best practices. As the larger community is discussing national PrEP initiatives it is important to recognize the workforce needed to implement any national PrEP program. The AETCs are in a unique position to assist in that. There is a history of partnership of the AETCs with CDC, as we have in the past successfully collaborated and received CDC funding to assist in the dissemination and implementation of HIV testing guidelines. The workforce needs to be in the forefront of any national PrEP program.

Thank you for the opportunity to comment.

Daria Boccher-Lattimore, DrPH MPH
Director and Principal Investigator
Northeast/Caribbean AIDS Education & Training Center
Associate Professor of Sociomedical Sciences (in Psychiatry) at Columbia University Medical Center
President, National Alliance for HIV Education and Workforce Development

Kentucky Primary Care Association, Chera Mattox

I want to thank you for this opportunity to attend the meeting today. I apologize for contacting you in this manner but like many of us, I was multi-tasking during the sessions and missed my opportunity to ask a question. I am in KY, and we are a priority state. I was wondering if there are any conversations on the federal level regarding starting treatment within the local jails for HCV/HIV/MOUD? In KY we have the barrier of not being allowed to test because treatment isn't allowable. The same with home testing. It is a wonderful tool, but it is not allowed in my state. I managed a region of SSPs and when I spoke to administrators and wrote my state representatives about individual's rights being violated under the ADA for not being able to continue Suboxone while in custody, it was met with silence. Often, people who previously were linked to care would get out and start injecting substances leading to overdose deaths. I am hopeful that these conversations have been initiated as we are looking at the syndemics that we are experiencing and actively developing programing to improve SDoH that people experience.

Thank you in advance for your response. Enjoy your day.

Chera H. Mattox, MPH
Kentucky Primary Care Association
Supported by funding from Gilead Sciences, Inc.
Program Manager
EHE Initiative
651 Comanche Trail
Frankfort, KY 40601

Undetectable = Untransmittable (U=U), Mariah Wilberg

Thank you for the opportunity to speak. I will start by celebrating recent progress. This year, our federal government has started using clear, plain language to describe U=U across federal agencies and affirmed national support for U=U.

I'm here today to respectfully that CHAC helps continue this momentum by advocating for the following.

Meaningfully include U=U in future notice of funding opportunities developed by HRSA and CDC, including prevention, EHE, RWHAP, and the AETCs.

This inclusion should not be limited to U=U as a primary prevention method. U=U awareness has been shown to increase HIV testing uptake and reduce internal and perceived stigma.

It is also related to better quality of life and health outcomes, particularly improved mental health and viral suppression, among others.

Therefore, U=U should be included not only in testing and early identification of status, but also in care linkage and engagement and treatment adherence support.

Research shows stronger relationships with improved outcomes when U=U is discussed in clinical settings; the AETCs can play a critical role in supporting providers to have these conversations.

We also ask that the HIV/AIDS Bureau issue a new “Dear Colleague” letter and also share it with colleagues in the Bureau of Primary Health Care for dissemination.

The most recent letter from 2018 uses language that has since been phased out and urges education only to people living with HIV, which doesn’t capture the larger role U=U can play in stigma reduction and early identification of status, for example.

It also refers only to treatment as prevention. The positive outcomes I have described are related specifically to the concept of U=U, so I therefore ask that U=U be specifically referenced in the NOFOs, Dear Colleague letter and in applicable planned future policy clarifications.

We also ask that CDC and HRSA ensure that the workforce is supported by providing adequate capacity building and technical assistance specifically related to U=U.

Implementing these recommendations can reduce stigma, mitigate existing knowledge inequities, and improve lives while making progress towards the goals of the national HIV strategy and EHE initiative.

We are here to support these efforts and are eager to provide feedback on draft language or provide suggested draft language upon request. Thank you for your time and your service.

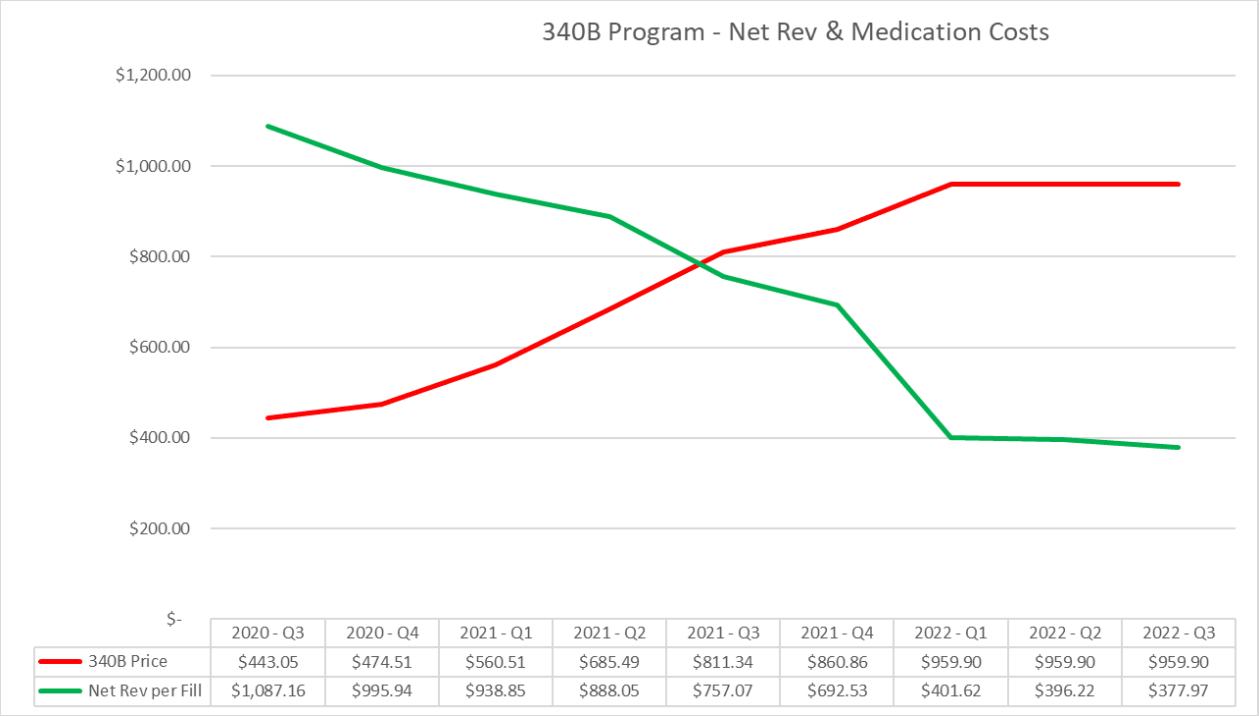
Delivered by:

