US 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

April 9-10, 2024

Record of the Proceedings

Contents

Executive Summary

The United States (US) 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 (HRSA) HIV/AIDS Bureau (HAB) convened a meeting of the CDC/HRSA Advisory Committee on HIV, Hepatitis, and STD Prevention and Treatment (CHAC) on April 9-10, 2024, in Atlanta, Georgia.

CDC presented updates on key issues, including CDC leadership and CHAC membership; an update on the Policy as a Public Health Intervention Cooperative Agreement PS23-0009; several project highlights; key program updates from NCHHSTP's Division of TB Elimination (DTBE), Division of STD Prevention (DSTDP), Division of HIV Prevention (DHP), and Division of Viral Hepatitis (DVH); and key program updates from NCCDPHP's Division of Adolescent and School Health (DASH).

HRSA presented updates on key issues, including HRSA HAB program updates on the 2024 National Ryan White Conference (NRWC); Ryan White HIV/AIDS Program (RWHAP) Part D Communities of Practice (CoP); HAB Library; RWHAP Best Practices Compilation and Center for Quality Improvement and Innovation; public health and policy updates; and Ryan White Program 2030, including Ending the HIV Epidemic in the US (EHE) updates and HRSA HAB's vision for reaching people with HIV who are out of care. HRSA HAB also presented updates on several recent HRSA HAB funding opportunities and a variety of data updates.

Two panels were convened to provide CHAC members with an overview of:

1) Syndemic approaches to testing, which included presentations and discussions on syndemic interventions; an example of community engagement in syndemic screening and testing in Tennessee; and an example of lessons learned from taking a syndemic approach to hepatitis C virus (HCV) testing and treatment using a Drug User Health Hub Model within the setting of a Colorado syringe services program (SSP).
2) Using prescription data to support the HIV care continuum and the importance of re-engaging out-of-care persons with HIV to confer important individual health benefits and population-level prevention benefits, which included presentations and discussions on an example from Michigan of a pharmacy re-engagement partnership to bridge gaps in HIV care known as the Data to Care Rx Program (Link-Up Rx Program) that supports adherence to antiretroviral therapy (ART); an implementation and evaluation study from Maryland of the pharmacy-based HIV ADHEREnce support intervention among people with HIV implemented through the collaboration of Pharmacies, Prescribers, Payers, and Public health agencies (AdhereP4); and an example from Virginia on barriers to Data to Care Rx (D2C Rx) based on insights from the Antiretroviral Improvement of Medicaid enrolleeS (AIMS) Study.

Three special presentation sessions were convened to provide CHAC members with an overview of:

1) Aging with HIV and the whole life approach, which included a discussion with lifetime survivors.
2) Doxy PEP, which included presentations on translating evidence into action for public health in terms of telling the doxy PEP story; and an example of doxy PEP at a Boston community health center and a discussion of national survey data.
3) Advancing diagnosis of current HCV infections in terms of new tools and new opportunities, which included presentations on HCV guidelines, tests, and upcoming innovations; a cost-effectiveness analysis of HCV testing strategies for diagnosis of US adults; and an overview of the progress on HCV testing guidance for laboratorians and clinicians.

The Long-Acting Injectable Workgroup (LAIWG) recapped its CHAC recommendations presented during the Fall 2023 CHAC meeting. The CHAC extended the LAIWG to allow for further insights into barriers and lived experience for those seeking or utilizing long-acting injectables for HIV prevention or treatment. The LAIWG described its work since that meeting, pointing out that due to challenges facilitating non-clinical external stakeholder input in the workgroup environment, the decision was made to review existing literature in the hope that the qualitative analyses would feature the voice of people with lived experience (PWLE). During this session, the LAIWG presented 4 revised considerations for CHAC. Based on additional input during this session, the LAIWG agreed to review and revise its proposed consideration and bring them for a vote during the next CHAC meeting.

The Community Partnership Workgroup (CPWG) presented best practices and put forward 4 considerations for CDC/HRSA. While some CHAC members thought it would be impactful to craft a letter to ensure that PWLE have meaningful involvement at all levels, others emphasized that the first 3 considerations (e.g., ensure PWLE have meaningful involvement at all levels, support bi-directional technical assistance, and support opportunities for bi-directional knowledge sharing) be included in the minutes as a powerful reminder of the important principles that the agencies should incorporate in their Notice of Funding Opportunities (NOFOs), practices, and policies. A brief summation was provided of the 80th Presidential Advisory Council on HIV/AIDS (PACHA), and it was noted that Kay Hayes passed the PACHA Executive Director position baton to Caroline Talev.

Major themes emerged throughout the 2-day meeting, including: 1) focus on the importance of systems working together, reacting together, and supporting each other; and 2) it is imperative to include PWLE in honest, thoughtful, and compassionate discussions in all topic areas (e.g., communication, lifetime survival, Doxy PEP, testing, innovative approaches, etc.) in order to move the work forward.

CHAC Actions

During this meeting, CHAC members voted unanimously to:

- Approve the October 24-25, 2023 CHAC meeting minutes, with no edits proposed.
- Accept and move forward the Youth Letter dated April 2024, with no edits proposed.
- Develop and submit a letter to HHS Secretary Becerra including suggested recommendations pertaining to holistic research and interventions for lifetime survivors.
- Amend the wording of the CHAC letter regarding lifetime survivors to add wording about removing eligibility barriers as lifetime survivors transition from pediatric to adult care, which can result in interruptions in care.
- Draft a CHAC resolution letter to HHS Secretary Becerra expressing support for SSPs as an essential tool for harm reduction.
- The LAIWG will continue to meet to develop a letter and revise its proposed recommendations, based on the business meeting input, and bring them for a vote during the next CHAC meeting.
- Publish 3 CPWG recommendations in the final meeting minutes ad issue a recommendation directly to CDC/HRSA to develop shared metrics to assess successful community partnerships across agencies considering syndemic and status-neutral approaches, including meaningful involvement of PWLE.

US 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
April 9-10, 2024

Minutes of the Meeting

The United States (US) 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 (HRSA) HIV/AIDS Bureau (HAB) convened a meeting of the CDC/HRSA Advisory Committee on HIV, Hepatitis, and STD Prevention and Treatment (CHAC) on April 9-10, 2024, in Atlanta, Georgia.

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

Day 1: Opening of the Meeting and Welcome

Wendy Armstrong, MD
CHAC Co-Chair

Dr. Armstrong called the proceedings to order at 9:00 AM Eastern Time (ET); welcomed everyone to the April 9-10, 2024 CHAC meeting; and thanked CHAC members, federal officials, HRSA and CDC staff, and the general public for their attendance and commitment. After reviewing the agenda, she called for a motion to approve the minutes from the October 24-25, 2023 CHAC meeting.

Marah E. Condit, MS
Public Health Analyst, Advisory Committee Management Lead
Office of Policy, Planning, and Partnerships
National Center for HIV, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention

Ms. Condit welcomed participants to the CHAC meeting, reviewed ground rules, and provided instructions for discussion periods. She indicated that members of the public would have an opportunity to provide oral comments at 3:45 PM ET during the second day, and that public comments would not be accepted at any other point during the meeting. Written comments will be accepted until April 19, 2024, and will be included in the official meeting record and be distributed to members for consideration.

Designated Federal Official (DFO) Meeting Roll Call

Jonathan Mermin, MD, MPH
Director, National Center for HIV, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention
CHAC Designated Federal Officer
Centers for Disease Control and Prevention

On behalf of CDC and HRSA, Dr. Mermin welcomed those present and reminded everyone that CHAC meetings are open to the public and that all comments made during the proceedings are a matter of public record. He explained that members should be mindful of potential conflicts of interest (COIs) identified by the Committee Management Office (CMO) and recuse themselves from voting or participating in any discussions for which they could be conflicted. He then conducted a roll call to determine the CHAC voting and *Ex-Officio* members who were in attendance and establish quorum. Quorum was maintained during both days of the meeting.

Conflict of Interest Disclosures

CHAC Voting Member Institution/Organization	Disclosure of Conflicts
Wendy Armstrong, MD Emory University School of Medicine	Works at an HIV Clinic that receives funding from Ryan White
Maggie Beiser, NP Boston Health Care for the Homeless	Works in a Ryan White clinic that is HIV-funded
Keiva Lei Cadena-Fulks Positive Women's Network	No conflicts
Jorge Cestou, PhD, MBA Chicago Department of Public Health	HRSA/Ryan White Parts A CDC HIV and STI Prevention and Surveillance
Jodie Dionne, MD, MSPH University of Alabama, Birmingham	Research Funding: NIH Works in an HIV Clinic funded by Ryan White
Shannon Brown Dowler, MD North Carolina Medicaid	Works in an STI Clinic that receives Ryan White funding HHS Syphilis and Congenital Syphilis Task Force
Daniel D. Driffin, DrPH, MPH D3 Consulting	No conflicts
Grissel Granados, MSW Planned Parenthood Los Angeles	No conflicts
Meredith Greene, MD University of California, San Francisco	Research Funding: NIH Works in 2 Ryan White-funded HIV clinics
Vincent Guilamo-Ramos, PhD, MPH, LCSW, RN, ANP-BC, PMHNP-BC, AAHIVS, FAAN Duke University	Research Funding: NIH, CDC, ACF
Christine Markham, PhD University of Texas Houston	Research Funding: NIH, ACF, OMH
Robert Riester Person Living with HIV Colorado Health Network	Research Funding: CDC and HRSA/Ryan White HIV/AIDS Program, Parts A & B
Leandro Rodriquez, MBA Latino Commission on AIDS	Research Funding: HRSA/Ryan White HIV/AIDS Program, CDC, SAMHSA, Gilead, ViiV
Renata Arrington Sanders, MD, MPH, SCM The Children's Hospital of Philadelphia	Recipient of funding from NIH, NIDA Works in a Ryan White-funded clinic
Samuel So, MD Stanford University	Research Funding: CDC, NIH

Ex-Officio and Liaison Members in Attendance:

- Dr. Carolyn Deal, National Institutes of Health (NIH) National Institute of Allergy and Infectious Disease (NIAID)
- Dr. Neerja Gandotra, Substance Abuse and Mental Health Services Administration (SAMHSA)
- Dr. Christopher Gordon, National Institutes of Health (NIH), National Institute of Mental Health (NIMH)
- Ms. B. Kaye Hayes, HHS Office of HIV/AIDS and Infections Disease Policy (OIDP)
- Dr. Richard Wild of the Centers for Medicare and Medicaid Services (CMS)
- Dr. Hansel Tookes, Presidential Advisory Council on HIV/AIDS (PACHA)

Dr. Mermin confirmed that a quorum of 20 was achieved and that CHAC could move forward with conducting its business on April 9, 2024.

CHAC Action
Dr. Renata Arrington Sanders made a motion to approve the minutes from the October 24-25, 2023 CHAC meeting. Dr. Shannon Brown Dowler seconded the motion. CHAC approved the minutes with 17 affirmative votes, 0 opposed, and 0 abstentions with no changes or further discussion.

CDC/NCHHSTP Welcome and Update

NCHHSTP Update

Jonathan Mermin, MD, MPH
Director, National Center for HIV, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention
CHAC Designated Federal Officer

Dr. Mermin began by welcoming and expressing appreciation to the following new CHAC Voting Members:

- Ms. Marguerite Beiser, Director of Hepatitis C Services, Boston Health Care for the Homeless Program (BHCHP)
- Dr. Jorge Cestou, Director of Programs and Operations, Syndemic Infectious Disease (SID) Bureau, Chicago Department of Public Health (CDPH)
- Mr. Brigg Reilley, Epidemiologist, National Programs HIV/HCV, Northwest Tribal Health Board (NPAIHB)

He also thanked departing members, Dr. Jodie Dionne and Mr. Kali Lindsey. Dr. Dionne has been a CHAC member since 2019. Dr. Mermin presented her with Certificates of Appreciation for her participation on CHAC. He indicated that Mr. Lindsey stepped down from CHAC due to a change in his position that would create a potential conflict.

Dr. Mermin presented CDC leadership updates. Dr. Robyn Neblett Fanfair is now the permanent Director of the Division of HIV Prevention (DHP) and Dr. Laura Hinkle Bachmann has been Acting Director of the Division of STD Prevention (DSTDP) for several months.

Dr. Mermin reported that the detailed response to the Mpox letter submitted by CHAC in January 2023 was distributed in January 2024 and was included in the meeting materials, and that the CHAC Charter is due to renew in November 2024.

Dr. Mermin reminded everyone that the Policy as a Public Health Intervention Cooperative Agreement (PS23-009) initiative is designed to support the establishment of state-level environments that embrace evidence-based policy strategies toward the agenda of HIV, viral hepatitis, STD, and TB prevention. Through this cooperative agreement, NCHHSTP is assisting leaders who make decisions in public health identify, assess, and implement evidence-based policy interventions. It includes 2 distinct components: 1) Legal Epidemiology - leveraging emerging methods in coding law and policy overtime and cross-sectionally to help us then study how and policy affect health outcomes; and 2) Technical Assistance- establishing a robust system of legal technical assistance to aide leaders who make decisions in public health in navigating complex legal and policy environments as well as create and promote resources in a proactive and reactive manner.

NCHHSTP celebrated the 20th anniversary of its Office of Health Equity (OHE) with the release of an accomplishments video and an internal CDC article. The NCHHSTP team also completed an extensive literature assessment to identify population-level, evidence-based interventions, policies, and best practices that are associated with reductions in disparities in HIV, viral hepatitis, STIs, TB and adolescent health. This assessment was a highly complex task that identified numerous gaps in the literature. The NCHHSTP team also continues to lead the HHS CDC Equity Challenge Taskforce that is focused on inclusion of persons with the lived experience (PWLE) of incarceration in the federal public health workforce. Considerable thought is being given to improving the transition of people from jails and prisons into society and ensuring that people receive prevention interventions and treatment for their infections.

To highlight some cross-cutting projects, applications closed on April 8, 2024 for the new 5-year cycle of the NCHHSTP Epidemiologic and Economic Modeling Agreement (NEEMA) CDC-RFA-PS-24-0028[1], which is set to begin September 30, 2024. NCHHSTP continues to support a wide range of modeling activities including the assessment of morbidity and mortality projections, the burden and costs of diseases, costs and cost-effectiveness of interventions, population-level program impact, and optimized resource allocation. In collaboration with experts across NCHHSTP, the Program and Performance Improvement Office (PPIO) has collaborated with the American Medical Association (AMA) to develop and release an online toolkit[2] to help physicians and other health care professionals increase routine screenings for HIV, STIs, viral hepatitis and latent tuberculosis infection (LTBI). The toolkit shares best practices and strategies for screening programs specific to community health centers (CHCs) and emergency departments (EDs). This longstanding effort has identified multi-pathogen screening as one of the most important gaps from a syndemic standpoint. Frequently in the US, EDs will conduct HIV screening but not hepatitis C screening, or syringe services programs (SSPs) may conduct HIV or hepatitis C screening but not syphilis screening. The limitation of not thinking more expansively of the whole person or the whole population and the venue has limited success. NCHHSTP has many efforts underway that are thinking carefully about the spaces where a syndemic approach can be implemented and improve from an efficiency standpoint and an outcomes standpoint for the people they serve.

[1] https://www.cdc.gov/nchhstp/neema/funding-opp-announcement.html
[2] https://www.ama-assn.org/delivering-care/public-health/routinely-screen-hiv-stis-viral-hepatitis-and-latent-tb-infection

Regarding provisional 2023 TB surveillance, after 2 decades of reductions in TB that included a fairly dramatic decline by 20% in 2020 in the first year of the COVID-19 pandemic, followed by increasing case counts every year since 2020. In 2023, the case count increased to 9,615 and the incidence rate increased to 2.9 per 100,000 persons. Levels this high have not been seen since 2013 and 2016, respectively. Increases occurred in most reporting jurisdictions and among most demographic groups, and were particularly associated with people who were born outside of the US. Several setbacks to TB elimination are present, some of which has to do with the widening gap between resources related to TB and the prevalence of LTBI and associated active TB disease. Renewed progress toward elimination will require strengthening the TB system. NCHHSTP is monitoring this increase and hopefully will be able to reverse the trajectory next year.

The Tuberculosis Trials Consortium (TBTC)[3] is a collaboration of North American and international clinical investigators whose mission is to conduct programmatically relevant research concerning the diagnosis, clinical management, and prevention of TB infection and disease alongside the TB Epidemiologic Studies Consortium (TBESC). Since it began in 1993, TBTC has been responsible for several major clinical trials that have significantly impacted TB treatment. The results of TBTC Studies 22 and 26 substantially influenced the most recent American Thoracic Society/CDC guidelines for treatment of both TB disease and latent TB infection (LTBI). Most recently, TBTC Study 31 demonstrated that the efficacy of a four-month daily treatment regimen containing a combination of rifapentine and moxifloxacin is non-inferior to the standard six-month daily regimen at curing drug-susceptible TB disease. As part of this, Study 38: Combination Regimens for Shortening TB Treatment (CRUSH-TB) is a Phase 2C trial that aims to identify new combinations of drugs that can shorten the length of treatment for TB disease. The trial compares the safety and effectiveness of 4-month bedaquiline (B), moxifloxacin (M) and pyrazinamide (Z) based regimens to the 6-month standard-of-care regimen. Study 38 also aims to have a modifiable methodology that can include additional TB treatment regimens as they become available. The trial will include a diverse group of participants including, children 12 years of age or older and people with HIV. This is a cutting-edge and adaptive design research methodology that allows changes that might occur in the treatment environment versus conducting research studies that are outdated when the results are done.

Division of STD Prevention (DSTDP)

Laura Bachmann, MD MPH, FACP, FIDSA
Acting Director, Division of STD Prevention
National Center for HIV, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention

Dr. Bachmann shared some highlights of the work that the DSTDP is doing. In November 2023, the division released a CDC *Vital*signs™ that described the congenital syphilis epidemic and missed opportunities. The *Sexually Transmitted Infections Surveillance 2022* report[4] was released in January 2024 and illustrates the need for STIs to be a public health priority. Related to the STI report, STIs cases continued to climb in 2022. While all STIs have increased over the last 10 years, syphilis and congenital syphilis cases stand apart in terms of the sheer magnitude of the increases. In the last 10 years, about a 367% increase occurred in syphilis cases and congenital syphilis cases are nearing a 1000% increase. These data emphasize the urgency of being innovative and working together with partners to address this epidemic.

[3] https://www.cdc.gov/tb/topic/research/tbtc/default.htm
[4] https://www.cdc.gov/std/statistics/2022/default.htm

Congenital syphilis is entirely preventable[5] with timely testing and appropriate and adequate treatment during pregnancy. Yet, the *Vital*signs™ report analyses found that 9 in 10 cases of congenital syphilis would have been prevented if timely testing or adequate treatment had been provided during pregnancy. The report hones this down further because these data vary by jurisdiction. It also provides a lot of innovative approaches that can be implemented in the future to address the epidemic.

Because of the increased syphilis rates, HHS established a multi-agency National Syphilis and Congenital Syphilis Syndemic (NSCSS) Federal Task Force. The first meeting was convened in August 2023. The Task Force's goals are to: 1) reduce rates of primary and secondary syphilis and congenital syphilis; and 2) reduce syphilis health disparities. The Task Force focuses on 14 jurisdictions on morbidity. Those 14 jurisdictions account for close to 75% of the cases of congenital syphilis and about 55% of the cases of primary and secondary syphilis. Some of the Task Force's actions to date have included conducting briefings with a variety of external partners for collaboration opportunities, such as membership organizations, professional organizations, and providers. The Task Force supported the temporary import of Extencilline, which is a long-acting formulation of Bicillin® penicillin. There has been a Bicillin® shortage for about a year. The Task Force has convened workshops to address disparities, identify gaps, and focus on research strategies. Many agencies collaborating with the Task Force have issued funding flexibility letters to grantees for more flexibility in terms of syphilis care. In addition to the surveillance report and the Task Force, DSTDP has newly released and upcoming guidelines. The first ever *CDC Laboratory Recommendations for Syphilis Testing, United States, 2024*[6] was released in February 2024 and encompasses every aspect of syphilis testing. The *Doxycycline Post-Exposure Prophylaxis* Guidance is in the final stages of development and is expected to be released in 2024.

There are some recent STI prevention and control Notice of Funding Opportunities (NOFOs). The first is Combatting Antimicrobial Resistant (AR) Gonorrhea and Other STIs (CARGOS). This opportunity was formerly known as "Gonococcal Isolate Surveillance Project (GISP)/eGISP and Strengthening the US Response to Resistant Gonorrhea (SURRG)." The current CARGOS NOFO is an umbrella to encompass strategies to focus on monitoring for AR, including laboratory testing; preparedness and outbreak response activities; monitoring, detection, and response to AR in STIs; and epi-lab-health information technology. This NOFO also opens the opportunity to include STIs other than gonorrhea that represent AR threats. DSTDP also continues to strengthen clinic infrastructure and improve service delivery for STIs and other syndemic conditions through a recent NOFO known as "Support and Scale-Up of HIV Prevention Services in Sexual Health Clinics (SHIPS)." This was Formerly Part C of the Ending the HIV Epidemic (EHE) in the US Initiative. Another aspect of this NOFO is to foster strategic partnerships to address the EHE goals.

[5] McDonald R, O'Callaghan K, Torrone E, et al. Vital Signs: Missed Opportunities for Preventing Congenital Syphilis — 11 United States, 2022. *MMWR* Morb Mortal Wkly Rep. ePub: 7 November 2023.
[6] https://www.cdc.gov/mmwr/volumes/73/rr/rr7301a1.htm

Division of HIV Prevention (DHP) Update

Robyn Neblett Fanfair, MD, MPH
Director, Division of HIV Prevention
National Center for HIV, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention

Dr. Neblett Fanfair presented information about 2 of DHP's NOFOs. The DHP has 2 large flagship NOFOs that published within weeks of each other in February 2024. The first is the large "PS24-0020: Capacity Building Assistance (CBA) for HIV Prevention Programs to End the HIV Epidemic in the United States." This will be active in the Summer of 2024, and is currently out for applications. Up to 15 organizations will be funded, with a total investment of approximately $120 million over the next 5 years. This NOFO supports the network of funded providers established and referenced as the CBA Provider Network (CPN), to implement the following 6 inter-related program components:

1. Component A: Technical Assistance to Enhance Integrated HIV Activities for Health Department Jurisdiction
2. Component B: Instructor-led Training for High-Impact HIV Prevention Programs
3. Component C: eLearning Training for High-Impact HIV Prevention Programs
4. Component D: Technical Assistance for High-Impact HIV Prevention Programs
5. Component E: Organization/Workforce Development and Management for Community-Based Organizations
6. Component F: CPN Resource and Coordination Center

The second NOFO is the large flagship NOFO "PS24 0047: High-Impact HIV Prevention and Surveillance Programs for Health Departments." This NOFO will be active as of August 1, 2024. A total of 60 health departments are eligible for funding. At level funding, this is an investment of approximately $485 million annually to support this critical work. The core strategies for the flagship NOFO are built around the evidence-based work for the EHE. The pillars of the core strategy are defined as follows:

1. **Diagnose:** Increase knowledge of status to 95% by ensuring all people with HIV receive a diagnosis as early as possible.
2. **Treat:** Implement a comprehensive approach to treat people with diagnosed HIV infection rapidly (increase linkage to care up to 95%) and effectively to achieve viral suppression up to 95%.
3. **Prevent:** Prevent new HIV transmission by increasing PrEP coverage to 50%, increasing PEP services and supporting HIV prevention, including prevention of perinatal transmission, harm reduction and syringe services program (SSP) efforts.
4. **Respond:** Respond quickly to HIV clusters and outbreaks to address gaps and inequities in services for communities who need them.
5. **Surveillance:** Conduct HIV surveillance activities as described in the "Technical Guidance for HIV Surveillance Programs" to ensure accurate, timely, complete, and actionable data.
6. **Community Engagement:** Support community engagement and HIV planning.

One of the changes for improved impact is increased flexibility. In addition to HIV prevention and surveillance, EHE is also included in this NOFO. DHP does not have the opportunity to take EHE national, but by including it under a single flagship NOFO, DHP hopes that the lessons learned from EHE successes and the increased flexibility for health departments to address specific community needs and innovate will allow jurisdictions to answer specific community needs and be innovative. Another change pertains to continuity of services. CDC

has added the ability to fund other organizations to ensure continuity of critical programs if a health department is unable or unwilling to receive CDC funding. The next change regards reducing burden. Grantee reporting burden will be reduced by moving it to later in the fiscal year to allow fewer funding packages, etc. The funding floor has been increased for all jurisdictions from $1 million to $1.2 million.

The NOFO is strategically aligned with national, HHS, and CDC strategic priorities, including community engagement, health equity, syndemics, and a whole person approach to HIV prevention. Applicants may use up to 10% of their total requested funding amount to enhance syndemic efforts. CDC-funded programs achieved a number of successes over the past 2 years in EHE, including the following:

- ❑ Over 500,000 free HIV self-test kits were ordered and distributed
- ❑ 831,000 HIV tests were performed at CDC-funded programs, with 3000 people newly diagnosed between January 2021 and June 2023
- ❑ More than 55,000 persons were prescribed pre-exposure prophylaxis (PrEP)
- ❑ 261 SSPs were supported, more than 60% of which are mobile
- ❑ Over 200 clusters were detected

To look more in-depth regarding the diagnoses pillar, the Together TakeMeHome Program officially launched in March 2023. Last year alone, over 367,000 tests had been delivered. This speaks to how important it is to meet people where they are and how they want to be met. According to the demographic data, the vast majority of these tests went to communities that are disproportionately impacted by HIV and almost one quarter of people who have ordered the test had never received an HIV test before. Within the prevent pillar, between January 2021 and June 2023, CDC EHE-funded programs prescribed PrEP for more than 55,000 persons. This work also speaks to the encouraging and innovative syndemic work. CDC EHE-funded programs have connected with over 260 SSPs, of which 93 are fixed locations and 158 are mobile outreach locations.

The CDC/DHP and HRSA held community engagement sessions between March 2022 through March 2023, it visited virtually all HHS regions. Over 1,600 people attended these sessions, including some in-person and held in Spanish at the United States Conference on HIV/AIDS (USCHA). The community engagement sessions have continued in 2024. DHP has partnered with the Southern AIDS Coalition (SAC) and the National Association of County and City Health Officials (NACCHO) and visited various cities in the South to hear directly about some of the successes, challenges, and asks specifically for their local state health departments as well as critical federal partners. In the initial cohort, there were 6 cities in the South. One session is left in Miami on May 22, 2024. These sessions are typically well-attended by a lot of the people who are doing critical work in communities. It has been an honor to visit them in their space and home to hear about this critical work.

The DHP team is working on guidelines that they expect to publish in 2024. One set of guidelines focuses on non-occupational post-exposure prophylaxis (nPEP), and another is being completed in collaboration with another division that focuses on occupational PEP (oPEP) guidelines. The team is also working to update the HIV testing guidelines.

Division of Viral Hepatitis (DVH) Update

Neil Gupta, MD, MPH
Captain, US Public Health Service
Chief, Epidemiology and Surveillance Branch
Division of Viral Hepatitis
National Center for HIV, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention

Dr. Gupta presented highlights from DVH. In January 2024, CDC updated *the Viral Hepatitis and Surveillance Case Management Guidance for State, Territorial, and Local Health Departments*[7] to align with an updated hepatitis B case definition that was approved by the Council of State and Territorial Epidemiologists (CSTE) to be implemented this year. The *Viral Hepatitis Surveillance Report, United States, 2022*[8] and the *2024 National Progress Report: Viral Hepatitis*[9] based on these data were published. Data from the report focusing on acute viral hepatitis shows some progress. A continuous decrease is observed for hepatitis A. This likely reflects successful state and national efforts to address widespread outbreaks of hepatitis A among people who use drugs (PWUD) and people experiencing homelessness. Despite this success, many people are still susceptible to HIV infection, so the importance of vaccination must be stressed. A decrease in hepatitis B cases occurred around 2020, which did not increase following the COVID-19 pandemic. This likely reflects successful vaccination efforts, including the childhood hepatitis B immunization recommendation that often is an unsung public health story. After more than a decade of consecutive annual increases in hepatitis C, a slight decrease in cases was observed in 2022. This is likely due in part to successful prevention initiatives, such as SSPs. A change also occurred in drug use patterns, such as a transition from injection to smoking. More work is being done to characterize these trends.

Despite the fact that some of the recent trends are encouraging, it is important to recognize that there is still a lot of progress to make. While some declines were seen in acute hepatitis C, these declines were not observed equally in all race/ethnicity categories. In fact, there were some increases in certain categories. In addition, there is still a lot of work to do to meet national hepatitis C elimination goals. In 2022 alone, it is estimated that there were more than 67,000 new hepatitis C infections and about 13,000 deaths. While incremental progress continues to be made toward 2025 goals, accelerated progress is needed to meet the 2030 goals.[10]

CDC's partnerships with jurisdictional viral hepatitis programs were strengthened through the agency's Integrated Viral Hepatitis Surveillance and Prevention Funding for Health Departments funding, which began in May 2021. With TA from CDC and the National Alliance of State and Territorial AIDS Directors (NASTAD), jurisdictions are building comprehensive surveillance programs, creating outbreak response plans, establishing elimination plans, and providing comprehensive services to people who inject drugs (PWID) in 18 demonstration projects. CDC is hosting a national meeting April 16-17, 2024, with all funded jurisdiction partners to provide updates and share best practices on surveillance and prevention. Successes and challenges continue to be documented through the developing of *Recipient Feedback Reports* and *Jurisdictional Profiles* to help CDC's state and local partners monitor their success. While these efforts have led to some incremental improvements, there is still a long way to go. The *2022 Viral Hepatitis Surveillance Status Report from CDC's partner*,

[7] https://www.cdc.gov/hepatitis/statistics/surveillanceguidance/index.htm
[8] https://www.cdc.gov/hepatitis/statistics/2022surveillance/index.htm
[9] https://www.cdc.gov/hepatitis/policy/npr/2024/index.htm
[10] National Notifiable Diseases Surveillance System (NNDSS); National Vital Statistics System (NVSS)

HepVu, characterizes some of the surveillance infrastructure and workforce challenges throughout the country. For example, they found that 1 out of 5 jurisdictions do not have even 1 dedicated fulltime employee (FTE) for viral hepatitis surveillance, even though most feel that they need approximately 3 to 5 FTEs to do the job.

Funding at CDC for viral hepatitis has been relatively flat over the last several years despite many calls from partners and jurisdictions that more funding is desperately needed. CDC has right-sized programs to create funding efficiencies. However, if the proposed National Hepatitis C Elimination Program is enacted, that would be a "game changer" to expand viral hepatitis surveillance, treatment, and prevention efforts. Another important opportunity that the White House proposal has afforded is the work behind the scenes to accelerate review and approval of a hepatitis C virus (HCV) ribonucleic acid (RNA) point-of-care test. Dr. Gupta pointed out that on the second day of the meeting, there would be a special panel discussing this effort and the future of hepatitis C diagnostic testing.

Division of Adolescent and School Health (DASH) Update

Kathleen Ethier, PhD
Director, Division of Adolescent and School Health
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention

Dr. Ethier noted that although DASH no longer sits within NCHHSTP and has been combined with a branch from the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) where they now sit, about 70% of DASH's current budget comes from the HIV subline. DASH's work in that area has not changed and they still have a very strong focus on the set of outcomes with which their programmatic work is associated, including sexual risk behavior, experience of substance use, experience of violence, mental health, and suicidal thoughts and behaviors. What they have added is an increased focus on physical activity and nutrition and management of chronic disease outcomes for young people. During this session, Dr. Ethier spoke about how DASH has adjusted and their priorities for the upcoming year.

The updated mission and vision for DASH 2.0 are as follows:

Vision: We envision a future where young people are empowered with the knowledge, skills, and resources to support health and well-being.

Mission: To work with and through schools to understand and improve the health and well-being of all students. We do this by strengthening school-based education, health services, healthy school environments, and community connections.

In terms of DASH's key programmatic activities for 2024, they are finishing out DP18-1807, which is the last 6 years' version of the *What Works in Schools* program as well as funding for state and local surveillance. The next NOFO will implement that program and stand up the next cooperative agreement for surveillance. Full stand-up of the Healthy Schools Program (DP23-0002) is state-based and is designed to improve physical activity, nutrition, and management of chronic conditions. Through this, they are trying to create a more cohesive approach to school health that addresses upstream prevention aspects that schools are good at.

Regarding key surveillance and research activities for 2024, DASH will be releasing the 2023 Youth Risk Behavior Survey (YRBS) data that will be published over the course of August and September 2024. That will begin with the *Data Summary & Trends Report* that focuses on the *What Works in Schools* outcomes (e.g., sexual risk behaviors, substance use, experience of violence, suicidal thoughts and behavior, and mental health). While it seems like a relatively short period of time since the last release in February 2023, the 2021 data collection was delayed to Fall 2021. However, the 2023 data was collected on time in Spring 2023. DASH is working to improve the interoperability of the YRBS, School Health Profiles (Profiles) and other datasets. It took a long time to get an assurance of confidentiality in order to use National Center for Education Statistics (NCES) IDs, which every school in the country has. DASH uses those IDs in order to select the sample, but did not have access to them as a protective measure. DASH will now use these IDs because they have the assurance of confidentiality to combine YRBS data with Profiles data, which is school policy and practices data, with any other datasets that use NCES IDs. This will allow DASH to assess the relationship between policies and practices and aspects of schools and outcomes in young people that might be associated with those polices, practices, and other aspects. They have been doing this to some extent in terms of examining school-level poverty and YRBS outcomes, which has been fruitful.

DASH is launching a research NOFO to examine What Works in Schools program expansion for schools serving rural and American Indian or Alaska Native (AI/AN) youth. They conducted a very large over-sample of AI/AN youth in the 2023 survey. One MMWR published with the release of the data will specifically focus on Tribal youth, which is a very exciting addition to the YRBS. DASH is also working to translate recent research findings to inform implementation of innovative school-based strategies.

One resource that resulted from this work is a school mental health action guide, *Promoting Mental Health and Well-Being in Schools: An Action Guide for School and District Leaders.*[11] This guide was previously called “Technical Packages.” This guide is information for the field, and it is designed for district and school leaders to implement in school districts to improve mental health. DASH began work on this guide in 2019 when they realized that schools needed some extra support in implementing universal Tier 1 and Tier 2 in the Multi-Tiered System of Supports (MTSS) framework to move further upstream to improve mental and behavioral health. DASH conducted literature searches, grey literature, and many focus groups and interviews with people in the field. The guide was released in December 2023. There has been overwhelming support for and uptake of the guide, which speaks to what schools are dealing with right now. In the first 2 months after the release, nearly 50,000 cumulative page views were received on the action guide web pages. When last Dr. Ethier checked, that had increased to over 100,000 views. They conducted over 20 presentations to partners on the guide and the guide has been downloaded almost 4,000 times. In addition, 27 federal and 5 partner accounts posted social media content on the action guide, which generated more than 20 million impressions at this point. *CDC’s 2022 School Health Profiles*[12] was recently released. A Profiles Explorer was added to help navigate through the Profiles data more easily.

[11] https://www.cdc.gov/healthyyouth/mental-health-action-guide/pdf/DASH_MH_Action_Guide_508.pdf
[12] https://www.cdc.gov/healthyyouth/data/profiles/index.htm

HRSA Welcome and Update

Laura Cheever, MD, ScM
CHAC Designated Federal Officer
Associate Administrator, HIV/AIDS Bureau
Health Resources and Services Administration

Dr. Laura Cheever extended her welcome and gratitude to participants for their participation in the meeting. She reminded everyone that the HRSA HAB vision and mission are as follows:

Vision: Optimal HIV care and treatment for all to end the HIV epidemic in the US.

Mission: Provide leadership and resources to advance HIV care and treatment to improve health outcomes and reduce health disparities for people with HIV and affected communities.

During this session, Dr. Cheever presented updates on HRSA HAB programs, public health and policy updates, the Ryan White HIV/AIDS Program (RWHAP) 2030 vision, recent HRSA HAB funding opportunities, and 2022 data.

Beginning with HRSA HAB program updates, HAB is very excited to be planning the next National Ryan White Conference (NRWC), which is convened every other year. This year's NRWC will be a hybrid conference that will take place on August 20-23, 2024, at the Marriott Marquis in Washington, DC. Registration opened on February 14, 2024. Approximately 3,000 to 4,000 slots are available for people to attend in-person, with extensive room for people to attend virtually as well. This year, over 400 abstracts and 150 posters were submitted. About 250 abstracted sessions will be presented. Individuals interested in attending may register at: https://ryanwhiteconference.hrsa.gov/. Exhibitor registration is now open through June 14, 2024. Exhibitors may register at: https://ryanwhiteconference.hrsa.gov/. For any questions or problems registering, contact: registration@ryanwhiteconference.org. All 2024 NRWC abstracts are currently under review. Submitters will be notified if their abstract was accepted in mid-April.

HRSA HAB is also working on its Part D Communities of Practice (CoP) program part of RWHAP's Women, Infants, Children, and Youth program. Several years ago, HRSA HAB had extensive engagement with community stakeholders who were current RWHAP recipients about what could be done to increase the impact of the program. It is a small, but important, part of the RWHAP. The RWHAP recipients requested more engaged TA focused on sharing best practices across their programs in some key areas. One area of interest identified last year was pre-conception counseling. This year, a Trauma-Informed Care and Behavioral Health CoP was launched in March 2024, and it will run through February 2025.

The HAB Library[13] has been updated with a new look. The HAB Library curates RWHAP articles, including articles authored by HRSA HAB staff HAB contractors and recipients, and academic researchers. It is a great place for individuals to find specific program information and impacts.

[13] https://ryanwhite.hrsa.gov/resources/elibrary

For many years, HRSA HAB has been engaged in implementation science work. This work is focused on ensuring that evidence-informed practices reach RWHAP clinics that are relevant for their work. These practices are implementable in RWHAP clinic settings. The RWHAP Best Practices Compilation is being collated on the TargetHIV.org website and has now reached 100 interventions. What used to be scattered across targethiv.org was specifically curated to make it easy to search for key words, type of organizations, outcomes, populations of interest, specific challenges, etc. The RWHAP Best Practices Compilation is organized so people can see how they may replicate programs in their own clinics.

Quality Collaboratives is another effort that has driven major RWHAP improvements. The RWHAP Center for Quality Improvement and Innovation (CQII) ran a series of Quality Collaboratives that have resulted in significant improvements in disparities among key populations over the years. The most recent collaborative, Impact Now, enrolled 30 RWHAP providers who are experiencing challenges making improvements for some key disparities. This 18-month learning collaborative is ongoing and aims to improve health outcomes, advance local quality improvement capacities, and reduce disparities nationally.

In terms of public health and policy updates, Dr. Cheever reminded everyone about Medicaid continuous enrollment unwinding. During COVID-19, people were continuously enrolled in Medicaid. Since this continuous enrollment period ended, the Kaiser Family Foundation (KFF) estimates that more than 19 million people were disenrolled from Medicaid, which has an impact for the RWHAP. It is estimated that about two-thirds of these 19 million people were disenrolled for administrative reasons rather than because they were no longer eligible for Medicaid. CMS developed a toolkit[14] to assist states during this transition period. Within the RWHAP, people should be working closely with their Project Officers on what can be done and done differently.

Dr. Cheever presented updates on the National Syphilis and Congenital Syphilis Syndemic Federal Task Force. Given the increased syphilis rates among people with HIV, particularly gay men with HIV, Dr. Cheever considers working in STIs as essential to the RWHAP. HRSA HAB is working closely with this Task Force. Every clinical conference, has sessions that address STIs in general and typically a session completely devoted to syphilis. The RWHAP AIDS Education and Training Center (AETC) Program also educates closely on STIs in general and syphilis specifically. HRSA HAB heard in a past RWHAP Clinical Conference that some AIDS Drug Assistance Program (ADAPs) did not consider funding STI medications as part of their purview, so HRSA HAB issued a program letter encouraging ADAPs to include STI medications in their formularies. Dr. Cheever encouraged everyone to join the April 2024 HAB You Heard meeting, which focused on STIs.

The Ryan White Program 2030 is a framework focusing the RWHAP's work for the next 5 years. EHE goals can be achieved through HRSA HAB focusing on people with HIV in care improving viral suppression and decreasing disparities; people newly diagnosed with HIV linked and engaged in care; and expanding re-engagement and improving retention in care for people with HIV who are out of care.

Within the RWHAP overall, client-level data published for the first time in 2010 reported a viral suppression rate of 69.5% that varied regionally. Since that time, the RWHAP has been laser focused on viral suppression. In 2022, tremendous progress occurred thanks to the work of RWHAP clinics, with an increase in viral suppression to 89.6% among people receiving care in the RWHAP. The challenge is that the overall viral suppression rate within most jurisdictions is

[14] https://www.medicaid.gov/sites/default/files/2023-11/patient-centered-messaging-clinical-offices-hlth-care-sett.pdf

under 70%. This disparity is largely due to people who know they have HIV but are not in care. CDC performed an analysis several years ago that estimated that about 80% of new infections come from people who either are not yet diagnosed or are diagnosed but are not in care. The RWHAP must continue to engage people who are not in care, particularly those who are diagnosed and not in care. The RWHAP legislation requires community participation, including people with HIV, in the planning process for the allocation of RWHAP funds. Consideration must be given to funding the services needed to engage and re-engage people who are not currently in care and usually not included in these planning processes. Dr. Cheever invited feedback on this issue from CHAC participants.

HRSA HAB EHE work continues to be on people in care not yet virally suppressed, people newly diagnosed with HIV, and people with HIV not in care. People with HIV not in care continues to be the biggest challenge in EHE for HRSA HAB. HRSA HAB EHE funding is less than $200 million., which is a very small investment compared to overall RWHAP jurisdictional funding. HRSA HAB asked jurisdictions receiving EHE funds to focus specifically on reaching people with HIV who are out of care. EHE funds afford increased flexibility beyond the standard RWHAP service categories and eligibility requirements. Few EHE recipients used the opportunity to develop new services outside of the parameters of what is allowable within the RHWAP. However, they leveraged flexibility in forming new partnerships, showing up at places where they had not been before, and engaging people differently. Some EHE services addressed issues such as homelessness, chronic mental health issues, substance use issues, and stigma. Community engagement is crucial, and consideration must be given to leveraging communities to better hear where populations are not being reached, who need to be reached, and then leverage the RWHAP resources.

EHE data for the first 2 years[15] beginning in March 2020 (in the midst of the COVID-19 pandemic), found that, although EHE funding was considerably less relative to the total RWHAP funding, EHE jurisdictions diagnosed and connected over 22,000 individuals into care and re-engaged about 15,000 clients in care. These numbers represent more than 20% of people in EHE jurisdictions who were undiagnosed or not in care were brought into care and served by HAB EHE-funded providers. Outside of EHE, the RWHAP funding has not significantly increased since 2013. Consideration must be given to how to continue service for those people who are not currently served while engaging more people into care.

Recent HRSA HAB funding opportunities include “Supporting People with HIV as Leaders in HIV Systems of Care” with a project period of September 1, 2024 – August 31, 2028. PWH are a very important consideration for RWHAP planning and provision of care. The project’s goal is to support leadership development and enhance meaningful engagement for people with HIV in health care planning and programs. Program activities include conducting training of trainers (ToT) for people with HIV on leadership in RWHAP activities; supporting ToT trainees to help them accomplish goals related to the ToT; and developing and disseminating relevant tools and lessons learned. Program activities will be conducted in Spanish as well.

HRSA HAB is committed to streamlining eligibility. Based on consultations with recipients, HRSA HAB has heard repeatedly that sometimes recertification of eligibility for RWHAP was getting in the way of people receiving care and treatment. For instance, someone might present to a pharmacy and find that they were not eligible for their drugs and never returned. In October 2021, HRSA HAB issued Policy Clarification Notice 21-02 that changed the recertification policy to give recipients flexibility beyond the six-month period required previously. HRSA HAB

[15] Custom data analysis from the HIV/AIDS Bureau Ryan White HIV/AIDS Program Services Report, January through December 2021, and the HIV/AIDS Bureau AIDS Education and Training Center Data System, July 2020 through June 2021.

continued its work on eligibility with a Request for Information of ADAPs in April 2023 to identify their challenges with recertification and eligibility. In May and June 2023, HRSA HAB obtained insights from HAB Project Officers from site visits and efforts to implement PCN 21-02. In August 2023, HRSA HAB convened a Technical Expert Panel with a cross-section of RWHAP recipients across several states to represent different RWHAP models and experiences for Parts A-D, including the ADAP. Based on these efforts, HRSA HAB issued a Notice of Funding Opportunity (NOFO) to award one cooperative agreement for $2 million annually for a two-year project period to determine best practices and barriers in order to implement evidence-informed interventions to improve eligibility across the RWHAP. HRSA HAB is committed to improving the customer experience.

The RWHAP AIDS Education and Training Center (AETC) Program has two new FY 2024 NOFOs informed by engagement with the community, RWHAP Parts A, B, and C recipients, and AETCs on how to maximize the impact of the program. While this is a small program, it has a major impact. The 2 opportunities include: 1) FY 2024 Ryan White HIV/AIDS Program Part F Regional AETC Program that will support eight regional AETCs; and 2) FY 2024 RWHAP Part F AETC Program: National AETC Support Center (NASC) NOFO. The NASC NOFO will support AETC Program recipients and their local partners to deliver highly effective HIV training and workforce development programs and improve program coordination and outcomes. HRSA will fund one entity under this announcement.

The RWHAP Implementation for HIV Clinical Quality Improvement re-competition will continue supporting RWHAP recipients in clinical quality management and quality improvement, which has been highlighted as successful. Given the amount of staff turnover in clinical sites in particular, it is important to ensure that people understand the basics of quality management. The NOFO's goal is to provide RWHAP Parts A through D recipients with training and technical assistance to implement quality improvement methodologies.

Another exciting effort across HRSA and HHS is the "NOFO 100 Process", an initiative to make NOFOs easier to understand in order to encourage more community-based programs and others who are not sophisticated grant writers to respond to announcements. It is anticipated to result in the receipt of grant applications that are easier to review.

In terms of data updates, HRSA's Ryan White HIV/AIDS Program By the Numbers: 2022 looks somewhat similar to 2021. The RWHAP serves over 560,000 people, which is over half of all people with diagnosed HIV. About 12% of this population is temporarily or unstably housed, and almost half of RWHAP clients are ≥50 years of age. Almost 60% live below the Federal Poverty Level (FPL), nearly 90% have achieved viral suppression, and about 75% are from minority populations. This demonstrates that the program is reaching the populations that it intended to serve when the RWHAP legislation was passed.

Significant progress was made in viral suppression among priority populations from 2010 through 2023. The national viral suppression rate was 69.5% in 2010 and increased to 89.6% in 2022, which was a 20.1% increase over that timeframe. Looking across subpopulations, some of the greatest improvements were made among populations with the greatest disparities. It is possible to reduce the disparity gap. For instance, viral suppression rates among the unstably housed increased from 54.8% to 77.9%, a 23.1% improvement, higher than the national average. However, it is the subgroup with a lower rate of viral suppression. Solution for housing instability and homelessness will require a broader response among multiple departments.

Another major change is that the RWHAP client population is aging. The percentage of clients 55 years of age or older grew by 20% from 2010 through 2022. It is a huge success that people are living long, healthy lives with HIV. It also means that thought must be given to the system of care. Between 2010 and 2022, most people with HIV now need one pill one time per day and resistance issues are different. This means changing the way that care is provided. It is important to give thought to a life course of HIV. The internal HRSA HAB Aging Workgroup is thinking about this life course approach, particularly for long-term survivors.

The new RWHAP ADAP Data Infographic[16] shows for the first time that in 2021 almost 300,000 people with HIV received ADAP services. Approximately 70% of ADAP clients in 2021 were racial and ethnic minorities, 46.1% were 50 years of age or older, and were living below the FPL. ADAP assists people at slightly higher levels of income than the general RWHAP. Although 45.5% of clients received full-pay medication from ADAP, 17.2% of ADAP clients received medication co-pay and deductible assistance and 4.6% received health care coverage premium assistance. While the provision of insurance seems relatively low, that is for people who are getting insurance assistance. Many people receive multiple services. About 32.6% receive one or more ADAP services, including healthcare coverage premium assistance and co-pay and deductible assistance.

The Ryan White HIV/AIDS Program Highlights Biennial Report: 2023 was released,[17] which highlights best practices across all the RWHAP program components. The *EHE Initiative Qualitative Summary of Progress: March 2021-February 2022*[18] also was released, which provides a qualitative summary of EHE recipients' activities and accomplishments. The report is an incredibly rich qualitative analysis of all the strategies EHE recipients have used to achieve results.

In terms of the client-level HRSA HAB EHE funding, by the end of 2021, 78.6% of clients new to care and were receiving HIV treatment reached viral suppression, 21.7% were temporarily or unstably housed, and 66.9% were living at or below 100% of the FPL. The 21.7% of unstably housed is much higher than the 12% in the overall RWHAP reflects the fact that EHE recipients are reaching people they have not reached before. The proportion living below the FPL is about 7% higher than the RWHAP, reflecting once again that with limited EHE funding per jurisdiction, it is possible to reach a different group of people. AETCs are critical in terms of training health care professionals who might not be reached if not for the EHE funding.

Another impactful activity is that HRSA HAB hosted a series of EHE Intensive TA Workshops where they convened jurisdictions to develop plans of what they would do differently based upon some best practices. A couple of jurisdictions followed up days later that they began implementing their plans. Participants had a great time at the sessions because it gave them dedicated time to focus on activities that could be implemented in their programs.

CDC/HRSA Updates Q&A and Member Discussion

The following questions, observations, and suggestions were raised:

- Mr. Rodriguez expressed gratitude to Dr. Cheever for including the territories in her national snapshots, given that it provides a complete picture of how the epidemic is trending. He asked Dr. Bachmann to comment on the challenges DSTDP might encounter in trying to collect data on STDs from territories, which he asked in the context of how

[16] https://ryanwhite.hrsa.gov/resources/hivaids-bureau-infographics
[17] https://ryanwhite.hrsa.gov/data/biennial-reports
[18] https://ryanwhite.hrsa.gov/data/reports

CHAC might advocate or facilitate the creation of systems in which those data could be collected and presented and implementation and assimilation of doxy PEP as an innovative biomedical strategy to impact the STD rates in certain populations. For instance, PrEP uptake in Puerto Rico is sadly under-represented. When territory information is not presented in spaces like this, it adds to the problem.

- Dr. Bachmann responded that she did not have a great answer because it is specific to the territories. She would need to speak with the surveillance group to gain more insight to adequately respond.

- Mr. Rodriguez expressed appreciation that the CDC is willingly and intentionally creating community engagement opportunities and focused on the South based on need. The territories also are active consumers of CBAs. He asked Dr. Neblett Fanfair whether there was an interest this year in creating direct engagement opportunities for Puerto Rico and the U.S. Virgin Islands (USVI).

- Dr. Neblett Fanfair indicated that she and her team were in the USVI and Puerto Rico last year. Given some opportunities identified for increasing PrEP, the DHP team is doing a lot of work in the territories. She and her team have visited both spaces to understand the barriers and challenges and determine specifically in the capacity-building space how to support that work.

- Dr. So asked Dr. Cheever about long-term outcomes for people with sustained virologic response and whether any people are dying from HIV-related complications. He also asked about the other causes of death, and if any interventions exist to minimize long-term mortality of HIV survivors.

- Dr. Cheever responded that she did not have those data available at the meeting, but as a general comment, many deaths are from aging related comorbidities that are accelerated among patients with HIV. People with HIV get liver, heart, and kidney disease from complications of aging and some cancers sooner than people who do not have HIV and often more severely. She pointed out that people are very encouraged about new data about more aggressive use of statins to reduce risk in this population. Increase attention should be paid to weight gain and smoking, for example. The smoking rate among people with HIV is significantly high, so simply getting patients to stop smoking would make a much bigger impact than certain pharmacologic interventions.

- Dr. So asked whether gaps exist among patients with HIV who are co-infected with hepatitis C or B who do not receive adequate treatment, and whether these patients are monitored for receipt of appropriate treatment and care for chronic viral hepatis.

- Dr. Cheever said that hepatitis B treatment is more straightforward because HIV treatment is also hepatitis B treatment, and most people know that treatment cannot be stopped without risking a flare of hepatitis. Most HIV specialists and RWHAP are aware of this factor. However, compared to the national average, the RWHAP is doing much better with hepatitis B treatment. It is more complicated for hepatitis C. HRSA HAB has made hepatitis C treatment a priority in the RWHAP and considers it to be an essential part of care and treatment. Some recipients have made amazing progress. HRSA HAB has funded a series of Special Projects of National Significance initiatives to advance hepatitis C treatment and cure within the RWHAP. Specifically, hepatitis and HIV surveillance teams in jurisdictions are working to link their data, determine a list of people dually diagnosed, and where they are getting care who have not shown to be cured of hepatitis C, and reaching out to those

clinics to build capacity. While this effort continues, it is very uneven. Some places have very high cure rates. People who are not virally suppressed for their HIV are not likely to be cured for hepatis C because they are not engaged in care.

- Dr. Gupta added that HRSA funded several jurisdictions to link their data, but many states could not link their HIV and hepatitis C data to identified persons who were co-infected and then present those data to clinics to help them engage people in care. It highlights some of the surveillance infrastructure challenges, most of which pertained to viral hepatitis. It also highlights that in states with successful linkages and build a continuum of care to look at hepatitis C, about 30% of patients achieved a cure within a 1-year timeframe. A lot of work is needed to understand and link with public health departments, identify people who are co-infected and did not receive curative treatment for hepatitis C, and leverage resources within a health system to bring those curative treatments to the people who need them.

- Dr. So asked whether any mechanisms were developed to link the data. He emphasized that it is tragic for people with HIV viral suppression to die of liver cancer because they are not monitored or treated for hepatitis C.

- Dr. Gupta indicated that this is one of the core initiatives of DVH's cooperative agreement for integrated surveillance and prevention. For the first time, they are funding 59 jurisdictions for viral hepatitis surveillance. Prior to 2021, only 14 states received any federal funds for surveillance. The building blocks for surveillance are building infrastructure to get laboratories to report data to health departments. Many states still do not have a database of hepatitis C cases, so they do not know who is infected in their jurisdictions. It is a deadly disease that is curable. In order to link with HIV databases, some of this involves building a foundation of surveillance infrastructure and then linking both to HIV, other chronic disease databases, death databases, and birth certificate databases. This foundational database capacity-building has started, but it certainly is not enough to do the job that needs to be done.

- Dr. Cheever added that HRSA HAB resources are for persons with HIV, so RWHAP program funds can be used to link people co-infected with HIV and HCV to services. By statute, RWHAP providers must provide care that is consistent with HHS treatment guidelines. An initial hepatitis C antibody test at time of HIV diagnosis is standard of care. The rates of people dying of liver disease has declined in this population, but there continues to be a need to do more in this area.

- Ms. Granados expressed excitement about seeing the reduction in the gap between people who were out of care and people who are undiagnosed. Regarding Dr. Cheever's request for input about how to reach those who are out of care, she stated the importance of peer-driven interventions. She is a huge proponent of PWLE in the workforce and leadership positions; however, peers are held to organizational and clinic policies, so something is lost in terms of how people can engage. She is a member of a WhatsApp group of lifetime survivors who often are case managing each other, leveraging the experiences of those who have either worked in the field or are currently working in the field. They may not be connected to their own clinics, but it is a clear example of how people living with HIV take care of other people living with HIV. She wondered if that was a gap for people who are out of care, and if/how peer-driven interventions currently are harnessed and what might be opportunities.

- Dr. Cheever responded that having peers as part of the team in the RWHAP, which typically provides team-based care, is very important and was expanded in the EHE work. Many good examples of peer-based programs exist in the HRSA HAB Best Practices Compilation. HRSA HAB funded a peer-based leadership program, a major component entails working with RWHAP recipients to improve their ability to hire and retain peers. This component of the project did not progress as far as it could, so HRSA HAB continues to learn from evaluations and improve. Within HRSA, during COVID funding existed for peer and outreach work that differed from past federal funding. Across HRSA, work is occurring to create health care career pathways. HRSA and CDC are doing work to help advance peers and community health workers in the future.

- Dr. Dowler said the PrEP utilization data that Dr. Neblett Fanfair shared seemed very low. She was curious to know how it compared to need and of those 55,000 what percent received long-acting injectables versus oral PrEP. While in some state statutes communicable disease is a public health department responsibility, many public health departments do not offer PrEP as part of their package of services. She wondered if there were federal levers that could be used to compel health departments that are receiving STI funding to provide PrEP services.

- Dr. Neblett Fanfair replied that remarkable progress has been made with PrEP to need, with about 36% of people with an indication for PrEP having a prescription. However, vast disparities remain. It is very important to increase PrEP in certain spaces and jurisdictions in the South, territories, and among certain communities. She said she will check with the team about the breakdown between long-acting injectable versus oral PrEP. Based on the work they are doing in the community, long-acting injectables for PrEP started in certain spaces in terms of building capacity around staffing. She clarified that some of the data she showed was part of Component C in EHE directly funded STI clinics to support PrEP work. STD will have its own NOFO to support PrEP in STI clinics. The DVH supports the work through research, implementation science, and program capacity-building in health departments, STI clinics, community-based organizations (CBOs), and spaces that are not HIV- and STI-specific (e.g., OB/GYN clinics, family planning clinics, gender-affirming care clinics, etc.).

- Dr. Markham congratulated Dr. Ethier on DASH 2.0. Given that the 2021 YRBS data on AI/AN youth showed challenges, she is looking forward to seeing the 2023 data. She emphasized that the YRBS surveillance tool is important nationally, but an increasing number of states opted out in 2023 for various reasons. She wondered if Dr. Ethier could comment on any perceived challenges for the next funding cycle for the 2025 YRBS and how CHAC and everyone could support making sure that survey continues and is nationally representative.

- Dr. Ethier expressed appreciation for everyone’s continued support of the YRBS. The local surveys will depend because they are tied to programmatic work. The applications were received, but DASH had not yet received them. Based on the letters of intent (LOIs), for a few places that declined to collect 2023 data, a different organization from the state submitted an LOI. Overall, they received many fewer applications across the board for the components of the NOFO than anticipated. She did not know yet whether it was from a programmatic or surveillance standpoint. DASH’s goal for any state that opts out is to maintain a positive relationship with the state officials who have traditionally collected the data (and therefore could again). They have to determine a strategy to offer funding to them over time. Their goal is to encourage any state that opts out to come back in, and for

any place that has not traditionally collected data (e.g., Washington and Minnesota) to come in. From the LOI, they believe both will come in this year. People often do not know or understand that because of the complexity of the YRBS. The state, local, and national surveys are separate and distinct, which allows for a nationally representative sample that is separate from whether any state decides to participate. The only caveat to that is that if a state passes a law that says no high school in the state could collect federal data, they could not collect data in that state. Currently, no states have that law in place, so DASH can include schools from every state in the sampling frame. Anecdotally, DASH saw an increase in schools opting out. Based on the 2023 data, that does not appear to have impacted the size of the sample. The 2023 data will be released in August and will go through the end of September, with the data publicly available in September.

- Dr. Dionne noted that, looking at the 2022 STI surveillance data, it was encouraging to see the decline in gonorrhea data and flatline in chlamydia not returning to prior rates. Syphilis was the outlier. She asked Dr. Bachmann to speak more about what is driving that trend, such as providers not performing a repeat test at 24 weeks, the syndemic nature of the drug use, etc.

- Dr. Bachmann responded that they are monitoring the gonorrhea trends carefully to determine whether it is a trend. Related to syphilis, the surveillance data have revealed a lot of information about missed opportunities and the multiple ways that it needs to be approached. For instance, 40% of congenital syphilis cases in 2022 occurred with a pregnant person who never received prenatal care. Testing and treatment cannot be done in a timely manner if people are unable to interface with and engage in prenatal care. More innovative approaches are needed for testing and treatment outreach outside of the clinical setting. Most STIs are diagnosed outside of STI clinics. A fair number of individuals had interfaced in some medical setting, such as the ED or urgent care, spaces where screening is not conducted historically. About 50% of those who received testing in a timely manner were not treated in a timely manner. This involves a variety of issues such as the patient being unable to follow-up and the provider not acting quickly enough or giving adequate therapy according to guidelines. It is unclear which or in what combination, but it points to the need for provider training, education, the ability to recognize syphilis when it does present with signs, and the need to act quickly. A variety of factors differ by area of the country and race/ethnicity. The federal government cannot conquer this alone. Many partners are needed, including at the local level because the jurisdictions understand the nature of epidemics and challenges their constituents are facing.

- Dr. Arrington Sanders said she was hoping to see an update on sexual and HIV education in the country and where that is headed. While 38 states and the District of Columbia (DC) mandate sex and HIV education, there is a lot of variation across those states about the content of the education and whether it is appropriate and reflective of the evidence. She asked Dr. Ethier to say more about how evidence-based sexual education and HIV education could be mandated in schools. If sexual and HIV education is not provided to youth and communities, it is not possible to prevent HIV and achieve EHE.

- Dr. Ethier responded that DASH has been working for a long time in this area. During the pandemic, they saw many places with health and sex education requirements in their districts let those requirements go because of virtual learning and the need to focus on core subjects. In the small number of districts that they fund, they are trying to get those programs back up and running. Mandates are not a role within the purview of DASH, so they are unable to create a lot of movement on mandates. However, they have plans to provide TA across the country and a number of other tools, such as the Health Education

Curriculum Analysis Tool (HECAT), that support districts in selecting curriculum that are of high quality, inclusive, and effective. It continues to be DASH's goal. In addition to providing TA, DASH also can continue to ensure that schools are doing other things that are known to support sexual health, such as making sure good systems exist to get young people to the sexual healthcare they need and to provide safe and supportive school environments, particularly for LGTBQ youth.

- Regarding the YRBS data, Dr. Arrington Sanders observed that 19 states include questions on sexual orientation and gender identity, which means that many states do not. She asked Dr. Ethier to speak to that and how it is rectified, given that these students are particularly marginalized and experience the greatest risk for HIV, mental health issues, STIs, etc.

- Dr. Ethier responded that at a national level, DASH added the same transgender identity question used at the state and local levels to the national survey. It is beneficial in terms of looking at that interaction. They will release the first nationally representative data on transgender youth when the 2023 data are released. She did not yet know how many states had opted out of including the transgender identity question, or if any additional states declined to answer the sexual orientation and gender identity (SOGI) questions. By allowing states and locals to choose the questions they want to include but encouraging them to add the SOGI questions, a larger number of states stay in the survey than when that is mandated. Continuing to allow that flexibility is likely to keep states in the system, which is the goal. DASH can only do so much to encourage people to stay in the system and collect the data. Preserving the national focus helps.

- Ms. Beiser noted that Massachusetts had enhanced surveillance for viral hepatitis for an extended time, which made a difference. She emphasized that standardization of cascades of care is also very important. As it expands around the country, she asked Dr. Gupta about whether holding states to those standards of care is part of the expectation. In addition, she asked whether there are plans to engage Bureaus of Substance Use Services to expand the reach around viral hepatitis to the substance use community.

- Dr. Gupta responded that, regarding cascades of care, they created standardized guidance so that states can compare apples-to-apples. The biggest challenge is having the data. Even with the cascade of care, it is necessary to know who is infected and who is cured. These two basic ingredients do not exist in most states in the U.S. More than half of the states are still building longitudinal databases, so it is the hard daily work of surveillance capacity-building. Many states do not have negative RNAs reported to them, so they do not know who is cured even if they know who is infected. Nothing can be done until these major hurdles are addressed, which should be possible for a condition that is deadly. In the meantime, DVH is supporting states with national data. State-level cascades are being created using commercial laboratory testing, which gives states something they can act on to inform public health interventions while they build capacity for their own data. They also work with substance and mental health agencies at the federal level. Part of DVH's funding is to support state and local elimination plans, and states and local health departments are working with substance and mental health partners.

Panel 1: Syndemic Approach to Testing

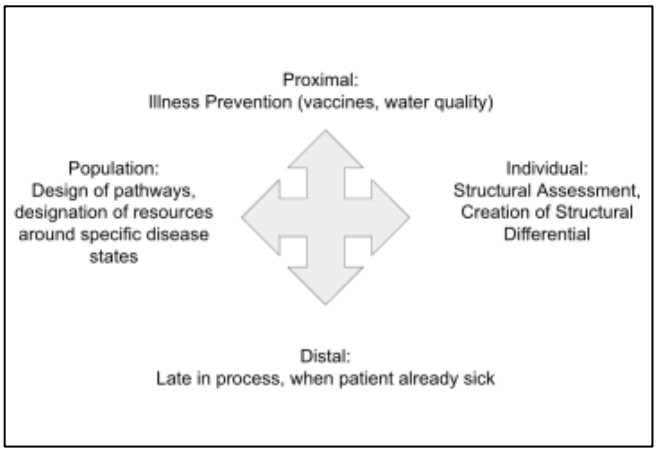
Moderator: Michelle Van Handel, MPH; Associate Director, Program and Performance Improvement Office, NCHHSTP, CDC

Syndemic Descriptions and Syndemic Interventions

Jason W. Wilson, MD, PhD, CPE, FACEP
Chief of Emergency Medicine
University of South Florida/Tampa General Hospital

Dr. Wilson said he was going to tell a syndemic story that had to do with testing and the growth of University of South Florida/Tampa General Hospital testing program over time, which had moved past the walls of the ED as they recognized that they had a responsibility to go where their patients were going and recognize that they were not going to go where they were told to go. Most EDs across the US are crowded due mostly to an ongoing capacity boarding crisis, given that many inpatients stay in the ED even more so than people entering through the front doors. An inpatient boarding crisis exists. In this context, sorting out how to determine the best testing strategy is a mess without spending some time thinking about it. Over time, the University of South Florida/Tampa General Hospital has spent time thinking about it and has recognized some clear patterns in how their patients seek care, what type of care they are seeking, what type of testing should be delivered, and what type of interventions should be provided.

What they have tried to understand from the syndemic approach and a space like an ED or a space expanding the walls of the ED out to an SSP or an office-based buprenorphine program, is how to make sense of intervening with patients at the bedside, structurally, and at a population level as illustrated in this diagram of loci of potential structural interventions:[19]



The idea is to build programs that do not provide an opportunity to engage the patient at the bedside, but also build programs throughout the entire healthcare system that can engage the patient no matter where they are in their journey of either opioid use disorder (OUD), HIV, or hepatitis C.

[19] Loci of potential structural interventions. Adopted from Farmer et al., 2006.

The traditional syndemic model includes multiple diseases at the same time, as well as the cultural aspect. The cultural aspect explains the variation of where patients seek care and where care also should be delivered. Structural vulnerability sets patients up to be vulnerable to the syndemic of hepatitis C and OUD, HIV, and hepatitis C co-occurring disease, or even syphilis and HIV co-occurring disease. The University of South Florida/Tampa General Hospital has done a lot of work to implement the Structural Vulnerability Assessment Tool developed by Bourgois and colleagues into the ED. When people have high-risk scores, they also may have higher vulnerability to hepatitis C and OUD, and also may require differences in the way their care is delivered. They are determining how to move qualitative tools like this into the same rigor as medical science in which a numeric score could be determined, people could be risk-stratified, and systems of care could be designed around those scores and designs.

Dr. Wilson began doing ED-based HIV testing in 2016, which came out of a journey that began in 2006 with the CDC Guidelines when he was in training. Some starts and stops occurred along the way and some oral swab-based testing occurred with a third-party health department, but not a lot of uptick. When they moved to 4th generation serum-based screening in 2016, there was a large increase in the hepatitis C and HIV testing program. When they began HIV testing, they quickly learned that it was easy to do HIV testing and link people to care because there were structural systems in place at this time. He did not have much interest in hepatitis C at the time they started this program. Ironically, his interest now is in hepatitis C and designing intervention strategies for patients who have both OUD and hepatitis C. Over time, they recognized that there was a big hepatitis C problem, and the major issue was that those patients were not linked to care. They now think about how to deliver the same types of alternative treatment delivery systems for HIV patients. Patients will present to the ED but will not go anywhere else, so consideration must be given to ways to capture that population and perhaps deliver treatment in the ED space.

In terms of taking a syndemic approach to hepatitis C, they first recognized that an OUD took place, most patients screen positive for opioid use, and patients were most interested in stopping opioid use or how to use them safely. To address both populations, they started by co-locating a system in which they initiated buprenorphine in the ED for OUD patients who may or may not have hepatitis C, but 80% do, and got that program working very well. They had a warm handoff for those patients who were linked to care. When it was stable after about a year, they began following those patients over time. They trained a group of Nurse Practitioners (NPs) at a Federally-Qualified Health Center (FQHC) where they were going, which was onsite at the CBO for the substance use disorder (SUD) center, to deliver buprenorphine simultaneously with direct acting antivirals (DAA). It was the strategy for people who wanted to stop using drugs, who were ready to engage in buprenorphine, but who did not necessarily care about their hepatitis C.

Dr. Wilson shared a conversation he had during some ethnographic work they have done around their HIV program. The structure that has to be changed involves patient structure, provider structure, and healthcare delivery system structure. In 2016, they really were changing something that took decades of engrained practice to move the needle. His group now has a great screening and linkage program for people who can go to a clinic between 9 am and 5 pm. Other patients engage them at 3 am in the ED space, so consideration must be given to what can be done about that patient moving forward. The ethnographic work helps to understand how to build systems of care. If syndemic interventions are going to be implemented, it is important to look at ethnography because it will look different in every place. The difference in how the syndemic of syphilis fits into HIV and hepatitis C looks different than the way that OUD fits into the exact co-located set of diseases.

Regarding the demographic characteristics of the first group of ED medicated OUD (MOUD) patients who had hepatitis C and OUD, were ready to stop using drugs, went to a linked CBO SUD treatment facility for outpatient therapy where the NPs and Physicians Assistants (PAs) were trained to deliver buprenorphine and DAA at the same time, sustained virologic response (SVR) was reached for a lot of those patients. That is wonderful, but they also wanted to engage the patient who is not ready to stop using drugs. In 2021, they became the second legal state SSP program in Florida, IDEA Exchange Tampa. Their team of anthropologists created a hepatitis C brochure to ensure that it was appropriate for patients and that they could understand the information being delivered. This brochure sits at the sites, where they do about 150 HIV and 150 hepatitis C tests a month at the IDEA Exchange Tampa. They do about 1,000 HIV and hepatitis C tests a month in the ED. Once someone tests positive for hepatitis C, Dr. Wilson prescribes hepatitis C drugs, the blood draws are all done right there, there are no barriers pertaining to whether someone is still using injection drugs, they use a lot of patient assistance plans, and they are successful at getting people on these drugs. Among people who inject drugs (PWID), they are still achieving SVRs. On site, there is insurance navigation, Feeding Tampa Bay (FTB), and other resources. Baseline hepatitis C linkage rates are approximately 30%. Getting people onto the MOUD pathway has moved to about 65% in the office-based setting. People on the MOUD/SSP pathway moved to approximately 75%.

In conclusion, syndemic descriptions can guide syndemic interventions. Social scientists will have to embrace the complexity of modern healthcare delivery, which is not just patient-physician relationships. Social scientists can render visibility to previously unseen patient populations. Structural competency is a route for formally considering interventions and education around social determinants of health (SDOH). Other syndemic interventions should be tested. Syndemic biomarkers could also be tested to integrate clinical prediction/outcomes. Structural approaches to payment and reimbursement will be important for scale up.

Engaging Community in Syndemic Screening and Testing in Tennessee

Amber Coyne, MPH
Syndemic Coordination Director
Tennessee Department of Health

Ms. Coyne discussed identifying the syndemic in Tennessee, community engagement, syndemic needs assessment, and data-to-action. Tennessee decided to take a syndemic approach because of a federal vulnerability assessment that the CDC conducted. At the time, the Viral Hepatitis Program Director and HIV Program Director looked at local indicators and performed their own statewide vulnerability assessment, which showed very widespread vulnerability to an HIV and hepatitis C outbreak among PWID. At that time, the decision was made to take a different approach.

They found that many people in Tennessee who were disproportionately impacted by HIV also were disproportionately impacted by STIs (e.g., chlamydia, gonorrhea, and syphilis), viral hepatitis (A, B, and C), and SUDs, and that these epidemics had similar social drivers of health. That led Tennessee to recognize that the epidemics were not separate, but instead were overlapping epidemics that fueled each other, or a syndemic. In addition to the vulnerability assessment, they also wanted to understand the current impact of the syndemic in Tennessee. They looked at the counties that fell into the top 15 for rates of chlamydia, gonorrhea, HIV, fatal and non-fatal overdose, syphilis, and viral hepatitis A, B, and C. The large impact in Tennessee was concentrated in metropolitan areas and the rural counties in the Eastern and Western areas of the state.

This inspired them to take a strategic approach to planning and implementation. This process began in 2019 when the internal Ending the Syndemic Tennessee (ETS) Workgroup was formed. This workgroup is comprised of program directors, epidemiologists, and key programmatic staff across HIV, viral hepatitis, STI programs, the 2 offices with the department of health that oversee injury prevention funds as they relate to overdose prevention, and partners at the Tennessee Department of Mental Health and Substance Abuse Services (TDMHSAS). The workgroup came together as a leadership team to discuss what this new approach may look like, and then turned that internal engagement external in January 2020 and began recruiting PLWE, subject matter experts (SMEs), representatives from CBOs, academics, etc. to Regional Planning Groups. Presently, there are over 407 people engaged in this process who represent 200 unique programs and organizations. Regional planning meetings were kicked off in October 2020. Originally, these were intended to be in-person meetings conducted across the state. Due to COVID, they pivoted and took a virtual approach. Midway through the regional process, they launched a demographic survey in April 2021 to take stock of who was engaged in the planning process. From there, more focused recruitment was done to recruit some of the individuals they felt were not adequately represented at the planning table. Additionally, they focused on some of those gaps for the syndemic needs assessment qualitative effort in June 2022. Everything learned from this process informed the drafting of the strategic plan in October 2022.

In total, 80 regional planning meetings were held across Tennessee. In 2021 alone, 233 unique participants were engaged who represented 133 programs/organizations. This included service providers, educators, researchers, funders, advocates, local health department staff, and PWLE across the syndemic conditions. They felt that this approach spurred natural connections across CBOs and sectors. As one of the planning members living with HIV said, “I finally have a voice . . . it’s been wonderful with many different aspects covered from many different voices.”

Formerly, a statewide HIV needs assessment had been done. This was the first time that the Tennessee Department of Health (TDH) wanted to take a syndemic approach to that needs assessment. They wanted to use a mixed-methods approach, so they used a survey that was conducted largely online but also included in-person surveys, focus groups, and in-depth interviews. The focus groups and in-depth interviews were largely informed by what was learned in the demographic survey. Data collection for the statewide needs assessment survey took place between June and August 2022. The survey was online and was offered in English and Spanish. An option existed to call for those who did not feel comfortable taking an online survey. The in-person surveying was done in partnership with CBOs and SSPs to meet folks who were unhoused and currently using drugs to make sure that their voices were captured. Overall, 848 consumers completed the survey. Focused recruitment materials were provided for various priority populations. The survey asked questions about the following syndemic services, additional services, and support services:

<u>Syndemic Services</u>
- HIV testing
- HIV PrEP & PEP
- STI testing & treatment
- HCV testing & treatment
- HBV testing & treatment
- HAV & HBV vaccination
- Harm reduction services
- SUD treatment & recovery services

Note: HIV care services were included in the survey but was its own section of questions for those who indicated they were a person living with HIV.

Additional Services

- Telehealth
- Mail-ordered services

Support Services Known to be Critical to Engaging and Sustaining People in Care

- Case management/navigation
- Prescription assistance
- Help obtaining health insurance
- Dental & eye care
- Language services
- Job readiness services
- Financial literacy services
- Legal services
- Childcare
- Food assistance
- Transportation
- Housing assistance

When answering questions, clients were asked whether they needed and received the service, needed the service and did not receive the service, or did not need that particular service. Anytime a client selected “Needed Service & Not Received” there was a follow-up question about their barriers to receiving that service. The most needed services included all of the testing services (STI, HCV, HIV), with about 5% or less of folks responding that they were unable to get the service that they needed. Less people overall indicated that they needed HIV PrEP, but 34% of those who needed that service were unable to receive that service. For those who indicated that they needed and did not receive services, there were follow-up questions. This was fairly common among all of the testing services, with key barriers including: did not know where to get services, unreliable transportation, and concerns related to costs.

Because the TDH was beginning to think about mail-order services, they asked questions about this type of service. Self-testing was fairly popular, with 56% to 50% of respondents indicating that they would be interested in receiving self-testing kits for HIV, STI, and HCV. There was even greater interest in mail-order services among priority populations. Among those who identified as PWUD, 72% indicated being interested in self-testing for STIs, 68% for HIV and 68% for HCV. Among respondents who identified as LGBQ, there was an elevated interest in self-testing for HIV, STI, and HCV. There also was elevated interest among respondents who identified as transgender or non-binary. The starkest elevated interest was among rural respondents, with 82% saying they would be interested in HIV self-testing, 84% would be interested in self-testing for STIs, and 85% would be interested in self-testing for HCV. As a female living in a rural area said in the qualitative efforts, “That would be great to be able to mail-order test. That way, they could just do it in their home privately. Like we were able to go online and order those COVID tests to have them at home. Nobody knew that but who we ordered them from.”

In terms of putting to action what was learned on the 80 planning meetings and the surveys, the TDH first established a Syndemic Coordination Program that sits within the HIV/STI/Viral Hepatitis Section at the TDH. This is a small but mighty team of 4 that includes a Syndemic Coordination Director, Director of Harm Reduction Initiatives, Syndemic Special Projects Coordinator, and Syndemic Screening and Testing Coordinator. Hiring the Syndemic Screening and Testing Coordinator was one of the first actions taken after reviewing what was learned from the syndemic needs assessment. They wanted a dedicated staff member to spearhead the implementation of an integrated mail-based testing program that includes HIV, hepatitis C, chlamydia, gonorrhea, and syphilis. Because of the strong partnerships formed during the ETS planning process, their partners at the TDMHSAS said they wanted to contribute in-kind naloxone, fentanyl test strips, and xylazine test strips so that this would be a holistic approach.