Mariah Wilberg
Senior Director, U.S. Strategy & Ending the Epidemic
Undetectable = Untransmittable (U=U) in the U.S.
In case you missed it: Prevention Access Campaign Evolves into Separate Global and U.S. Organizations

Nashville/Davidson County Local Response Plan
Last updated 10/24/22 2:27pm CT

Problem
Gilead's unilateral decision to modify its payment assistance program for uninsured patients diverted 340b revenue back to Gilead and away from 340b STD clinics. Many of these clinics are non-profit or government-based entities and depend on this revenue to provide service to uninsured patients. Mission dictates that these clinics serve a significant number of uninsured patients since they tend to be disproportionately affected by HIV. The Music City PrEP Clinic

MCPC's expected revenue. By effectively reducing the net revenue per fill by 50%, it required MCPC to provide services to all of its patients with just half the planned budget if it continued to serve uninsured patients at the same proportion.



	2020 - Q3	2020 - Q4	2021 - Q1	2021 - Q2	2021 - Q3	2021 - Q4	2022 - Q1	2022 - Q2	2022 - Q3
340B Price	$443.05	$474.51	$560.51	$685.49	$811.34	$860.86	$959.90	$959.90	$959.90
Net Rev per Fill	$1,087.16	$995.94	$938.85	$888.05	$757.07	$692.53	$401.62	$396.22	$377.97

Source: MCPC

This devastating budgetary blow is compounded by Gilead unilaterally regularly increasing the price that 340b clinics must pay for Descovy Finally, the situation is further compounded by insurance companies unilaterally disallowing the coverage of Descovy, instead pushing generic PrEP. This convergence of unregulated profit-seeking is crippling the concept of using the 340b Drug Pricing Program as a funding source for the national HIV prevention strategy.

National Crisis

It is expected that the crippling of the 340b model will result in the cessation of HIV prevention services nationwide as 340b entities struggle to operate in a downward spiral of escalating costs and decreased revenue while Gilead reaps record profits from PrEP.

"'This will shut us down': HIV prevention clinics brace for Gilead reimbursement cuts: HIV Prevention Clinics Brace for Gilead Reimbursement Cuts" (*Benjamin Ryan, NBC News, 7/7/21*)

> *"An expected funding loss of at least $100 million annually will soon drain front-line clinics, threatening the federal government's pledge to end the HIV/AIDS epidemic by 2030." (NBC News analysis)*

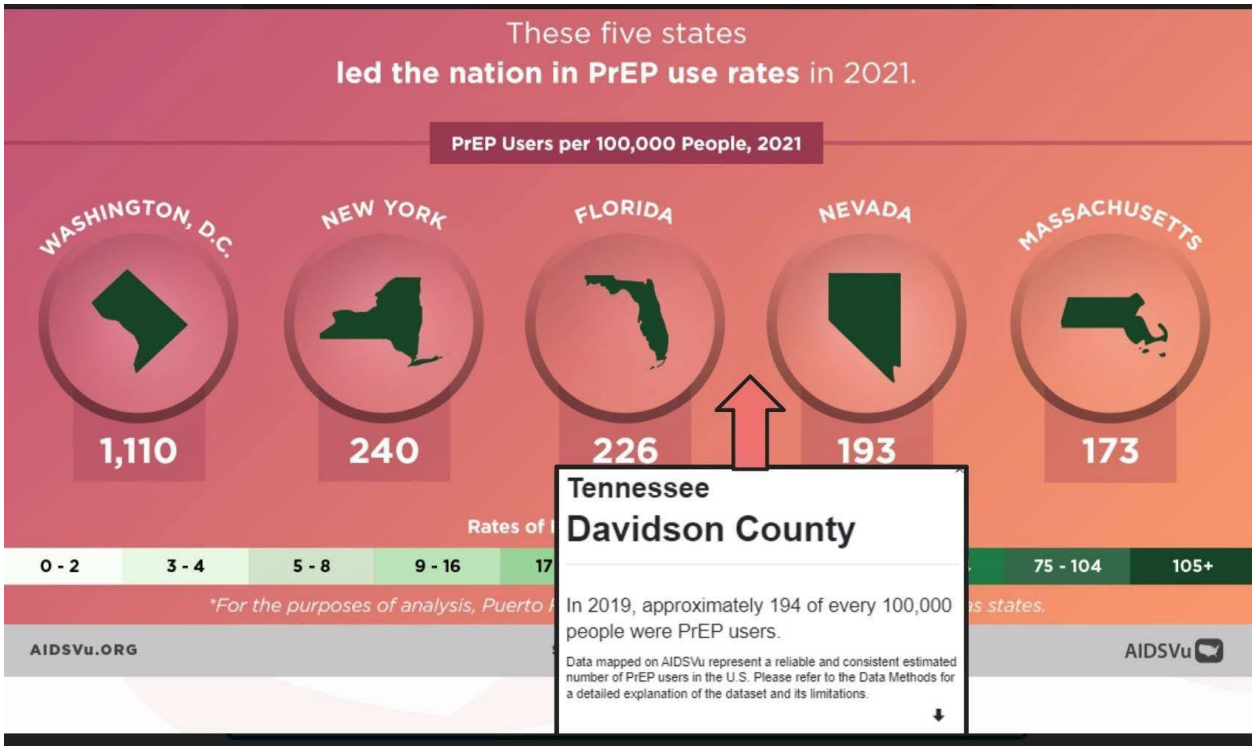
- **Fear of retaliation:** NBC News asked nearly 120 HIV prevention-focused 340B clinics for their PrEP-patient figures. "The vast majority were unresponsive or refused to share their data. Many said they were wary of alienating Gilead, given the clinics' further dependency on charitable grants from the company, which is the dominant manufacturer of HIV-treatment pharmaceuticals."
- "An expected funding loss of at least $100 million annually will soon drain front-line clinics, threatening the federal government's pledge to end the HIV/AIDS epidemic by 2030."
- **Memphis:** During an April 8 call between HIV advocates and Gilead to discuss the impending financial changes, Eric Leue, vice president of prevention services at the HIV-prevention clinic Friends for Life in Memphis, Tennessee, was clearly distraught as he pleaded with company representatives to reconsider their change in policy. Noting that Memphis has one of the nation's highest HIV diagnosis rates, Leue said, Gilead's "unconscionable" impending reimbursement cut will force his clinic to close, and that overall, it "will set this county and our population back by at least another decade."
- **Alabama:** "This will shut us down," said Christon-Walker, of how Gilead's policy change will affect AIDS Alabama's PrEP clinic. Losing the funds, he said, will "destroy our program and totally inhibit our ability to see uninsured clients, which make up the bulk of our business."
- **Chicago:** "It's going to put a lot of our programs in serious harm's way at best," Jim Pickett, senior director of prevention advocacy and gay men's health at AIDS Foundation Chicago said. "Some of them will be decimated and destroyed."
- **Austin/San Antonio:** "HIV has a disproportionate impact on Black and brown communities, especially here in Texas. I really fear that we will have more Black and Latinx people acquiring HIV if other funding sources aren't in place," Christopher Hamilton, CEO of Texas Health Action, an HIV- and LGBTQ-focused nonprofit health care provider, said as he echoed a concern shared among his colleagues across the country.