In Tennessee, there are 2 options for identifying and selecting a vendor to deliver these services on behalf of TDK. The first is a sole source for when there is only a single vendor in the market that is able to provide the necessary services. In order to initiate a sole source contract, a justification and research must be provided to substantiate that there is only a single source on the market that can provide said services. Additionally, sole source contracts are subject to review by the fiscal review committee if the contract is going to be over $250,000 or the contract will be over 1 year. The second option is a competitive bid process, which requires drafting and posting a Request for Proposals (RFP) to solicit applications. The applications are then reviewed and scored by a selected team of 3 to 5 individuals and a recommendation is made. That recommendation is then submitted to central procurement, which reviews the information and makes the final determination. To better inform this process at the state level, a Request for Information (RFI) can be posted. Specific questions of interest may be asked and responses from the RFI can help to make a case for a sole source or help create a smart request for grant proposals in order to end up with a desired vendor. They posted an RFI that asked 23 questions, which helped them learn a lot about the market. Coincidentally, NACCHO has done something similar with an STI Mail-Order Test Repository and made it public.

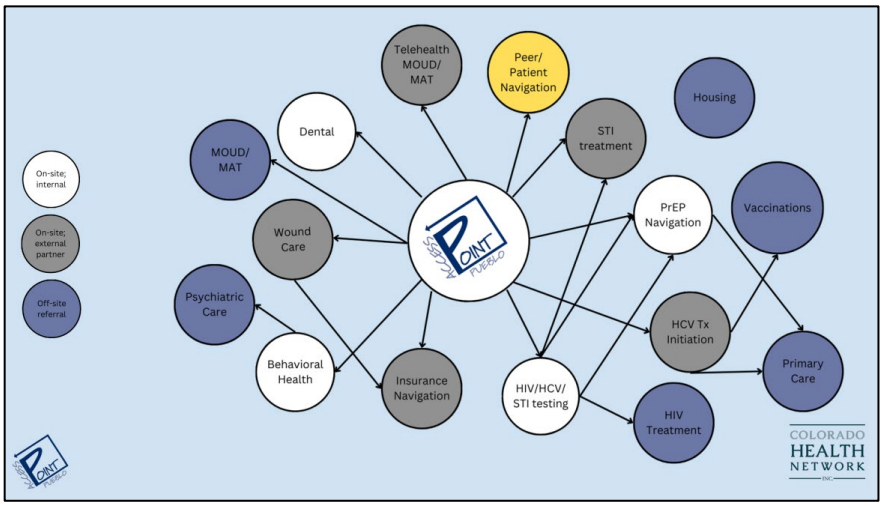
The next steps are to use the RFI responses to create a specific RFP that outlines all of the required services. They are identifying SMEs across the HIV/STI/Viral Hepatitis section to serve on the RFP review process. They are also creating a linkage-to-care workgroup to establish protocols for ensuring clients are linked to prevention and treatment services across the syndemic.

Current Lessons Learned in Taking A Syndemic Approach to HCV Testing and Treatment: Using a Drug User Health Hub Model

Sarah Money, MPH
Health Hub Program Manager
Access Point Pueblo
Colorado Health Network

Ms. Money explained that Access Point Pueblo is the name of the SSP under the Colorado Health Network (CHN), which is a statewide AIDS service organization founded in 1983. Access Point Pueblo serves over 3,500 unique participants annually. They have over 12,000 visits and have had over 2,000 overdose reversals reported since 2018, with a record year in 2021 with 515 overdose reversals reported. In the past few years, they have been working hard to expand their linkage to care capacity, first through Overdose Data to Action (OD2A) and now through the Drug User Health Hub and braiding together some opioid settlement funding.

To provide an idea of program flow, Ms. Money works onsite at a SSP that is open for 13 hours per week. This includes evening hours and mobile services to expand accessibility. The Drug User Health Hub Team with whom she works is focused on linkage to care for people who present for syringe access. They are present outdoors every day and try to be the first point of engagement when people are coming to the SSP. They make sure that everyone is aware of all services that this office provides on their initial visits. Reminders are provided with annual updates, handouts, and sandwich board updates. The key factor in increasing linkage to care and supporting folks is building familiarity and rapport, which they have done with staff and bringing in Peer Navigators (PNs). To better understand the network, Ms. Money created the following graphic:



The white circles represent services that are provided onsite through CHN at Access Point Pueblo, including PrEP navigation, SSP services, HIV/HCV/STI testing, behavioral health, and dental. The gray circles represent services that are provided by external providers on site with Access Point Colorado on a limited basis. This includes HCV treatment initiations, insurance navigation, wound care, telehealth MOUD/MAT, and STI treatment. The blue circles refer to linkage to care with offsite referrals, including housing, vaccinations, primary care, HIV treatment, psychiatric care, MOUD/MAT treatment. The yellow circle represents peer and patient navigation. They try to encourage people to work with a peer specialist, whether it is one who works with Access Point Pueblo or another one in the community. One of the special things about Pueblo, Colorado is the very strong network of peer support specialists. Many agencies have peers, some of whom are based in EDs and others who travel alongside the paramedics and fire departments to respond to overdose calls. If someone wants to work with a peer, Access Point Pueblo will work hard to find them the right peer.

In terms of working with community providers, last year a needs assessment was done with 25 participants and 100% of respondents mentioned that transportation is a barrier to accessing services. The 2 other barriers most often cited were untreated mental illness and provider stigma. Access Point Pueblo is working to address this is with telehealth and creating a one-stop-shop and hub and spoke model to provide as many services as possible on-site. For about 2.5 hours each week during syringe access, they work with a residency clinic in Southern Colorado. Medical residents are eager to learn, non-judgmental, and are champions of services. The clinic first started initially as just wound care. Since this clinic started, the medical residents have been championing and are now providing onsite STI treatment, initiating HCV treatment, and are working toward a pilot to prescribe buprenorphine. Some of the providers with whom they have had conversations are hesitant, but the medical residents are eager to

learn and recognize that working outside in a non-clinical setting like this with a population that is very disengaged from the healthcare system is very important as far as their future work, especially if they are staying in the community or working in another community where there is a larger population of PWUD. Working with the medical residents has been special to watch. People who have not engaged in healthcare for 4 or more years suddenly are getting engaged. Peer and patient support are always offered, and they like to check in with clients after they have met with their provider to make sure that they are receiving good services and that providers are culturally competent. Patients are returning on a weekly basis and treating the Access Point Pueblo site as their primary care provider, so they are working with their residents to explore this in the future.

According to the *Viral Hepatitis Surveillance in Colorado, 2021 Annual Report*, the increasing diagnoses of chronic HCV in young people mirrors the opioid epidemic trends in Colorado. Ms. Money noted that Pueblo County is the only county within the region with SSPs, and one county on the Eastern border is also one of the top 220 identified counties vulnerable for an HIV outbreak. They see chronic HCV and overdose rates impact the same population disproportionately of men 25 to 34 years of age. With some braided funding streams, Access Point Pueblo is working to expand into the Southeast, which is very rural and not particularly harm reduction friendly. For example, they were told a provider in the Southeast does not test pregnant persons for syphilis because “their girls aren’t dirty.”

Looking at a cascade of care for October 1, 2022 through February 29, 2024 that is specific to PWUD presenting onsite to Access Point Pueblo for SSPs, of those who were tested for HCV, there were 5 reactive results. Ms. Money emphasized how hard she and her staff work to keep people engaged and not lose them along the process. The key component of that is peer support. They now have 1 person who has completed treatment and should have labs drawn soon and another person who started treatment and possibly completed but is currently incarcerated. They are trying to coordinate with that individual’s provider and the nurse in the jail to find out whether there is any opportunity to obtain a blood draw for this person so that when they are released, they have 2 things in their pocket—not using substance and cured of hepatitis C. It takes dedicated support to keep people on this continuum to make sure that they achieve SVR.

To highlight additional referrals during that same timeframe, 6 people were successfully linked and engaged in MAT/MOUD, 10 people received onsite STI treatment (chlamydia, gonorrhea, syphilis), 16 people with bacterial or fungal infections were treated onsite by residents, 6 people were linked to primary care, 5 people are receiving ongoing behavioral health, and 3 have received dental care. Behavioral health is a new component that launched in January 2024. Since then, 150 people have made initial contact and 5 people are continuing. Among the 3 dental patients, 1 initiated hepatitis C treatment the same day and then received dental care. All of the other barriers that people experience in connecting to treatment and care and what they do to support that include activities such as identification, Medicaid enrollment, transportation, self-efficacy and working with individuals to help them understand that they have rights when they go to a doctor and are allowed to express those in a safe way.

In terms of major takeaways, Access Point Pueblo has learned is that co-location of services is ideal, critical, and highly effective in facilitating culturally competent linkage to care. They have experienced huge success with services being located onsite and people connection. There are perceived and real barriers to linkage to care that require dedicated support to facilitate linkage to care, such as identification, patient finances, and the perceived barriers and actions they are taking to build support. Building self-efficacy is important because stigma from providers seems to be the most consistent barrier people are expressing. The way that Access Point Pueblo works with people is to engage them with their primary need first. As mentioned earlier, MAT might be the first need followed by hepatitis C or vice versa. As a result, they are working at a client's pace and following their lead, which ensures a higher chance of success with treatment. Frontline staff capacity is a challenge, in particular due to the complexity of the participants and patients they are serving. Onsite, Access Point Pueblo has 2.5 staff dedicated to this. They work with people as best they can and try to tap into other resources in the community, such as peer support specialists, case managers, and patient navigators. Again, they see that people are most likely to engage in services that are provided directly onsite with warm hand-offs and supporting cultural competency of the services provided.

Panel 1: Q&A with Speakers and Member Discussion

To focus the discussion, Dr. Armstrong reminded CHAC members of the advice related to this topic that was requested from CDC/HRSA and asked them to be thinking about action items CHAC might address and vote on later in the business section related to these questions:

1. What role does CDC/HRSA have in expanding screening in non-public health clinical settings?
2. What other effective models can CDC/HRSA consider?
3. How can CDC/HRSA fill research gaps to better model effectiveness or scalability?
4. What recommendations can CDC/HRSA make to programs thinking about scaling up these types of services in similar settings?

The following questions, observations, and suggestions were raised:

- Dr. Dowler noted that when looking at syphilis and congenital syphilis, they are seeing that EDs and urgent care facilities are not doing the testing. That was her experience when she worked in a health system. It takes time to get the results and syphilis results are never easy if they are positive, which always requires a confirmatory test and interaction with the health department, a disease intervention specialist, and looking at 20 years of history. Because it is never an easy clinical visit, it is logical why that does not fit into an urgent care or ED paradigm. Having said that, there are literally over 600 health systems in the country, many of which are now creating urgent care environments and a standard in which STI testing is not allowed. Therefore, it is not part of the order sets because of this challenge. She asked Dr. Wilson's thoughts on the levers that would help health systems invest in having clinical pharmacists or others manage the results, knowing that it is not appropriate for the ED doctor who is not even at the hospital anymore when the results come in.

- Dr. Wilson responded that a major difference in the mission and role of urgent care versus the mission and role of the ED. Emergency medicine physicians and EDs all recognize that there is a safety net role, public health infrastructure role, and federal law that drive the mission differently. For better or worse, urgent care facilities provide a way for people to gain entry into new healthcare systems for big hospital systems. The mission in those settings is to drive people into primary care, orthopedic care, etc. That is a bigger lift. Separating those 2 out first and then concentrating on emergency medicine where other

programs like this have been done before may be the first step. Along with that step, emergency medicine doctors may presume that OB doctors will do the syphilis screening. Linkage to care also is important. The HIV program was so successful because they had linkage built into it on the back end. The way in which the linkage is scaled up will be very important, especially for multi-level testing.

- Dr. Mermin noted that the work the TDH is doing is impressive. At the same time, a unique situation is occurring in Tennessee. He asked Ms. Coyle whether they have been able to link some of their programs supported by the state government with the CBOs that are supported through CDC HIV resources.

- Ms. Coyle responded that there is a unique situation in Tennessee and the silver lining is that they were allocated state dollars and CDC still graciously funded CBOs. The challenge is not repeating the work of others, so they must work in synch with one another. They have only had 6 months to figure this out, so they are still navigating that. They certainly are still partnering with United Way and the CBOs that they fund and the CBOs TDH funds. A lot of communication occurs across levels in ways that they have not had to communicate before, because there are now so many key players. It is a challenging environment, and they are basically "building the plane while flying it."

- Dr. Mermin thanked Dr. Wilson for his mixed-methods presentation and emphasized that it was see data on how things were progressing over time. He was particularly interested in how Dr. Wilson was able to get people access to HCV treatment, and how they overcame what are essentially fatal paperwork obstacles for many others.

- Dr. Wilson said it is basically a resilience of paperwork. They learned a little in the office-based setting where there were people who were experienced in addressing insurance denials. They learned about website-based programs to get patients into access plans, which insurance companies might be easier to work with, which drug companies might be easier to work with, etc. Then they set up a workflow. His team keeps a list of letters that he has signed for the various denials. The denials are very common. The letters almost always work. They do a lot with the SSP, including anonymous work there because for buy-in, participants must move from anonymous to confidential to have laboratory tests, prescriptions, etc. Most are great at this point at moving through that because they have already had a confirmatory test. During the laboratory testing, they begin to gather the information they know will be needed for the marathon of paperwork.

- Dr. Greene said she was struck by the comments about the medical residents and how gung-ho they are. Regarding scaling up programs like this, she asked what could be done to help overcome the workforce challenges and a lot of the stigma seen amongst healthcare providers.

- Ms. Money said that one of the biggest challenges they have is the availability of other services. If they had a clinician onsite working with them, they could instantly bring someone to treatment. Having more peer specialists is the direction harm reduction needs to go, especially PWLE with hepatitis C and HIV, not just SUD. When many people are thinking about harm reduction, that is where their minds go, but it needs to be all. They have learned over the last year and a half that activities will look different based the community. She lives in Pueblo where there are 116,000 people in the city limits. It is a small community and there are 2 large SUDs and only 12 inpatient beds, so the work they do has to be very creative. It means working with residents because the attendants do not have time. It means working with telehealth options for HCV treatment and being creative to get around that. Trying to get around that as harm reductionists, they often find that they do not have the right language, sphere of influence, etc. Having more clinical support is key. Additional support behind training for harm reduction programs and clinicians across communities and service providers would be her best answer for those.

- Dr. Wilson added that he has been training residents for a long time and has learned that if they come into a reality and the reality stays that way, they will leave and perpetuate that reality. If they come into a reality and see a shift, they will be change agents. If they come into a reality that is a new way, but they do not know it was different before, they will adopt the new way as well. They have been operating this type of program for 8 or 9 years. Multiple residents have gone on to start programs like this in other places, which is huge. They basically guide horizontal position behavior. Their position is that attendings must do this and it must be routine for them. These are not money-making endeavors. A lot of this is not a clinically reimbursable activity. They recognize this and have to be able to carve out ways that residents themselves can participate.

- Dr. Armstrong asked whether Dr. Wilson saw a pathway forward in which programs like his would not require grant funding and what types of policy changes would be needed for these to be sustainable within a health system, given that it is unlikely that grant funding could be scaled across the country.

- Dr. Wilson noted that a lot of variations exist across states with Medicaid and across local entities in terms of the types of healthcare plans, neither of which would change the direction of a strategy for healthcare systems. Their current thinking if they could cross-subsidize some by other efforts such as through the building of a toxicology fellowship and an addiction medicine program overall to move it from being grant-funded to at least covering salaries for people to do the work. Where care is provided is also very important. Providing services with chairs and tents outside is not sustainable. They do not perform STI testing right now because they do not have a bathroom. Their healthcare system is supportive and provided gave them clinic space to use the same day as the mobile clinic is in the parking lot of the hospital's indigenous care clinic. While that is a major step, the grant funding is so complicated that people with certain types of funding will lose that grant support if they walk through the doors of that clinic. There are barriers that they cannot get around. He has a private bathroom in an air-conditioned space where he could expand services for those patients, but he cannot use it. He is passionate about this and does not mind sitting in a tent under a tree, but to expand and scale this to physicians doing normal practice and patients, there should be some normality about how they are approaching this type of care that also will decrease stigma for providers and patients as well.

- Dr. Arrington Sanders indicated that Philadelphia has had a needle exchange program for 30 years, which is at risk of being taken away because of a Mayoral opinion despite evidence demonstrating that it is cost-effective, saves lives, and prevents HIV and other co-infections. She wondered how to change policy and practice in order to continue these programs in a way that is not at the will of funding.

- Ms. Money said their community is starting the same thing, and it was difficult to be at this meeting knowing that was happening at home.

- Ms. Feffer added that it was difficult from the perspective of someone who works at a state health department who is watching Ms. Money work with their community and facing those exact same issues. The difficulty that state health departments face in terms of advocating for and creating sustainability for these programs is a lack of consistent messaging from their partners above them and equal to them (e.g., state legislature, federal legislature, leadership in Washington). They receive inconsistent messaging specifically about harm reduction programs. For example, funding that becomes available always has caveats of who can be paid and how and what can be purchased. They are seeing a shift away from injection and toward smoking because of massive and significant shifts in the drug supply. That shift is good for infectious disease. They are seeing reductions in terms of syringe sharing and risk of infection with HIV and hepatitis C. They do not see that being reflected in funding support. They are not able to allocate funding toward those resources or engage with folks who may have changed their routes of administration and as a result, they are seeing pushback in communities. Inconsistencies exist in terms of support, focus, and a syndemic approach. Much of their funding is funneled through overdose, HIV, and hepatitis, which creates difficulties when writing an RFA in terms of whether Ms. Money and her team can use the funds.

- Dr. Armstrong asked whether non-stigmatizing things that they offer such as wound and dental care are primary levers that pull people in. While she was grateful to see so much effort to address things in a holistic syndemic way, wound and dental care are often less consistent parts of what are thought of as a syndemic approach.

- Ms. Money indicated that a dentist within the company comes onsite 1 day a month. They have observed that people who already are engaging in wound care or other clinical services are now shifting into dental. Wound care absolutely opens the door for people to feel safe. In the last month, quite a few antibiotic prescriptions were written. They had someone with a spider bite, a couple of people with burns, and someone who lost their medication in a camp raid. Wound care draws people in and then within the conversation, care begins to move in different directions. They have found that super low barrier wound care under a tent outside is where people want to be. They try to encourage people to go inside because they now have an exam table that was donated by a hospital because they were not able to purchase it, but people are completely comfortable sitting outside. Even having a clinical room on site is too scary and people would have to walk through some doors when they could just sit outside and show someone the surgical wound that did not close up a year and a half ago when they got surgery. Once people are in, then they shift to dental.

- Dr. Arrington Sanders asked Ms. Coyne to share more about the data she presented in terms of whether there were differences in various groups by age, race, ethnicity, and geographic status. Given that the data suggest that one size does not fit all, she wondered how to create a package that meets needs and is flexible to all individuals.

- Ms. Coyle responded that they have a 156-page syndemic needs assessment report that she could share with CHAC that dives into all of the analyses by race, ethnicity, needs and experiences of PWUD, qualitative data, etc. While size does not fit all and the report makes that clear, there are a lot of common barriers. The largest barrier in all of the services is that people do not know where to go, which is fixable for a low amount of money. Several questions were included in the RFI about customization, because not everyone who visits the online portal is going to need all of the tests, naloxone, fentanyl test strips, xylazine test strips, etc. They want the package to be customizable to a client. They do not want to send resources to people that they do not need. They are seeking a vendor who will allow that type of customization for their clients.

- Dr Armstrong closed the session by asking the panelists, as an advisory group for CDC and HRSA, how CDC and HRSA could help think about scaling up these services, fill research gaps, and make a difference in terms of expanding these types of programs.

- Dr. Wilson pointed out that barriers to buprenorphine have now been decreased by removing the waiver. Removal of barriers to prescribing medications and the spaces in which the medications can be prescribed is beneficial. Consideration must be given to how to pay for and support those medications in non-traditional spaces. They may not give long-acting HIV medications during an ED visit because of the pricing of that drug, but it would be helpful to make that possible. A remaining gap of patients exists who they know how to find who are lost to care or cannot stay in care. It would be beneficial to experiment with ways to treat these patients, such as through a syndemic grant that allows someone to receive all of these treatments at once.

- Ms. Coyne seconded the request for syndemic grants. She was pleasantly surprised to see the loosened language on the new HIV NOFO in which 10% can be used for syndemic services, which previously was more specific to testing. She would like to see that replicated in the grants for viral hepatitis and STI, which could patch things up until a syndemic NOFO is released. As someone who did a lot of strategic planning, it is a huge process to write strategic plans. Having separate planning requirements is extremely burdensome on communities that are asked to return to the table several times, local and state health department staff, etc. There should be a single strategic plan that addresses HIV, STIs, substance misuse, and viral hepatitis.

- Dr. Mermin indicated that in the past, NCHHSTP has issued a NOFO that was specifically oriented toward a syndemic approach. Although there were some excellent demonstration projects, this was special funding that limited engagement across programs. They are working diligently on changing the administrative, programmatic, and scientific barriers to have that type of coordinated program. He observed that all of the panelists have populations who could benefit from doxy PEP and wondered whether that was something that could be ensconced into SSPs, EDs, or other places where populations are being engaged who are at risk for STIs or are just diagnosed who could be given a certain number of doxycycline pills and empowered to take them when needed rather than having to go to a clinician for a prescription after an exposure.

- Ms. Feffer said that incorporating something like this specifically into SSPs is where they begin to see simple and addressable barriers in terms of how those programs are run, what facilities they have available to them (including backpacks), and so forth. In terms of doxy PEP, she was thinking about storage, whether SSPs have coolers available, if there is medication storage that is available 24/7 or only when the SSP is open, if the medication is available to any participant of the program or anyone who is prescribed in that area who

needs support, etc. The state health department could support and implement that in Ms. Money's program and that would reduce many barriers, including people being able to go to a trusted provider in an SSP setting. That is a tangible and simple way to support SSPs that can help them do much more in terms of supporting STI treatment and prevention that they do not have the capacity to do right now because they have to spend all of their time and money on doing the basics and constantly proving that they should run those programs that are known to work.

Panel 2: Using Prescription Data to Support the HIV Care Continuum

Moderator: Kathy Byrd, MD, MPH; Medical Epidemiologist, Treatment Research Team, HIV Research Branch, DHP, CDC

Overview

Kathy Byrd, MD, MPH
Medical Epidemiologist, Treatment Research Team
HIV Research Branch, Division of HIV Prevention
National Center for HIV, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention

Dr. Byrd emphasized that re-engaging out-of-care persons with HIV confers important individual health benefits and population-level prevention benefits. Until recently, most antiretroviral (ARV) medications were prescribed as a 30-day supply. Although because of the COVID-19 pandemic, some providers began to prescribe 90-day supplies. Prescription data, such as pharmacy refill data, claims or billing data, and health systems data can be used to identify persons who are not filling their medications on a monthly or 90-day basis. Tracking ARV prescription claims can be a more real-time indicator of adherence and retention in care challenges. Using real time prescription data to identify persons who fail to fill ARV prescriptions and to intervene could have a significant impact on adherence and potentially on retention in care.

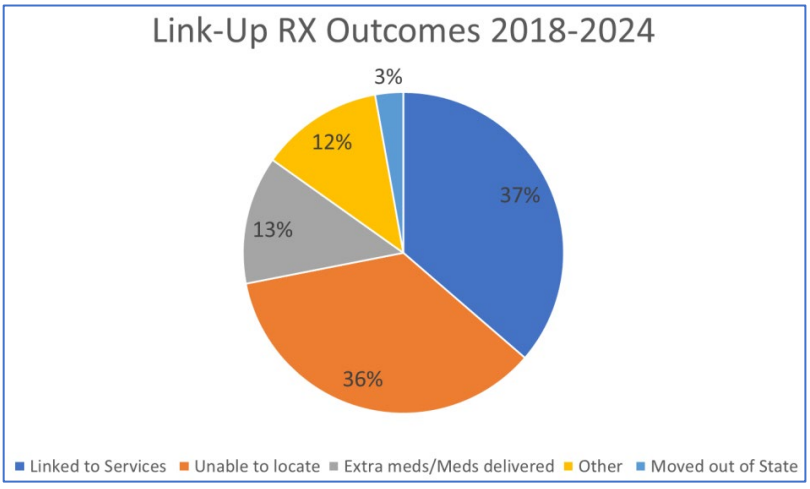
Bridging Gaps in HIV Care: A Michigan Pharmacy Re-Engagement Partnership

Alina Whitener, MS, CHES
Return to Care Project Coordinator
Michigan Department of Health and Human Services

Ms. Whitener shared information about the Michigan Department of Health and Human Services (MDHHS) their Data to Care Rx program (Link-Up Rx Program), that supports adherence to antiretroviral therapy (ART). The Link-Up Rx program supports re-engagement in care using pharmacy prescription fulfillment data. Link-Up Rx started as a pilot program with the Detroit Health Department (DHD) and MDHHS in 2018. Since 2022, Link-Up Rx has expanded to a statewide program. Ms. Whitener noted that the term "outstate" would be used throughout her presentation, which is how they refer to their statewide team and the area outside of the Detroit service area. The expansion in the program allows them to work with partners outside of the Detroit area, given that they have access to statewide surveillance information. They currently are working with 2 pharmacy partners. CAREWare is the main data system that is used for inputting information they receive from the partnered pharmacies and for tracking all outcomes. One aspect that may distinguish the Link-Up Rx program from other jurisdictions is that pharmacists are considered care providers in Michigan. Therefore, data sharing agreements are not required to work together on this program.

In terms of the Link-Up Rx process timeline, the timeframe depicts the time lapsed after an ART prescription is not picked up or not delivered correctly or successfully. During Week 1, the pharmacist reaches out to the individual. If that attempt is unsuccessful, during Week 2, the pharmacist contacts the prescriber who attempts to reach the individual. If the prescriber is unable to get in touch with the client by Week 3, the pharmacist compiles a list of missed ART pick-ups and shares them with MDHHS. These lists are shared via DCH File Transfer Application. DCH allows for sensitive information to be shared securely. DCH is secured on state servers. Once MDHHS receives the information from the pharmacy via DCH, MDHHS and DHD attempt outreach depending upon the location of the client. MDHHS conducts outreach for all individuals outside of Detroit. In terms of outreach outcomes for the entire Link-Up Rx program, including Detroit and outstate efforts, from 2018-2024, the “linked to service” category makes up 37% of outcomes. The “unable to locate” outcome comprises 36%, “extra medications on hand or ART already delivered” is 13%, the “other” category is 12%, and the “moved out of state” category is 3%. There were 957 total outcomes, with 268 of these clients linked back to the pharmacy and 340 were not located.

To compare the traditional Data-to-Care (D2C) to the Link-Up Rx program, these data are not inclusive of all of the outcomes. There are many more categories, but this information is for clients who accepted or denied linkage to services. “Identification” refers to when someone is placed on either a D2C list or a Link-Up Rx list. This indicates whether they are out-of-care or have missed their ART pick-ups. “Initiation” is when outreach attempts begin. There is a much lower timeframe from identification to initiation for the Link-Up Rx program of 4 days compared to 76 days for D2C. D2C lists are run twice a year and have been shrinking in size and becoming more focused since 2018. However, there are still many people who qualify for the D2C not-in-care list. Therefore, there are many people who may not have had their outreach initiated until months after being added to the not-in-care list because of the way the system is set up. The percentage of Link-Up RX outcomes from 2018–2024 are shown in the following pie chart:



There also is a slightly better initiation to linkage of 8.9 days for the Link-Up Rx program compared to 10.9 days for D2C. The main point is the short time in which they are able to initiate outreach after someone is identified on a Link-Up Rx list. The percentage of clients successfully linked to services is 37% for the Link-Up Rx program compared to 12% for the D2C program. The timeframes are somewhat different for each of these programs. The timeframe for Link-Up Rx was 2018 to 2024 and the timeframe for D2C was 2020 to 2024.

Qualitative information was collected to explore the impact this program has had so far after running for a few years. Community feedback was gathered from the DHD Link-Up Rx Team. They reported that clients were always grateful when receiving a call, as it gave them a sense that someone does care and wants to ensure that they are in care and receiving medications. During the previous year, DHD received a great number of individuals who had successfully been referred back to the pharmacy. DHD's major contribution to this success is the process of using discretion when calling. They inform clients that they are calling on behalf of DHD and ask if they are familiar with the pharmacy. For those who say "yes," DHD can proceed with the outreach call. This program has been a success because of DHD's communication efforts with the pharmacy. Each time they gain a successful contact, DHD will reach out to the pharmacy and the pharmacy will ensure that the client receives their medications. Some feedback also was compiled from the outstate Link-Up Rx point of view, which is statewide outside of Detroit, for which the findings were similar. Community members appreciated the link to the pharmacist if someone's phone number had changed, they lost the number for the pharmacy, or could not reach the pharmacy for any reason. Community members also appreciated the follow-ups that were provided through the outreach and the offer for resources as the MDHHS has a wide view of available resources across all of its programs. The partnering pharmacists are quick to reach clients if that is the client's preference. The partnering pharmacies have been efficient to work with regarding communicating outcomes and updating contact information back and forth.

Among the many successful aspects of the program, several operational barriers have been encountered. There has been a lot of pharmacy staff turnover, which has resulted in delays in sending consistent lists to MDHHS for outreach, lack of clarity around who the point person is at the pharmacy, and lack of understanding of the program among more than 1 or 2 people at the pharmacy. MDHHS is currently working with just one local health department, DHD, and the 2 current partnering pharmacies are based in Metro Detroit. While MDHHS truly values the existing partnerships, this is a barrier due to the limited area of service. Pharmacists do not readily respond to offers to partner with MDHHS on this program at this time. MDHHS leads an in-kind onboarding program, but the time commitment and staff workload are barriers to partnering with MDHHS on Link-Up Rx. Another barrier that is not quite under MDHHS's control is pharmacists not sending weekly lists as planned, which could be due to them not having anyone eligible for the list at that time or just other commitments overshadowing the partnership. From the point of view of another jurisdiction wanting to implement a program similar to Link-Up Rx, data sharing could be a barrier. MDHHS uses the internal DCH File Transfer system for the pharmacies to securely upload the lists containing protected health information (PHI). If a group does not have DCH File Transfer system capability, this could be a barrier to running this type of program. For other jurisdictions wanting to implement this type of program, securing which data management system to use is key. CAREWare does work well, but Excel or other data tracking systems could be used. It is important to note that the data are captured comprehensively with any system that anyone chooses. MDHHS is happy to share their best practices in terms of how they have been using CAREWare for this program to track all of the outcomes. Electronic medical record (EMR) access is another avenue that can be used for data sharing.

In terms of potential solutions to strengthen and optimize the Link-Up Rx program, it is important for partnering pharmacies to understand the process and expectations for the Link-Up Rx program. MDHHS also is working on having multiple staff at the pharmacies trained on the Link-Up Rx program and offers onboarding procedures to any partnering pharmacy brought on board. They walk through these onboarding procedures with any incoming partners to explain the time commitment and provide clarity of the pharmacy's role. They also are consistently updating these processes to make sure everything is communicated correctly. To support understanding of the Link-Up Rx program for internal and external partners, MDHHS

plans to develop a 1-pager for easy access to program information. As the Link-Up Rx program is currently limited to the Detroit area, MDHHS plans to expand to serve additional counties and pharmacy partners in Michigan with a statewide reach that they have along with surveillance data encompassing the entire State of Michigan. Partnering with health or hospital systems could be an avenue to expansion, as they do have EMR access at the state level. Link-Up Rx has been a very valuable program so far as MDHHS continues to work toward assisting optimal adherence to care and improving health outcomes for people with HIV, and they look forward to expansion.

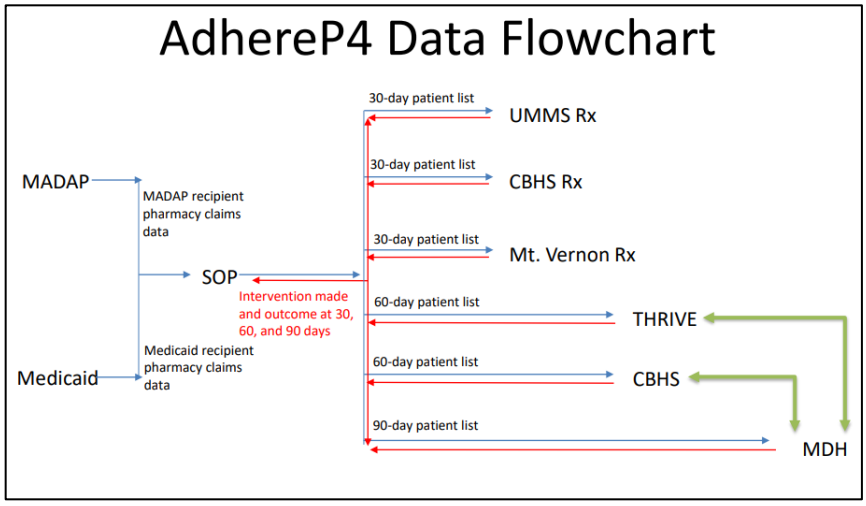
Implementation and Evaluation of a Pharmacy-Based HIV Data-to-Care and Treatment Adherence Intervention

Neha Sheth Pandit, PharmD, AAHIVP
Professor and Vice Chair for Research and Scholarship
University of Maryland School of Pharmacy

Dr. Sheth Pandit presented information about the AdhereP4 project, which focuses on enhancing adherence to antiretroviral therapy (ART) among individuals living with HIV. Typically, what happens in her HIV clinic in Baltimore City, is patients come in, are asked about their adherence, subjective information is given, blood is drawn and with the results of that blood test, they are determined to have controlled or uncontrolled HIV. After that laboratory test, the client is then referred to other services for adherence interventions. The goal of AdhereP4 is to avoid some of the multiple steps in this process.

The objective of this project is to evaluate the effectiveness of an ADHEREnce support intervention among people with HIV implemented through the collaboration of Pharmacies, Prescribers, Payers, and Public health agencies (AdhereP4). The partners started with the Maryland Department of Health (MDH), which are the payers. They use Maryland AIDS Drug Assistance Program (MADAP) claims and Medicaid claims. They partnered with 3 pharmacies: the pharmacy within the University of Maryland Medical System (UMMS Rx), an FQHC pharmacy in Baltimore City with multiple sites in Maryland and Baltimore County, Chase Brexton Health Services Pharmacy (CBHS Rx), and a community pharmacy that was strategically placed between the clinic sites, Mt. Vernon Pharmacy (MVP). The 2 HIV clinic sites they partnered with include Chase Brexton Health Services (CBHS) and the THRIVE Program. MDH is the public health agency because the goal also to engage Disease Intervention Specialists to help re-link individuals if needed on a state or city level.

The data flow of this project was complicated. Pharmacy claims data came to the School of Pharmacy in route from MDH, but these data were the claims data that originated from MADAP and Medicaid. The School of Pharmacy partnered with individuals who are adept at cleaning up large datasets and pushing out line lists of individuals who may be 30, 60, or 90 days late in filling ARV medications. Those line lists went out to pharmacies or clinics to perform an intervention. This graphic depicts the complicated data loop:



One thing to appreciate from this graphic is that line lists were pushed out to the sites, but the sites were asked to send data back to the School of Pharmacy as well to ensure that they were cleaning the data. Therefore, individuals who were incarcerated, transferred, moved out of state, deceased, etc. would not be included in the line list again. When creating 30-, 60-, and 90-day line lists, they were looking for a cumulative request for someone's medications, which was done during the pandemic. Typically, 30 days of medication are dispensed, which did not always happen in Maryland during the pandemic. People sometimes received more drugs than they needed to ensure that they were not having to return to the pharmacy. The intent was to determine the cumulative amount of medications the patient had received and begin with that date rather than basing it off of the last time the medication was dispensed. Once those lists were sent to collaborating pharmacies or clinics, the collaborators first conducted a chart review to ensure that the individuals truly were non-adherent to their medications based on the data given to them. If the patient was confirmed to need an adherence intervention, the collaborator contacted the patient in multiple ways, determined the reasons for non-compliance or non-adherence, and determined barriers. They did not dictate what type of interventions were needed. Instead, this was patient-specific based on the barriers identified. An intervention was then completed, documented, and sent to the School of Pharmacy.

The timeline of the AdhereP4 project began in 2019. It took some time to complete data use agreements (DUAs) and contracts because they needed to work with many partners in different divisions within the MDH. Once most of the agreements were in place, the School of Pharmacy had discussions with each site to talk about each site's process. In all of the collaboration, the School of Pharmacy wanted to instill that they were not trying to disrupt the site's flow. A lot of the sites already were funded in some ways to provide adherence interventions, so the goal was to make this as seamless as possible to determine if there was sustainability in the process. Once interventions began in about January 2021, the School of Pharmacy spent some time cleaning the data because they also struggled with consistency of the data coming back. Time was needed to clean all of the dataset in order to get to the analysis and dissemination point of the project. The outcomes of this project focused on 4 measurements: HIV Viral Suppression (Prescribers), ARV Adherence (Pharmacists/Payers), Retention in Care (Prescribers), and Re-linkage to Care (Public Health Agencies).

For eligibility for this project, there were about 12,000 clients who were sent to the School of Pharmacy as MADAP and Medicaid clients. Once all of the claims were reviewed, it was identified that about 3,000 of them were determined to be non-adherent. Once each of the collaborators reviewed those cases, it was identified that about 1,702 clients truly needed an intervention by the end of this project. In terms of baseline characteristics for this project, about 33% of clients were female, the majority of the population was Black or African American, the majority of the population resided in Baltimore City and Baltimore County, the mean age was about 45 years, and the majority of the patients had a baseline HIV RNA of <200. They were not waiting for a laboratory test to provide the intervention, but were trying to identify individuals who were at risk for virologic failure, which is why some of the numbers were somewhat higher.

An intervention was attempted on everybody as a standard of care. All of the interventions were placed in 3 categories: Full Intervention, Soft Intervention, and No Intervention. A full intervention meant that 2-way communication occurred with the patient via phone call, text message, telehealth, or an in-person visit. A soft intervention meant a 1-way conversation such as leaving a voicemail message. No intervention meant that there was no way of contacting the individual due to missing or incorrect contact information. About 48% (N=810) of the 1,702 persons identified as needing an intervention received a full intervention, about 27% (N=465) received no intervention, and about 25% (N=427) received a soft intervention.

For the first success metric, HIV Viral Suppression (Prescribers), viral suppression was defined as HIV RNA <200. The need to have a baseline viral load and a post-viral load dwindles the number evaluated out of the 1,702 to 508 individuals. They looked at how many individuals were viremic before and after, depending upon whether they received a full intervention, soft intervention, or no intervention. The number of viremic patients decreased from 30% to 27% among those who received a full intervention, the number decreased from 33% to 24% among those who received a soft intervention, and the number increased from 4% to 7% among those who received no intervention. Also interesting was the quantitative amount of overall RNA. Because it may take some time for individuals to become virally suppressed, they wanted to look at the quantitative number. The viral load number decreased among individuals who received a full or soft intervention and largely remained the same for those with no intervention at all. To summarize this metric, after a full or soft intervention, less patients were viremic (HIV RNA >200 copies/mL) as opposed to an increase in the number of viremic patients seen among those who did not obtain an intervention.