Local Crisis

MCPC had projected in March 2022 that it would be experiencing cash flow issues by June 2023. It adopted a “sinking Titanic " strategy to mitigate and prolong the inevitable capsizing of Tennessee’s largest PrEP clinic and one of the titans in the national fleet of super large, successful HIV prevention programs. At $50MM in revenues, 15,000 patients growing at a rate of 500-600 per month, it was indeed a sinking ship because of a structural flaw in the funding design of the national HIV prevention strategy--the lack of sufficient federal oversight and regulation of Gilead and the insurance carriers whose collaboration is necessary for the strategy to be buoyant. With Gilead and the carriers acting in their self-interest and no watchdog to supervise the crippling effects of their unilateral moves, the 340b funding strategy is doomed to fail.

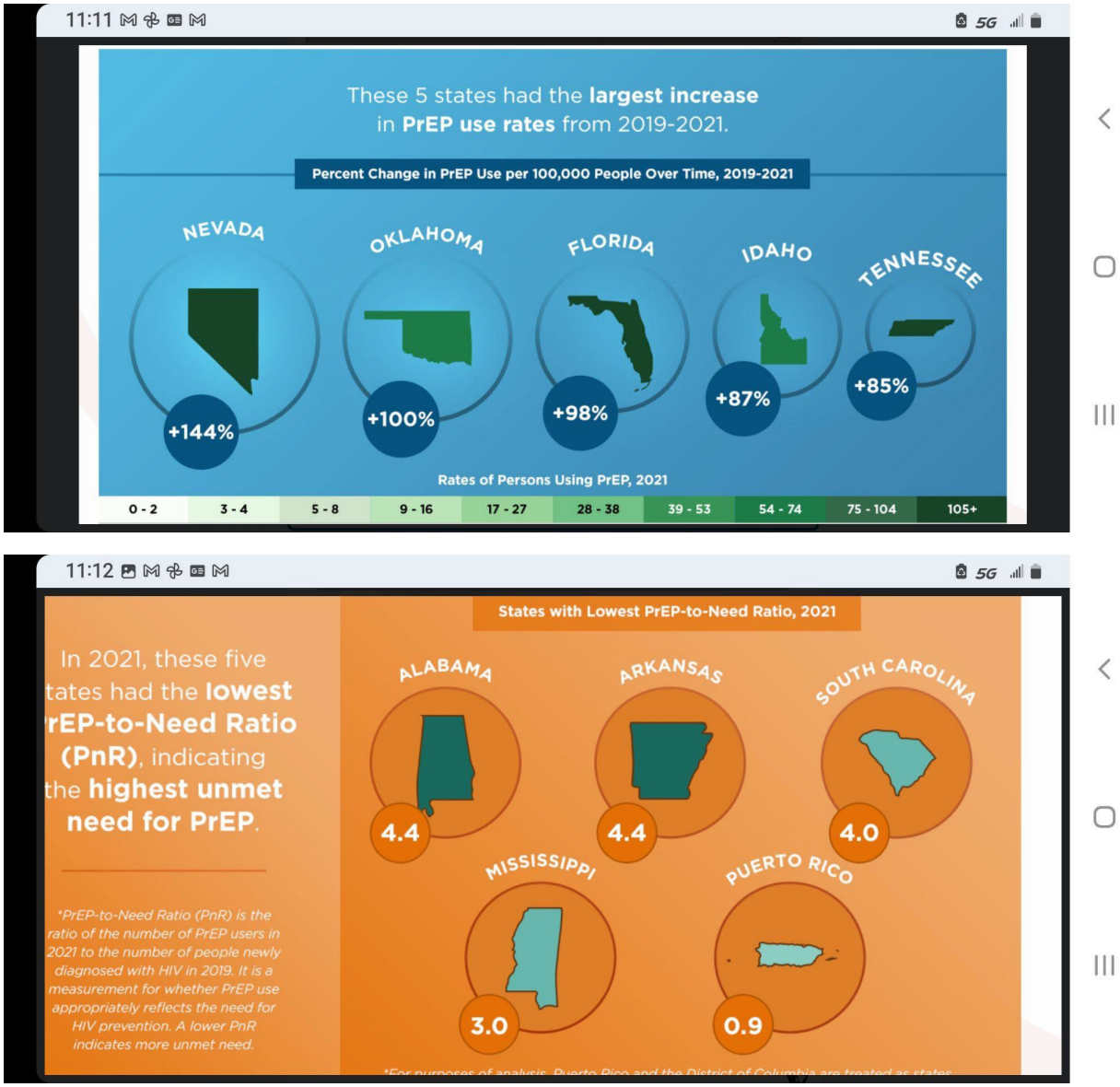
While it was not possible for MCPC to prevent itself from sinking indefinitely, its strategy was intended to keep it afloat for as long as possible, buying time for the federal government to receive its S.O.S. and send out a rescue party. As of now, the call for help has been heard, but no immediate rescue plan is in place to save MCPC or the rest of the clinics still treading water. Unfortunately, Gilead’s continued unilateral price hikes paired with insurance companies refusing to cover Descovy has increased at a rate beyond the doomsday predictions of MCPC, and the clinic is now projecting cash flow issues in January 2023, not June.