The second success metric, ARV Adherence (Pharmacists/Payers), was defined as the proportion of days covered (PDC) with an adherent PDC cutoff of ≥ 80% based on other chronic disease medications and non-adherent PDC cutoff of < 80%. For this metric, only individuals who had a single-tablet regimen (STR) before and after the intervention or a multi-tablet regimen (MTR) before and after the intervention were included in this analysis. The rationale for this was to ensure that if someone was deemed to be adherent to their regimen, it was the full regimen. Of the total 1,702 intervention-eligible persons, 465 were identified as having an STR or MTR regimen before and after intervention for this outcome. Of these, 222 (48%) received the full intervention, 131 (28%) received the soft intervention, and 112 (24%) received no intervention. The percentage of patients who were adherent to their ART increased from 5% at baseline to 21% among those who received the full intervention and from 3% at baseline to 23% among those who received the soft intervention. In individuals who did not receive an intervention, even the baseline number was somewhat higher at 10% and the follow-up was at 21%. In terms of the individuals who were not adherent at baseline but became adherent at follow-up, 21% of the individuals who received a soft or full intervention met the PDC adherence criteria. To summarize this metric, HIV adherence improved in the population

evaluated; however, similar adherence improvement was seen regardless of the intervention group.

For the third success metric, Retention in Care (Prescribers), retention in care was defined as 2 patient care visits occurring at least 90 days apart over a continuous 365-day period post-index date and individuals who also had 2 patient care visits occurring at least 90 days apart over a 365-day period prior to the index date. The index data was defined as the data someone was eligible for intervention. Because 365 days were needed before and after, it was possible to evaluate 513 persons from among the 1,702 intervention eligible persons. This included 233 (45%) individuals who received the full intervention, 119 (23%) who received the soft intervention, and 161 (31%) who received no intervention. For this analysis, they looked at the odds ratio for retention in care and considered different demographic information to determine whether that would have impacted the ability to be retained in care. This analysis considered baseline HIV RNA < 200 vs. >/= 200 copies/mL, Other Race vs. Black or African American, Female vs. Male, Age 20-44 vs Age 45-85 years, Full vs. No Intervention, and Soft vs. No Intervention. To summarize this metric, there were no statistically significant differences in the odds of retention between intervention groups in terms of retention in care. When the full and soft intervention groups were combined, there was no difference in the odds of retention between those who received an intervention (full or soft) and those who did not (OR=0.95; 95% CI: 0.55 – 1.65). The odds of retention were not different based on age, race, gender, or baseline HIV RNA levels.

For the fourth success metric, Re-linkage to Care (Public Health Agencies), re-linkage was defined as a medical visit occurring within the 365-day period after the index date. Of the 1,702 total intervention eligible persons, 554 were identified as meeting this definition. Of those, 296 (53%) received the full intervention, 149 (27%) received the soft intervention, and 109 (20%) received no intervention. Again, this analysis examined the odds ratio for relinkage to care looking at the same factors as assessed for retention in care. Baseline HIV RNA < 200 vs. >/= 200 copies/mL showed some statistical significance in these individuals being less likely to be relinked to care. Females were more likely to be relinked to care. As a reminder, the overall population was approximately 33% female.

Some of the project's successes include that collaborations were built with prescribers, pharmacies, payers, and public health agencies. This project started communications across the entire line of the healthcare system, which helped. Monthly meetings were held during the implementation part of this project, which opened up discussions between the collaborators to talk about some of the issues and barriers patients were having and to better serve the population for whom they are all working. Oftentimes, pharmacists refer patients to a clinic after they already fail a treatment regimen. The proactive aspect of this project allowed targeted adherence interventions to be implemented before seeing serologic failure. Having those discussions with the collaborators led them to think about that process and understand that they were not waiting for a laboratory test to make those interventions. Even with all of the successes, it is frightening to think that this entire project after many years dwindled down to about 16 slides. It took a lot of effort in this entire process and there were many challenges, 2 of which included the COVID-19 pandemic and the false positives associated with the project.

Barriers to D2C Rx: Insights from the AIMS Study

April D. Kimmel, PhD
Associate Professor
Virginia Commonwealth University

Dr. Kimmel presented on barriers to D2C Rx based on insights from the Antiretroviral Improvement of Medicaid enrolleeS (AIMS) Study. The AIMS Study originally was designed as a cluster-randomized, statewide trial of support for Virginia Medicaid members, and their providers, with ART prescriptions between 30–90 days late. This is a multi-agency, multi-institutional collaborative research partnership. Multiple state agencies are involved, including Virginia Medicaid, Virginia Department of Health (VDH), some academic institutions, CDC, and NIMH. The study involves real-time administrative and prescription claims from Virgnia Medicaid and HIV surveillance data from VDH. To highlight some differences about this study relative to the others presented during this panel because this may inform some of the barriers identified, the AIMS Study uses data from all Virginia Medicaid members statewide and was not focused on or restricted to a specific clinic with a higher volume of patients with HIV or specialty pharmacies. The majority of the clinicians managing treatment and care of Virginia Medicaid enrollees in the AIMS Study data had only 1 Medicaid patient with HIV, suggesting perhaps a lower HIV patient volume. This presentation focused on the barriers to program implementation. This was a randomized controlled trial (RCT) research study, but the barriers relate to implementation of a state program, Virginia Medicaid program, or managed care organization (MCO) that may be interested in implementing such a program and are not really focused on the research aspect of the study.

In Fall 2018, the study received agency buy-in for this work. Commitments and agreements were secured at high- and mid-levels to implement the study. The study began in July 2019 and barriers began immediately. The planned implementation was approximately July 2020 and by the time implementation occurred, it was April to May of 2023. The numerous barriers encountered included laws, data sharing, data flows, turnover, SARS-CoV-2, political changes, identifying cases, linking providers, timeliness of data, enrollee reach, and so forth. These were categorized into the 5 barrier domains of legality, leadership, and priorities; data governance; data access, usability, and support; reach and relationships; and unexpected events. This is the current framework, but it is a work in progress to assess what happened.

The first barrier domain is conceptualized as legality, leadership, and agency priorities. This involves state laws and regulations impacting cross-agency data sharing and release to a third party or contactor who may be used to implement such a program of members' personal information. This domain also involves program champions and agency leadership buy-in, as well as competing priorities and leadership and staff turnover. Relevant to program implementation in Virginia is the Virginia Administrative Code, which involves agency-specific regulations regarding the release of identifiable Medicaid member information, including to a third party. Dr. Kimmel emphasized that there were 2 types of legal codes they had to consider, the Virginia Code and the Virginia Administrative Code, and there were obstacles for both. A major barrier encountered was agency disagreement about the allowability or legality of releasing Medicaid member information to a third party. This resulted in involvement by the agencies' attorneys at Virginia's Office of the Attorney General, as well as within-agency legislative attorneys. Another barrier related to this domain was high turnover of leadership at high- and mid-level and at times due to state-level political changes that occurred in 2022. These leadership changes dramatically affected the agency champions of this program at times and resulted in conversations that occurred repeatedly in order to get people to the table and on the same page. While agency staff changes also occurred that were not directly related to

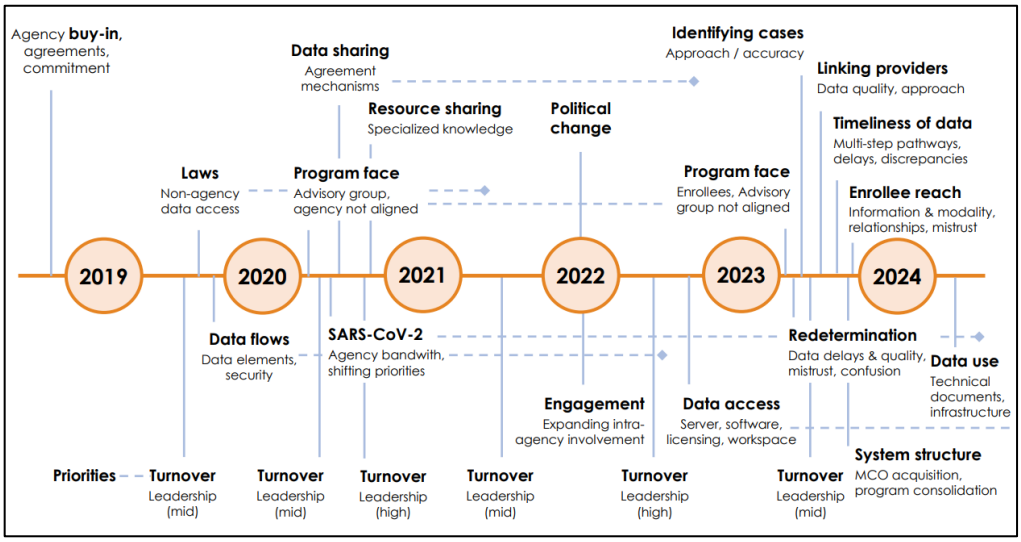
this domain, they directly affected program implementation. All of this resulted in shifts in agency priorities and commitments, disagreements about the agency that was the face of the program, challenges with resource sharing across agencies, and ever-expanding inter-agency engagement.

The second barrier domain of data governance includes processes for data sharing and maintaining data confidentiality and security, and contractual obligations regarding data provision to agencies. In this domain, barriers were encountered related to data flows, including which data elements the study was allowed to access and the specifics of security involving data transfers. For this particular program, all of the data stayed within the different agencies. Virginia Commonwealth University (VCU) could access only the data on Virginia Medicaid networks or VDH networks; the agencies could share data, but no data were coming to. The conversations regarding the data flows were specific to those agencies. In addition, data sharing was an issue and involved agency-specific mechanisms such as legal and contractual mechanisms for the DUAs. These 2 issues combined took over 3 years to resolve. Related to this was timeliness of the data. For this particular issue, there were contractual obligations for transferring data from Virginia's Managed Care Organizations (MCOs) to Virginia Medicaid. Contractually, data could be transferred from the MCOs to Virginia Medicaid up to 4.5 months after a late ART prescription claim was identified, meaning that a member already could have filled the prescription but what the investigators were seeing in the data was that they were late. The barrier domains intersect. Underlying the domain related to data governance are issues related to agency leadership turnover and priorities.

The third domain of data access, usability and support involves technologies and management systems used to work with the data; data usability, including data quality and completeness; and technical documentation and infrastructure to support analyses. This occurred in a very compressed period of time, given the amount of time that had been spent on getting data governance issues resolved. All of these other barriers occurred over the course of 1.5 years. Barriers related to data access involving server access, software licensing, and general workspace; data usability; contact information for enrollees; and an enrollee's link to an HIV provider; and up-to-date information on member enrollment. This was due to a variety of reasons, including redetermination and the specific process in Virginia that enrollment occurs through the Virginia Department of Social Services (VDSS) not through Virginia Medicaid. In terms of the timeliness of the data, multi-step pathways regarding the release of the claims called into question what constitutes "real-time" data. Discrepancies also existed between identification of members with late ART prescriptions and what the members were reporting. Regarding data use, there were issues with the technical documentation. Data dictionaries were not as complete as preferred for effective analyses. The agency infrastructure and expertise to support data analysis was an issue in terms of this extremely complex data, which requires people who are committed to understanding the data and who have a lot of specialized knowledge. Approaches to accurately identify members with HIV that posed some obstacles. Again, this domain intersected with other domains. The issues of turnover and priorities come up repeatedly.

The fourth domain of reach and relationships involved effectively contacting and engaging with members, particularly via a known and/or trusted source. This again was very compressed and is an area for future work and understanding. There was the issue of timeliness data again that prohibited effectively reaching members, which occurred despite multiple modalities. In particular, there was either mistrust or an unwillingness to engage because there was not an established, known, trusted, or personal relationship with the front-facing agency, Virginia Medicaid. This was despite the fact that the stakeholders said that it would be okay for Virginia Medicaid to be contacting individuals and that it could be effective.

The fifth barrier domain of unexpected events includes unanticipated, but impactful, incidents that occur outside the immediate boundaries of the program such as SARS-CoV-2. While agency bandwidth decreased during the pandemic, Dr. Kimmel did not believe COVID was the primary source of these barriers. There was a bandwidth issue, but she believes the delays they experienced would have occurred anyway. Another unexpected event was the shift away from what in Virginia is an annual redetermination or reenrollment process. During COVID, this annual process did not occur. Shifting away from that made the work a lot more difficult, which was an unexpended event. Similar events could cause a shift away from annual redetermination in the future. Another unexpected event was system structure, which involved MCO acquisition. One MCO was absorbed into another, which was confusing to members. The MCOs had different programs they implemented through the structure of Virginia Medicaid that were collapsed. This was happening in real-time, so the changes that were occurring through Virginia Medicaid had to be adapted to in real-time as well. Once again, there was an intersection of the domains, with a trend of leadership and priorities underlying many of the issues. This graphic depicts the timeline and barriers in their entirety:



In terms of key insights, multiple barrier domains intersected at different levels and occurred repeatedly over time. Just 1 barrier can substantially delay timelines and has the potential to derail implementation. Legal and regulatory issues, leadership turnover, and data governance can eclipse data access and program implementation. Nuanced knowledge of data pathways is vital to identifying the population of interest, in this case members with late ART prescriptions. Strong data expertise and underlying infrastructure are absolutely essential. Reaching and engaging participants, or members, is not a one-size-fits-all approach.

Regarding recommendations for claims-based D2C Rx, it is important to identify champions early and to be flexible if there is champion turnover. Agency incentives for D2C Rx must be understood and used as an opportunity to bolster relationships, promote communication, and elevate D2C Rx among competing priorities when possible. This includes discussions with agencies indicating that the work is not limited to people and members with HIV. It is important to engage an intra-agency, multi-disciplinary team with expertise in administrative and regulatory law, data governance and access, and the specific population of interest. Adequate time must be built in for a nuanced understanding of the data and data pathways in order to understand what “real-time” is. For future work, it is important to take a differentiated D2C Rx approach that is based on known and trusted relationships.

Panel 2: Q&A with Speakers and Member Discussion

To focus the discussion, Dr. Armstrong reminded CHAC members of the advice related to this topic that was requested from CDC/HRSA and asked them to be thinking about action items CHAC might address and vote on later in the business section related to these questions:

1. What should CDC/HRSA consider to be the next steps to advance programs using prescription data as an intervention for persons with HIV who fail to fill their ART in a timely manner?

The following questions, observations, and suggestions were raised:

- Dr. Armstrong inquired as to whether patients were asked what the barriers were to picking up medications, and if there were opportunities to think about different ways to get them medications other than having to go to a pharmacy, such as home delivery, delivering to centralized lockers, or other unique models of care to overcome some of the existing barriers.

- Ms. Whitener indicated that they document barriers whenever possible. For example, people on outreach calls are asked if they are willing to take a few extra minutes to discuss barriers. They have a list of barriers they can discuss, or they note barriers people bring up themselves as well. The 2 partnering pharmacies they work with deliver medications. The failed pick-up refers to a delivery not being successful. This comes into play when someone is unstably housed, or an address has an error. Getting medication to the unstably housed is a work in progress. The state has some housing resources, but there are many barriers to receiving those resources. They try to help the unstably housed as much as possible, but in the meantime, getting their medications to them is a challenge.

- Dr. Sheth Pandit indicated that they did not assess abandoned medications. Instead, they looked at individuals who were late in getting their medications. They did not document barriers, mostly because they wanted it to be individualized in each of the clinics with which they worked. The clinics had social workers, case managers, and other staff who did a phenomenal job in addressing some of the existing barriers. All of the pharmacies allowed delivery or mail-order if needed, so if that was the barrier it was addressed.

- Dr. Mermin noted that when they started D2C, the idea was to merge the concepts of surveillance and prevention and to see that surveillance is part of program implementation, and the separation is problematic. They now have a much better understanding of what is occurring in jurisdictions that have implemented D2C, and the outcomes in access to treatment have been improved for people to some extent. However, it was too long a period of time from the time someone stopped accessing their medications to when they were detected as out-of-care by surveillance systems. By definition, it had to be over a year and was generally 1.5 years. All of this work by the health departments found that 30% of people had been re-engaged, so the thought was to get closer to the time of need when someone does not pick up their medications, such as the first 2 presentations showed. Yet, there was not a substantial a difference in outcomes. If they are getting closer to the point that 20% of people need extra help, what is that extra help? That is where the efforts need to be focused. He wondered whether anyone considered injectable Cabenuva for some of these patients and taking the medication to them, because it is a smaller population.

- Dr. Sheth Pandit responded that they are at the forefront in terms of long-acting injectables (LIAs) in their discussions, but not in their timeline. By the time their project was rolled out, they saw the tail-end of LAIs being implemented. Had there not been a pandemic and if LAIs had been much more accessible, they would be having a very different discussion. That would have helped drive how they got patients engaged in the process and the types of interventions they were allowed to council patients on at that point. By the time this project ended, only a handful of people were started on LAIs. Her clinic has about 200 patients on LAIs right now whose adherence is managed by the staff who are injecting them, so it is less on the patient.

- Dr. Driffin recalled seeing in one of the presentations that a third were unable to be located and wondered what type of contact information is being utilized. Long gone are the days of calling someone and leaving a voicemail. Medical teams are managing LAI adherence moving forward, but there is still room to ensure that those people are being contacted who do not keep those appointments. As a person 2 years in, it is difficult to go to the doctor's office as a result of work picking up again. He wondered how to capture that conversation in the daily navigating of clinical services.

- Ms. Whitener indicated that they try to make contact attempts as robust as possible, but the number of "unable to locate" is similar across the board and may be the biggest barrier. They try calling, texting, and sending certified letters. Due to concerns about confidentiality, they have not explored social media. However, they are working on this. Since they are a state health department, they have to ensure that handling privacy and confidentiality are done properly. They have had some success with a follow-up text after the phone call. No one answers non-familiar numbers, so they send a non-identifying text to identify who is calling with no information beyond that. They learned this from the DHD. They brought a lot of their D2C in-house to the state with the formation of the new team, so they have learned a lot of best practices from local health departments that have had success with D2C. Some local health departments are doing D2C very well. They have a person to search database that they are authorized to use at the state and are training on how to do that so they can get multiple phone numbers. However, someone who does not answer their first phone number is unlikely to answer the others.

- Dr. Sheth Pandit indicated that another way they have contacted individuals is using EMR portals. Sometimes the person will have an email set up or something within the portal itself. They also compare telephone numbers within their pharmacies to see if the clinics have a different number than the pharmacy. They have not utilized social media due to the many legalities behind that. Regarding LAI, they use a different process to ensure that patients stay within their window of being able to obtain their LAIs. There have been numerous publications on how to ensure that this project and this pilot of LAIs is implemented appropriately. There is a designated individual within the clinic who is making sure appointments are made, people are presenting, and that they can be tracked down if they are outside of the window of their target date of getting their LAIs. The difficulty with using pharmacy claims data is that the medication would have been dispensed by a pharmacy and the person would not have gone to a clinic.

- Dr. Greene emphasized that as someone who cannot do their clinical work without the pharmacist in her clinic, being proactive in using pharmacists is very important. She asked whether the partnering pharmacies in Maryland were specialty pharmacies versus corner retail pharmacies. She also asked what HRSA could do to help overcome some of the data sharing barriers.

- Ms. Whitener indicated that their partner pharmacies are specialty pharmacies at this time, but they have big dreams of expanding beyond their capacity. They are trying to focus on getting to different counties in the state since they are focused only in Metropolitan Detroit right now due to the nature of how the pilot program started with DHD. Most of the community members on the list are in the metro Detroit area or close by.

- In terms of sharing data, Dr. Sheth Pandit said any help with data sharing agreements would be vital in this process because it does take a long time. Each entity with which they collaborated has had different DUAs and processes. There was a lot of legality that those with boots on the ground trying to get the work done are not privy to. What the data mean, what data are needed, and the longevity of the data need to be included in a data sharing agreement. They have very little control over that. Some guidance to individuals who are creating those DUAs would be helpful in terms of explaining why this is important, what it means to be able to share data when there is a vested interest on both sides to be able to provide patient care, and what the continuity of care responsibility is. Framing those discussions would be very helpful.

- Dr. Carney added that Maryland is working on a more in-house process, the Strategic Data Initiative, such that if someone is requesting MDH data, the same questions are asked and the requests go to the same place. This is something new that came after the AdhereP4 project started.

- Dr. Kimmel added that she has a slightly different lens and looks at it based on her own training from a business perspective in terms of incentivizing agencies to cooperate. Partnerships across CDC, HRSA, and CMS to promote that this is important and that data sharing and how data can be used crosses different conditions and diseases would be beneficial. CMS has a quality measure related to viral load suppression. Virginia Medicaid was a great partner but was not incentivized necessarily to engage in this. Having a quality measure would be one way to do that. For her it goes beyond guidance and involves figuring out how sharing can be a win-win for the agencies.

- Dr. Cheever indicated that HRSA has been working with CDC and CMS for years in trying to do a better job of sharing data. They view this as essential, but it takes years to improve data sharing processes. CMS convened Affinity Groups comprised of other states that want to participate, the first of which focused on HIV. After a long time of intensively working on this, these groups began to understand what their different data and legal issues were. It is incredibly complicated even when CMS is convening the groups together. A second follow-on Affinity Group was done on hepatitis with the three large agencies trying to encourage, cajole, and move and it takes years. Virginia has done an interesting job of building capacity to do this work, it has been iterative in terms of developing systems, identifying where the holes are, etc. This involves integrating incredibly huge and expensive IT systems that other people control to make this happen. It is essential, but it is complicated. HRSA is committed to the long-term goal of integrating these systems. Some of the eligibility work is important in terms of knowing who has what kind of insurance, or even what someone's income was on their taxes. Moving those systems with a patient-centered approach is complicated and is absolutely something that HRSA is committed to doing.

CMS is needed in the room and is committed to doing this. HRSA has been working with the CMS Adult Core Set of measures. Different states can report different quality measures and can help with incentivizing payments and so forth. HRSA has viral suppression in that set. In order to make it happen, there needs to be data sharing at the state level so that the Medicaid programs know what the viral suppression rates are that the surveillance people may or may not have. It is incredibly complicated, but worth it. It is difficult to incentivize in terms of HIV because it is a small proportion of the total population in a state and not even a huge part of healthcare costs in terms of Medicaid, it is hard to incentivize states.

- Mr. Riester said that while texting is great, he would be cautious about how many texts come in. Someone receiving a text back indicating that their prescription is ready could be too much of a good thing.

- Ms. Beiser said that speaking from experience as a clinician taking care of people who are homeless, she was not sure that pharmacy data was the right lever for everyone. A lot of this work is happening at the clinic level and innovative strategies are being used by the people taking care of the patients every day. The pharmacy data will never reflect that. The clinics have and are managing the LAI data, which is an important element of this. She gets a little steamed about line lists because they are not really helpful. All of the ways clinics report out retention, the care being provided, and suppression based on other factors has a lot more meaning. It was interesting to her that the outcomes from the interventions based on the pharmacy data did not show benefit. In terms of investments, especially when dealing with complicated systems where a ton of bureaucracy is involved, is it worth it?

Business Session: Part 1

Wendy Armstrong, MD
CHAC Co-Chair

Dr. Armstrong indicated that the agenda for this Business Session would be to address 1 item of business and engage in a CHAC discussion to reflect on the presentations and consider areas in which CHAC might be able to make a difference.

Business Item 1: Youth Letter Dated April 2024

This letter to the HHS Secretary includes the follow 4 proposed recommendations, which are to:

1. Support the development and implementation of routine and effective screening tools for youth for mental health problems, substance use/abuse, violence, and STIs.

2. Support development and implementation of standardized protocols for sexual health in youth, which integrate youth voices throughout the planning process.

3. Develop mechanisms for youth-focused services to incorporate community health workers; use of peer-to-peer supports, and identify and use champions/influencers, and listening sessions with youth to identify and implement best strategies to engage, educate, link to care and impact behavior, recognizing how young people are different and differences change over time and vary between individuals.

4. Ensure support for the ongoing collection of YRBS data in all states and jurisdictions every 2 years through CDC's DASH.

CHAC Action
Dr. Dionne made a motion to accept the Youth Letter Dated April 2024 and move it forward, which Dr. So seconded. CHAC members unanimously approved the motion with no changes or further discussion.

CHAC Discussion

The following questions, observations, and suggestions were raised:

- Regarding HIV self-testing, an article was published in 2023 highlighting the lack of Food and Drug Administration (FDA)-approved HIV self-tests available in the US. Other tests have been used worldwide that have been endorsed by the World Health Organization (WHO) that are not available in the US. The US has third generation OralSure® technologies. Testing services are needed in the US that include fourth generation testing that is reflective of HIV testing guidelines, expansion of self-testing, and expansion of access to testing for adolescents that currently includes ≥17 years of age.
  - In 2023, CDC funded the clinical trials necessary to bring a finger stick test to the US that has been approved in other countries for several years so the data could be submitted to the FDA for assessment and ideally made available in the US. The initial RCT conducted for HIV self-testing involved 2 tests, the OralSure® and a finger stick test. When participants were asked which test they preferred, the preference was equally divided at 50% for each test. The finger stick test is positive closer to the time of infection, which would be highly beneficial, especially in circumstances where people are interested in starting PrEP.
  - Because there is no competition, the cost even wholesale for CDC is about $30. The cost of the test itself is the biggest obstacle to expanding HIV self-testing through the internet, CBOs, and health departments.
  - POC testing has resulted in increases in receipt of treatment to as much as 95%, but the challenge regards how to make POC tests reimbursable.
  - CDC is interested in diagnostic changes for a variety of other infections as well and has supported the development of a gonorrhea and chlamydia point of care (POC) test. Questions exist about hepatitis C testing, especially nucleic acid amplification tests (NAAT), closer to the POC. There is a joint NIH and CDC effort to have a POC NAAT test that can differentiate Mpox from chicken pox, syphilis, and others that is not yet available. Interest exists in having a POC treponemal/nontreponemal test available in the US, which is available in many other countries with relatively good accuracy.
  - Interest exists in empowering people to know what is going on with their own health.
  - Payers pay for some things and not others. Payment for POCs tests has lagged. COVID home-based tests were being paid for, which was exciting but wound down as soon as the Public Health Emergency (PHE) ended. There is tremendous variability.
  - In 2022, CHAC submitted a letter to the Secretary recommending expanding the availability of self-testing and self-collection and addressing existing regulatory and legal barriers.
  - An opportunity for policy will be to encourage and support syndemic-based testing and recommend a package of testing that will cover as many infections as possible.

- There are still many people who do not understand the meaning of the word “syndemic.” Therefore, it is important to push this into all healthcare and community settings.

- A striking point from the presentations regarded the need to get people to the table who are not at the table.

- Given the changing landscape, systems and how care is provided are going to have to change as well.
  - It is important to engage and retain people who are not in care, so trusted settings and providers are critical. This can be as simple as painting the walls, changing the clinic flow, putting humanity back into care, providing LAI. It is important to remember the least common dominator in terms of keeping people in care and taking a more holistic and dignified approach. For example, providing non-traditional incentives such as the ability to wash one’s clothes can keep folks engaged in care.
  - Outreach needs to be taken to spaces where people are not thinking about accessing healthcare unless they need wound care. Recommendations are needed for getting frontline folks back into the most accessed spaces where unhoused, mentally challenged, substance using communities are, because they are not presenting to clinics. This is a key tenant of harm reduction, but it is not written into the programs of early intervention services enough.
  - Half of all people in the Ryan White HIV/AIDS Program are ≥50 years of age.
  - Integration of clinical and community services and fostering those partnerships would be beneficial. Thought also must be given to integrating other aspects of care delivery besides HIV, STIs, and hepatitis C providers. Perhaps CDC and HRSA could do something to help facilitate these connections.

- It is concerning that EDs and urgent care facilities are limiting STI testing. This seems like a missed opportunity to get ahead of the congenital syphilis epidemic.

- It is commendable that the NOFO process is being shifted to be more client-centered and easier to navigate for smaller organizations.

- Consideration must be given to messaging. How can someone be reached who is only on TikTok and does not read CDC reports about increasing rates? What about reaching policymakers who are making politically-based not science-based decisions to pull back harm reduction programs that have significant evidence behind them?

- Potential future agenda topics:
  - An update would be appreciated from the FDA on the status of approving POC and self-testing for HIV, syphilis, gonorrhea, hepatitis, etc.

Public Comment Period

No public comments were provided.

Recap of Day 1

Wendy Armstrong, MD
CHAC Co-Chair

Dr. Armstrong observed that the overwhelming issue, growing ever more important, is how to get systems to work together, react together, and support each other. That is a central challenge now that so many advances have been made in so many ways.

Recess

Jonathan Mermin, MD, MPH
Director, National Center for HIV, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention
CHAC Designated Federal Officer
Centers for Disease Control and Prevention

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

Day 2: DFO Meeting and Roll Call

Jonathan Mermin, MD, MPH
Director, National Center for HIV, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention
CHAC Designated Federal Officer
Centers for Disease Control and Prevention

Dr. Mermin welcomed participants to the second day of the CHAC meeting. He conducted a roll call and asked members to disclose any new COIs. COIs did not differ from the previous day and are reflected in the table on page 5 of this document. He confirmed that 19 members were in attendance, which established quorum for the CHAC to conduct its business on April 10, 2024.

Special Presentation 1: Aging with HIV and the Whole Life Approach

Moderator: Grissel Granados, MSW; Senior Director, Planned Parenthood Los Angeles

Overview

Grissel Granados, MSW
Senior Director, Planned Parenthood Los Angeles

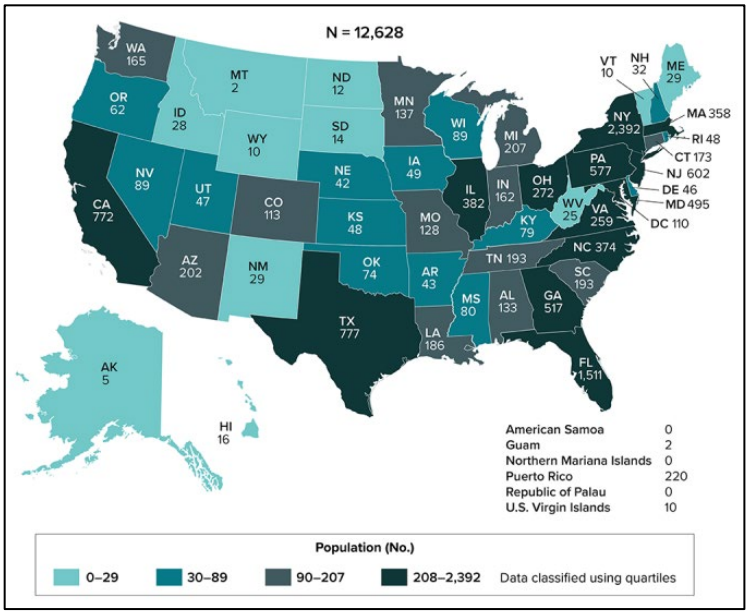
Ms. Granados noted that the term "lifetime survivors" refers to people who have been living with HIV since birth or early childhood. There currently are about 12,600 people in the US with perinatally acquired HIV. Because it sounds like a small number in the grand scheme of things, this population has long been left out of conversations. Meanwhile, this population also has been experiencing opportunistic infections, comorbidities, mental health issues, and deaths over the past 40 years. The conversations in pediatric and adolescent care do not reflect the majority of the population in their 30s and 40s anymore, and the conversations around aging also have long overlooked their experiences despite them being among the longest survivors of HIV. For context, Ms. Granados noted that this year marks 38 years of living for HIV for her. She explained that the goal of this panel was to shed light on a few issues that are top of mind for this community.

Aging with HIV and the Whole Life Approach

Allison Agwu, MD, ScM, FAAP, FIDSA
Professor, Pediatric and Adult Infectious Diseases
Director, Pediatric Adolescent HIV/AIDS Program and Accessing Care Early Clinic
Johns Hopkins University School of Medicine

Dr. Agwu shared a timeline[20] to illustrate how far the epidemic has come from the first known infants to be born with HIV in 1977, to injectables, to cures—all of which should be highlighted and celebrated with many of the advances funded by CDC and NIH. As Ms. Granados said, there are about 12,600 plus young people living with perinatally acquired HIV in the US. This 2021 map shows the areas where persons living with perinatally acquired HIV reside:

[20] https://www.hiv.gov/sites/default/files/aidsgov-timeline.pdf; Rogers et al. 1987 (79): 1008-1014



In terms of youth 13–24 years of age living with HIV overall,[21] the perinatally acquired group's make up is about 40% of young women and about 80% among young men, which is due to the number of young men who have sex with men (MSM) who contribute to the numbers for young people. Regarding the age distribution of persons diagnosed with perinatally acquired infection as of 2017,[22] about 50% were 13–24 years of age and about 40% were 25–35 years of age. Both of these groups are growing and are important in terms of being part of the conversation. While there are approximately 12,600 persons living with perinatally acquired HIV in the US, globally there was an increasing number of young adults 15–-24 years of age living with perinatally acquired HIV between 2018 to 2022. When these data were projected forward in a 25-year forecast of individuals living with perinatally acquired HIV, by 2047 it is anticipated that there will be about 2 million plus worldwide.[23] What is happening in the US is a harbinger of what is to come elsewhere, so it is important to be thinking globally when having these conversations. Many lifetime survivors like Ms. Granados are thriving and many are being more vocal about their experiences. Oftentimes, they are not as vocal about the challenges that are worth paying attention to. The Conference on Retroviruses and Opportunistic Infections (CROI) in March 2024 highlighted everything from the epidemiology to the psychosocial and psychological aspects of living into young adulthood.[24]

Regarding the continuum of young adults, the focus often is on how they are feeling and how they are doing. Yet, they have the lowest rates of viral suppression and lowest rates of retention in care. It is amazing that they have levels as good as this in the context of the life course and all of their challenges. An article in 2020 by Drs. Agwu and Yusuf aimed to talk about the life course perspective.[25] Often, people who are diagnosed with HIV are diagnosed in their second or third decade of life. It is important to talk about what it means to live with a diagnosis one's whole life, even before knowing what that diagnosis is. It also is important to think about events from how evolution happens and HIV's impact on life events (e.g., school, employment, partnerships, children), self-management, disclosure (to self, to others, repeatedly over the lifetime), stigma (internal and external), ART, adherence, co-morbidities, care delivery, and risk

[21] CDC. Diagnoses of HIV Infection in the US and dependent areas, 2021. HIV Surveillance Report, 2021; Vol 34. Published May 2023
[22] Yusuf and Agwu. Expert Review of Anti-Infective Therapy. Sep 2020
[23] Courtesy of Dr. Mutsa Bwakura-Dangarembizi
[24] https://watch.croiwebcasts.org/croi2024/n/day/all
[25] Zinyemba TP et al. J Econ Surveys 2019; Yusuf and Agwu. Expert Review of Anti-Infective Therapy. Sep 2020

factors. People like Ms. Granados tell the story of what has happened to HIV regimens and what that means in terms of resistance, regimens they are eligible for now, and how that impacts their capacity to live simply with their HIV. Over the last several years, there has been an increasing understanding of the role of inflammation and outcomes and looking at the pathways that lead to inflammation, immune activation, accelerated aging, and ultimately increased risk of co-morbidities.

In order to understand what is happening, it is critically important to hear the voices of lifetime survivors and their friends and to look at case reports/series, observational data, collecting cohorts, qualitative and quantitative data, and modeling studies.[26] Regarding the long-term morbidity of HIV and/or ART, data up to 2006 showed the changing dynamics of what people were dying of, which primarily was end-stage HIV and AIDS. By 2006, they started to see the shift to other non-AIDS-defining co-morbidities such as cardiovascular disease, pulmonary disease, malignancy, medication side effects, metabolic abnormalities, central nervous system, longstanding inflammation, and the unknown.[27] Data from the North American AIDS Cohort Collaboration on Research and Design (NA-ACCORD) on the cumulative incidence of selected non-AIDS defining co-morbidities by age 30 among young adults with perinatally acquired HIV show higher rates of diabetes, hypercholesteremia, hypertriglyceridemia, hypertension, and chronic kidney disease.[28] Comparison to the National Health and Nutrition Examination Survey (NHANES) data showed that they were significantly higher. These data spark a call to think about preventive strategies to prevent co-morbidities in this population.

Transition is a time that is fraught with challenges as people move from pediatric to adult care and have to leave their support and entire history and then be traumatized in some cases as they tell their story again on the adult side. Flexibility is needed on the adult side as young people transition over to adult care in terms of engagement and retention as they truly make a life transition to the adult side. Success in the transition from pediatric to adult care should result in equal or better clinical outcomes. In terms of how to improve outcomes, it is important to ask the people who are living with perinatally acquired HIV. Improving outcomes involves multimodal combination strategies and approaches, addressing co-morbidities improving engagement strategies, optimizing care models, including lifetime survivors in research, and advocacy.

In conclusion, lifetime survivors are a unique population who are aging into adulthood. They have challenges and potential comorbidities that may impact their outcomes across the lifespan. Awareness of the potential impact of lifetime HIV is key. This population needs to be included when designing and conducting research and optimizing clinical care.

Discussion With Lifetime Survivors

Grissel Granados, MSW
Senior Director, Planned Parenthood Los Angeles

Ms. Granados indicated that in addition to the presentation from Dr. Agwu, joining the panel discussion would be 33-year-old lifetime survivor Richard Adkins from the Lifetime Survivors Network and 28-year-old lifetime survivor Antoinette Jones from Dandelions, Inc. She posed the following questions for the panelists to consider and discuss:

[26] Yusuf 2021; CDC. Pediatric HIV Surveillance 2018; Althoff et al Lancet HIV 2019; Griffith OFID 2018
[27] Griffith D et al. OFID 2018; Hazra R et al.; Izbudak, Agwu J Neurorad 2013;, Venkataramani 2012; Eckard et al Curr HIV/AIDS 2016; Neilan et al JAMA Peds 2017
[28] Haw NJL et al. AIDS 2024

1. While Dr. Agwu shared some of the best data available, more data are needed. This is one of the most blatant gaps in documenting the impact of HIV on lifetime survivors. What kind of data do you think is necessary and why it is important to this community?
2. It is known that people living with HIV as a whole are greatly impacted by mental health issues. How might addressing mental health among lifetime survivors differ from the general HIV population and what do you think has been the impact in development through the lifespan?
3. It is known that the transition from pediatric to adolescent to adult care is one of the key medical experiences among lifetime survivors. Please talk about what you see as the impact of this transition.

Richard Adkins
Lifetime Survivors Network

Mr. Adkins began by uplifting lifetime survivors who acquired HIV through blood transfusions. Those who are perinatally infected are barely mentioned, but those who acquire HIV through blood transfusions are not mentioned at all in most cases. However, they also are survivors and have many of the same needs as those who have perinatally acquired HIV. One of the biggest data gaps is that no data or very limited data exist once they turn 18 because they are mixed in with the general population. When he looks at data for someone 30 years of age, there often is no way to tell whether that individual has been living with HIV for 30 years. For those who have kidney disease, heart disease, or inflammation, it is not necessarily the HIV about which they are worried. He has been virally suppressed for most of his life, but he worries about the other co-morbidities more than the HIV. The data say that if someone 25 years of age acquires HIV and is virally suppressed, he or she has a life expectancy of 50 years and will live to be roughly 75 to 77 years of age. What does that mean for lifetime survivors? Do they have 50 years of life or do they have 75 years? The answer he gets is that this is unknown. What happens next? That is not good enough. Further research is needed in this population to keep them alive.

In terms of mental health, Mr. Adkins' family learned of his HIV status when he was 5 years of age. Suddenly, he was put on medicine, wondered why he was taking it, and kept asking questions. A therapist explained to him that he has a virus in his body and that it was important for him to take his medicine every day. But in that same sentence, she told him it also was important that he not tell anyone or they would treat him badly or differently. He did not think much of this until he was staying at a family member's home, got a small scrape on his knee, and was rushed to the bathroom where they put on gloves, masks, and gave him a band-aid. It was then he perceived that he was dangerous, not normal, and not like everybody else. He carried that throughout life, thinking that his life was over or severely limited as a child because of HIV status. That stigma prevented him from even saying the 3 letters H-I-V until he was 16. He was in no condition to survive on his own and he was severely depressed. It was not until he was able to join a support group with people who were also living with HIV since early childhood that he began to see that their hopes and dreams were possible, so there was hope for him as well. The narrative is that people born with HIV are a thing of the past—this does not happen. But people born with HIV who are still here live with increased isolation, not being connected to the community, not hearing about others who are still here, and it is hard.

Regarding the transition from pediatric/adolescent to adult care, one of Mr. Adkins first memories of going to the hospital was Nurse Kim's smile, energy, and high fives. She made him feel less scared to go to the doctor so often and that she was someone he could turn to who had his back. That was his experience throughout all of his pediatric care. The doctors went above and beyond to recognize him as a person and not just him as his status and made him feel comfortable. He also received the mental help that he needed. The transition was

supposed to be a smooth experience, but it was not. The first doctor he saw made him feel uncared about as a person, he questioned the competency of the second doctor, and the third made him want to drop out of care. During that time, he was able to work with a transition social worker who helped him. Even recently, he saw a new HIV doctor. One of the first things the doctor said to him when told Mr. Adkins was born with HIV was, “Wow, you got the short end of the genetic lottery. If only you were born 5 years later, the medication would have prevented it.” If this had been the first, second, or even seventh time, it would have left him very upset. However, he has learned how to handle this and unfortunately, this is what he has to expect in adult care. He is doing well, is healthy, is thriving, and is part of a lifetime survivors network that advocates and comes together for those who are living with HIV. It is more an experience of surviving adult care than thriving with adult care.

Antoinette Jones
Co-Executive Director/Co-Founder, Dandelions, Inc.
National Field Organizer, Positive Women's Network

Ms. Jones said in terms of data, she wonders where the data are from when they were children about their experiences and diagnoses. Many perinatally infected survivors were born in the early 1980s and 1990s and there should be data to look at to determine what their lives will look like for the next few years, or when they are 50, or when they are older than that. She would like to see detailed data about the impact of medications on their bodies after a lifetime of taking them and the impact of HIV in general on people who have been aging with HIV their entire lifetime. Co-morbidities are occurring from an early age. They are not just happening later in life for those who are aging with HIV. Some of them were born with co-morbidities. What does that look like for the life expectancy of people who identify as lifetime survivors or dandelions? She feels like there is a huge gap from the past and the future. They should be able to engage in research opportunities to help generate detailed data about their life experiences and inform the generations after them. Even though the numbers have been reduced greatly, people are still being born with HIV. They should be able to access data to know what their life experiences will be like.

Regarding mental health, she agreed about the isolation. Ms. Jones also was told to keep her HIV status a secret so that she would not experience any judgment or discrimination while she was in school or from other people in her life. At Dandelions, they make sure to include core values of violence and discrimination, because those are the events they can think of that lead to mental health issues and have a great impact on how they show up in this world. She struggled with isolation until she was 26 years old when she found another Dandelion living with HIV. It took that long to even open up and share openly that she was living with HIV. She had never been to a camp or a support group until that time, and she could only imagine what the younger generation was experiencing or would experience because of this isolation. She also thinks about neurocognitive issues from birth that may have been ignored, especially in the Black and Brown community which often does not address mental health as a real issue. There are many things that Dandelions and lifetime survivors are born with that are not addressed because HIV is the major health condition, so other issues may go unnoticed and unaddressed. From her experience, she thinks about pregnancies and experiencing pregnancy on her own having been born herself with HIV, and how the stigma of not birthing another generation with a positive baby could impact one’s mental health while pregnant. She calls it “pre-partum depression” that she experiences along with post-partum depression because stigma convinces her that she needs to stay on top of her medicine and make other efforts so that she does not give birth to a baby that society will consider negatively—a baby born with HIV. All of the stigma impacts stress levels, whether to have babies, and whether to experience a journey that should be beautiful that often is not because of so many negative thoughts around having to do this

perfectly. She thinks about before giving birth as well as after. As one of the first people in Georgia to make a decision to breastfeed her child, along with the many mental health issues that accompanied that decision, she realized that early mental health care is definitely important to the community of lifelong survivors.

In terms of transition to care, Ms. Jones experienced extensive pediatric care. Being born and raised in the Bronx, New York and then moving to Statin Island, New York, she experienced 2 different types of care. When she moved to Virginia, she had to go to the children's hospital in DC. That is where she experienced her transitional care at the age of 18 when she was not ready or prepared to enter adult care. Pediatric care has a more family atmosphere and is as if one's hand is being held through the journey of aging with HIV. Once she entered adult care, all of the responsibility fell on her and the assumption is, "Well, you've been living with HIV your whole life so you should know how to care for yourself now that you are legally considered an adult." That oftentimes is not the case. She had to navigate a lot when she entered adult care, such as what it meant to be a woman living with HIV, a Black woman, how to schedule appointments, how to pick up medication, how to go to a provider office that was around the corner from her high school and not feel stigmatized by that if she saw someone she knew—it was definitely a lot. She encountered a lot of issues with her adult care. She experienced a provider who had not worked with a lot of women living with HIV, let alone people who were born with HIV, so they did not understand her experience as a person living with HIV. They lumped her in with all people living with HIV, even men who are living with HIV. At the time, she was on a medication regimen that she had been on for the previous 5 or more years. They took her off of that regimen and kept her on a 1-pill a day regimen. For somebody who had been taking HIV medications her whole life, from 8 pills, she was excited that this provider said she only need 1 pill 1 time a day, without realizing that she was on that 8-pill regimen because she had resistance to a drug that was in the 1-pill and she needed the additional medication. She expected her provider to know this information and she expected to be well taken care of, yet that resulted in her almost losing her life because her viral load skyrocketed. She did not understand what was happening because she was following what her provider said about taking the pill every day and she was not seeing any changes in her health. It took advocating for herself, leaving that provider, and going to a new provider where once again she had to tell her story from the very beginning. That provider knew she was not supposed to be taken off the original regimen because of the resistance. That provider saw Ms. Jone as an individual and a person versus somebody living with HIV. She saw the diagnosis through the lens of "just Antonette." She appreciated that provider and often gives her credit for saving her life because she had no clue as a new adult entering new adult care how she was supposed to vocalize that she was taking her medication, but thought there was something wrong with the pill. Nobody teaches them how to maneuver the system when transitioning from pediatric/adolescent to adult care. Peer-to-peer mentorship is very important, especially among lifetime survivors and people who are born with HIV. She never had a peer, but she could imagine the impact of having a peer to guide her along her journey of living with HIV from the perspective of also being born with and diagnosed in early childhood.

Special Presentation 1: Q&A with Speakers and Member Discussion

To focus the discussion, Dr. Armstrong reminded CHAC members of the advice related to this topic that was requested from CDC/HRSA and asked them to be thinking about action items CHAC might address and vote on later in the business section related to these questions:

1. What does CHAC recommend CDC/HRSA focus on to 1) determine if lifetime survivors and long-term survivors of HIV under 50 years old should be screened and linked to preventive therapy for non-communicable comorbidities of aging at a younger age than is

recommended for the general population – or after a certain duration of HIV infection; and 2) ensure timely linkage to/integration of that screening and treatment to reduce comorbidities of aging as recommended by current practice guidelines, in addition to their HIV care?
2. What other data gaps and other activities should CDC/HRSA focus on to improve quality of life for lifetime survivors of perinatal or childhood HIV infection?
3. What specific activities do you recommend CDC/HRSA prioritize to improve quality of life among older adults aged over 50 years?
4. What is the role of CDC/HRSA in supporting lifetime survivors of HIV as they transition from pediatric care to the reality of adult care?

The following questions, observations, and suggestions were raised:

- Dr. Agwu emphasized the importance of thinking about young people with HIV in pediatrics and beyond, in terms of mental health and other support services, as more than their viral load. It is crucial to recognize and support the other actions they need to survive and thrive and to provide resources to do that. In terms of transition to care, she runs pediatric and adult clinics and is intimately aware of the transition process and how if providers do not do it right, they become part of the problem. The onus should not be on young people to retell their entire stories. Systems of care need to do better in handing off and continuing the dialogue and coordination that will help prevent negative experiences that should not happen.

- Dr. Driffin expressed gratitude to the panel for bringing this conversation to this level of importance. Not only as he approaches 20 years of living with HIV, but also as he approaches umpteen years of working in HIV, he has never experienced this level of specificity in having this conversation. These real conversations are needed for the people most impacted, as well as the 51 jurisdictions, and 7 states, and any local health department that provide a life-altering diagnosis 10 to 20 minutes after a test. He thanked the panelists for being brave and lifting this up.

- Dr. Mermin also expressed gratitude to the panelists for their courage and kindness in presenting to CHAC, which was inspiring. He said he was interested in the daily lives of lifetime survivors, which are so wrapped up in the social, psychological, and other aspects of health, even beyond physical health. Those issues have to be addressed by the system, including the healthcare system. He also was struck by Mr. Adkins' existential angst about medical care in terms of what his future would be like and what he should be doing now so he does not worry about HIV. There are many issues for people with HIV that researchers and clinicians are struggling with, but other than perhaps use of cholesterol lowering agents, he asked whether there is something else from a clinical standpoint that should be researched because it has not been or that CHAC should be thinking about in terms of young people with HIV that they might be missing because they are assumed to be adults.

- Dr. Agwu responded that she spends a lot of time thinking about this. The data on statins did not include the majority of those living with perinatal HIV because it started at over 40. Perhaps they should be thinking about someone living for 40 years with HIV differently from a 40-year-old. Because they are seeing higher rates of malignancy, HCV, liver cancer, colorectal disease, and so forth among people living with perinatal HIV, perhaps they should be thinking about screening and prevention earlier for younger people. This is true for every co-morbidity. Every young person with perinatal HIV should receive the human papillomavirus (HPV) vaccine. The reality is that when people living with perinatal HIV were 10, no one thought that these children would survive, but that was then. Now, these

individuals cannot be forgotten. It is about asking intentionally and taking opportunities to prevent.

- Ms. Cadena-Fulks thanked the panelists for sitting with CHAC and sharing their very personal stories. She has been living with HIV for 20 years and has been working in the field for the last 15 years. Intentional conversations about lifetime survivors and Dandelions started occurring only in the last. As someone who has worked in frontline services for the majority of her career, she said she was curious about how the panelists had received services such as case management and early intervention support, and how the relationships with those types of HIV support services have impacted their health care. She also expressed interest in knowing more about medication fatigue and what that looked like as a child and as adults today.

- Mr. Adkins said that after he turned 18 and went to an adult provider, there were no support services. He was simply told to return in 3 to 4 months and had to ask whether there were any support groups, resources for assistance paying for medication, housing assistance, etc. He had to seek those out because they were not discussed. What led him to this field was attending the International AIDS Conference in 2014 in Australia. Prior to that, he wanted nothing to do with HIV. He went to school for accounting. By chance, he had the opportunity to attend the conference and saw that lifetime survivors were missing from the conversation. He attended all of the programs looking for something that addressed people perinatally infected, and there was nothing. It was at that moment of realizing that they were not being talked about that he told his personal story and entered the field of advocacy. In addition to his own struggles, there are people still coming up who are being left behind. For instance, he thinks about the 11-year-old who does not have support services like a camp or support group to learn that it is okay. To address the question about medication fatigue, it was a major challenge when younger to take pills due to not understanding how to swallow pills, taking multiple pills a day, and wondering when it would end. As he got older, he realized that he did not have a choice and had to take the medication. Seeing lifetime survivors pass away, he realized that by taking the medicine he was giving himself hope that someday in the future the medication would not be required so often or there would be a cure and that he would be able to live to see that day.

- Ms. Jones said that she always had case management, but she did not think her mom took full advantage of the case management. In Black households, they are taught not to share everything that needs to be shared with providers because of the risk around criminalization with Child Protective Services (CPS) or where the information would go. In retrospect, she does not feel that she received the amount of care that she truly needed because of how hesitant her mom was about sharing. When she entered adult care, that was the first time she experienced case management in a way that was beneficial to her and her mental health. She experienced mental health care with a therapist who assisted her in finally putting a name to what it was she was experiencing around depression, anxiety, suicidal ideation, and other issues she did not understand. She knew she had strange feelings and thoughts because she was living with HIV and did not feel that anyone around her could understand her experience. In terms of medication fatigue, she always has had issues with adherence. If not for her mom who adopted her who literally had to hold her hand in the process of taking medications from liquid to pills, who had to watch her like a hawk to make sure she took it, she would not take the medication. Even though she is on a great pill once a day now at 29, she still has fatigue around medication and HIV in general and she gets sick and tired of it. Now that she has accepted loving who she is and living with HIV, it is easier to take the pill so she knows she can live. It is key to have a provider who understands and supports her as somebody who has been taking medication her whole life

and what that is like. Having a provider who understands and accepts that she might take her medication only 5 of 7 days a week rather than being the medication police is the type of support that she needs.

- Mr. Riester thanked the panelists for their amazing presentations and discussion, their bravery, and their advocacy. For the last 7 or so years that HIV and aging has become a "hot topic," it was the first time he heard the lifetime survivors' voices and he loved that they were doing what they are doing. In his own experience in Colorado, the case manager at Children's Hospital also was a person living with HIV. She was a fierce advocate for the transition from child to adult care, which was amazing. They now have 2 people on their HIV Resources Planning Council who are lifetime survivors. He thanked the panelists for all of their dedication, especially their struggles. No matter how many times they tell their stories, people still will not know exactly what they have gone through. Therefore, it is very important to continue to advocate for research because their experiences and the experiences of other long-term survivors are different and that needs to be looked at.

- Dr. Arrington Sanders said her heart went out to all of the panelists for being there, sharing their stories, and having the courage to do so. She asked what CHAC could do to move forward to help young people who acquired HIV at birth or were diagnosed in adolescents not only survive, but also thrive and what that looks like from an economic and life perspective and not just focusing on HIV in order to live the best life possible.

- Ms. Granados said that as they heard during this session, many lifetime survivors consider adolescent medicine the gold standard. She thinks there should be an intentional model to support that transition like Dr. Agwu mentioned. It is not just about the nostalgia and fuzzy feelings of being children in a supportive environment. Anytime she speaks with anyone who had the experience of pediatric or HIV care, they talk about what holistic care they received that was lost when they entered adult care. She hears story after story about people being lost to care or having inconsistent care. She personally switches doctors every 2 to 3 years because she feels like she is always in search of the gold standard that she received in adolescent medicine. It is important to look at the best practices from those settings and create a model that fully supports people as they transition into adult care. They also heard about the need for models for medical, social, and service support that are specific to this population, knowing that the numbers in any given jurisdiction are small. Creative models are needed for how to do that. While every clinic may not be able to afford a full-time person, perhaps there are ways to encourage partnerships across clinics to ensure that there are local navigators who are specialists. This also raises the concern about the aging and retirement of lifetime survivors medical specialists. Going to providers who say, "Wow, you're the first person I have ever met with pediatric HIV" does not instill any confidence that her doctor is going to be able to care for her in the way that she needs. The reality of being a cisgender woman is yet another issue to consider. Investing in capacity-building for providers to develop more specialists is one opportunity. Based on the diffusion of where lifetime survivors are in any given jurisdiction, innovative models will be needed for how to do that. Echoing Dr. Agwu's recommendation around looking more closely at medical indications should be considered earlier for this population is crucial and ties back to the psychological impact of still seeing their friends dying. As lifetime survivors are getting older and are seeing highly visible activists in their community dying, it makes them face their own mortality—even in 2024 with the best medication and the best medical model available. Not having accurate reasons for that mortality makes them even more scared. It is very important to share data more publicly not only from CDC, but also from states, counties, and smaller jurisdictions. Lifetime survivors need to see themselves in the data so that conversations are occurring at planning councils, and they do not continue to

think that people have forgotten they exist. If they do not talk about it, their needs will never be addressed.

- Mr. Adkins added that 10 years ago when he returned from a conference, he realized that lifetime survivors need to have their own community organizations because they have specific needs that are different from the rest of the HIV population at large. He was met with, “Your numbers are so small. There is no data to support that.” For instance, data are needed for grant funding. Some of the best help that he has received in his adult life has come from the Lifetime Survivors Network. They share data amongst themselves to stay current on the latest research, medications, efforts to battle depression and stigma, etc. This all goes back to data.

- Dr. Armstrong noted that while unfortunately they were out of time for this session, there were still many questions online and at the table, which showed how deep the interest is in the topics the panelists raised and their experiences and wisdom. She added her gratitude for their courage, resilience, and willingness to tell their stories again and again. This session highlighted the importance of conducting research that breaks out lifetime survivors and people who are perinatally infected, identifying gaps in knowledge, and recognizing the need for sensitivity on the clinical side and partnering with lifetime survivors and uplifting their experiences rather than making that a negative.

Special Presentation 2: Doxy PEP Update

Moderator: Lindley Barbee, MD MPH; Chief Medical Officer, DSTDP, CDC

Overview

Lindley Barbee, MD MPH
Chief Medical Officer, Division of STD Prevention
National Center for HIV, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention

Dr. Barbee expressed her excitement about sharing an update on what is occurring in the doxy PEP space. Doxy PEP is one of the first biomedical interventions available to prevent bacterial STIs. No vaccines exist for chlamydia, syphilis, or gonorrhea. Yet, 2.5 million cases were reported in 2022 and possibly many more went undiagnosed. This number has been rising over the past 10 to 15 years. Doxy PEP is the practice of taking 200 mg of doxycycline within 72 hours after sex and has shown great reductions in bacterial STIs, particularly syphilis and chlamydia in 3 large RCTs among MSM and transgender women. While CDC’s guidance is not yet published, draft guidance was posted on the Federal Registry Notice (FRN) in Fall 2023. This guidance is forthcoming and hopefully will be released in the next couple of months. She noted that this session would include presentations from 2 doctors who already have implemented doxy PEP at a clinic and at a local level.

Translating Evidence into Action for Public Health: The Doxy PEP Story

Stephanie Cohen, MD, MPH
Director, HIV/STI Prevention Section
San Francisco Department of Public Health

Dr. Cohen emphasized that STIs are a critical public health issue across the US and in San Francisco. San Francisco faces a particularly high burden of these infections, with rates that are higher than the US overall, California, Los Angeles, and New York City. From 2011-2022, while San Francisco had quite a decline in the number of new HIV diagnoses, steeply rising rates of STIs occurred over this same time period. From 2014-2019 during a period of a lot of progress with HIV Getting to Zero San Francisco, there was a 76% increase in chlamydia, 72% increase in gonorrhea, and a 45% increase in early syphilis in San Francisco.

With this high burden of STIs and rising rates, across the field of sexual health, San Francisco has been very interested in pursuing new interventions to prevent STIs. With that in mind, San Francisco was excited to participate in the US Doxy PEP study that launched in November 2019 in San Francisco and Seattle. In terms of background, doxycycline (doxy) is an oral antibiotic that is safe, well-tolerated, and inexpensive. It has known activity against chlamydia and syphilis and often is used as a treatment for those infections. It is not currently used as treatment for gonorrhea because about 20% of gonorrhea strains in the US have some resistance to doxy. Proof of concept data from 2 smaller prior studies[29] showed that doxy as prophylaxis could work to prevent STIs. The first was a small pilot in Los Angeles that enrolled 30 people living with IV who were randomized to take doxy-PrEP daily. Despite being a small study, it demonstrated effectiveness. The second was a subset of 232 people from the Ipergay study of 2-1-1 PrEP in France that assessed doxy PEP that also indicated that this intervention could be effective in preventing chlamydia and syphilis specifically. It also was known from surveys and anecdotal experience talking to patients that there was strong interest amongst MSM in a biomedical prevention tool for STIs. With that context, 3 studies launched around the same time in 2019, the US Doxy PEP study, the French DOXYVAC study, and the Kenya D-PEP study, all of which aimed to assess the impact of doxy PEP on bacterial STIs incidence and on drug resistance in STIs and other bacteria.

In terms of the overall findings from the US Doxy PEP[30] and DOXYVAC[31] studies, both demonstrated the efficacy of this intervention. Doxy PEP involves taking 200 mg of doxy ideally within 24 hours and up to 72 hours after condomless oral, anal, or vaginal sex. The US Doxy PEP study that enrolled people living with HIV and those who were not living with HIV found an overall 63% reduction in time to first chlamydia, gonorrhea, or syphilis infection. The DOXYVAC study showed an 83% reduction in time to first chlamydia or syphilis. Unfortunately, the Kenya D-PEP study[32], which is the only of the 3 trials that enrolled cisgender women, did not find that doxy PEP reduced STIs in cisgender women. There were no differences between the 2 arms of the study (e.g., those who took doxy PEP and those who received standard of care). Initial analyses from this study reported high self-reported adherence to doxy PEP and that participants self-reported taking about 4 doses of doxy PEP per month. Additional analyses that looked at levels of doxy in hair found that a low proportion of participants had doxy detected, which suggested that the participants in this study likely were not taking very much doxy PEP. This may be the reason doxy PEP was ineffective in the Kenya D-PEP study.

[29] Bolan, et al. Sex Transm Dis 2015; Molina, et al. Lancet Infect Dis 2018
[30] Doxy PEP, Luetkemeyer et al, NEJM 2023; 388:1296-1306
[31] DOXYVAC, Molina et al, CROI 2024
[32] Stewart, et al. NEJM 2023

With this foundation of trends in STIs, high interest in the intervention, and a growing body of evidence that it is effective, San Franciso considered how to implement this in the jurisdiction. A number of discussions regarding to whom doxy PEP should be offered (e.g., eligibility criteria), how the roll-out could be supported to ensure equitable uptake and access for the community, and what would need to be done to monitor the impact of doxy PEP to assess for disparities, track STI rates, assess for the potential emergence of antimicrobial resistance, and to monitor for adverse events (AEs) in individuals such as impacts on the microbiome. The first question the community tackled regarded the eligibility criteria for doxy PEP. The US Doxy PEP and DOXYVAC studies that demonstrated efficacy enrolled MSM and transgender women who had at least 1 bacterial STI in the last year. In the early phase of implementation, some suggested that more restrictive criteria should be used while still learning about this tool to maximize the benefit-risk ratio and minimize excess antibiotic use. However, there are some downsides to a more restrictive approach, which include that it could be more complex to identify candidates and it potentially could reduce the reach and impact of this highly effective tool. Others suggested that broader use made more sense in order to meet the high patient demand, embrace a sex-positive and anti-stigma approach, and result in the greatest possible reduction in the absolute number of STIs prevented. A broader approach means that more antibiotics would be used.

To address this question, stakeholders, experts, community members, and the local Getting to Zero consortium were assembled and together developed guidelines that were released in October 2022 on doxy PEP. The San Francisco Department of Public Health (SFDPH) was the first jurisdiction to release local guidelines for doxy PEP use.[33] The Doxy PEP Interim Guidelines made the following recommendations about to whom and how doxy PEP should be offered:

1. **Recommend Doxy PEP** to cis men and trans women who: 1) have had a bacterial STI in the past year and 2) report condomless anal or oral sexual contact with ≥1 cis male or trans female partner in the past year. Patients with a history of syphilis should be prioritized for doxy PEP.

2. **Offer Doxy PEP using shared decision making** to cis men, trans men and trans women who report having multiple cis male or trans female sex partners in the prior year, even if they have not previously been diagnosed with an STI.

3. **Results from the Kenya D-PEP study found that Doxy PEP was not effective at preventing STIs among cis women.** Drug level data suggest that this may have been due to low adherence to doxy PEP. Providers can consider offering doxy PEP to cis women on a case-by-case basis, for example to women with a history of syphilis or women who exchange sex for money or drugs.

To support implementation, readable, concise, non-stigmatizing patient and provider facing education materials were developed in multiple languages. These materials are available on the San Francisco City Clinic website for those who are interested in downloading and using them.[34] The guidelines also recommend that doxy PEP be offered as a comprehensive package of sexual health services to sexually active cis men and trans people who have sex with cis men or trans people rather than as a standalone intervention. Instead, it should go hand-in-hand with primary prevention; vaccines; PEP, PrEP, and TASP; secondary prevention; addressing SDOH; and advocating for policy change.

[33] https://www.sfcityclinic.org/sites/default/files/2022-10/Health%20update_Doxy PEP_FINAL.1.pdf
[34] https://www.sfcityclinic.org/

With the release of the guidelines at the end of October 2022, San Francisco City Clinic (SFCC) began offering doxy PEP in November 2022. SFCC is the health department run STI clinic and is a nationally recognized center of excellence in sexual health services. Many other clinics in San Francisco also began offering doxy PEP in November 2022. SFCC offers integrated HIV, STI, and reproductive health care grounded in a syndemic approach. It is a low-barrier free clinic where a diverse population of patients come to seek these services. SFCC has high uptake of doxy PEP. When doxy PEP was initially rolled out in November 2022, SFCC systematically informed its patients about doxy PEP at PrEP initiation or PrEP follow-up. This was done by SFCC's highly skilled PrEP Navigators who have a lot of experience counseling patients about biomedical prevention tools. Other patients not in the SFCC PrEP program also were offered doxy PEP during a clinician visit, but this was not done quite as systematically as in the PrEP program. Between November 2022 and May 2023, 74% of PrEP patients had a bacterial STI in the prior year chose to initiate doxy PEP and 60% of patients who had ≥2 sex partners who had not been diagnosed with a bacterial STI also chose to initiate doxy PEP. Uptake was associated with having a higher number of sex partners in prior 3 months, but not with any demographic factors such as age, race, or ethnicity.

There also was high uptake of doxy PEP in other clinics in San Francisco after the release of the guidelines. The local Getting to Zero Consortium has supported an effort to conduct sentinel surveillance of doxy PEP in San Francisco to help track how many people are using doxy PEP and to assess for any early signs of disparities in uptake. Between October 2022-December 2023 data from SFCC; Magnet PrEP, run by the San Francisco AIDS Foundation; and a large HIV clinic based at San Francisco General, a safety net hospital; showed high uptake of 3,779 cumulative doxy PEP initiations. This is just a subset of clinics that does not include high volume health maintenance organizations (HMOs) and primary care clinics. Across the 3 clinics (SFCC, Magnet PrEP, San Francisco General), tracking is also underway for evidence of disparities. Between October 2022-December 2023, uptake was lower in the HIV care clinic setting. Overall, there was similar uptake across racial/ethnic groups within existing clinic cohorts. It is important to note that Black/African Americans had somewhat lower uptake at all 3 sites.

They have heard positive feedback from patients[35] on their experience with doxy PEP and there have been very few AEs and no serious adverse events (SAEs) reported. Overall, patients are reporting that they are using doxy PEP selectively. At follow-up visits, 89% of those prescribed doxy PEP reported using it, but not with every condomless sex act. There have been occasional discontinuations related to gastrointestinal (GI) side effects, but these are infrequent. Patients are reporting that this is a sex-positive and person-first intervention and that they are experiencing improved peace of mind and sexual pleasure, decreased stigma around STI diagnosis and disclosure, increased self-awareness about sexual behavior, and facilitation of communication with partners about sexual health.

In terms of the impact of doxy PEP on STI rates in clinics, across the city, and in San Francisco, Dr. Cohen shared data that was presented at the CROI conference from her colleague Dr. Scott from the San Francisco AIDS Foundation and Dr. Bacon who is the Medical Director at SFCC.[36] Both of them analyzed rates of STIs within the PrEP cohorts at the 2 clinics and found significant decreases in chlamydia and syphilis among those PrEP patients who started doxy PEP. Neither clinic has seen a significant decrease in gonorrhea in these initial analyses.

[35] Fredericksen R, et al. AIDS Pt Care STDs 2024 (forthcoming)
[36] Scott H, CROI 2024 (abstract #126); Bacon O, CROI 2024 (poster #1151)

One of the SODPH epidemiologists, Dr. Sankaran,[37] assessed citywide rates of STIs before and after the release of the doxy PEP guidelines. To do this, a modeling approach was used to estimate the number of monthly cases that were expected in San Francisco if trends had continued as they were. Chlamydia cases were 50% lower by November 2023 compared with the modeled forecast, and syphilis cases were 51% lower than the modeled forecast. However, no decline was observed in citywide gonorrhea cases in MSM after the release of the doxy PEP guidelines. The same modeling approach was used to look at chlamydia cases in cisgender women, a population to whom doxy PEP was not recommended. Chlamydia cases increased 2.46% per month among cisgender women over this same timeframe.

In conclusion, SFDPH moved quickly to translate evidence from a research study into services for the community. This was possible because of a remarkable citywide collaboration and the engaged community that facilitated early adoption of this new tool. Some early evidence exists of a population-level impact of doxy PEP on chlamydia and syphilis rates, but not gonorrhea. Longer follow-up is needed to determine whether these trends are sustained and to replicate findings in other jurisdictions. More information is needed about potential impacts on antimicrobial resistance. Providers are recommended to support their patients in assessing their need for, interest in, and use of doxy PEP. The guidelines for doxy PEP can and should evolve as evidence emerges that are informed by community input.

Doxy PEP at a Boston Community Health Center and National Survey Data

Kenneth H. Mayer, MD
Medical Research Director, Fenway Health
Professor of Medicine, Harvard Medical School

Dr. Mayer presented information on doxy PEP at a Boston FQHC, Fenway Health, which was founded in 1971 and is based in downtown Boston, as well as data from a national survey. Fenway Health always has had a large LGBTQIA+ population and was ground zero in the early days of the AIDS epidemic in terms of developing a community-based response in New England. Currently, Fenway Health provides primary care for approximately 35,000 patients, including over 2,200 patients living with HIV and about 3,500 people who are currently on PrEP. To provide some context of the organization, Dr. Mayer works in the Fenway Institute, which is the research, education, and policy part of Fenway Health. The Fenway Institute is involved in many studies supported by the NIH, CDC, and others and also has a large public health program focused on needle exchange and walk-in STI sexual health.

Given that Fenway Health is the health center providing care to the largest number of sexual and gender minority people in New England, in the absence of guidelines in the early days, they looked at the San Francisco guideline, New York State Department of Heath guidance, and their own internal data. With Michael Traeger from the Brunet Institute in Australia, who was a Fulbright Post-Doc with the Fenway Institute,[38] they looked at individuals assigned male sex at birth who received STI screening in recent years, which was the analytic population. Then they engaged in a thought experiment about what the most efficient prescribing strategies would be based on STI history rather than HIV status or PrEP use for prescribing doxy PEP. The efficacy trials clearly showed that doxy PEP worked, but consideration needed to be given to who would most benefit. They found that if everybody who was screened for an STI received doxy PEP, they may be able to prevent over 70% of new STI infections. However, that is not necessarily the most efficient strategy because 29% of people would be taking doxy PEP who would not have an STI. At the other extreme, individuals who had concurrent STIs represented

[37] Sankaran M, CROI 2024 (abstract #127)
[38] Traeger MW, CID 2023

a very small number of individuals but was a much more efficient strategy. That is, more STIs would be prevented than the number of people who would be given prophylaxis.

That led the Fenway Institute to develop a program to educate the medical department. The goal was to develop some simple algorithms for busy primary care providers and also some tools for patients. In terms of offering doxy PEP, the decision was made to focus on those who were assigned male at birth who were ≥18 years of age plus one of the following and shared clinic decision-making:

- ❑ A diagnosis of a bacterial STI in the last 12 months
- ❑ PrEP use and ≥2 sexual partners with condomless oral/anal sex
- ❑ PLWH and ≥2 sexual partners with condomless oral/anal sex

In the Fenway Health EMR, which is an Epic system, there were a number of tools where the primary provider can click and print out information to give to patients. They developed materials to include in these tools to explain what doxy PEP is for, how to take it, and other important considerations. In terms of how to take doxy PEP, they called this "3-2-1" to represent taking it within 3 days or 72 hours, taking 2 tablets, and taking it 1 time a day. Other important things to consider includes patient education that people should understand. They have had very few discontinuations due to side effects.

In assessing the sociodemographic data, they found that the largest number of individuals availing themselves of doxy PEP were in the group of adults 30-39 years of age. In terms of race and ethnicity, the largest percentage of patients prescribed doxy PEP at Fenway Health were White. However, that is not necessarily a differential reflection of less uptake of doxy PEP among individuals of color. This ties very well to the demographics of who accesses clinical services at Fenway Health. About 16% of patients prescribed doxy PEP were Latinx, over 10% were African American, and less than 10% were people living with HIV. By the end of 2023, 1712 patients received at least 1 doxy PEP prescription. STI testing frequency increased, while the percent positive tests for syphilis and chlamydia decreased. Testing more and seeing lower prevalence of infection suggests some amount of clinic level impact. Like other reports, this same finding was not observed with gonorrhea.

To better understand who was using doxy PEP and who was not, they looked at early adopters in implementation of doxy.[39] A comparison of doxy PEP users with other men screened for a bacterial STI at Fenway Health (N=4,927; >1100 doxy PEP users, Fall 2023) did not identify any disparities in terms of doxy PEP use. What stood out about doxy PEP uptake in this analysis were that 73.8% of doxy PEP users also were PrEP users, 85.4% had private insurance, 31.3% had a bacterial STI diagnosed in 2022, and 8.6% were people living with HIV. Among doxy PEP users, 39.9% of doxy PEP non-users also were PrEP users, 71.3% had private insurance, 15.0% had a bacterial STI diagnosed in 2022, and 18.1% were people living with HIV. Flipping that to look at doxy PEP uptake among people with an active PrEP prescription, 24.1% of patients have an active PrEP prescription, 4.8% are people living with HIV, 13.7% of those screened for a bacterial STI in 2022, and 24.7% of uptake was among those diagnosed with a bacterial STI in 2022. This speaks to the fact that although Fenway Health has scaled up doxy PEP, they still have a long way to go. Based on the algorithm, someone diagnosed with a bacterial STI might be a good candidate for doxy PEP, yet three-quarters of those individuals are not yet on doxy PEP, so there is room to grow within the clinic.

[39] Mayer et al, CROI, 2024

Turning now to other data with the theme of "elsewhere USA," with Dr. Traeger they conducted a national survey in September 2023 in 2 sexual networking sites where MSM and other individuals assigned male sex at birth who have sex with men frequently access.[40] This resulted in a large national sample of almost 1,000 individuals (N=903). Among these individuals, the mean age was 42 years, 95% identified as gay or bisexual male, 19% identified as living with HIV, and 42% indicated that they were using HIV PrEP. The participants were asked about antibiotic prophylaxis in general and about doxy PEP in specific. This study found that given a hypothetical scenario about antibiotic prophylaxis, almost all of the individuals who answered the survey were interested, about half were aware on some level, about a fifth had used some antibiotic, and 16% said they used antibiotic in the past month. When asked more specifically about doxycycline prophylaxis, a little over a third were aware of doxy PEP and 13% had used it in the past 12 months. Clearly, there is need for upscaling.

In terms of some of the other characteristics, antibiotic use before sex was not uncommon in this sample, with 45% reporting use of antibiotics before sex. About 72% reported use after sex. With casual sex partner in the past 12 months, 47% used antibiotics some of the time, 32% used is most of the time, and 21% used it all of the time. Among doxy PEP users, about 24% had used a dosage other than the single 200 mg dose that is recommended, which is a concern. Although the vast majority (78.1%) of antibiotic use was doxycycline, a number of other antibiotics are being used, some of which raise concerns about potential resistance. Where people are getting their antibiotics is another issue. While 60.2% received their antibiotics from a doctor or clinician, a fair number also used leftover antibiotics or antibiotics from a friend. This speaks to the need for provider and community education to ensure that people understand how to best use this medication in the most appropriate ways.

In conclusion, the experience at Fenway Health shows that doxy PEP scale up is feasible and highly acceptable. Attention to ensuring equity remains important. Fenway needs to follow up on some signals regarding insurance and that people with HIV are less likely to be using doxy PEP. Early suggestions suggest that doxy PEP roll-out may be having a local population impact, which needs further study. National data suggest that there are high levels of interest and some possible misuse of antibiotic prophylaxis. Community and provider education and clear guidelines are important in order to enhance optimal uptake of this innovative technology.

Special Presentation 2: Q&A with Speakers and Member Discussion

To focus the discussion, Dr. Armstrong reminded CHAC members of the advice related to this topic that was requested from CDC/HRSA and asked them to be thinking about action items CHAC might address and vote on later in the business section related to these questions:

1. What barriers should CDC/HRSA anticipate for the implementation of doxy PEP?
2. What can CDC/HRSA do to ensure equitable implementation and uptake of doxy PEP?
3. How can CDC/HRSA best support implementation in non-public health clinical settings?

[40] Traeger et al, CROI 2024

The following questions, observations, and suggestions were raised:

- Dr. Mermin expressed gratitude for the quick work on developing the draft guidelines that hopefully soon will be finalized. It is tough to do this as information is coming in, but doxy PEP is clearly an important potential intervention with a very thoughtful approach. He asked how many pills Drs. Cohen and Mayer give their patients. In the RCTs, use was about 4 times per month.

- Dr. Cohen indicated that they prescribe 60 pills with no refills, which lasts most of their patients 3 months. They were trying to find a balance where people would not need to come in early for refills, but also would not necessarily have a lot of leftover pills at the end of the 3-month period. It clearly is not a one-size-fits-all approach. People's level of sexual activity varies greatly, so they sometimes have patients who call in and need an early refill and others who return in 3 months with plenty of pills left, which is where they have landed for now.

- Dr. Mayer said they have done the same. The 60 pills are 30 doses in case people are taking it every day. Their initial finding is that most people are not taking it every day. They do allow 2 refills just in case. The rationale is that they want people who are sexually active to return quarterly for a routine STI screening.

- Dr. Mermin observed that for both the San Francisco and Boston sites, there is a strategic approach to cover most people who would benefit from doxy PEP: people visiting STI clinics who have been diagnosed with an STI, people taking PrEP who are at high risk for STIs or who have been diagnosed with an STI, and people with HIV. If all 3 of those populations were covered, it would make a massive difference in the epidemiology of STIs in communities. Some people with HIV are much older than the people visiting STI clinics, or on PrEP, or are in long-term relationships. They do not have as many different partners or risky exposures for STIs. However, epidemiologically, the overlap of syphilis in particular is quite strong in the sexual networks of people with HIV. His understanding is that now about 30% of syphilis is still occurring in people with HIV, but he wondered if the 8.6% of people with HIV that Dr. Mayer showed as doxy PEP users were really having a lot of sex and their risk for STIs was increased, or if it was because there were concerns among people with HIV about taking additional pills. The corollary is that if this is really important to help people with HIV, it would be great to work with Ryan White clinics and others through a strategic approach to make sure that there is a clinical decision reminder to talk to patients about doxy PEP.

- Dr. Mayer said he thought it was due to multiple reasons. There is still a lot of stigma for people with HIV to talk to some primary care practitioners about being sexually active. Unfortunately, with many providers, it is "don't ask, don't tell." A lot of barriers exist, but providers and the community need to be educated about the need for disclosure so that people can take advantage of these tools.

- Dr. Cohen agreed that this is multifactorial and may be driven largely by some of the differences in demographics and sexual activity between the 2 populations, at least in San Francisco where they compared their 2 sexual health clinics with their large HIV primary care clinic. It is fascinating how well that aligned with the Fenway data that Dr. Mayer presented. San Francisco had about 6% to 7% uptake at the HIV clinic and about 25% uptake at the STI clinics. That was nearly identical to what Dr. Mayer showed. It is critical to assess whether there are not differences in uptake that are related to factors like stigma and biases on the part of the provider. It already is known that HIV care providers have not

historically conducted STI screening amongst their HIV primary care patients at the recommended levels. Many efforts have been made to improve STI screening in HIV primary care. She thought Dr. Mermin's suggestion was a good one about using clinical decisions support tools to remind providers about screening and offering STI prevention.