What’s at risk for Nashville/Davidson County and Tennessee?



Source: SEATC

MCPC played a significant role in Tennessee's meteoric rise from the bottom tier of the country to the Top 5 states leading the nation in PrEP use rates in 2021. It's worthwhile noting that it is not the state of Tennessee that actually appears in the #4 spot, but Nashville/Davidson County punching above its weight as if it were a state in its own right--besting the states of Nevada and Massachusetts in the Top 5 and the other 48 states ranked below them. As nearly a third of new HIV infections in TN are diagnosed in Davidson County, this feat clearly has substantial impacts in reducing new infections in the state. Where the state of Tennessee does appear is in the Top 5 rankings of most improved--again powered by MCPC.



Source: SEATC

MCPC's specific mission to end the HIV epidemic in Nashville and middle Tennessee enabled it to focus its passion and 340b-derived resources in a way that no other organizations, with

broader missions, in the city, county, and state could match. Indeed, Nashville became a health care destination for out-of-state patients seeking PrEP, most of them driving in from neighboring Kentucky. Note that four of the states in the Bottom 5 are members of Tennessee's neighborhood and present a clearer picture of where Tennessee and its regional partners were before MCPC's push to end the HIV epidemic. Without a concerted effort to address this local crisis, the State of Tennessee will lose its newly gained and hard-fought leadership position purchased with a significant investment in the health of its residents. The consequence of this loss is dire, as a return to the bottom will be measured in the uptick of HIV cases that had been prevented as a result of the overwhelmingly successful execution of the national HIV prevention strategy within its borders. Furthermore, the price to treat the newly diagnosed (and preventable) HIV cases will exceed the costs to prevent them, and will pale in comparison to the cost in terms of dollars and quality of life years lost to treat the complications arising from the inevitable new undiagnosed HIV cases. Given that new infections occur most frequently in young adults (ages 25-34) in TN, and the frequency of new infections among those ages 15-24 is close behind (and growing), the cost to treat spans many decades and the potential for quality of life years lost is massive (cit: tn.gov).

Analysis: Cost to Prevent versus Cost to Treat

"The lifetime treatment cost of an HIV infection can be used as a conservative threshold value for the cost of averting one infection. Currently, the lifetime treatment cost of an HIV infection is estimated at $379,668 (in 2010 dollars)." (CDC, "HIV Cost-Effectiveness"). Adjusted for 2022 dollars, the cost is $516,349.

The 2019 State of TN Surveillance Report noted that in 2018, there were 156 newly diagnosed cases of HIV in Nashville/Davidson county and 147 and 134 in the years before. Based on these 3 years alone, the community responsibility to provide care for 437 HIV patients for the rest of their lives is $225,644,513 in 2020 dollars. It must be remembered that the HIV prevention strategy is designed to reduce or eliminate new cases of HIV. Without an adequately funded strategy, the number of new cases each year, and the associated lifetime costs, will increase. While these costs alone are breathtaking, they fail to fully capture the impact on the quality of life for the affected patients, and certainly don't include the costs in dollars and suffering of patients who are undiagnosed, untreated, and suffering from diseases and complications arising from HIV cases developing into AIDS.

The CDC recognizes that testing and prevention saves lives, improves quality of life, and saves money (CDC, "CDC's HIV Works Saves Lives and Money"; CDC, "High-Impact HIV Prevention: CDC's Approach to Reducing HIV Infections in the United States"; Flackman, B.R., Fleishman, J.A., Su, A.E., et. al. "The Lifetime Medical Cost Savings from Preventing HIV in the United States", CDC, "Evolution of HIV/AIDS Prevention Programs--United States, 1981-2006")

MCPC's success in Nashville/Davidson County can be quantified by calculating the number of HIV cases averted through its efforts to educate, inform, and treat. Using the methodology described in "Estimated Impact of Targeted Pre-Exposure Prophylaxis: Strategies for Men Who

Have Sex with Men in the United States" (Elion, RA, Kabir, M,2, Kenneth H. Mayer, KH, et. al., Int J Environ Res Public Health. 2019 May; 16(9): 1592), we are able to combine treatment data from MCPC with the "number needed to treat" to determine how many cases of HIV, and the associated costs for HIV treatment, were averted.

Source: SEATC

Treated with PrEP by MCPC 2018-Present				
MSM-10+	BMSM-10+	YBMSM-10+	HMSM-10+	YHMSM-10+
6235	985	342	776	331

HIV Cases Averted by MCPC 2018-Present				
MSM-10+	BMSM-10+	YBMSM-10+	HMSM-10+	YHMSM-10+
89.07	29.85	34.2	12.32	9.46

HIV Treatment Costs Averted by MCPC
$45,991,205.43

Solution Paths

Definitions:

NASTAD: A leading non-partisan non-profit association that represents public health officials who administer HIV and hepatitis programs in the U.S. We work to advance the health and dignity of people living with and impacted by HIV/AIDS, viral hepatitis, and intersecting epidemics by strengthening governmental public health through advocacy, capacity building, and social justice.

CHAC: The purpose of the CHAC is to advise the Secretary, HHS; the Director, CDC; and the Administrator, HRSA, regarding objectives, strategies, policies, and priorities for HIV, viral hepatitis, and other STDs. During the November meeting, CHAC members will discuss issues related to HIV and workforce including non-traditional partnerships to address out of care people with HIV, what's next for the AIDS Education and Training Center (AETC) program, integrating innovative programs to address HIV workforce challenges into the Ryan White HIV/AIDS Program, and how to more effectively use community health workers and disease intervention specialists in HIV and STI prevention, care, and treatment.

SEATC: The Southeast AIDS Education and Training Center (SE AETC) is one of eight regional AETCs across the country. Encompassing Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee, the SE AETC offers comprehensive, collaborative educational opportunities designed to increase the size and strength of the HIV clinical workforce, improve outcomes along the HIV Care Continuum, and reduce the number of new HIV infections. This project is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) under grant number U1OHA30535, AIDS Education and Training Centers Program.

Fast Track Cities: The Fast-Track Cities initiative is a global partnership between cities and municipalities around the world and four core partners – the International Association of Providers of AIDS Care (IAPAC), the Joint United Nations Programme on HIV/AIDS (UNAIDS), the United Nations Human Settlements Programme (UN-Habitat), and the City of Paris.

Mayors and other city/municipal officials designate their cities as Fast-Track Cities by signing the Paris Declaration on Fast-Track Cities, which outlines a set of commitments to achieve the initiative's objectives. Initially heavily focused on the 90-90-90 targets, the Paris Declaration was recently updated to establish attainment of the three 90 targets as the starting point on a trajectory towards getting to zero new HIV infections and zero AIDS-related deaths. Click here to access the Paris Declaration 4.0 Grounded in the principle of data transparency, the initiative includes a Fast-Track Cities Global Web Portal that allows cities to report on their progress against the fast-track and other targets.

As the initiative's primary technical partner, IAPAC supports Fast-Track Cities with technical assistance to local health departments on data generation, monitoring, and reporting. implementation planning among key local stakeholders, capacity-building support for clinical and service providers, community-based organizations, and affected communities. eliminating HIV-related stigma in healthcare settings and assessing quality of life among communities of people living with HIV.

Nashville became a Fast Track-City in 2022.

Clare Bolds (SEATC) writes:
I did mention the 340B concerns to our Fast Track Cities rep since he has a broader perspective on how this is playing out nationally, and this is what he said:

> *Without a change or update from Gilead, there will have to be something to advocate for a at other levels like a city/county fund (Tampa/Hillsborough County has developed a fund to provide health insurance coverage for individuals who need it, more than happy to make a connection for how they set it up), or at the state or federal level! This coming year we do plan on a White House meeting to discuss directly with HHS administrators about necessary changes needed to update the national HIV response, but for Nashville it seems leveraging Tennessee would be the key.*

Three Identified Solution Paths
1. Change from Gilead
2. Fund for health care coverage or uninsured financial assistance at city/county/state level
3. Change at HHS

Local Response Plan
Create a team to pursue each of the three identified solution paths. Each team should have working volunteer members committed to working the problem and delivering a solution. Each team should be

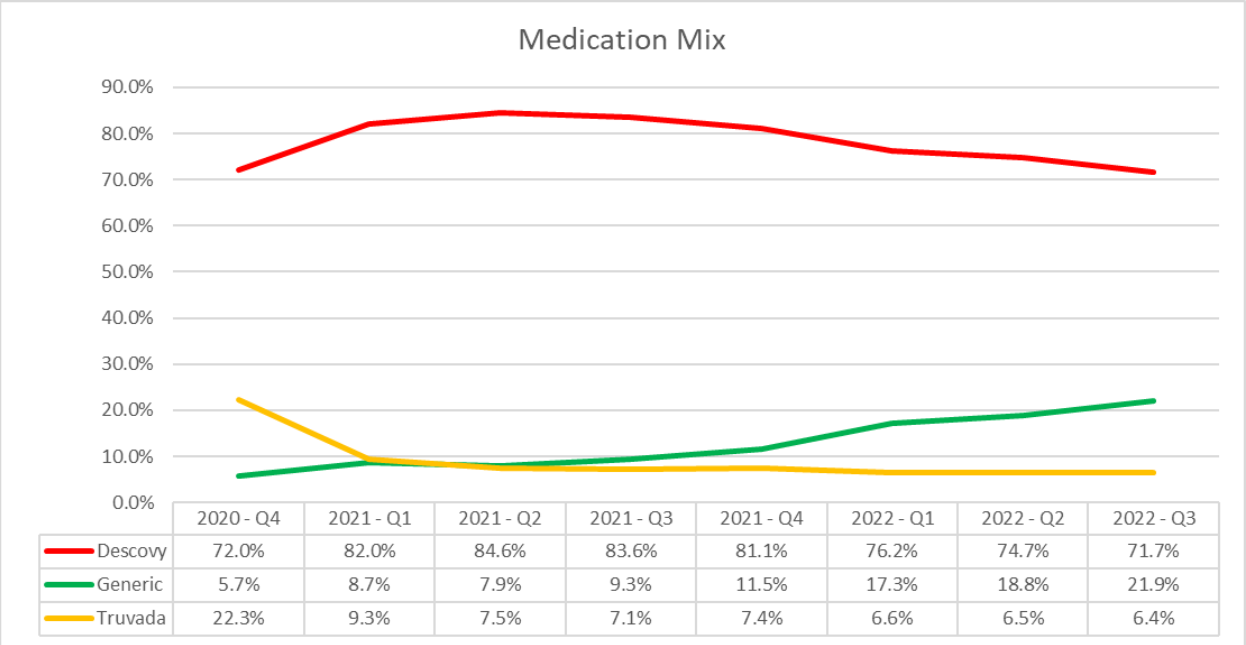
supported by a group of advisors who can facilitate networking and the recruitment of additional working volunteers.

Solution Path 1: Change at Gilead
Team members: Rich MacKinnon, Exec. Dir, MCPC Advisors: Lauren Gaffney, Bass, Berry & Sims

10/2122 Rich: Dwight Watson is under the impression that Gilead is not increasing Descovy and Truvada prices monthly. He suspects it may be McKesson. Rich invited Dwight to view the price increase chart in the LRP. He sent an invite to Jerry Purcell, Founder of Avita Pharmacy. Avita is the MCPC's 340b contract pharmacy that processes most of the eligible prescriptions. Avita manages the McKesson relationship on behalf of MCPC.

10/11/22 Rich: Communicated unsustainable price increases to Dwight Watson, Gilead SE Regional Director (404-391-6785 / Dwight.watson@gilead.com). Watson believed that MCPC's Descovy med mix could be much better than 70% and as high as 86%, based on peer performance in Florida. Watson believed that PAs could be more effective. Rich said he would utilize Gilead recommendations to improve PA and appeal success rate. He also noted that any gains from improved med mix would be wiped out by Gilead's continued, unpredictable price increases for Descovy. Rich said that business planning was nearly impossible without any visibility into Gilead's price hikes. Business planning requires predictable costs of goods sold and predictable revenue from the sale. With insurance companies increasingly disallowing coverage of Descovy and Gilead continually raising the price of Descovy, the only knowable business trend is that the 340b PrEP prevention strategy is unsustainable.