- Dr. Armstrong asked whether they were experiencing pushback from providers who are nervous about the potential for resistance, or if they felt like it was more oversight in terms of not thinking about it.

- Dr. Mayer said he thinks pushback exists and they have received this question from providers, so it seems to be on people's minds. More work is needed to ascertain how pervasive those concerns are among providers as a barrier.

- Dr. Cohen agreed. It is difficult to generalize from their environments where there are many strong champions and thought leaders, as well as a lot of buy-in from providers who have been diagnosing and treating too many STIs for a long time. The attitudes and concerns around antimicrobial resistance in provider communities likely vary a lot based on setting. It is possible that HIV providers would have a higher level of concern.

- Regarding cisgender women, Ms. Beiser noted that the data Dr. Cohen shared did not show any change in terms of outcomes. However, there was no information about uptake by cisgender women. She was curious if that was tracked and what Dr. Cohen's thoughts were on what more would be needed to better inform how this opportunity potentially could be used for cisgender women.

- Dr. Cohen said the most challenging question in this space right now regards how to proceed with cisgender women, how to get the data they need, and what is reasonable to do at this point. They have not been tracking uptake systematically in cisgender women, but recently participated in a case series that a colleague at the University of Chicago is leading to look at prescriptions in people assigned female sex at birth because there are no other sources of data for this. Among those who contributed to this case series, there are very small numbers of prescriptions in cisgender women. Overall, across the clinics that participated, there were about 0.5% of doxy PEP prescriptions given to cisgender women in this large dataset. Not much is happening at this point, given the RCT data that are available thus far. They can assess uptake in terms of how much prescribing has been done, but it is difficult to assess uptake in terms of a proportion of people who are offered doxy PEP who use it because a systematic approach does not exist to offering doxy PEP to cisgender women.

- Ms. Granados expressed concern about the exclusion of cisgender women from the recommendations. This reminded her of PrEP, particularly with the high rates of syphilis and congenital syphilis occurring among cisgender women of color, particularly Black women. Unless she heard something incorrectly, if there is no biomedical counterindication for cisgender women, this seemed to be an adherence issue for which adherence interventions are needed in order to increase that uptake. Thinking about the importance of risk screening for cisgender women and transgender men, even the risk screen needs to be tailored to be specific to their vulnerabilities. Oftentimes, she finds with PrEP that the risk screening is from a gay man's experience and perspective, which leaves cisgender women out of the picture. She also wondered whether either of the presenters had any ideas or recommendations pertaining to adherence interventions to ensure that they are educating, offering, and tracking the interest and uptake of doxy PEP for cisgender women.

- Dr. Mayer said that to his knowledge, there are several intervention studies underway now to combine best practices for adherence counseling and doxy PEP for cisgender women. Doxy PEP is not promoted at Fenway Health for cisgender women and transgender men because there are no data, but they do have a shared decision-making protocol so if someone has an STI, providers are triggered to at least think about doxy PEP. He agreed that they need to do more and better.

- Dr. Driffin thought it would be interesting to hear this same conversation across jurisdictions with higher HIV diagnoses, especially across the Deep South. From the conversations he has among his friend groups on social media, he is still hearing that a number of Black and Brown men are being told by their providers that the clinical trials are pending, providers are not authorized to prescribe doxy PEP, and that they should just have less sex. His provider gave him 60 pills, which he thought was a lot until he heard that this is what others are doing. He asked whether the intersection is with CDC and HRSA HAB in terms of ensuring that the clinics are beginning to use these more intersectional solutions to reduce STIs and ultimately HIV.

- Dr. Cohen agreed that broader geographic representation is needed in this conversation, and implementation studies are needed that include clinics and jurisdictions in the Deep South to hear more about provider attitudes, patient attitudes, and what can be done to support uptake. STI rates in the Southeast are amongst the highest in the country, so the South absolutely needs to be included in the work. They do have champions and colleagues in Atlanta, Miami, and other parts of the South who are interested in this work, so she thinks there will be data forthcoming.

- Dr. Dionne said she still had a lot of concerns in terms of moving from efficacy to effectiveness for these studies. Looking at the people who were enrolled in the DOXYVAC trial had on average 10 partners within the past 3 months, with the MSM included. When they begin to build broad categories of everyone living with HIV and everyone who is MSM, they may not meet the eligibility criteria that would have gotten them enrolled in that trial. She was impressed when Dr. Molina presented the updated data at CROI showing that the benefit in the reduction of gonorrhea appears to be waning already, with an increase in gonococcal resistance in some of the patients who were sampled. Thinking about the long history of STIs, especially for gonorrhea, it is known that resistance occurs and that it occurs in the setting of widespread antibiotic use. Doxycycline is not like HIV PrEP. It is used for people with skin and soft tissue infections and pneumonia. It is a first-line antibiotic that practitioners turn to for many patients in infectious disease. She expressed interest in hearing more thoughts about the need for data regarding some of the risks of widespread doxy use.

- Dr. Mayer agreed with these excellent points, acknowledging that potential unintended consequences exist. In the face of rising syphilis and chlamydia epidemics, it is very hard to justify not rolling something out that is showing evidence from multiple trials. The French experience is a cautionary tale. The prevalence of gonococcal resistance to tetracyclines in the US is substantially lower at 20% to 30% versus 70% to 80% in France. That does not mean the US will not get there sooner or later. Some modelers say that there is a thorough focus on the population who can benefit, such as individuals who are in sexual networks where there have been recent STIs and people who are non-monogamous, that may have less of an ecological impact than wider dissemination. This has to be tracked and CDC and other federal colleagues are supporting surveillance work. The hope is that eventually there will be a gonococcal vaccine, but that is not a given.

- Dr. Cohen added that making access to doxy PEP broader does not mean that everyone is going to use it. They have seen in the uptake analyses that people who have more partners and who have had STIs are more likely to choose doxy PEP. She thinks they sometimes underestimate their patients' ability to self-identify what tools make sense for them to use. They may be overly concerned that doxy will end up in the water because it was offered more broadly, but that needs to be tracked. The points regarding gonorrhea are well-taken. It is a concern in France, San Francisco, and Boston that in the post-RCT phase, impacts are not being seen on gonorrhea. However, she did not think that anyone ever thought that doxy PEP would be the solution for gonorrhea because it was known that gonorrhea strains already had a baseline resistance to this class of antibiotics and tend to develop resistance quickly. Therefore, new and other strategies are needed for gonorrhea. That does not mean that doxy PEP should not be used against syphilis and chlamydia at this point. There are many other sources of doxycycline that outstrip the doxycycline being prescribed for STI PEP. It is used to treat other infections, there is doxycycline in agricultural settings, and more has been used in STI for the past few years before doxy PEP because chlamydia treatment guidelines changed from azithromycin. This is an important issue that has many drivers.

- As a provider who provides gender-affirming care and care for transgender youth, Dr. Arrington Sanders expressed gratitude to Dr. Cohen for including transgender men in the study, analyses, and approach. She thought it would be helpful to understand about transgender men, particularly for people who are assigned female sex at birth or have a vagina, in terms of the impact of doxy PEP in that population and how it compares to other people with a vagina. The population is different and there is not a lot of data about how hormones impact metabolism and efficacy. She expressed concern that a lot of the doxy PEP data she had seen so far would contribute to further disparities. Only 19% of one of Dr. Cohen's clinics was focused on African Americans and the other was 21%. They were lower than the other groups. It reminded her of the PrEP data, including those disparities. She wondered about how to avoid perpetuating those disparities, addressing myths, and getting out in front of this so that those individuals actually receive the doxy PEP that the evidence has shown is needed. She emphasized that they must not forget about adolescents. She asked the same question at CROI. The adolescent data are not being presented. There are no data focused on adolescents and youth in terms of doxy PEP. STIs occur mostly among adolescents and young adults at 50% or more. It is a disservice not to address this in these populations.

- Dr. Cohen agreed. She clarified that transgender men were not in the RCT, but they were included in the citywide guidelines for all of the reasons mentioned. They often are left out of research. Transgender men who have sex with men often are in the same sexual networks as MSM, so they were looking at this from an epidemiological standpoint. However, in terms of transgender men who can become pregnant, there are some potential risks of doxy PEP in pregnancy. The risk may not be as high as people think, but it is another reason for some caution in doxy PEP in people who can become pregnant, so it is important to include that information in counseling for anyone who could become pregnant. They hope to learn more about that population from their implementation experience.

- Dr. Mayer added that perhaps CHAC could make some recommendations for their colleagues at CDC and HRSA. CDC is thinking about how to roll out education to providers and HRSA has some wonderful tools like the AIDS Education Training Center and CDC has a Prevention Training Center. Addressing all of the reasons for disparities in this country is going to be problematic because so many states have not enacted full provision of the Affordable Care Act (ACA), which is fundamental in getting people access to medication. At least the CDC and HRSA have a great role to play in promoting provider education in the broader frame of sexual health 2024. A variety of modalities exist, but providers need to be comfortable asking questions and be familiar with the medications and how to manage them. This seems like something that could be done fairly quickly.

- Mr. Riester asked whether resistance testing is done prior to prescribing.

- Dr. Cohen responded that it is not, and it is not really possible to do this because they would be able to test only for resistance in the setting of the diagnosed STI. They do recommend that people get screened for STIs as they are initiating doxy PEP so if someone had an STI and was starting doxy PEP, they would know that and would prescribe a full treatment course for any prevalent or existing STI they may have. Unfortunately for syphilis and chlamydia, it is very difficult to do resistance testing because it is not widely available. For gonorrhea, resistance testing requires having a culture. Most gonorrhea diagnoses are made with a NAAT not a culture. CDC has supported a sentinel network for decades to monitor for gonococcal resistance. It will be important to continue to monitor those data and to try to have more access to resistance testing for gonorrhea.

Special Presentation 3: Advancing Diagnosis of Current HCV Infection

Moderator: Saleem Kamili, PhD; Chief, Lab Branch, DVH, CDC

Overview of Hepatitis C Guidelines, Tests, & Coming Innovations and Policy Changes

Nate Furukawa, MD MPH
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Division of Viral Hepatitis
National Center for HIV, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention

Dr. Furukawa provided an overview of CDC's existing guidelines, tests, upcoming innovations, and upcoming policy changes. In 2020, CDC released its HCV screening guidelines that recommend universal adult screening, screening during each pregnancy, and interval testing for people with ongoing risk. He reviewed the algorithm of CDC's current recommended testing guidelines for diagnosing current HCV infection. This table lists currently available FDA-approved HCV antibody tests:

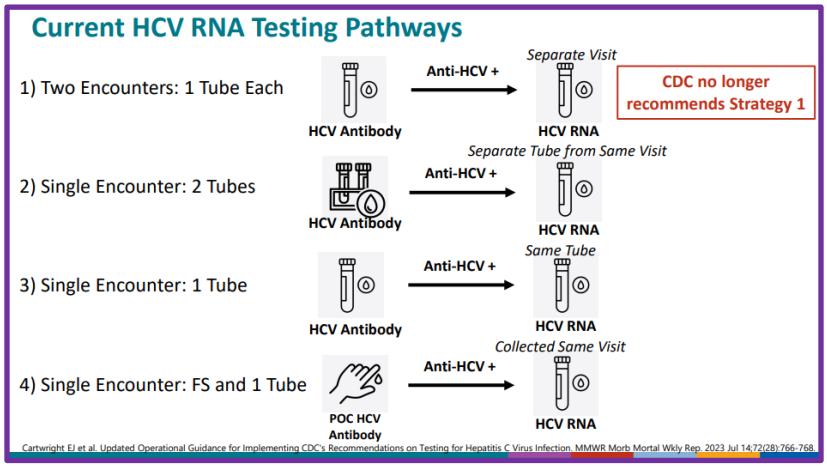
Manufacturer	Platform	Assay
Abbott	ARCHITECT	ARCHITECT anti-HCV
Abbott	Alinity I	Alinity I Anti-HCV
Diasorin	LIAISON® XL	Murex HCV Ab
Quidel Ortho-Clinical Diagnostics	*Vitros* ECi	*Vitros* Immunodiagnostics Anti-HCV
Roche	Cobas e 601	Elecsys Anti-HCV II
Siemens	Advia Centaur	HCV (aHCV)

There are several large platform HCV antibody tests and there is one POC HCV antibody test, the OraQuick®, which offers HCV antibody testing results in approximately 20 minutes. In addition, there are several currently available large platform FDA-approved HCV RNA tests, shown in the table below and no POC HCV RNA tests in the US currently:

Manufacturer (PMA #)	Device[a]
Abbott Molecular (P00017)	Abbott RealTime HCV
Hologic (P020011)	Aptima HCV Qual Dx Assay
Hologic (P160023)	Aptima HCV Quant Dx Assay
Roche Molecular (P150015)	cobas-HCV (for 6800/8800)
Roche Molecular (P060030)[e]	COBAS Ampliprep/ COBAS Taqman HCV Test

Some challenges with the diagnostic algorithm include incomplete testing, which is ameliorated by implementing reflex testing, where a laboratory can automatically conduct HCV RNA test on the same sample used for the HCV antibody test. Challenges also exist with loss to follow-up, which results in a longer time to diagnosis, and with detecting early HCV infection based on an antibody first approach. Because there is not a POC test for viremia, same visit test and treat is not possible.

There currently are 4 HCV RNA testing pathways shown in this diagram:



While frequently used, CDC specifically no longer recommends Strategy 1 because it requires 2 encounters. Strategy 2 entails drawing 2 tubes, the first of which is tested for HCV antibody and if positive, the second is tested for HCV RNA. Strategy 3 is similar but allows for the HCV RNA test to be drawn from the same tube. Strategy 4 uses a POC HCV antibody test, which if positive can then proceed to phlebotomy for an HCV RNA test. The traditional HCV antibody to RNA approach misses early infection, limiting opportunities to interrupt transmission. HCV RNA becomes detectable at around 10 days after infection, whereas HCV antibody can lag 2 months or longer. Particularly for people in high-risk settings, that window might represent a lost opportunity for interruption of transmission chains.[41]

The good news is that in 2021, the FDA down-classified HCV diagnostics from Class III to Class II, which has generated a lot of interest in bringing more diagnostics to market and is exciting in terms of moving toward new diagnostic approaches that promote viral first testing. There are 2 large categories of interest, including POC HCV RNA tests and the large platform HCV Ag/Ab tests.

In terms of the POC HCV RNA tests, globally there are at least 4 POC HCV RNA tests currently available. They all tend to have high sensitivity and specificity and have been successfully used to further decentralize care. The power of POC testing is that it is associated with higher rates of treatment uptake. It is one thing to have a result, but the goal is for that to translate to people actually getting treated and cured. A meta-analysis of HCV RNA POC compared to the standard of care[42] showed that on average, there was about a 32% higher rate of starting treatment. It is important to note that these all involved different visits. The real power here is unlocking same day test and treat. This was nicely illustrated in a study out of Australia called the PIVOT Study.[43] This study was conducted in some prisons in Australia and compared the old approach of sequential phlebotomy to developing a one-stop-shop intervention in which people would receive POC testing and if positive, would receive same day liver fibrosis assessment, medical evaluation, and direct acting antiviral prescription. This has an astounding effect of reducing the time from enrollment to treatment from 99 days to 6 days and increasing treatment initiation from 22% to 93%.

[41] https://www.cdc.gov/hepatitis/statistics/SurveillanceGuidance/HepatitisC.htm
[42] Trickey A et al. Impact of hepatitis C virus point-of-care RNA viral load testing compared with laboratory-based testing on uptake of RNA testing and treatment, and turnaround times: a systematic review and meta-analysis. Lancet Gastroenterol Hepatol. 2023 Mar;8(3):253-270
[43] Sheehan Y et al. A 'one-stop-shop' point-of-care hepatitis C RNA testing intervention to enhance treatment uptake in a reception prison: The PIVOT study. J Hepatol. 2023 Sep;79(3):635-644

CDC has been working with the Independent Test Assessment Program (ITAP), which is part of the Rapid Acceleration of Diagnostics (RADx) program at NIH, to accelerate bringing a Clinical Laboratory Improvement Amendments (CLIA)-waived POC HCV RNA test to market. In mid-2023, CDC worked with ITAP to identify 1 manufacturer to move through the ITAP process. In late 2023, CDC started independent laboratory testing, analytic studies, and clinical trial preparation. In early 2024, clinical trials were launched and are currently ongoing and are anticipated to be completed in the next 1 to 2 months. It is anticipated that sometime in Summer 2024, the analytic and clinical trial studies will have competed FDA review so that the test can join the market. In anticipation of this, CDC reviewed its existing guidance to determine whether there is flexibility within the current algorithm that would allow for POC HCV RNA testing. Looking at the footnotes in the 2013 guidance,[44] HCV RNA testing is currently recommended for the diagnosis of HCV infection among persons who might have been exposed to HCV within the past 6 months regardless of anti-HCV result.

What CDC envisions moving toward, particularly for high-risk populations, is a same-day test and treat approach for hepatitis C. The POC HCV RNA testing is the crucial linchpin of facilitating that. However, there are still remaining barriers. A major barrier is that there is a lack of a POC HBsAg test to rule out HCV/HBV co-infection. A black box warning exists for treating individuals who are co-infected. Several POC HBsAg tests exist outside of the US and the FDA has signaled down-classification of HBV diagnostics to Class II, so the hope is that this is just a temporary barrier. Simplified guidelines exist to treat hepatic C, but this still requires a number of labs and visits. CDC also has been working with the American Association for the Study of Liver Diseases/Infectious Diseases Society of America (AASLD/IDSA) Guidelines Group to work on envisioning a same-day hepatitis C treatment algorithm.

Moving to the large platform Ag/Ab tests, hepatitis C core antigen (HCV Ag) as it currently exists is a large platform test for viremia. It is a great test for diagnosing infection. HCV RNA can be detected within 1─2 weeks after HCV infection. A downside is that the HCV Ag test is slightly less sensitive than HCV RNA (LLoD 500─3,000 IU/mL). A benefit is that it can be run on the same sample as that used for HCV antibody testing. Since it is an antigen test, it is simpler and can be priced lower than HCV RNA tests. Given the challenges with sensitivity, HCV Ag testing alone may not be sufficient for testing in the general population.[45] The lower sensitivity of HCV Ag creates challenges of its use in low prevalence settings (i.e., the general population), such as the risk a false negative in someone receiving their 1-time universal screening. The sensitivity can be improved by combining HCV Ag with HCV antibody to improve performance.

There are at least 3 globally available combined HCV Ag/Ab tests, all of which are large platform, from Roche, Abbott, and Bio-Rad. No POC HCV Ag/Ab tests are available currently. Thinking about unlocking the potential of HCV Ag/Ab testing, this is a viral-first option that can reduce incomplete testing, shorten the time to diagnosis, and capture early HCV infection. At some point in the future, it may be possible to develop a discriminatory POC HCV Ag/Ab test. Some remaining barriers, such as a lack of an FDA-approved HCV Ag/Ab test. CDC is working with FDA to evaluate some of the large platform HCV Ag/Ab tests. Guidelines do not exist on the use of HCV Ag/Ab in the US. CDC is conducting cost-effective analyses and revising its HCV testing guidance for clinicians and laboratorians.

[44] CDC. Testing for HCV infection: An update of guidance for clinicians and laboratorians. MMWR 2013;62(18
[45] Sepúlveda-Crespo D.. Diagnostic performance of hepatitis C core antigen assay to identify active infections: A systematic review and meta-analysis. Rev Med Virol. 2023 May;33(3):e2436.

In conclusion, Dr. Furukawa emphasized that it is an exciting time in diagnostics in that the additional diagnostics tools needed to eliminate hepatis C should soon be added to the armamentarium.

Cost-effectiveness Analysis of Hepatitis C Testing Strategies for Diagnosis of US Adults

Eric W. Hall, PhD
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OHSU-Portland State University (PSU) School of Public Health

Dr. Hall presented the findings of a cost-effectiveness analysis of hepatitis C testing strategies for diagnosis among US adults that he led with several colleagues at DVH and others in the center. This project was born out of the idea that the current 2-step algorithm of antibody testing followed by RNA testing could be missing the opportunity to diagnose earlier infections or more recently occurring infections in order to get those individuals on treatment and limit potential opportunities for future transmission. The objective of this analysis was to assess the cost-effectiveness of various HCV testing strategies compared to the current 2-step testing algorithm among a cohort of US adults at average risk. The following 4 strategies were modeled:

Comparison
1. Anti-HCV followed, when reactive, by
2. HCV RNA

Intervention 1
1. Anti-HCV followed, when reactive, by
2. HCVcAg followed, when non-reactive, by
3. HCV RNA

Intervention 2
1. Anti-HCV and HCVcAg concurrent testing test followed, when Ab/Ag results are discordant, by
2. HCV RNA

Intervention 3
1. HCV RNA

To provide some highlights of this model, this analysis was approached through a decision-tree framework with a Markov model of HCV disease progression. Individuals were modeled through different stages of health complications that result from HCV infection. Microsimulation was used to model a cohort of individuals that represent individual adults ≥18 years of age, defined by single year of age reflective of the overall US distribution. As part of that cohort, they modeled persons who are susceptible to infections, persons who have current infections, and persons who cleared a previous infection. That is important for this approach because those who have current infection, depending upon the timing of the test, will test positive for each of the 3 markers. People with a cleared infection will have a reactive antibody test, but will not have reactive antigen test or be RNA positive. People who are susceptible to infection experienced a risk of infection that was estimated using surveillance data and a multiplier for under-reporting of surveillance data. This analysis was approached from a limited societal perspective, which means they included costs that are associated with the individual HCV tests, along with all direct medical related to HCV infection and resulting sequela in 2023 US dollars. Then effectiveness was quantified using quality adjusted life years (QALYs), which were

calculated using previously published utility weights for a variety of stages of HCV infection. Importantly, the time span in this model was 1 month and the time horizon was over the lifetime of this cohort.

Many inputs go into this model, so Dr. Hall highlighted some of the key inputs. Model inputs for diagnostic performance of each type of test came from a variety of published studies. Although antibody cannot be detected before 7 to 8 weeks after infection, HCV RNA and HCV RNA and HCV cAg are detectable at 1 to 2 weeks. Therefore, it was assumed for this analysis that HCV cAg were detectable within the first month of the modeling process and that anti-HCV was first detectable at the end of the second month after the point of infection. Considering that these strategies focus on the identification of undiagnosed infections, all individuals were eligible for HCV testing, except those currently in health states of advanced liver disease. A snapshot of the universal testing recommendation was modeled, meaning across all strategies, all adults are tested at a single point in time. Anti-HCV & HCV RNA costs came from the CMS Clinical Diagnostic Laboratory Fee Schedule, which was $14.27 (10.70-17.88) and the RNA cost was 42.84 (31.14-53.55). Considering that there are no cAg tests currently approved for testing in the US, that cost is not available. In the base case analysis, it was assumed that the cAg test would be priced the same as an anti-HCV test of $14.27. Another key piece to note is that to align with treatment targets from WHO and HHS, 80% linkage to treatment was modeled across all the different strategies. This analysis did not necessarily try to model linkage to treatment, but rather it started with an analysis of differences in test performance, test performance inputs, early diagnosis of picking up infections, and the costs of the tests.

To highlight how the analysis was conducted, each intervention was compared to the comparison strategy. These comparisons were approached by prioritizing health and money. In scenarios in which the intervention results in fewer QALYs or worse health benefits, they would say that the comparison strategy is preferred. In scenarios that resulted in more QALYs and lower cost, the intervention strategy preferred. In scenarios in which the intervention resulted in more QALYs and higher cost, that is when the cost per QALY gained is summarized using the incremental-cost effectiveness ratios (ICERs). A base case analysis as conducted in which a point estimate was used, which is a “best value” for all of the inputs, which is a primary set of results. Then sensitivity analyses were conducted to try to quantify some of the uncertainties around those inputs. A probabilistic sensitivity analysis was done that sampled from inputs concurrently and then a one-way sensitivity analysis was done to focus in on the cost of HCV cAg test using from $10.00 to $50.00 for that test in increments of $5.00 to see how that impacted overall results.

In terms of the primary results, in this base case analysis, Intervention 1 resulted in equivalent health outcomes as the Comparison strategy. That is because that intervention, just like the comparison strategy, starts off with the antibody test first in step 1. It is an identical step 1, so it is going to pick up the same number of infections and the path forward for those health outcomes is going to be the same. However, by using that aAg test second in this base case analysis, it was cost-saving and was cheaper by 26 cents per person. As a reminder, this is per person as in per every adult. Intervention 2 and Intervention 3 (the 2 viral-first strategies) both had increased costs per person. Intervention 2 was $8.60 more per person and Intervention 3 was $21.48 more per person. They also both resulted in increased diagnosed infections, treated infections, and resulting QALYs and health benefits. Relative to the Comparison strategy, the cost per QALY gained for Intervention 2 was about $8.500 and for Intervention 3 it was about $20,500 relative to the Comparison strategy.

The key takeaway from the probabilistic sensitivity analysis is that all interventions resulted in equivalent or improved health outcomes relative to the comparison strategy at a willingness-to-pay threshold of $100,000 per QALY gained. All models in Intervention 1 were under that, 99% of Intervention 2 were under that, and 99% of Intervention 3 were under that as well. The following table depicts the results from the one-way sensitivity analysis on the cost of the 4 antigen tests:

Cost of HCVcAg test	Intervention 1: Anti-HCV (+) → HCVcAg (−) → HCV RNA	Intervention 2: Anti-HCV & HCVcAg (+/−) → HCV RNA	Intervention 3: HCV RNA alone
10.00 USD	Lower cost, same QALYs	ICER=$5,723	ICER=$20,513
15.00 USD	Lower cost, same QALYs	ICER=$10,839	ICER=$20,513
20.00 USD	Lower cost, same QALYs	ICER=$15,956	ICER=$20,513
25.00 USD	Lower cost, same QALYs	ICER=$21,073	ICER=$20,513
30. 00 USD	Higher cost ($0.12/person), same QALYs	ICER=$26,189	ICER=$20,513
35.00 USD	Higher cost ($0.27/person), same QALYs	ICER=$31,306	ICER=$20,513
40.00 USD	Higher cost ($0.42/person), same QALYs	ICER=$36,423	ICER=$20,513
45.00 USD	Higher cost ($0.57/person), same QALYs	ICER=$41,540	ICER=$20,513
50.00 USD	Higher cost ($0.72/person), same QALYs	ICER=$46,656	ICER=$20,513

Abbreviations: USD, US dollars; ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life-years.
Note: The comparison strategy for all intervention strategies is an anti-HCV test with automatic HCV RNA test when anti-HCV is reactive. All trials were tested once at a single point in time. For each analysis, Intervention 1 results in the same number of QALYs

These results arose when varying just the single input of the cost of an antigen test. For Intervention 1, as long as the cAG test is priced at $25 or less, it results in a lower cost than the compassion strategy. For Intervention, not surprisingly, as the cost of the cAg goes up, the ICER increases. Even at a cost of $50 per antigen test, the ICER is $46,000. Intervention 3 did not change based on this because it does not use a cAg test.

In conclusion, Intervention 1 that starts with the antibody test and then goes to cAG can be a cost-saving approach. It does not lead to improved health outcomes or diagnosis, but it could be cost-saving. The strategies that incorporated viral detection in the first step (Interventions 2 and 3) resulted in increased detection of infection and improved health outcomes. This model has a few key limitations that elaborate on the conservative approach taken in this model. Importantly, only 1 cohort of adults was modeled from now through their lifetime and maintained a static risk of infection. Basically, that means that the benefits of early diagnosis and early detection likely impact future risk of transmission rates and ongoing transmission, which are not captured in this model. An average of the US adult population was modeled. With some of these interventions, there could be potential for additional benefits among persons with higher HCV prevalence or risk of infection. The model assumed test performance (sensitivity and specificity inputs) was the same for all persons. Test performance could differ slightly in some age groups or in individuals with other health conditions, but that is not incorporated in this model. Test cost and performance were modeled in this analysis, so the potential impact on linkage to care is not incorporated or quantified. Those could be applied to POC testing, which could play a unique role in advancing same-day testing and treatment.

Updating HCV Testing Guidance for Laboratorians and Clinicians

Emily J. Cartwright, MD
Clinical Intervention Team
Division of Viral Hepatitis
Centers for Disease Control and Prevention

Dr. Cartwright discussed updating the current HCV testing guidance for laboratorians and clinicians. As a reminder, the current sequence for identifying current HCV is a 2-step testing sequence that CDC is hoping to update. *Updated Operational Guidance for Implementing CDC's Recommendations on Testing for Hepatitis C Virus Infection*[46] was published in the *Morbidity and Mortality Weekly Report* (*MMWR*) last summer to assist with implementing this 2-step sequence. CDC stated that hepatitis C testing should be completed in a single visit with automatic HCV RNA testing performed on all HCV antibody reactive samples. Automatic testing means it should be automatically done by the laboratory with no additional action on the part of the clinician or the patient. CDC also stated that any testing strategies that require a person to make multiple visits to collect the HCV testing samples should be discontinued.

One of the downsides to the current testing sequence is that it relies on a positive or reactive hepatitis antibody to diagnose current HCV, which can take 7 to 8 weeks on average from the time of infection to the time the test is positive. HCV RNA can be detected within 1 to 2 weeks of infection. The HCV cAg can be detected in 2 to 3 weeks after infection. Antibody first sequences miss early infection, but virologic tests shorten the window period by at least 4 weeks. The objective is to update the current 2013 Hepatitis C Testing Guidelines to incorporate assays that detect viral markers (HCV RNA or HCV cAg) in the first step of the testing sequence ("viral-first"). The goal is to shorten the window period and increase early diagnosis of HCV infection.

The research questions will be formulated using the PICO (population, intervention, comparison, outcomes) framework. The population is the general US adult population. The interventions will be the viral-first hepatitis C testing strategies: #1: Concurrent anti-HCV/ HCV cAg followed, when discordant, by HCV RNA; and #2: HCV RNA. This is somewhat analogous to the fourth generation HIV antigen antibody test that is in use. The comparison will be the current HCV antibody-first strategy of anti-HCV followed, when reactive, by HCV RNA. The outcomes will include diagnosed current HCV infections, treated HCV infections, and hepatitis C morbidity and mortality. The research questions will be as follows:

Compared to the comparison strategy:

Does Intervention 1:

1. Increase the diagnosis of current HCV infection
2. Increase HCV treatment
3. Decrease morbidity and mortality attributable to HCV infection?

Does Intervention 2:

1. Increase the diagnosis of current HCV infection
2. Increase HCV treatment
3. Decrease morbidity and mortality attributable to HCV infection?

[46] https://www.cdc.gov/mmwr/volumes/72/wr/mm7228a2.htm

The key questions are shown on this table:

How many additional cases diagnosed?	How many additional cases treated?	Do benefits outweigh harms?	What is the effect on morbidity and mortality attributable to HCV infection?*
K.Q.1.a What is the prevalence of past or present HCV in the U.S.?	K.Q.2.a. What proportion of persons who are diagnosed with current HCV infection are treated in the U.S.?	K.Q.3.a. What are the benefits of hepatitis C screening?	K.Q.4.a. What is the effect of DAA treatment on HCV viral load?
K.Q.1.b What is the prevalence of current HCV infection in the U.S.?		K.Q.3.b. What are the harms of hepatitis C screening?	K.Q.4.b. What is the effect of DAA treatment on hepatitis C-related morbidity (including cirrhosis and hepatocellular carcinoma)?
K.Q.1.c. What is the incidence of HCV infection in the U.S.?			K.Q.4.c. What is the effect of DAA treatment on hepatitis C-related mortality?
K.Q.1.d. What is the diagnostic accuracy of anti-HCV, HCVcAg, HCV RNA?			K.Q.4.d. What are the adverse effects of DAA treatment?

* As key questions 4.a – 4.d. have been reviewed recently, they will not be included in this review

In terms of additional considerations, the intended audiences for the guideline are US healthcare clinicians, public health officials, and organizations involved in the development, implementation, delivery, and evaluation of clinical diagnostics and laboratory testing services. The plan is to systematically review the domestic and global literature from 2013 through 2023. It is important to note that neither of the interventions to be evaluated is currently FDA approved for this intended use. The HCV cAg test is not currently available in the US or FDA-approved. The HCV RNA test is currently only FDA-approved for the diagnosis of HCV in context of a reactive anti-HCV.

Regarding the partner engagement strategy, CDC shared with CHAC that this guideline development process is now underway. In Fall 2024, the Association of Public Health Laboratories (APHL) will be leading a convening of key stakeholders in the field of hepatitis C diagnostics with a similar audience to those who attended the APHL-led convening on HCV diagnostics held in 2021. CDC also will explore possibly presenting at professional meetings in Fall 2024, such as ID Week and the Liver Meeting in November 2024. They also will invite key stakeholders to participate in the peer review process. The following table reflects the steps in the process and target dates:

Step	Duration	Target date
Complete systematic literature review	4 months	June 2024
Complete draft guidelines	3 months	September 2024
CDC Clearance of draft guideline	2–3 months	Oct–Dec 2024
Federal Register Notice of 60-day public comment period	2 months	Jan–Feb 2025
Peer review from external experts	1 month	Jan–Feb 2025
Disposition of Peer review and Public comments	1 month	March 2025
CDC clearance of finalized guideline	1 month	April 2025
MMWR Production and Publication	3–4 months	May–July 2025

Special Presentation 3: Q&A with Speakers and Member Discussion

To focus the discussion, Dr. Armstrong reminded CHAC members of the advice related to this topic that was requested from CDC/HRSA and asked them to be thinking about action items CHAC might address and vote on later in the business section related to these questions:

1. What approaches can CDC/HRSA take to facilitate implementation of POC HCV RNA testing once this test is available in the United States?
2. What is the most effective way for CDC/HRSA to engage partners (industry, regulatory) to support advancing earlier diagnosis of hepatitis C and closing the window period (i.e., the period where HCV antibody is negative and RNA is detectable)?
3. What approaches can CDC/HRSA take to facilitate implementation of HCV core antigen testing if this test is available in the United States?

The following questions, observations, and suggestions were raised:

- Dr. So asked Dr. Kamili why the extra step if they do not trust the cAg test.

- Dr. Kamili clarified that the proposed algorithm would be that if a patient is tested for antibody and antigen simultaneously and both are positive, that is a confirmed diagnosis of current HCV infection. If antibody is positive but cAg is negative, those will need to be tested for HCV RNA because it is known that cAg is not as sensitive as HCV RNA and may miss less than 5% of individuals who may have HCV RNA levels below 5,000 IU/mL. It is not a question of not trusting cAg.

- Ms. Beiser expressed concern about what the utility would be of the cAg and where it would be most clinically useful, and that any decision about treatment would still require the RNA. She recalled mention that POC HBsAg testing also would be on the table and wondered whether there have been lessons learned from this process that might speed up that testing as well. A same-day test and treat approach should be used regardless of the diagnostics, but this cannot be achieved with the current insurance and pharmacy regulatory standpoint.

- Dr. Furukawa said that in working with the RADx ITAP program, it is incredible how fast things have gone. Normally, this process would have taken 5 years or longer. They are a well-oiled machine at this point in terms of their experience through COVID and bringing all of those diagnostics to market. No funding currently exists and there is still a Class III rating for hepatitis B diagnostics, so there is not a clear timeline of when that could occur. But if that possibility arises, it may go through very quickly in the way that this HCV POC RNA diagnostic has occurred. Even if the diagnostic challenge is removed, the reimbursement challenges would still exist. CDC also is looking into ways to try to simplify that process in terms of the Hepatitis C Elimination Initiative currently under consideration in Congress.

- In terms of the clinical utility of the cAg testing if RNA will still be needed as well, Dr. Cartwright responded that part of the utility they could envision with the cAg is closing the diagnostic window. Similar to 4th generation HIV antigen antibody testing, this would close the window by as much as 4 weeks and would be done in the large platform setting to avoid the issues of having to send additional samples out to a reference laboratory for molecular testing. In theory, the antigen and antibody could be run concurrently, and the window period would be closed. There would be a benefit to health outcomes in that setting.

- Dr. Furukawa emphasized that these are very different approaches, and it is certainly not a one-size-fits-all. To some degree, the more options there are the more it can make sense to customize to the setting in which one is practicing. High-risk settings exist where people are exposed and perhaps there is a baseline high seroprevalence with people who have been naturally cleared or have been treated before but continue to engage in risk behaviors that put them at risk for reinfection. In the context of trying to decentralize care, in that setting an HCV POC RNA test could make a lot of sense. But in other settings where there is already an established multi-panel screening such as for people who are incarcerated and enter into jails, a battery of tests is performed that cover HIV, viral hepatitis, and STIs. This is a setting that is not going to go to an HCV POC RNA because that messes with their workflow in their phlebotomy-based system. The viral-first approach in a population that has a much higher baseline prevalence than the general population is still a large platform.

- Dr. Cartwright added that in some populations, including some patients with advanced HIV and a low CD4 count, the antibody does not perform as well and they see more seronegative infections. Including a viral-first test in the beginning of the testing sequence could identify infection in more people.

- Dr. So commented that if a recommendation was made for the combined cAb and antigen test, it will inspire the industry to produce more POC Ag/Ab tests. That would be a game changer with just a drop of blood and treatment could be provided for those who are positive.

- Dr. Kamili noted that OraSure has the technology. This is the first FDA-approved HCV antibody test, so it is hoped with the down-classification of hepatitis B diagnostics, that they could combine testing on the same strip.

- Dr. Armstrong pointed out that there is so much emphasis on rapid start/rapid treat once identified, but this offers the opportunity to find people potentially in that window. She asked whether the strategy still would be used to see if people will spontaneously clear or if they imagined this would be used to rapid start those folks as well.

- Dr. Cartwright said she thought the idea was to get people on treatment faster. A lesson learned from HIV is just how valuable rapid start is. If an infection is diagnosed and someone is started on treatment, that emphasizes to them how important treatment is. Whereas, if an infection is diagnosed and the person is told to return in 3 or 6 months, it sends the message that this is not really that important. The idea would be to shorten not only the window to diagnosis, but also the window to treatment, which could have impacts not only on the individual, but also on transmission.

- Dr. Furukawa agreed that with natural clearance rates of 20% to 40%, it is more likely that someone will not naturally clear. Given that the population who is affected by hepatitis C may already have difficulties in returning to care, it would be a missed opportunity. Given how readily curable this is, he would not delay treatment.

- Dr. Cheever emphasized that there are people who clear spontaneously. She wondered in the modeling what percent of people diagnosed in the acute phase or phase might clear versus not clear, and who essentially would be over-treated.

- Dr. Hall responded that he did not know, but that is an outcome they could examine in this model. Because this was a general population approach, the bulk of people being identified and linked to treatment were longstanding infections.

- Ms. Beiser suggested that one interesting opportunity might be the ability to use shorter treatments in the acute treatment window. In communities where there is active transmission and frequent injection use, practitioners are comfortable treating in the acute window and not waiting for confirmation of chronic disease in order to prevent transmission. Perhaps this testing opportunity is about tailoring treatment for those folks.