It should be noted that MCPC had already reached Gilead's so-called high efficiency rate of 84.6% in 2Q21; however, 1Q22 showed a dramatic increase in denied prior authorizations by insurance companies.



	2020 - Q4	2021 - Q1	2021 - Q2	2021 - Q3	2021 - Q4	2022 - Q1	2022 - Q2	2022 - Q3
Descovy	72.0%	82.0%	84.6%	83.6%	81.1%	76.2%	74.7%	71.7%
Generic	5.7%	8.7%	7.9%	9.3%	11.5%	17.3%	18.8%	21.9%
Truvada	22.3%	9.3%	7.5%	7.1%	7.4%	6.6%	6.5%	6.4%

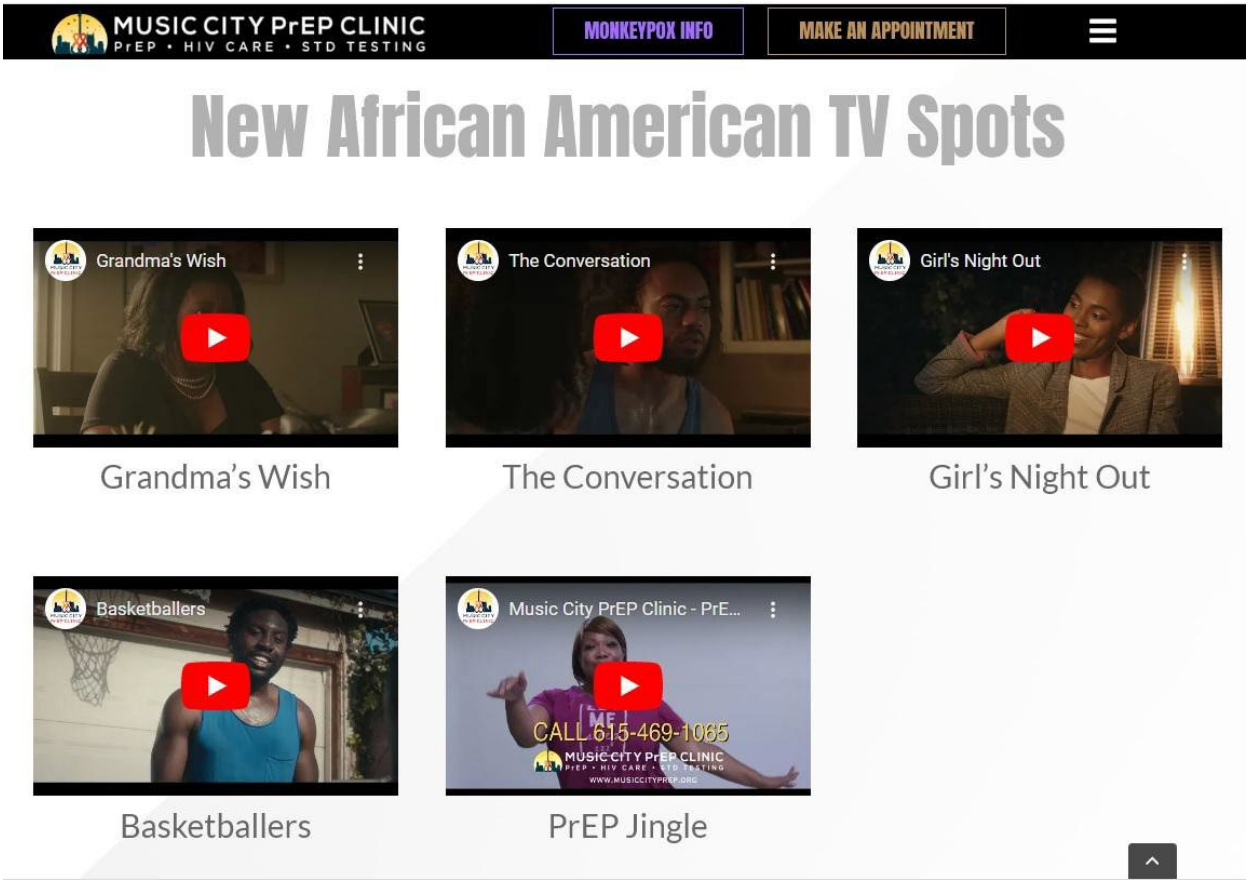
Source: MCPC

Solution Path 2: Local Fund
Team members: Rich MacKinnon, Exec. Dir, MCPC; Jenny Ford, lobbyist
Advisors: Mark Yancy, CEO, Nashville Health; Dr. Gill Wright, Assoc. Medical Director/Clinical Services, MPHD; Clare Bolds, Program Coordinator, SEATC; Dr. Sean Kelly, Medical Director, Vanderbilt CCC; Lauren Gaffney, Bass, Berry & Sims

Proposed ask: A fund and/or in-kind contributions to provide HIV prevention continuity for uninsured and under-insured patients. Could be administered as a financial assistance program or an in-kind program with a health care partner. Could be modeled after MCPC's need-based program.

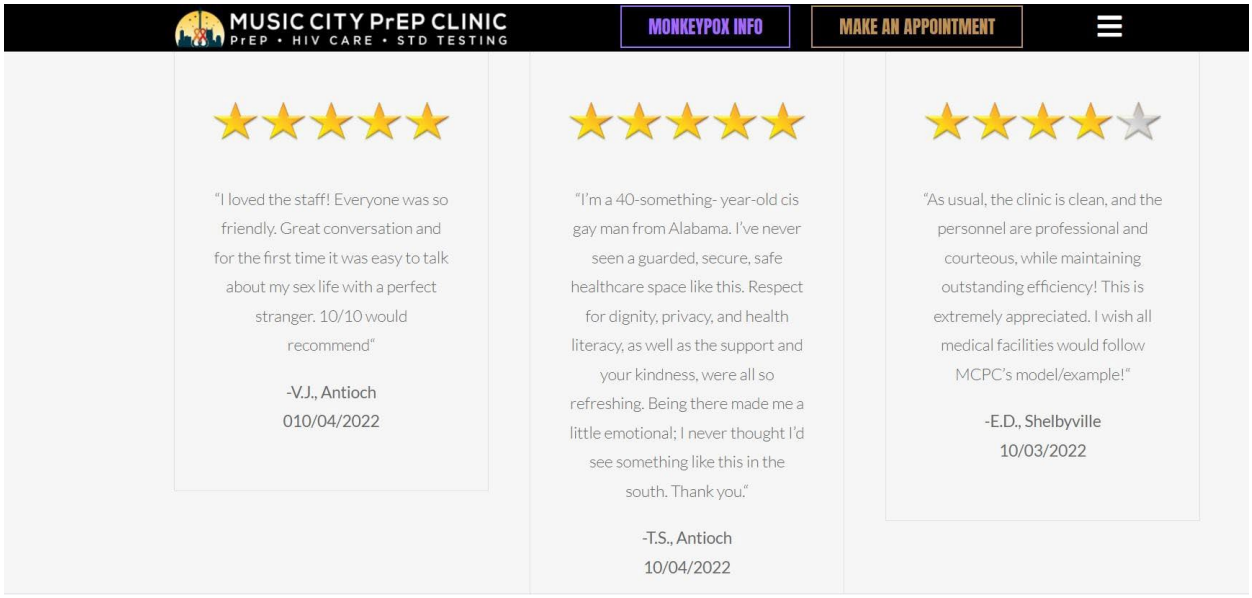
Considerations: (1) Without intervention, MCPC's uninsured patients in the Nashville Metro may seek PrEP care at MPHD. Outside the Metro, they can seek care at TDH. Currently, approximately half of MCPC's PrEP patients are uninsured. This percentage changes throughout the year. (2) The percentage of uninsured patients is highest just before the ACA open enrollment period, and drops significantly just after, then it increases again throughout the year until the next open enrollment period begins. (3) It should be noted that the MCPC financial assistance program includes paying ACA insurance premiums for patients in need. (4) The eventual insolvency of MCPC's HIV prevention program will lead to the cessation of this financial support and an increase in uninsured patients seeking PrEP. (5) While MPHD and TDH operate PrEP programs, they likely are unprepared and under-resourced for the influx of former MCPC patients. (6) If MPHD and TDH seek additional resources to add capacity to their programs, they could consider applying those resources to the existing capacity at MCPC rather than going the slower route of hiring and training more staff and acquiring additional clinical space--MCPC already has demonstrably trained staff and world-class clinical space. (7) MCPC's extraordinary investment in research-based public outreach has enabled it to grow at 500-600 new patients per month. The patients are responding to messaging in targeted campaigns never before seen in the region. MPHD concurs that the messaging has

attracted patients to STI testing and treatment who would not have otherwise participated. The messaging has been so successful with the hard-to-reach Black/African American community, that 35% of MCPC's new patients identify with this demographic. Many more patients from this community are apparent, but declined to identify. This is, quite frankly, extraordinary. Black persons in the USA comprise 42% of new HIV infections, yet only 14% of PrEP users (cit: aidsvu.org). PrEP use equity is a critical target needed to hit to end the epidemic. At the 2022 AIDS Conference in Montreal, Patrick Sullivan, DVM, PhD said, "HIV prevention programs should be guided by PrEP use equity – the use of PrEP relative to the impact of the HIV epidemic on that group. Today's data shows that we have a long way to go." MCPC's effort to reach communities of color not only moved this needle in Tennessee, it completely rebuilt the compass. To our knowledge, no other large HIV prevention strategy in the USA has achieved such real-life progress in reducing racial/ethnic HIV risk disparities. We are at risk of losing this progress, losing our model deserving of replication across the nation, and losing the ground we have gained in dismantling systemic racism in healthcare in Tennessee.



Source: MCPC (https://www.musiccityprep.org/mcpc_tv/)

(8) MCPCs investment in staff training to create a judgment- and stigma-free, sex-positive health care environment enables it to create unparalleled health care experiences for its patients. The service delivery philosophy created by MCPC called “Great Experiences by Design " often provides patients with the best healthcare experience they’ve experienced of any kind.



Source: MCPC (https://www.musiccityprep.org/reviews/)

"I loved the staff! Everyone was so friendly. Great conversation and for the first time it was easy to talk about my sex life with a perfect stranger. 10/10 would recommend"

-V.J., Antioch

010/04/2022

Source: MCPC (https://www.musiccityprep.org/reviews/)

"I'm a 40-something- year-old cis gay man from Alabama. I've never seen a guarded, secure, safe healthcare space like this. Respect for dignity, privacy, and health literacy, as well as the support and your kindness, were all so refreshing. Being there made me a little emotional; I never thought I'd see something like this in the south. Thank you."

-T.S., Antioch

10/04/2022

Source: MCPC (https://www.musiccityprep.org/reviews/)

"As usual, the clinic is clean, and the personnel are professional and courteous, while maintaining outstanding efficiency! This is extremely appreciated. I wish all medical facilities would follow MCPC's model/example!"

-E.D., Shelbyville

Source: MCPC (https://www.musiccityprep.org/reviews/)

What Makes Us Special: Video training series for staff
https://youtu.be/43KrpvE65o4

Conclusion: While the minimum ask should be the continuity of care fund, it's clear that MCPC's success in the region is dependent on its unparalleled investment in public outreach, staff training, and service delivery. To-date, MCPC has relied on research to strategically market its services initially to the LGBTQ community, then in 2021, the Black/African American communities. It has not yet had the opportunity to serve the much more challenging Spanish-speaking community because of language and cultural barriers. Concurrently, through its Partner Strengthening Grant (PSG) program, it has provided an additional $1MM in support to community partners serving B/AA communities, IDU clients, as well as housing unstable LGBTQ youth. Without this sustained effort with each succeeding at-risk community, the capacity for care will be under-utilized.

Action-To-Date
10/20/22 Rich shared LRP with Metro Council Member Zach Young

10/19/22 Rich: Rich briefed Alie Chamber, Exec Assistant to Chief Programs Officer, Friends for Life, Corner Clinic (Memphis), who briefed Mia Cotton - Chief Programs Officer, Tshaka Chambers - Director of Supportive Services, and Terra Cousin - Director of Clinical Operations at The Corner. Rich also looped in Diane Duke, Executive Director, Friends for Life.