- Dr. Furukawa pointed out that the standard of care based on AASLD/IDSA guidelines is to treat acute hepatitis C and not to wait.

- Dr. So asked whether the model assumed that with all of the different scenarios all of the patients received the same treatment rates of 80% and would not be less if a delay caused a decrease in treatment rates.

- Dr. Hall reiterated that linkage to treatment, treatment completion, and SVR rates were the same across all strategies in this model. If someone were diagnosed in one strategy, they would have the same trajectory as if they were diagnosed in another strategy, which was one of the limitations he mentioned at the end. Some of these intervention strategies might impact treatment linkage, but that was not captured in this model.

CHAC Workgroup and Liaison Reports

Long Acting Injectables Workgroup

Shannon Dowler, MD
Chair, Long Acting Injectables Workgroup

Dr. Dowler presented the Long Acting Injectables Workgroup (LAIWG) report. CHAC recommendations following the fall 2023 meeting included the following:

- CDC and HRSA work with CMS to investigate how to standardize the provision of LAIs across payers for HIV prevention and treatment and to increase access for all populations.
- CDC and HRSA work and partner with Indian Health Service (IHS) to add LAIs to the IHS formulary.
- CDC and HRSA work with the HHS Adolescent and Adult Antiretroviral Treatment Guidelines Committee on two items: 1) evaluating the emergence of new data that will allow people living with HIV to access direct to inject broadly and in settings of non-viral suppression; and 2) reevaluating the LAI PrEP guidelines to include permissive utilization in unique circumstances.

The LAIWG has had 3 synchronous convenings and engaged in a lot of asynchronous work reviewing articles since the last CHAC meeting. Dr. Mermin attended one of the meetings, which was helpful as they thought through the next steps. One of the reasons the LAIWG continued to meet after the last CHAC meeting was because they felt like they were missing the lived experience voice and that input to help guide them on the challenges with LAIs. CHAC extended the LAIWG in Fall 2023 to allow for further insights into barriers and lived experience for those seeking or utilizing LAI for HIV prevention or treatment. Due to the challenges facilitating non-clinical external stakeholder input in the workgroup environment, the decision was made to seek to understand existing literature in the hope that the qualitative analyses would help them get that voice. Collectively, the LAIWG reviewed 14 qualitative studies published between 2018-2023 to understand the lived experience of over 300 people, which is more than they would have gotten through a panel discussion. Based on this work, the LAIWG developed several considerations for the CHAC.

<u>Consideration #1</u>

- Ask the CDC/HRSA to work with partners, such as NIH and Ryan White programs, to request current grantees working in the LAI space to share the current experience including patient feedback and best practices from 2022-present.
- Ask CDC/HRSA to convene existing advisory boards of people with lived experience to discuss the current barriers to access and uptake of LAI (for HIV treatment and prevention) (for instance in 8/24 Ryan White Conference).
- Ask CDC/HRSA to partner with CBOs specifically related to populations demonstrating rising risk, such as women and young adults, to increase uptake of LAI.

The LAIWG found through the article review that in general, a lack of awareness existed regarding LAI for both consumers and providers from 2020-2022. The studies also did not necessarily represent lived experience in real world settings (e.g., non-randomized control settings) to understand the impact of/address access barriers. The studies were limited geographically, many were conducted outside of the US, very few were conducted in the Southeast US, and the populations focused on older white men. Therefore, there is still a need to expand the understanding to adolescents, younger adults, women, and Southeast US involvement. The literature review revealed consistent concerns about the increased burden on the number of required visits and a lot of anxiety and suspicion about the safety of LAIs. As raised over the last 2 days of the CHAC meeting, the articles also identified the importance of patient-provider communication to identify unique needs and preferences among individuals.

<u>Consideration #2</u>

- Ask the CDC/HRSA to work with partners (e.g., providers, consumers, pharmacists, insurers) in clinical practice to obtain information on variation of coverage, basis for variation, and optimal mechanism for reimbursement of LAI for best patient access.
- Request CHAC to consider revisiting the fall 2023 recommendation to more explicitly ask CDC/HRSA to seek standardization of LAI under the most optimal benefit and to eliminate cost sharing/co-pays.

The LAIWG asked CDC and HRSA to work with CMS to investigate how to standardize the provision of LAIs across payers for HIV prevention and treatment and to increase access for all populations in the Fall 2023 meeting.

Consideration #3

- Request CHAC to consider revisiting the Fall 2023 recommendation to more explicitly ask CDC/HRSA to drive study and recommendations related to increasing inter-injection intervals, decrease the burden of additional labs, and allow treatment of viremic patients when clinically appropriate.

As a reminder, the Fall 2023 recommendation was, "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.

Consideration #4

- Request CHAC consider modifying the scope of LAIWG and extending to include tracking the emergence of new LAI for other conditions, driving ongoing study to evaluate and eliminate barriers for access to LAI.

One great example of this is that the Affordable Care Act (ACA) explicitly calls out PrEP as a service that should be provided with no co-pays or co-insurance for office visits, labs, and medications. However, anecdotal reports suggest that this is not how this is operationalized, and it is creating many barriers. The LAIWG feels that its work has not ended and that opportunities exist to move the work forward and to think about novel agents on the horizon that will experience the same challenges that are occurring with HIV treatment and prevention.

Workforce Group

Vincent Guilamo-Ramos, PhD, MPH
Chair, Workforce Workgroup

Dr. Guilamo-Ramos reminded everyone that the PACHA Workforce Group developed a good overview of the current state of the HIV workforce and developed a set of recommendations that were presented during a previous CHAC meeting. At the time, the Workforce Workgroup felt that it was very important to work in collaboration with PACHA and that PACHA consider some actions together in collaboration with CHAC. As part of the recent PACHA meeting in Houston, there was some strategic planning. Several ideas came out of that meeting that are culminating in next steps. First, it was very clear that a strong commitment remains from PACHA to collaborate with CHAC on the workforce. Second, the task of moving the workforce forward was placed within PACHA's Ending the Epidemic Subcommittee, which is under the new leadership of Guillermo Chacón, who will be leading the PACHA component of the collaboration with CHAC.

PACHA has had numerous membership changes, which has brought a lot of enthusiasm and energy. Several members, including Dr. Tookes who is now the liaison from PACHA to CHAC, are part of PACHA's Ending the Epidemic Subcommittee that is going to be reviewing the recommendations and the presentation that came from CHAC. The sentiment at PACHA was that the CHAC presentation was fantastic and recommendations from CHAC were very strong, but there were questions about the specificity of the recommendations and whether they need a specific "ask" that is more focused. That is likely to be the work that will move forward within PACHA under the new leadership and the newly formed workgroup.

Drs. Guilamo-Ramos and Armstrong met with the workgroup recently. There were some changes and additional issues of interest to PACHA that were not addressed, both of which need to be revisited. More information is anticipated to come from PACHA. The HIV workforce is prioritized as part of the strategic planning moving forward.

Community Partnerships Workgroup

Meredith Greene, MD
Chair, Community Partnerships Workgroup

Dr. Greene reminded everyone that the Community Partnership Workgroup (CPWG) first presented in Fall 2023, with a focus on the definitions of "community partnerships" and "community engagement" and an emphasis on moving toward partnerships. They began to share best practices, with some of the key points focused on taking a syndemic approach, involvement of PWLE, the metrics of success that CDC/HRSA can and should use to measure its support of community partnerships, and the type of structure CDC/HRSA should support to provide technical assistance to jurisdictions and community partnerships. This framework was used from the CDC:

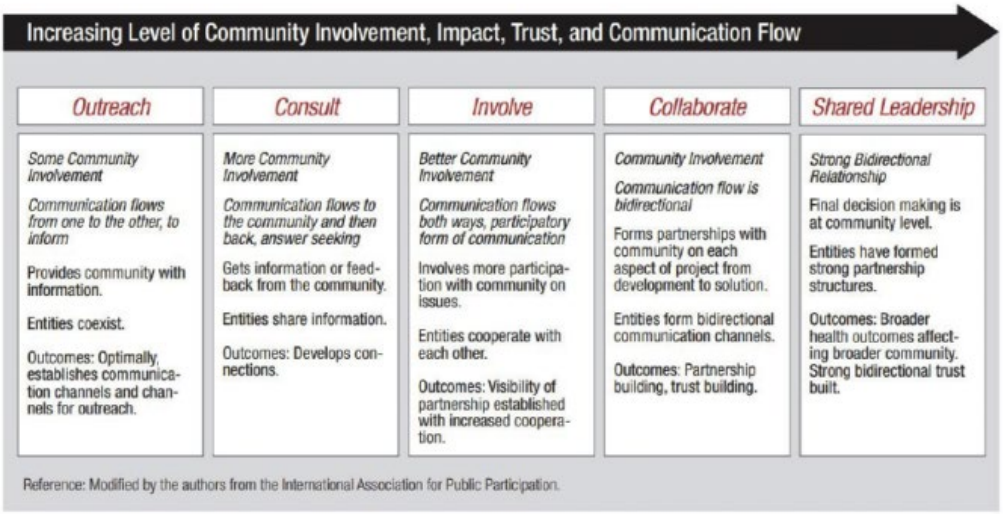

Figure adapted from the International Association for Public Participation and titled "Increasing Level of Community Involvement, Impact, Trust, and Communication Flow."

There are some new initiatives from CDC and HRSA and there is a role for listening sessions and having ways of moving forward to the shared leadership of a community partnership with CBOs and higher levels of government, and the CPWG diagramed out how grantmaking can affect different community partners.

During this session, the CPWG presented some best practices and discussed an approach that needs more work, molecular HIV surveillance/cluster detection and response (MHS/CDR). In 2022, PACHA presented to CHAC some components of their resolution specifically around the concern about lack of meaningful community engagement in this area. PACHA asked the CDC to provide guidance to health departments on: 1) how to take a more community-engaged approach that would include meaningful engagement with people living with HIV; 2) how to address some of the issues regarding people living in states and areas where there are HIV criminality laws; and 3) requiring establishment of Community Advisory Boards (CABs) that could directly influence the MHS/CDR programs and show how the CABs are being used to move programs forward.

CDC updated the MHS/CDR guidelines in February 2024,[47] which include wording based on the PACHA resolution of engaging PWLE. One challenge identified is the existing mistrust in the community that needs to be addressed and overcome with regard to molecular surveillance. CPWG members discussed that there seems to be less involvement at the state level than the local level, and that there is need for continuous and meaningful involvement of PWLE at all levels of government.

Using the theme of molecular medicine or precision medicine, the CPWG wanted to present a successful model of community engagement. The NIH model, All of Us™, is a strategic research model designed to engage the community and CBOs in this precision medicine initiative.[48] An aspect of the All of Us™ research program that worked well is a Division of Engagement and Outreach as a core pillar of the program. Within that are the subgroups of: Communications Design, Engagement & Retention Innovators, Community Advocate Network, and Community Engagement Partners. An outside partner/infrastructure was built in to help establish and maintain this community and provider gateway initiative to engage various stakeholders. Part of that task was holding regular meetings during which there were opportunities to share best practices bidirectionally and engage in continuous quality improvement.

Several examples worked well with regard to the meaningful involvement of PWLE. HRSA has legislatively mandated spots on local community planning bodies. In some areas this has worked very well, with more than half of the membership being comprised of PWLE who are engaged in active leadership roles, which has not always translated in all parts of the country. Another example is the 5280 Fast Track Cities Task Force that involves many stakeholders such as CBOs, universities, hospitals, various groups of PWH, and others willing to listen to the people at the table. Another example is an HIV One-on-One Peer Mentor Program that is a ToT model involving long-term survivors who mentor newly diagnosed persons. An example of long-lasting engagement is the People Organizing Positively (POP), a grant administered through AIDS United. Hawaii developed a Leadership Workshop series that taught self-advocacy, person first language, understanding funding steams, understanding Ryan White, and elevator speeches for key stakeholders. This led to the community becoming motivated to volunteer, write testimony, secure funding, and become involved in the local HIV services and concerns in Hawaii. This continues to have long-lasting impact on how HIV services are implemented in the state. Another example from Hawaii is the Kumukahi Health & Wellness Sexual Health Clinic within a Ryan White Part C funding mechanism in which local grassroots initiatives created a clinic embedded within a CBO to address the lack of specialists in rural parts of Hawaii.

Some of the key takeaways for the CHAC to consider from these examples of best practices are that PWLE must have a seat at the table, but their involvement must be meaningful, and they must have shared leadership and decision-making. Funding and mandates can help, but there must be sustained, shared leadership. In addition, bidirectional training and opportunities for discussion are needed to ensure that health departments and healthcare organizations have a skillset focused on community-based engagement and that information and data are shared both ways. CPWG identified the “Supporting People with HIV as Leaders in HIV Systems of Care” program as an example of PWH being able to learn leadership skills, with a goal of being in higher level leadership positions within HRSA, which Dr. Cheever mentioned the previous day.

[47] https://www.cdc.gov/hiv/programresources/guidance/hiv-cluster-detection-and-response-guidance/community-engagement-and-partnerships.html
[48] https://allofus.nih.gov/

In terms of measuring the success of partnerships, the CPWG identified some outcomes and measures of success, although notably they could not find a lot of information in the literature about how to measure these outcomes:

Outcomes
- Improved health and reduction in disparities
- Community building and empowerment
- Meaningful engagement
- System and capacity improvement
- Skills that last beyond funding

Metrics
- A combination of qualitative and quantitative metrics and logic model development
- Meaningful Involvement of people with HIV/AIDS and Greater Involvement of People Living with HIV and/or AIDS (MIPA/GIPA) frameworks[49]
- HIV and Aging Special Projects of National Significance (SPNS) survey examples
- National Academy Medicine for community based participatory research (CBPR)[50]

In terms of TA that CDC and HRSA can provide now, there should be an emphasis on skill-building that can have long-lasting effects beyond grant lifespan. This can be done through provision of infrastructure for meetings with community partners to share best practices that can continue beyond grants that offer opportunities for real discussion, open dialogue, listening, and including diverse voices. Examples of ToT models exist for lasting skill-building development. This may not always be within the structure of the grant. Other training initiatives could be supported that might be separate from grant mechanisms. PWLE should be trained to have a seat at the table and know what to do with that seat. It is also important for universities and health departments to have these skillsets as well. Some additional considerations that came from the CHAC survey were for provision of TA focused on data support that lasts beyond grant period that focuses on making sure CBOs have data collection and organization skills; and having PWLE involved in all levels of the grant process and project development, including grant review and awardee selection to make sure that the voices of PWLE are heard throughout the process.

In summary, the CPWG put forward the following considerations to the CHAC for further discussion, including asking CDC/HRSA to:

- Ensure that PWLE have meaningful involvement at all levels (local to national, including employment).
- Support bi-directional TA, including trainings for PWLE and health departments and organizations for skills that last beyond funding.
- Support opportunities for bi-directional knowledge sharing.
- Research further and prioritize developing metrics to assess meaningful involvement of PWLE and successful community partnerships, with metrics that are shared across agencies considering syndemic, status neutral approaches and translating CBPR into a service delivery realm.

[49] https://data.unaids.org/pub/briefingnote/2007/jc1299_policy_brief_gipa.pdf; Coleman et al. Journal Racial Ethnic Health Disparities 2023

[50] https://nam.edu/programs/value-science-driven-health-care/achieving-health-equity-and-systems-transformation-through-community-engagement-a-conceptual-model/

Presidential Advisory Council on HIV/AIDS (PACHA)

Hansel Emory Tookes III, MD, MPH
Board Member, PACHA

Dr. Tookes provided an update from the 80th PACHA meeting in Houston on March 27-28, 2024. At the beginning of the meeting, PACHA noted their enthusiasm and happiness that with the finalization of the federal government's FY2024 budget in March, all of the programs under the CDC's NCHHSTP, HRSA's RWHAP, and HHS's EHE all received level funding. However, they also noted that continued efforts would be needed to fully fund these programs in the coming years.

The PACHA meeting began with a presentation from Dr. Tim Harrison on the national syphilis and congenital syphilis syndemic from the National Syphilis and Congenital Syphilis Syndemic Task Force. Since the Task Force was convened, HRSA and the IHS sent letters to grantees and healthcare providers with links to resources. CDC published prescribing guidelines for treating syphilis. The IHS developed a strategy for STIs. HHS mapped cases of syphilis in the 14 priority jurisdictions. The FDA made Extencilline® temporarily available due to the shortage of Bicillin L-A®. Numerous other efforts are underway as well.

The PACHA meeting proceeded to the subcommittee updates. The Aging with HIV Long-Term and Lifetime Survival Committee met with Housing and Urban Development (HUD) representatives and learned about other resources outside of Housing Opportunities for People with AIDS (HOPWA) and are planning to meet with CDC and CMS representatives. The EHE Subcommittee has been discussing what it means to end the HIV epidemic and how EHE can better prioritize reaching marginalized populations. The Sigma and Disparities Subcommittee hosted a 2-day strategic planning session in which they created workgroups on the 3 priority topics of stigma disruption, HIV criminalization and discrimination, and PrEP and PEP. The Global Agenda Subcommittee primarily informs PACHA about the President's Emergency Plan for AIDS Relief (PEPFAR) and other global efforts and contributes to bidirectional learning.

"PACHA-to-the-People" is such an amazing experience. The day before the meeting started, they had the opportunity to visit 3 amazing organizations in Houston: Avenue 360, The Normal Anomaly, and Fundacion Latinoamericana De Accion Social (FLAS), Inc. These incredible people are on the ground doing incredible work under very difficult circumstances.

The first session with the people in Texas was "EHE in Texas: Setting the Stage in County Perspectives." This began with a presentation of data on HIV incidence and prevalence, profound disparities, and the academic research programs in Texas. A phenomenal Texas House of Representatives member joined the panel and advocates described challenges and successes with the State Legislature around HIV. He noted in that meeting that he was truly proud to be from Florida, given that Texas faces unique challenges. In terms of the Texas House of Representatives, new faces have been able to push legislation further than ever, which was a noted cause for optimism. He enjoyed the last presentation and the meaningful inclusion of people with lived and living experience. A phenomenal House of Representatives member who is living with HIV presented, and it was amazing and remarkable to have an advocate like that in such a high-level position. People noted that the language of federal funding should clarify the obligations of grantees, such as what constitutes community engagement. Panelists representing county-level programs pointed out that their organizations need funding to support some basic tools, not just innovations. They also asked PACHA members for specific items, which were to make it easier to stay on Medicaid and Ryan White programs; make it harder to kick people off of Medicaid; send more funding to places that have

higher needs; and identify more data to support the case for routine HIV testing, Medicaid expansion, and increased access to care. They noted that the EHE goals should be re-envisions and efforts should be centered to end HIV with more attention to coordination within and across jurisdictions. The panelists urged individuals to advocate for themselves by voting and communicating with their elected representatives. This was an amazing start to "PACHA-to-the-People."

PACHA then moved on to addressing the needs of Black and Latina cisgender women and efforts to increase PrEP access and uptake. The panelists urged PACHA to focus on women of color, particularly Black women, including funding and resources for cisgender and transgender women who have or are at risk for HIV. They were concerned that resources eventually would disappear, and they thought that federal funding should include money for small organizations to build capacity so that they can qualify for grants. Routine HIV testing and access to PrEP should be seen as a component of women's overall health. They also noted that current programs create artificial barriers around the HIV infrastructure that pit programs against each other and separates people with HIV from the HIV possibles. They also noted that advocacy organizations should offer more advocacy training and leadership development opportunities, and noted that cultural sensitivity means ensuring that healthcare providers, other staff, and patients' families are educated about HIV, PrEP, PEP, and U=U. They also noted that special attention should be paid to SDOH and boosting political will among decision-makers and funders.

The next session addressed the needs of Hispanic and Latinx communities, including new immigrants and setting the stage and local perspectives. This was an extraordinary panel. This panel was interesting because it noted the efforts to address HIV in the US should take a transnational perspective that acknowledges migration back and forth across the border. They noted that local programs need more flexibility to address the mechanisms that contribute to HIV and more integration with national programs and services. Texas has a "Green Zone" that is inland from the Mexico Border, which is an artificial border enacted by Texas where individuals can be stopped by police if they are suspected to be undocumented, which negatively impacts people who are seeking services. The panel noted that organizations are needed to provide care near the border. The panelists and Texas legislators are working hard to counter efforts to end HIV, which is unfortunate, and they noted that stronger efforts are needed to dismantle discrimination, stigma, and HIV criminalization and that federal partners should reconsider how to better write funding opportunities to provide support for organizations with meaningful community ties, selecting grant reviewers who are not beholding to the status quo, and level the playing field for CBOs.

On the second day, PACHA heard about addressing unique rural and urban needs. In terms of rural issues, the organizations stated that they lack providers with expertise in HIV care and have insufficient infrastructure and workforce in general. They noted that in some small communities, people with HIV face stigma and lack of privacy when seeking healthcare services and they are subject to political and religious discrimination. In Texas, hospitals play a central role in HIV care, especially in rural areas and they can be valued partners in serving people with HIV. They also noted that hospitals should educate providers, participate in clinical studies, and have links to the private sector so that they can facilitate public-private partnerships. This panel noted that limitations on funding can prevent organizations from serving surrounding counties and they thought that federal funding mechanisms should support collaboration within communities that facilitate linking patients to care. They also noted that no interventions or prevention strategies have been developed specifically for rural communities. They also noted that state and national definitions of "rural" prevent some communities from receiving funding and that EHE should be extended to more rural areas, particularly in Texas.

In terms of the urban issues, the panel noted the unique challenges that people with HIV in Texas cities face because of the lack of affordable housing; food deserts; insufficient infrastructure; lack of awareness around HIV, STIs, transmission, and where to get treatment, and stigma; and insufficient funding for people with HIV who are not among priority populations. They also noted the lack of culturally competent providers and inadequate support for people living in prison. The panelists also noted that people with HIV live, work, and recreate across the borders of the cities, suburbs, and counties but programs are limited to narrow jurisdictions. They felt that competition for funding discourages collaboration and also noted that individuals do not see themselves as having a role in the EHE and that Texas organizations need more federal funding so that they do not have to rely on the state. They urged that there be more training, leadership development, and capacity-building.

A "PACHA-to-the-People" was held during which people raised even more topics. In addition, some activists in Texas continued urging to place a moratorium on the use of molecular HIV surveillance. There were then remarks from Admiral Rachel Levine, which was incredible. She highlighted recent efforts around HIV and syphilis and summarized key points of the President's proposed FY25 budget.

In terms of PACHA's reflections, after many years of steadfast leadership, Kaye Hayes has stepped down as PACHA's leader. They are thrilled that she passed the baton to Caroline Talev, who will be PACHA's new DFO, with Dr. Tim Harrison serving as the alternate DFO.

CHAC Member Discussion on Workgroup and Liaison Reports

The following questions, observations, and suggestions were raised:

- Dr. Armstrong said she thought that working together with PACHA on the workforce issues, they could develop some more granular suggestions.

Business Session: Part 2

Wendy Armstrong, MD
CHAC Co-Chair

Business Item 1: Lifetime Survivors Letter

Based on the discussion throughout the meeting, CHAC was requested to consider developing a letter regarding holistic and meaningful research and interventions for lifetime survivors focused on the following:

- Addressing long-term health outcomes for survivors (e.g., metabolic outcomes, mental health, fatigue, cancer, etc.).
- Including long-term survivors in all aspects of programming at all levels of HHS.
- Including lifetime survivors as a separate category in studies and surveillance, including NIH sponsored research, including those who acquire HIV through blood transfusions or perinatal transmissions.
- Exploring different models of care and provider resource needs in terms of best practices, center of excellence, and hub of expertise.
- Developing a healthcare transition toolkit
- Potentially having a HRSA panel on transition of care across the lifespan.

CHAC Action
Dr. Dionne made a motion for CHAC to develop and submit a letter to Secretary Becerra including the suggested recommendations pertaining to lifetime survivors. Dr. Sanders seconded the motion. CHAC unanimously approved the development of a lifetime survivors letter to be led by Ms. Granados.

CHAC Action
Dr. Greene made a motion to amend the wording of the CHAC letter regarding lifetime survivors to add wording about removing eligibility barriers as lifetime survivors transition from pediatric to adult care, which can contribute to interruptions in care. The motion was seconded. CHAC unanimously approved the amendment to the lifetime survivors letter.

Business Item 2: Holistic Approach to Hepatitis B and C Testing

Based on the discussions throughout the meeting, CHAC was asked to address hepatitis B and C testing and treatment barriers (e.g., insurance payors) and integrate with PrEP access by potentially establishing a workgroup, developing and submitting a letter to the HHS Secretary/CMS, and/or having a panel to further assess these issues during the next CHAC meeting.

Business Item 3: Testing and Treatment

A suggestion was made to foster CDC/HRSA collaboration with CMS and USPSTF to ensure coverage for testing and treatment of HIV/Viral Hepatitis/STDs. A need exists for wraparound testing and POC testing, especially in terms of multiple modalities, which should be kept on the CHAC agenda. It is important to expand testing, ensure access to testing for individuals in their spaces, and link people to service more rapidly for treatment and care. It would be beneficial to have someone speak to CHAC from the FDA, as meaningful FDA engagement with CHAC is needed. A CHAC letter was recently written regarding self-sampling for gonorrhea, chlamydia, and syphilis outside of the clinical setting. It would be beneficial to hear about any substantive progress that has been made specific to this letter.

Business Item 4: Doxy PEP

Members recognized the importance of monitoring doxy PEP for unintended consequences (e.g., AMR and equity in research and implementation). Suggestions were made to: 1) have panels/presentations during the next CHAC meeting to address research, data needs, gaps, potential side effects, intersection of people with HIV's sexual lives; 2) make sure that populations who were left out of the original studies (e.g., cisgender women, transgender men, adolescents, Southeastern US) have an opportunity to get doxy PEP and be studied to understand outcomes; and 3) potentially establish a doxy PEP workgroup.

Business Item 5: Congenital Syphilis and Syphilis Outbreaks

Members made suggestions to consider having panels/presentations during the next CHAC meeting on syphilis/congenital syphilis (e.g., prenatal care interventions across settings), and discussed missed opportunities for prenatal care and testing. It is important to consider that congenital syphilis and syphilis outbreaks have impacted Native communities throughout the country, primarily due to the cultural differences in access to healthcare and in receiving healthcare.

Business Item 6: Screening in EDs and Urgent Care Settings

There was a suggestion to consider a potential letter to address barriers on HIV, STI, and hepatitis screening in EDs and the lack of evidence-based STI testing in EDs and urgent care clinics. It was suggested that perhaps CHAC could write a letter about partnering with ED physicians, hospital associations, and health systems to understand how to overcome barriers so that safety net providers are performing best practice, evidence-based testing for sexual health. However, there may be other ways in which CHAC can make a difference such as an update on screening and/or the establishment of a workgroup.

Business Item 7: HIV Planning Groups

A suggestion was made to consider a potential letter to the HHS Secretary to recommend ensuring meaningful reform of jurisdictional HIV planning groups to ensure people with lived experiences have leadership roles. Currently, there are integrated HIV prevention and care strategies and separate EHE strategies for which there may be opportunities to consider efficacy. In addition, there are opportunities for innovation. Some communities have been omitted from planning efforts, such as lifetime survivors. This is an opportunity for CHAC to provide some innovation. Perhaps a panel during the next CHAC meeting could focus on new leadership models for planning councils moving forward.

Business Item 8: Syringe Services Programs

During the syndemic panel, concerns were raised about the risk of SSPs being phased out, defunded, and/or illegal. It is important that policymakers have information so that they understand the evidence base and the importance of these evidence-based SSPs. This speaks not only to SSPs, but also to other areas for which there is misinformation or disinformation. Perhaps a CHAC letter could be created to add an additional voice of support to these issues and point out that in the face of these new restrictions/repeals of evidence-based modalities, CHAC and the HIV, hepatitis C, STI prevention community support SSPs and all methods of harm reduction that support the evidence as a prevention mechanism.

CHAC Action
Dr. Greene made a motion to draft a CHAC resolution letter to the HHS Secretary expressing support for SSPs as an essential tool for harm reduction. The motion was seconded. CHAC unanimously approved the drafting of the SSP letter to the HHS Secretary.

Business Item 9: Long Acting Injectables Workgroup

CHAC supported the LAIWG's recommendations, but questioned whether this workgroup needs to continue as it seems that they have accomplished the full scope of their charge. The proposed recommendations presented by the LAIWG for CHAC consideration included the following:

- Ask the CDC/HRSA to work with partners, such as NIH and Ryan White programs, to request current grantees working in the LAI space to share the current state of their learnings from 2022-present.

- Ask CDC/HRSA to convene existing advisory boards of people with lived experience to discuss the current barriers to access and uptake of LAI (for HIV treatment and prevention) (for instance in 8/24 Ryan White Conference).

- Ask CDC/HRSA to partner with CBOs specifically related to populations demonstrating rising risk, such as women, adolescents, and young adults, to increase uptake of LAI.

- Ask the CDC/HRSA to work with partners (e.g., providers, consumers, pharmacists, insurers) in clinical practice to obtain information on variation of coverage, basis for variation, and preferred mechanism for reimbursement of LAI (pharmacy vs. medical benefit) for best patient access.

- Request CHAC to consider revisiting the fall 2023 recommendation to more explicitly ask CDC/HRSA to seek standardization of LAI under exclusively pharmacy or medical benefit and to eliminate cost sharing/co-pays.

- Request CHAC to consider revisiting the fall 2023 recommendation to more explicitly ask CDC/HRSA to drive study and recommendations related to increasing inter-injection intervals, decrease the burden of additional labs, and allow direct to treat when clinically appropriate.

- Request CHAC to consider modifying scope of LAI WG and extending to include: tracking the emergence of new LAI for other conditions, driving ongoing study to evaluate and eliminate barriers for access to LAI.

Some of these items were identified as not being within the purview of CHAC, CDC, or HRSA; some were identified as having already been completed and presented at CROI; and others were identified as pertaining to information that could be provided to CHAC via panels and/or special presentation.

CHAC Action
A motion was made and seconded for the LAIWG to review and revise the proposed recommendations, based on the business meeting input, to bring before the CHAC for a vote during the next CHAC meeting. CHAC unanimously approved.

Business Item 10: Community Partnership Workgroup

The CPWG presented the following considerations:

- Ask CDC/HRSA to ensure that PWLE have meaningful involvement at all levels (local to national, including employment).
- Ask CDC/HRSA to support bi-directional TA, including trainings for PWLE, health departments, and organizations for skills that last beyond funding.
- Ask CDC/HRSA to support opportunities for bi-directional knowledge sharing.
- Ask CDC/HRSA to research further and prioritize developing metrics to assess meaningful involvement of PWLE and successful community partnerships, with shared metrics across agencies considering syndemic, status neutral approaches, and translating CBPR to service delivery.

The CPWG clarified that they did not necessarily intend for these to go in a letter. CHAC expressed support for the recommendations, and some members thought it would be impactful to craft a letter to ensure that PWLE have meaningful involvement at all levels, which was a resonating theme throughout this meeting. If a decision was made to create a letter, it was suggested that the specificity of "CDC/HRSA" be changed to "HHS Agencies" and that the recommendations better specify what is meant by "meaningful involvement." Several members noted that some of these items were completed. Perhaps in order to make these points, they could state that meaningful involvement with PWLE has been articulated in all presentations to the CHAC as being highly important. CHAC decided that the first 3 considerations will be included in the minutes and are a powerful reminder of the important issues that the agencies should ensconce in their NOFOs, practices, and policies.

CHAC Action
Dr. Driffin made a motion that CHAC recommends CDC/HRSA to develop shared metrics to assess successful community partnerships across agencies considering syndemic and status neutral approaches including meaningful involvement of PWLE. Dr. Dionne seconded the motion. CHAC unanimously approved the submission of this recommendation to CDC and HRSA.

Recap and Meeting Summary

Wendy Armstrong, MD
CHAC Co-Chair

Dr. Armstrong expressed gratitude to all the presenters and participants for the high-level discussions with incredible and thoughtful points and a lot of mind-expanding moments. These discussions help them move forward in ending the epidemics that CHAC addresses. A major theme that stood out is that they can think about and discuss communication, lifetime survivors, clinicians and patients talking about doxy PEP, addressing testing, innovative approaches, and so forth. However, unless what happens with people is inclusive, honest, thoughtful, and compassionate—none of this is going to work.

Adjourn

Dr. Mermin thanked everyone for their participation and recognized that this 2-day meeting had reflected the importance of having different methodologies (e.g., economic analyses, qualitative presentations, thoughtful interpretations of guidelines and science, incorporating the views of PWLE into the discussions), given that it informs more truthful and accurate decisions. He emphasized how grateful CDC is for CHAC's work and the time the members have taken during these meetings and during workgroup meetings that occur between CHAC.

Dr. Cheever agreed with Dr. Mermin. She suggested in future meetings having the workgroups report out on Day 1 in order to engage in discussions and bring items back on Day 2 rather than having to table issues for months until the next CHAC meeting.

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

Certification

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

Wendy Armstrong, MD
CHAC Co-Chair Date

Attachment A: Participant List

CHAC Members Present

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

CHAC Members Absent

Brigg Reilley, MPH

CHAC *Ex-Officio* Members Present

Carolyn Deal, PhD
National Institute of Allergy and Infectious Disease
National Institutes of Health

Neerja Gandotra, MD
Substance Abuse and Mental Health Services Administration

Christopher Gordon, PhD
National Institute of Mental Health
National Institutes of Health

B. Kaye Hayes, MPA
Office of Infectious Disease and HIV/AIDS Policy
US Department of Health and Human Services

Richard Wild, MD, JD, MBA, FACEP
Centers for Medicare and Medicaid Services

CHAC *Ex-Officio* Members Absent

Mr. Richard Haverkate
Indian Health Service

Iris Mabry-Hernandez, MD, MPH
Agency for Healthcare Research and Quality

Aditi Mallick, MD
Centers for Medicare and Medicaid Services

CHAC Liaison Representatives Present

Hansel Emory Tookes, III, MD, MPH
Presidential Advisory Council on HIV/AIDS

CHAC Designated Federal Officers

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

Laura Cheever, MD. ScM
Health Resources & Services Administration
HIV/AIDS Bureau Associate Administrator

Federal Participants

Lindley Barbee, MD MPH
Division of STD Prevention, NCHHSTP, CDC

Kathy Byrd, MD, MPH
Division of HIV Prevention, NCHHSTP, CDC

Emily J. Cartwright
Division of Viral Hepatitis, NCHHSTP, CDC

Kathleen Ethier, PhD
Division of Adolescent and School Health, NCCDPHP, CDC

Robyn Neblett Fanfair, MD, MPH
Division of HIV Prevention, NCHHSTP CDC

Nate Furukawa, MD MPH
Division of Viral Hepatitis, NCHHSTP CDC

Neil Gupta, MD, MPH
Division of Viral Hepatitis, NCHHSTP CDC

Federal Participants (continued)

Saleem Kamili, PhD
Division of Viral Hepatitis, NCHHSTP, CDC

Michelle Van Handel, MPH
Program and Performance Improvement Office, NCHHSTP, CDC

Kristin Roha, MS, MPH
Substance Abuse and Mental Health Services Administration

Public Participants

Richard Adkins
Lifetime Survivors Network

Allison Agwu, MD, ScM, FAAP, FIDSA
Johns Hopkins University School of Medicine

Misty Carney, BS, PharmD, AAHIVP
Maryland Department of Health

Stephanie Cohen, MD, MPH
San Francisco Department of Public Health

Amber Coyne, MPH
Tennessee Department of Health

Sophie Feffer
Colorado Department of Public Health and Environment

Eric Hall, PhD
Oregon Health & Science University
Penn State University School of Public Health

Antoinette Jones
Dandelions, Inc.
Positive Women's Network

April D. Kimmel, PhD
Virginia Commonwealth University

Kenneth H. Mayer, MD
Fenway Health
Harvard Medical School

Public Participants (continued)

Sarah Money, MPH
Colorado Health Network

Neha Sheth Pandit, PharmD, AAHIVP
University of Maryland School of Pharmacy

Alina Whitener, MS, CHES
Michigan Department of Health and Human Services

Jason W. Wilson, MD, PhD, CPE, FACEP
University of South Florida
Tampa General Hospital

Attachment B: List of Acronyms

ACA	Affordable Care Act
ADAP	AIDS Drug Assistance Program
AdhereP4	ADHEREnce support intervention among people with HIV implemented through the collaboration of Pharmacies, Prescribers, Payers, and Public health agencies
AE	Adverse Event
AETC	AIDS Education and Training Center
AI/AN	American Indian or Alaska Native
AIMS Study	Antiretroviral Improvement of Medicaid enrolleeS Study
AMA	American Medical Association
AR	Antimicrobial Resistant
ART	Antiretroviral Therapy
ARV	Antiretroviral
BHCHP	Boston Health Care for the Homeless Program
CAB	Community Advisory Board
CAMP	Coalition for Applied Modeling for Prevention
CARGOS	Combatting Antimicrobial Resistant (AR) Gonorrhea and Other STIs
CBA	Capacity Building Assistance
CBHS	Chase Brexton Health Services
CBOs	Community-Based Organizations
CBPR	Community-Based Participatory Research
CDC	Centers for Disease Control and Prevention
CDPH	California Department of Public Health
CHAC	CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment
CHC	Community Health Centers
CHN	Colorado Health Network
CHW	Community Health Workers
CLIA	Clinical Laboratory Improvement Amendments
CMO	Committee Management Office
CMS	Centers for Medicare & Medicaid Services
COI	Conflicts of Interest
CoP	Communities of Practice
CPN	CBA Provider Network
CPWG	Community Partnership Workgroup
CRUSH-TB	Combination Regimens for Shortening TB Treatment
CSTE	Council of State and Territorial Epidemiologists

D2C	Data to Care
DAAs	Direct-Acting Antivirals
DASH	Division of Adolescent and School Health
DFO	Designated Federal Officer
DHAP	Division of HIV/AIDS Prevention
DHD	Detroit Health Department
DHP	Division of HIV Prevention
DSTDP	Division of STD Prevention
DUA	Data Use Agreements
DVH	Division of Viral Hepatitis
ED	Emergency Department
EHE	Ending the HIV Epidemic
EMR	Electronic Medical Record
ET	Eastern Time
ETS	Ending the Syndemic Tennessee
FACA	Federal Advisory Committee Act
FDA	Food and Drug Administration
FLAS, Inc.	Fundacion Latinoamericana De Accion Social, Inc.
FPL	Federal Poverty Level
FQHC	Federally Qualified Health Center
FRN	Federal Registry Notice
FTE	Fulltime Employee
GISP	Gonococcal Isolate Surveillance Project
HAB	HIV/AIDS Bureau
HCP	Health Care Provider/Practitioner
HCV	Hepatitis C Virus
HECAT	Health Education Curriculum Analysis Tool
HHS	United States Department of Health and Human Services
HIV	Human Immunodeficiency Virus
HMO	Health Maintenance Organization
HOPWA	Housing Opportunities for People with AIDS
HPV	Human Papillomavirus
HRSA	Health Resources and Services Administration
HUD	Housing and Urban Development
ICERs	Incremental-Cost Effectiveness Ratios
IHS	Indian Health Service
INH	Isoniazid
ITAP	Independent Test Assessment Program
KFF	Kaiser Family Foundation

LAIWG	Long Acting Injectables Workgroup
LGBTQ	Lesbian, Gay, Bisexual, Transgender, Questioning
LTBI	Latent Tuberculosis Infection
MADAP	Maryland AIDS Drug Assistance Program
MCO	Managed Care Organization
MDHHS	Michigan Department of Health and Human Services
MHS/CDR	Molecular HIV Surveillance/Cluster Detection and Response
MMWR	*Morbidity and Mortality Weekly Report*
MOUD	Medicated Opioid Use Disorder
MSM	Men Who Have Sex with Men
MSW	Men Who Have Sex with Women
MTR	Multi-Tablet Regimen
MTSS	Multi-Tiered System of Supports
NA-ACCORD	North American AIDS Cohort Collaboration on Research and Design
NAAT	Nucleic Acid Amplification Testing
NACCHO	National Association of County and City Health Officials
NASC	National AETC Support Center
NASTAD	National Alliance of State and Territorial AIDS Directors
NCCDPHP	National Center for Chronic Disease Prevention and Health Promotion
NCES	National Center for Education Statistics
NCHHSTP	National Center for HIV, Viral Hepatitis, STD and TB Prevention
NEEMA	NCHHSTP Epidemiologic and Economic Modeling Agreement
NHANES	National Health and Nutrition Examination Survey
NIH	National Institutes of Health
NIMH	National Institute of Mental Health
NNDSS	National Notifiable Diseases Surveillance System
NOFO	Notice of Funding Opportunity
NP	Nurse Practitioner
NPAIHB	Northwest Tribal Health Board
nPEP	Non-Occupational Post-Exposure Prophylaxis
NRWC	National Ryan White Conference
NSCSS Federal Task Force	National Syphilis and Congenital Syphilis Syndemic Federal Task Force
NVSS	National Vital Statistics System
NYC	New York City
NYC Health	NYC Department of Health and Mental Hygiene
OD2A	Overdose Data to Action
OHE	Office of Health Equity
OHSU	Oregon Health & Science University
OIDP	HHS Office of HIV/AIDS and Infections Disease Policy
oPEP	Occupational Post-Exposure Prophylaxis
OUD	Opioid Use Disorder

PACHA	Presidential Advisory Council on HIV/AIDS
PDC	Proportion of Days Covered
PEP	Post-Exposure Prophylaxis
PEPFAR	President's Emergency Plan for AIDS Relief
PHE	Public Health Emergency
PN	Peer Navigators
POC	Point-of-Care
PrEP	Pre-Exposure Prophylaxis
PSU	Portland State University
PWID	People Who Inject Drugs
PWLE	People With Lived Experience
PWUD	People Who Use Drugs
QALY	Quality Adjusted Life Years
QOL	Quality of Life
RADx	Rapid Acceleration of Diagnostics
RCT	Randomized Controlled Trial
RFI	Request for Information
RFP	Request for Proposals
RIF	Rifampin
RNA	Ribonucleic Acid
RWHAP	Ryan White HIV/AIDS Program
SAEs	Serious Adverse Events
SAMHSA	Substance Abuse and Mental Health Services Administration
SDOH	Social Determinants of Health
SHCs	Sexual Health Clinics
SHIPS	Support and Scale-Up of HIV Prevention Services in Sexual Health Clinics
SID	Syndemic Infectious Disease Bureau
SME	Subject Matter Experts
SOGI	Sexual Orientation & Gender Identity
SPNS	Special Projects of National Significance
SSP	Syringe Services Program
STD	Sexually Transmitted Disease
STI	Sexually Transmitted Infection
STR	Single-Tablet Regimen
SUD	Substance Use Disorder
SURRG	Strengthening the US Response to Resistant Gonorrhea
SVR	Sustained Virologic Response
TA	Technical Assistance
TB	Tuberculosis
TBTC	Tuberculosis Trials Consortium
TDMHSAS	Tennessee Department of Mental Health and Substance Abuse Services
ToT	Training of Trainers

UMMS	University of Maryland Medical System
US	United States
USCHA	United States Conference on HIV/AIDS
USPSTF	United States Preventive Services Task Force
VCU	Virginia Commonwealth University
VDH	Virginia Department of Health
VDSS	Virginia Department of Social Services
VH	Viral Hepatitis
WG	Working Group
WHO	World Health Organization
YRBS	Youth Risk Behavior Survey

Attachment C: Youth Letter

CDC/HRSA ADVISORY COMMITTEE
on HIV, Viral Hepatitis and STD Prevention and Treatment

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Iris Mabry-Hernandez, MD, MPH
Aditi Mallick, MD

LIAISON
Hansel Emory Tookes III, MD, MPH
Presidential Advisory Council on HIV/AIDS

April 15, 2024

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

Dear Mr. Secretary,

Thank you for your support and leadership in the continuing work to improve public health among all US individuals. The Centers for Disease Control and Prevention/Health Resources and Services Administration (CDC/HRSA) Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHAC) met in Atlanta on April 18-19, 2023, where we discussed a number of critical public health issues including some concerning trends in health and behavior in our nation's youth, based on national data. During this meeting, the CHAC expressed great concern regarding youth mental and sexual health and vulnerability to violence and substance abuse. CHAC passed a resolution and is sending recommendations, described below, for your consideration.