10/17/22 Rich briefed Mark Yancy, CEO of Nashville Health. A second meeting will be scheduled. Both noted that the community LGBTQ+ is disproportionately under- and uninsured. The 340b crisis will disproportionately affect the uninsured. Rich outlined the possibility for restructuring MCPC to continue serving under- and uninsured patients through a locally-generated continuity fund that provides financial assistance for out-of-pocket costs. Staffing could be addressed by in-kind partnerships with incumbent organizations. Attention to proper staff training is key to maintaining the trust-building relationship that MCPC has with 15,000 patients. Also briefed Tennessean health care reporter Frank Gluck (fgluck@tennessean.com)

10/19/22 Rachel Franklin, Bureau Director for Communicable Disease and Emergency Preparedness for Metro Public Health Department, confirmed that MPHD top personnel will be responding directly to this crisis.

10/14/22 Rich briefed all hands at MCPC on the state of MCPC sinking faster than previously projected

10/13/22 Rich briefed Bass, Berry, & Sims (BBS) and they will provide at least discounted, possibly pro bono, legal advice for messaging and the structuring of arguments.

10/12/22: Clare suggests recruiting Dr. Stephen Raffanti, Founder of Vanderbilt CCC. Sean Kelly, Vanderbilt CCC medical director can recruit Pam Talley (TDH) and Rob Nash (TDH). Rob Nash introduced Rich to Mark Yancy (Nashville Health) and Rich shared this plan with him.

Solution Path 3: Change at HHS
Team members: Rich MacKinnon, Exec. Dir, MCPC
Advisors: Dashiell Sears, Fast Track Cities (dsears@ftcinstitute.org), Tim Horton, Dir. Medication Access and Pricing, NASTAD; Dr. Sascha Meinrath; Lauren Gaffney, Bass, Berry & Sims; Stephanie Taylor, Progressive Change Campaign Committee.

Proposed ask: The success of the 340b Drug Pricing Program as a funding mechanism for the national HIV strategy depends on (a) a stable "spread" or margin between the drug prices paid by PrEP clinics and the revenues they receive from insurance companies; and (b) insurance companies agreeing to cover the PrEP medication most likely to generate revenue so that the "spread" is sufficient enough to fund the strategy. Without proper supervision of the program, Gilead has made unilateral decisions to increase the price of PrEP and reduce the spread. Further, the insurance companies are increasingly disallowing the coverage of PrEP medications most likely to produce sufficient revenue. The proposed ask is for HHS to supervise the administration of the 340b Drug Pricing Program as it relates to the funding of the national HIV prevention strategy. Supervision initiatives could include (1) returning the price of PrEP medications under patent to 2019 levels; (2) requiring public notice and hearing for any proposed price increases; (3) setting a cap on the percentage and frequency of price increases; (4) requiring insurance companies to cover any PrEP medication as prescribed; (5) allowing patients diagnosed at-risk of HIV and prescribed PrEP the immediate ability to enroll in ACA plans.

Action-to-Date:
10/20/22 Rich: Rich added journalists from Washington Monthly to this shared doc

10/19/22 Rich: Rich briefed Alie Chamber, Exec Assistant to Chief Programs Officer, Friends for Life, Corner Clinic (Memphis), who briefed Mia Cotton - Chief Programs Officer, Tshaka Chambers - Director of Supportive Services, and Terra Cousin - Director of Clinical Operations at The Corner. Rich also looped in Diane Duke, Executive Director, Friends for Life.

10/17/22 Rich: Rich was briefed by Nicole Thibeau, PharmD , Director of Pharmacy Services at the LA LGBT Center confirming that they too have faced significant revenues losses stemming from Gilead's unilateral changes and will have to revisit their programs in the coming year.

10/17/22 Rich: Theresa Jumento, Senior Advisor Division of Policy and Data, HIV/AIDS Bureau, HRSA advised Rich on how to provide a public comment at the CHAC fall meeting and how to become a CHAC member.

10/14/22: Rich registered for the CHAC fall meeting (Nov 1-3) and requested time for oral comment (CHACAdvisoryComm@hrsa.gov). Also requested membership in CHAC. The next CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHAC) meeting will take place on November 1, 12:30 – 5:00 pm ET, November 2, 12:30 – 5:30 pm ET, and November 3, 12:30 - 4:00 pm ET. The meetings will be held virtually with access through Zoom. While the meetings are open to the public, advance registration is required. The deadline for online registration is October 28,12:00 p.m. ET.

1013/22: Sascha believes that pricing/revenue curves may be of interest to FTC. He says filing a complaint for price gouging is step 1. Will also facilitate an introduction to FTC staff for pharma.

About the Music City PrEP Clinic
The Music City PrEP Clinic (MCPC) is a 501(c)(3) non-profit STD clinic headquartered in Nashville with the mission to end HIV in middle Tennessee. Our FY 21-22 budget is approximately $50MM and our staff numbers 80. Initiating business in 2019, we have served over 15,000 patients across 3 facilities, mobile unit, and popup clinics in TN and KY. After completing the Vanderbilt CCC's Practice Transformation and SEATC curriculum, we expanded into HIV care with antiretroviral therapy. We own and practice in two medical office buildings—one in Centennial Midtown and the other in 5 Points East Nashville. The latter is a new $10MM mixed-use development featuring clinical space, on-site pharmacy, LGBTQ community center, and gay bar/restaurant. Our third location is rented clinical space carved out of a gay bar in Louisville, KY.

The Music City Physicians Group doing business as Chosen Family Medicine (CFM) will provide primary care medicine tailored to LGBTQ patients in 1Q23. CFM will co-locate with MCPC at the 5 Points location. Also in 2023, will be the launch of Rod Bragg Diversity Health (RBDH), a health care management service organization enabling us to bring our brand of practice to new markets.

As a single organization, we cannot end HIV on our own. We developed the Partner Strengthening Grants (PSG) initiative to buttress and develop community partners sharing our mission. To-date, we have granted over $1MM through this program to several organizations in our community including Oasis, StreetWorks, Nashville CARES, First Response Center, Vanderbilt CCC, and Fisk University. To ensure as many people as possible can benefit from the MCPC Experience, we provide need-based financial assistance to those who are uninsured and underinsured.