Background and Rationale:

The Youth Risk Behavior Survey (YRBS) provides key data on health risk behaviors and experiences among high school students, including information on sexual behavior, substance use, experiences of violence, mental health and suicidality and emerging data in these domains. This is the only federal surveillance system to provide representative national and state data and is critical for identifying emerging issues and supporting program planning, implementation, and evaluation.

The Advisory Committee advises the Secretary, the CDC Director and the HRSA Administrator of the U.S. Department of Health and Human Services on activities related to prevention and control of HIV, viral hepatitis and other STDs, the support of health care services to people living with HIV, and education of health professionals and the public about HIV, viral hepatitis and other STDs.

The 2021 YRBS is the first such data since the beginning of the COVID-19 pandemic. In terms of substance use where there has been a decreasing trend in the proportion of high school students acknowledging current use of alcohol (23% in 2021 vs 39% in 2011), marijuana (16% 2021 vs 23% 2011) or ever use of illicit drugs (13% 2021, vs 19% 2011), with no change in current misuse of prescription opioids (6%). Though higher than desired, the trends are relatively reassuring. However, in terms of experiences of violence, trends are more concerning. Compared to 2011, a higher proportion of students in 2021 reported missing school because of safety concerns (9% vs 6%) and 11% reported experiencing sexual violence (data not captured in 2011); there was essentially no change in proportion of students who were threatened or injured with a weapon at school (7% in 2021 and in 2011); those who were electronically bullied (16% in 2021 and in 2011); and those forced to have sex (8% in 2021 and in 2011). However, within these data there are substantial disparities among groups: Black and Hispanic students were significantly more likely than Asian, White, and multiracial students to not go to school because of safety concerns; American Indian and Alaska Native (AI/AN) students reported the highest levels of teen dating violence (physical and sexual dating violence) and bullying victimization, including being bullied on school property and being electronically bullied, compared to their racial/ethnic peers[1]; LGBTQ+ youth were two times as likely as their heterosexual peers to be electronically bullied and to miss school because of safety concerns; 18% of female students said that they had experienced sexual violence in the past year and almost 14% said they had been ever physically forced to have sex when they did not want to.

As has been reported widely, mental health indicators, including suicidality, among youth are of great concern: in the 2021 YRBS 42% of students reported persistent feelings of sadness or hopelessness, as compared to 28% in 2011; 22% seriously considered suicide and 10% attempted suicide in 2021 (vs 16% and 8%, respectively in 2011). AI/AN students reported the highest percentage of attempted suicide (16%) among racial/ethnic groups, and Black students were significantly more likely than Asian, Hispanic, and White students to attempt suicide. Female students were nearly twice as likely as their male peers to experience depressive symptoms and to attempt suicide in the past year. And LGBTQ+ students were about two times as likely as their heterosexual peers to feel persistently sad and hopeless, and nearly four times as likely to attempt suicide during the past year.

The percentage of high school students who have ever had sex has declined from 47% in 2011 to 30% in 2021, with 21% currently sexually active vs 34% in 2011 and those with 4 or more lifetime sexual partners also significantly decreased. However, fewer sexually active youth are using condoms during last intercourse (52% in 2021 vs 60% in 2011) and fewer have ever been tested for HIV (6% in 2021 vs 13% in 2011) or sexually transmitted infections (STI) in the

[1] Clayton HB, Kilmer G, DeGue S, et al. Dating Violence, Sexual Violence, and Bullying Victimization Among High School Students —Youth Risk Behavior Survey, United States, 2021. MMWR Suppl 2023;72(Suppl-1):66–74. DOI: http://dx.doi.org/10.15585/mmwr.su7201a8.

previous year (5% vs 9% in 2019-no data for 2011). Only one-third of heterosexually active students reported use of effective hormonal contraception with most recent sexual exposure, with Black and Hispanic students less likely to use these methods.

In the National Survey of Family Growth (NSFG), a national probability sample of 15–44-year-olds in the US, data collected from 2017-2019 also found declines in STI testing among sexually active females 15-19 years with small declines among males in the same age range.

There are likely multiple factors that contribute to these trends, including the well-documented adverse effects on the health of youth related to the COVID-19 pandemic, as well as concerns about confidentiality and access to health insurance coverage. However, it is critical that these issues be monitored in real time and on an individual basis, so that problems can be identified and addressed promptly and comprehensively. With these facts in mind, CHAC proposes the following specific recommendations:

1. Support development and implementation of routine and effective screening tools for youth for mental health problems, substance use/abuse and violence, and STIs.
2. Support development and implementation of standardized protocols for sexual health in youth which integrate youth voices throughout the planning process.
3. Develop mechanisms for youth-focused services to incorporate community health workers, use of peer-to-peer supports, identification and use of champions/influencers, and listening sessions with youth to identify and implement best strategies to engage, educate, link to care and impact behavior, recognizing how young people are different and how differences change over time and vary between individuals.
4. Ensure support for the ongoing collection of YRBS data in all states and jurisdictions every two years through CDC's Division of Adolescent and School Health.

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

With best regards,

Wendy Armstrong, MD
CHAC Co-Chair

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

Attachment D: Workgroup Reports

LONG -ACTING INJECTABLE WORKGROUP

Spring 2024 Report to CHAC

Christopher Gordon
Daniel Driffin
Richard Haverkate
Christine Markham
Wendy Armstrong
Renata Sanders
Jorge Cestou
Shannon Dowler, Chair

OVERVIEW FALL '23 TO SPRING '24 LAIWG ACTIVITIES

- CHAC recommendations following the fall 2023 meeting included:
  - CDC and HRSA work with CMS to investigate how to standardize the provision of long -acting injectables across payers for HIV prevention and treatment and to increase access for all populations.
  - CDC and HRSA work and partner with IHS to add long -acting injectables to the IHS formulary.
  - CDC and HRSA work with the HHS Adolescent and Adult Antiretroviral Treatment Guidelines Committee on two items: 1) evaluating the emergence of new data that will allow people living with HIV to access direct to inject broadly and in settings of non -viral suppression; and 2) reevaluating the long -acting injectable PrEP guidelines to include permissive utilization in unique circumstances.
- LAIWG convenings:
  - Synchronous:
    - February 28
    - March 18, with special guest Jonathan Mermin, MD, MPH
    - March 21
  - Asynchronous:
    - Online document and article reviews

LIVED EXPERIENCE: QUALITATIVE ANALYSES CONSIDERED

- CHAC extended the LAIWG in Fall 2023 to allow for further insights into barriers and lived experience for those seeking or utilizing LAI for HIV prevention or treatment.
- Due to challenges facilitating non-clinical external stakeholder input, the decision was made to seek to understand existing literature.
- LAIW reviewed 14 qualitative studies published between 2018-2023 to understand lived experience of >300 people.(See appendix for full details of articles reviewed)

LAI CONSIDERATIONS FOR CHAC #1

- Ask the CDC/HRSA to work with partners, such as NIH and Ryan White programs, to request current grantees working in the LAI space to share the current experience including patient feedback and best practices from 2022 -present.
- Ask CDC/HRSA to convene existing advisory boards of people with lived experience to discuss the current barriers to access and uptake of LAI(for HIV treatment and prevention)(for instance in 8/24 Ryan White Conference).
- Ask CDC/HRSA to partner with CBOs specifically related to populations demonstrating rising risk, such as women and young adults, to increase uptake of LAI.

OVERARCHING "TAKE -AWAYS" FROM ARTICLES REVIEWED

- Lack of awareness re. LAI for both consumers and providers from 2020-2022
- Lack of lived experience in real world settings (e.g., non -randomized control settings) to understand impact of/address access barriers
- Population focused on older white men; need to expand understanding to adolescents, younger adults and women.
- Lack of qualitative studies in the southeast US
- Consistent concerns about the increased burden on number of required visits
- Anxiety and suspicion about the safety of LAI
- Importance of patient-provider communication to identify unique needs/preferences among individuals (eg, history of injection drug use, currently on other injected treatments)

FLASHBACK: FALL RECOMMENDATION

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.

LAI CONSIDERATIONS FOR CHAC #2

- Ask the CDC/HRSA to work with partners (e.g., providers, consumers, pharmacists, insurers) in clinical practice to obtain information on variation of coverage, basis for variation, and optimal mechanism for reimbursement of LAI for best patient access.
- Request CHAC to consider revisiting the fall 2023 recommendation to more explicitly ask CDC/HRSA to seek standardization of LAI under the most optimal benefit and to eliminate cost sharing/co-pays.

FLASHBACK: FALL RECOMMENDATION

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.

LAIWG CONSIDERATIONS FOR CHAC #3

- Request CHAC to consider revisiting the fall 2023 recommendation to more explicitly ask CDC/HRSA to drive study and recommendations related to increasing inter -injection intervals, decrease the burden of additional labs, and allow treatment of viremic patients when clinically appropriate.

LAIWG CONSIDERATIONS FOR CHAC #4

- Request CHAC consider modifying scope of LAI WG and extending to include: tracking the emergence of new LAI for other conditions, driving ongoing study to evaluate and eliminate barriers for access to LAI.

SUMMARY OF CONSIDERATIONS

- Ask the CDC/HRSA to work with partners, such as NIH and Ryan White programs, to request current grantees working in the LAI space to share the current state of their learnings from 2022-present.
- Ask CDC/HRSA to convene existing advisory boards of people with lived experience to discuss the current barriers to access and uptake of LAI (for HIV treatment and prevention)(for instance in 8/24 Ryan White Conference).
- Ask CDC/HRSA to partner with CBOs specifically related to populations demonstrating rising risk, such as women, adolescents, and young adults, to increase uptake of LAI.
- Ask the CDC/HRSA to work with partners (e.g., providers, consumers, pharmacists, insurers) in clinical practice to obtain information on variation of coverage, basis for variation, and preferred mechanism for reimbursement of LAI (pharmacy vs. medical benefit) for best patient access.
- Request CHAC to consider revisiting the fall 2023 recommendation to more explicitly ask CDC/HRSA to seek standardization of LAI under exclusively pharmacy or medical benefit and to eliminate cost sharing/co-pays.
- Request CHAC to consider revisiting the fall 2023 recommendation to more explicitly ask CDC/HRSA to drive study and recommendations related to increasing inter-injection intervals, decrease the burden of additional labs, and allow direct to treat when clinically appropriate.
- Request CHAC consider modifying scope of LAI WG and extending to include: tracking the emergence of new LAI for other conditions, driving ongoing study to evaluate and eliminate barriers for access to LAI.

AIDS Care	2022	Antiretroviral Therapy Experience, Satisfaction, and Preferences Among a Diverse Sample of Young Adults Living with HIV C. K. Campbell, K. Dubé, J. A. Sauceda, S. Ndukwe, P. Saberi	To gain understanding of YLWH's perceptions, concerns, and interests in long-acting ART (LAART) treatment modalities (e.g., injectables, implants, patch).	Participants were recruited as part of the Youth4Cure (Y4C) study Eligibility criteria: *18-29 years old living with HIV *English-speaking *Living in the US *Access to mobile telephone &/or computer with internet Qualitative research (1-1 semi-structured virtual interviews) Interview topics: *Perceptions, motivations, and barriers to participation in HIV cure research *Experiences with ART, perceptions of their current treatment, how treatment experiences could be improved Interview length: 45-60 minutes Analysis: *Framework analysis: Thematic analysis involving interdisciplinary team in coding and developing analytic framework *Author charted data into a framework matrix (sorted data into priori & emergent categories)	Demographics (N=20) *Gender: 60% male, 25% female, 15% nonbinary/genderqueer *Sexuality: 50% gay, 30% bisexual, 10% heterosexual, 5% queer, 5% pansexual *85% have been living with HIV between 10-months-8 years (15% diagnosed at birth) *95% self-reported being on ART & had an undetectable viral load ART experience: *Side effects: More than 1/3 of participants reports side effects attributed to ART at some point but only a few reported mild side-effects at the time of the interview. *Adherence: (1) Anxiety related to challenges with adherence and consequence of non adherence. (2) Treatment fatigue, (3) Most reported rarely/never missing a dose. Some reported taking a daily pill as routine/automatic, but for some when outside of regular routine it was easy to forget ART Improvements: *Injectables: Most were enthusiastic of the possibility of periodic injection. Viewed injectables potentially making life easier, improve adherence, social benefits (traveling w/out meds), lower risk of disclosure. 3-6 month injection interval would be ideal for some, but others were excited about a once a month option as well. Some expressed a fear of needs, including participants w/ history of injection drug use. *Patch: 10 participants were interested in a potential patch. Similar advantages as injectable, but some concern about patch visibility (fear of stigma). *Implants: Least interested in implants. A few liked the idea of having something not visible to others that is changed periodically. Most uncomfortable with the thought of an object in their bodies and fear of complications. *Other: Change the daily pills (chewable gummies, smaller pills). Participants diagnosed at birth expressed concern of changes in their current ART regimens.	*Consideration of YLWH preferences and concerns about ART modalities during development has the ability to ensure uptake and acceptability of YLWH *YLWH ART non-adherence contributed to being out of their routine, forgetting, & treatment fatigue, which was consistent with previous studies *Perinatally infection persons were less interested in changes to their medication (similar to data on adults) which could be due to less tolerable regimens previously prescribed *Concerns of short-term side-effects associated with LAI-ART are similar to daily pill, but people would wait until long-term side-effects are more well known for LAIs. *Fear of needles/needle aversion associated with injection drug use another concern for YLWH considering LAI *Preference for less frequent injection (some 1 month, most 3-6 months). Compared to older PLWH, YLWH have less concern over receiving injection- potentially prefer contact with clinical team *Other modalities (patch, implant) are acceptable and were recognized as modalities for other types of medication Limitations: *Small sample size, may not be generalizable

APPENDIX: ARTICLE SUMMARIES

AIDS Care	2020	Perspectives of injectable long acting antiretroviral therapies for HIV treatment or prevention: understanding potential users' ambivalences S.Carillon, L.Gallardo, F.Linard, C.Chakvetadze, J.Viard, A.Cros, J.Molina & L.Slama	Assess potential LA-ART users' perceptions based on their experience with ART (prevention & treatment).	Participants were recruited as part of the Considerations about Long-Acting injectable therapies in HIV Prevention & Treatment (CLAPT) study Eligibility: *PLWH taking ART or taking PrEP for 6+ months Qualitative (in-depth individual interviews) with PLWH & PrEP users Interview topics: *Personal experience taking ART/PrEP *Knowledge of new ART treatments/PrEP prevention *Willingness to change ART modality Analysis: *Interview audio was transcribed and manually coded *Cross-cutting thematic analysis	Demographics (N=28) *15 PLWH (9 M, 6 F; M = 54 years) *13 PrEP users (100% M; M = 42 years) LA-ART Concerns (1) Social (daily life w/ART) - most participants had a routine relationship with daily oral regimen *Apprehension: Long history of complex ART regimens made participants skeptical of LA-ART and viewed a change in a regimen they felt comfortable with as a risk to their health *Simplification: Potential to step up daily life by reducing stigma, reduce concern about missing doses/being nonadherent, simplified therapeutic routine (2) Material (mode of administration): Injectable perceptions based on participants paster experiences (good experience = greater interest; negative experience = more reluctance). More common to have negative injectable experiences. Concerns expressed about not being in control when receiving injections. (3) Experimental (relationships to innovation): Higher skepticism about effectiveness and will "wait and see" approach. Most participants trusted their doctors' referrals and would be open to injectables if recommended.	*Feelings toward LA-ART are ambivalent and revealed mixed feelings (skepticism, hope, distrust) *PLWH & PrEP have difference context for taking medication which result in different concerns *Medication practices are made according to socio-cultural contexts *Distrust in medicine due to historic mistreatment creates apprehension for innovative treatments, and there was a real concern for loss of autonomy. Participants expressed potential interest once they see LA-ART be successful. *Participant perspectives seemed to be influenced by their history with ART, relationship with HIV, and sociodemographic. Limitations: *Study excluded non-adherent participants. Authors justified this decision due to concerns for resistance developing with patients were are non-adherent or patients who would be ineligible for LA-ART because existing resistance
Journal of Urban Health	2023	Perceptions of Long-Acting Injectable Antiretroviral Therapy Among People Living with HIV Who Use Drugs and Service Providers: a Qualitative Analysis in Rhode Island A.Collins, EC Macon, K.Langdon, R.Joseph, A.Thomas, C.Dogon, C.G. Bechwith	Examining LAI-ART perspectives among PLWH who use drugs and providers who support these populations. Assess LAI-ART ability to mitigate barriers to HIV care among PLWH who use drugs & how location of LAI-ART roll-out may shape access to, and uptake of, this emerging treatment option.	Eligibility *PLWH who use drugs & are 18+ years old (excluded if only marijuana use self-reported) *Clinical providers & ancillary services (harm reduction/housing outreach workers) Qualitative Semi-structured interviews with PLWH (~45 mins) *Substance use patterns, experiences with HIV treatment, HIV -related stigma, perceptions of LAI-ART, and implementation considerations (oral lead in was a requirement as time of the interviews) Focus groups with providers (~60 mins) *Feasibility, acceptability, & implementation considerations for LAI-ART Analysis *Audio recorded, transcribed, & coded & analyzed thematically using NVivo	Demographics PLWH (n=15) *M=51 years of age (24-68 years; 7 women (transgender-inclusive) & 8 men (transgender-inclusive)) *47% white, 20% multi-racial, 13% Black, 13% Indigenous, 13% Hispanic *60% used alcohol &/or other drugs daily; 27% used drugs 34X/week, 13% one or fewer times per week Providers (n=13) *Clinicians = 8 (all knew of LAI-ART and had experience with administration) *Ancillary service providers = 5 (1 of 5 knew of LAI-ART) One-size fits all concerns about LAI-ART *PLWH: A single LAI-ART regimen viewed as a limitation, which was reflective of how they perceived LAI-ART to be at odds with existing ART regimens that participants felt required "trial and error" for their specific treatment *Providers: Some patients have resistance to a medication in the injection formula Injectable vs. Oral Treatment *PLWH with experience with finding their oral regimen (treatment challenges, disruptions, etc.) they felt their oral regimen was the best, but others expressed difficulty having their oral ART available *Providers shared for this population it can be extremely difficult to take oral ART and LAI-ART could be a critical solution to HIV management & mental health Perceived Risks of LAI-ART *PLWH felt medication was safe, but worried about how switching may impact viral suppression and overall health *Some concerns focused on if an injection appointment was missed, will this increase risk of adverse HIV outcomes, especially considering competing priorities & barriers *Uncertainty of side effects and newness created hesitancy that may go away with time LAI-ART Implementation Consideration *Equitable roll-out and offering this as an option to all participants was highlighted, although some participants felt people who have unstable housing and/or drug use should be prioritized (providers echoed this sentiment) *Community based delivery options, potential for ancillary service providers to receive training and administer injections, at home self injection option	*Experience with oral ART and concerns about HIV health outcomes drive participant's perceptions of LAI-ART *LAI-ART is a possible mech to address barriers for PLWH who use drugs *More time on an oral ART regimen made participants more hesitant to change medication compared to participant who experienced frequent disruptions *Barriers to care were framed around levels of structural concerns (housing, socio-economic, etc.) and not substance use *Receiving LAI-ART from community settings may be preferred over clinics *Equitable roll-out of LAI-ART is important Limitations *Participants were recruited from an HIV clinic and may not reflect perspectives of PLWH who are not engaged in care *Not representative of transgender & gender diverse participants *Not generalizable *Removal of an oral lead as a requirement may have impacted some participants' perspectives

Harm Reduction Journal	2023	Perspectives on long acting injectable HIV antiretroviral therapy at an alternative care site: A qualitative study of people with HIV experiencing substance use and/or housing instability L.Fletcher, S.Burrowes, G.Khan, S.Johnson, S.Kimmel, G.Ruiz-Mercado, C.Pierre, M.Drainoni	Assess attitudes among PLWH about the injection and whether a more accessible alternative care site would increase their likelihood of adherence	Eligibility *18+ years old *English or Spanish speaking *Have a history of nonadherence to ART Qualitative: Semi-structured interviews with PLWH who receive care at Project Trust (PT) or disengaged from HIV care at Boston medical center (BMC). Analysis: Direct content analysis in core constructs of i-PERIHS	Demographics (N=26) *Gender: 18 M, 8 F *Race/ethnicity: White (11), Black (11), Latinx (10) *Time since diagnosis: 3 months-30 years *Age: 18-34 years old (10), 35-49 years old (10), 50-64 years old (6) Themes: Participants are knowledgeable about their HIV care & importance of ART adherence *Motivated by being undetectable & confident discussing lab values *Barriers to adherence related to taking a daily pill included remembering to take it everyday, substance use, housing, and HIV health issues Participants prefer a long-acting injection over a daily pill *Convenience of a LAI was motivating aspect to switch from current ART regimen and viewed it as less of a burden to day to day life *Not carrying medication with them was another benefit of LAI *An injection was identified as a potentially improving mental health Participants expressed concerns about injection safety & efficacy *Transition period to LAI and potential side effects were noted as a barrier to LAI *Long-term concerns and the thought of something in your body for extended time was a potential barrier *Participants worked hard to achieve viral suppression, so there were concerns about LAI not working as well Admin logistics of injections *Participants said to be acceptable injection site should not disrupt patients routine *Questions about frequency of appointments and transportation posed barrier *Relationships with care teams determined participants preference of where to receive their injections Participants were confident of their ability to complete oral lead-in requirement *Being able to receive LAI ART was enough of a motivator for participants to confidently express their ability to complete the oral lead in Concerns about adhering to injections *A barrier to LAI is showing up to a care site for some considering instability of housing and substance use	*Strong interest in LAI ART was expressed by participants in this study and saw the potential an injectable treatment had to address adherence barriers *Barriers to LAI ART, especially vulnerable populations, will persist and need to be addressed to tailor their care and ensure cultural competency in LAI ART implementation Limitations *May not be generalizable and sample was mostly men and white people *May have been selection bias in recruitment because participants aware of purpose of the study
PLOS ONE	2022	Perspectives on preparing for long acting injectable treatment for HIV among consumer, clinical and nonclinical stakeholders: A qualitative study exploring the anticipated challenges and opportunities for implementation in Los Angeles County O Jolayemi, L Bogart, E Storholm, D Goodman-Meza, E RosenbergCarlson, R Cohen, U Kao, S Shoptaw, R Landovitz	Address perceived policy, systems, financial, operational, clinical, and consumer-level barriers to and facilitators of rollout and scaleup of LAI ART, from the perspective of clinical and nonclinical HIV providers, healthcare administrators, and other key stakeholders, as well as potential consumers	Eligibility: Consumers, clinical stakeholders, and non-clinical stakeholders were invited to participate Consolidated Framework for Implementation Research (CFIR) *Barriers and facilitators were addressed in the following contact: Intervention characteristics, outer setting, inner setting, individual characteristics, & implementation process Focus group (4 total) *2 consumers focus groups *1 clinical & non-clinical stakeholders focus group *1 clinical stakeholder focus group 1 Semi-structured interview with a clinical stakeholder Analysis *Descriptive statistics *Inductive thematic analysis (dedoose used to code)	Demographics: *18 consumers *24 clinical/non-clinical stakeholders Intervention characteristics Relative advantage: Compared to daily oral ART, injectable ART seen as easier to adhere to, reduce treatment management burden and decrease treatment frequency and responsibility for consumers Perceived adaptability & complexity: Going to clinic monthly for injections was identified as a barrier to willingness to switch to LAI ART. Vulnerable populations may benefit the most from LAI ART but there was concern about non-adherence to injection schedule and the potential for drug residence. Perceived likelihood of a disruption to clinical workflow and demand by clinic and non-clinic stakeholders. Key features: Needle based injections and potential side effects were identified as barriers across groups. Cost: Cost was a barrier identified to implementation and financial burden/insurance coverage for consumers Characteristics of individuals Knowledge & beliefs: All groups expressed support and willingness to adopt LAI ART & providers appreciate an additional HIV treatment method Self-efficacy: Clinical and non-clinical stakeholders were concern about their ability to share efficacy, safety and other questions & concerns of patients Outer setting Patient needs & resources: A key facilitator was ability to address stigma across groups (ease burden of HIV related internalized and social stigma, reduce shame and constant reminder that comes with taking a daily pill, reduce unwanted disclosures). Barriers included increased clinic visits at HIV care locations could cause anxiety and fear of being seen, transportation &/or housing access External policy: Limit access to LAI ART to people who are virally suppressed, which takes it away from populations that struggle with adherence and have the greatest benefits. Clinic & non-clinical participants said they required clear recommendations Inner setting Implementation climate: Organizations admis and providers may be hesitant to complicate workflow, especially for patients who are successful with oral ART Readiness for implementation: Potential barrier if teams do not have effective and clear procedures and adequate training & education Structural characteristics: Staff capacity and physical space was a key barrier identified in implementation Process Planning & engaging: Pre-plan implementation and include community members to better engage patient populations. Community engagement would help facilitate the establishment of trust and buy-in. Advertisements were suggested across platforms (social media, twice). Planning needs to be done for education and adherence support to be successful as well.	*Preparation for engagement, adherence support, education, and training is anticipated to greatly influence the success of LA ART implementation *LAI ART's ability to address stigma was identified as a key facilitator *There is willingness among clinical, non-clinical stakeholders, and consumers to adopt LAI ART as an HIV treatment option Limitations *Themes were based on small sample size of stakeholders and patients *Younger, transgender, and sex worker population was not represented *May not be generalizable because only recruited participants in LA county

AIDS Patient Care & STD	2019	Long-Acting Injectable Antiretroviral Treatment Acceptability and Preferences: A Qualitative Study Among US Providers, Adults Living with HIV, and Parents of Youth Living with HIV J Simoni, K BeimaSofie, Z Mohamed, J Christodoulou, K Tapia, S Graham, R Ho, A Collier	Assess potential acceptability and identify preferences among potential end users for characteristics of a proposed LAI-ART treatment regimen	Eligibility PWLH *18+ years old *English speaking *Living with HIV HIV care providers *18+ years old *English speaking Qualitative PWLH - 6 Focus group discussions (FGD) (heterosexual men (n=8), MSM (n=8), women (n=9), people struggling with adherence (n=4), 2 with young adults (n=6) Providers: 1 FGD Parents: In-dept interviews with parents of children living with HIV (n=5) (demographic questionnaires completed before interview/focus groups) Analysis: Direct content analysis (Dedoose used for coding, analysis, & data management)	Demographics: PLWH (n=36) Providers (n=7) Parents of children living with HIV (n=5) Qualitative: Initial reactions *PLWH were generally supportive of LAI ART if it met certain perimeters (less risk of disclosure, normalcy), but for those who had been taking pill a long time, they were less interested in changing their routine or if they have to take pills to manage other chronic conditions *Providers expected patients to be enthusiastic & expected LAI to improve adherence *Parents had positive reactions, especially if their child already receives regular injections. For parents who were hesitant, they changed their mind considering their child's future need to manage their own care Key Factors *Acceptability most influenced by efficacy and side effects of LAI *Providers and parents expressed concern over efficacy of LAI compared to oral therapies *Implicit trust in providers influence medication decisions which was validated by providers Fear of needles *PLWH with experience receiving and/or self-administering injections unconcerned of injections, but this was rare and the fear of needles decreased injectables as acceptable treatment option (esp. for parents with children who have a fear of needles) *PLWH with history of injectable drug use were concerned needles could trigger a relapse *Fear of needles was mitigated by possibility for smaller gauge needle &/or lower dose volume *Injection site, frequency of injections, and clinician vs self-administered vs pharmacist influence PLWH views on acceptability *Providers expressed concern that self-injections would be too hard for people without secure housing (where would they store medication) *PLWH, parents, & providers saw benefits in availability for LA-ART Barriers to acceptability (listed in order of most mentioned) * Multiple injections/dose *Increased cost (if receiving oral ART for free, a copay may deter patients of preferring LAI-ART) *Shorter intervals between injections (providers concerned of injection schedule being different than recommended routine visits patients might skip visits)	*All PLWH stressed need for LA-ART to be an efficacious medication and minimal side-effects for them to be willing to switch from daily oral ART *For those struggling with adherence and young adults, if they thought they would have better adherence to injectables compared to a daily pill, they were more interested in injectables *Frequency in injection varied, but some were willing to receiving weekly injections making 1 or 2 month interval acceptable to many *Providers were supportive of injectables, but stressed patients must continue to attend regular HIV care appointments Limitations *Sample only included western US residents *Public health officials, policy makers, insurance companies, or pharmaceutical companies not interviewed *Self-reported hypotheticals *Potential group think during FGD

AIDS Patient Care & STD	2021	A Qualitative Exploration of Women's Interest in Long -Acting Injectable Antiretroviral Therapy Across Six Cities in the Women's Interagency HIV Study: Intersections with Current and Past Injectable Medication and Substance Use M. Philbin, C Parish, S Bergen, D Kerrigan, E Kinnard, S Reed, M Cohen, O Sosanya, A Sheth, A Adimora, J Cocohoba, L Goganju, M Phil, E Golub, M Fischl, M Alcaida, L Metsch	Gain a better understand how women with a history of injectable medications and substance use perceive LAI-ART	Eligibility *Women living with HIV or at risk for HIV *Used injectable medication &/or history of substance use *Age 32+ years older (unclear if eligibility requirement) Qualitative: In -depth interviews *Women's attitudes & willingness to use LAI-ART/PrEP, experiences with injectable medication, knowledge and attitudes toward injectables, perceived barriers and facilitators Analysis: Thematic content analysis (manually coded)	Demographics (N = 89) *WLWH (n=59) & HIV negative women (n=30) *Age: 32 -72 years old (M=51) *Black/African American (76%), White (5%), Hispanic (5%), Biracial (1%), Other (6%) *Ever used any injectable medication (68%) and self -report regular flu shot (72%) *Ever drug use (55%) and ever injection drug use (15%) *50% would prefer LAI PrEP & 56% would prefer LAI ART Qualitative (4 major categories) Woman who received episodic injections (e.g., for birth control or physical comorbidities) and had few LAI related concerns *Having experience with shots will make people less afraid of injectable ART/PrEP *HIV therapy was compared to birth control options and had the ability to take away the stress of a daily pill Woman who required frequent injections (e.g., diabetes) and would refuse additional injections *Not interested in adding more needles to medication routine - just because shots are tolerated, doesn't make them liked *Fear of needles would be a hard-stop for some women Woman with a history of injection drug use, some of whom feared LAI might trigger a recurrence, while others had few LAI-related concerns *ongoing recovery from injection drug use makes treatment involving a needle triggering for many, but not all who feel more than comfortable and view an injection as "easy" Woman who were currently injecting drugs and had few concerns about LAI *LAI might be a better option due to unpredictable living situations and daily life	*History of injection influence women's attitudes toward LAI ART & PrEP *LAI's perceived to have ability to improve adherence and reduce treatment fatigue and stigma while increasing privacy *Women who may benefit the most from LAI ART & PrEP options may be determined by their injection experiences, but ultimately varies woman to woman Limitations *Some women were unaware of LAI modalities and had less time to consider what they thought of them *Older cohort of women, yet older women on average have more experience with injectable medications/substance use
AIDS Education Prevention	2023	"What is the Benefit?": Perceptions and Preferences for Long -Acting Injectable Antiretroviral Therapy Among People living with HIV H Rodriguez, A Volcan, B Castonguay, J Carda-Auten, C Ruiz, M Peretti, A Suarez, D Kerrigan, D Wohl, C Barrington	Assessment of LA -ART awareness, perceived benefits and concerns, and preferences among PLWH engaged in routine clinical care in the United States to inform development of a shared decision -making tool for patients and clinicians to engage with when choosing among ART options	Eligibility *HIV injection *18+ years old *English or Spanish speaking *Engaged in HIV care at participating clinic Qualitative: Semi -structured interview *Experience living with HIV and receiving HIV care, communication and HIV treatment decision making, perception of LA-ART (monthly or every 2 -month dosing of CAB+RPV) Analysis: Narrative & thematic analysis (theory of qualitative data analysis)	Demographics (N=71) *Mean age 46 years old (SD = 12; range: 24 -72) *Gender: Cismen (55%), ciswomen (27%), transgender women (17%), Non -binary (<1%) *Race self -reported Other (42%), white (24%), Black (24%) *44% conducted interview in Spanish *Mean years diagnosed with HIV = 15 years (range: <1 -36 years *73% virally suppressed Qualitative *LA-ART awareness - 54% had not heard of LA -ART & remaining 46% had heard little about it via clinical research or word of mouth. Mix of enthusiasm and caution *Perceived benefits: Reduce adherence stress, more privacy (less involuntary HIV disclosures), & potentially greater effectiveness compared to oral ART, potential to reduce stigma around HIV *Concerns: Worried it would be less effective (in contract to others who perceived it as more effective), treatment resistance, short term (injection reaction) and long term (injection sites look and feel over time) side -effects in addition to the lack of research on long -term effects, increased clinic visits and cost burden *Additional information requested from participants to address questions & concerns (how does LA -ART work, how does effectiveness, cost, and side -effects compare to daily oral ART, need more information on injections and potential pain) * Most preferred the option for an injection every 2 -months over 1 -month frequency (few did like idea on monthly injections to see their provider more often, or because they believed it would be less potent -more gentle than current oral ART) *Required support for attended more frequent clinic visits via earlier appointment reminders, quicker appointments, consistent injection days available so easier to schedule work hours	*Findings were consistent with other studies (benefits included less adherence burden, more privacy, & potentially more effective & concerns included effectiveness, side -effects, cost, and increased clinic visits) *Participants with suppressed viral loads more focused on maintaining viral suppression compared to participant who struggled with adherence highlighted achieving viral suppression as a goal - both perspectives stressed importance of LA -ART effectiveness *Time and financial burden heavily influenced participants willingness to try LA-ART (structural barriers will need to be addressed for an equitable clinical implementation) *Almost all participants wanted more information on LA -ART Limitation *LA-ART was asked about in a hypothetical context at a time when LA -ART was not available as a treatment option *Many participants had lived with HIV for a long period of time which may not be generalizable to people recently diagnosed and starting oral daily ART

PLOS ONE	2018	Deanna Kerrigan , Andrea Mantsios , Miguel Gorgolas, Maria-Luisa Montes, Federico Pulido, Cynthia Brinson, Jerome deVente, Gary J. Richmond, Sarah W. Beckham , Paige Hammond , David Margolis, Miranda Murray	qualitatively explore the views and experiences of PLHIV and their providers participating in the LATTE-2 trial in the United States and Spain	Background - LATTE-2 trial, a phase IIb study accessing the safety, tolerability, and acceptability of LA CAB and RPV for the treatment of HIV, trial included 309 treatment naïve HIV -infected participants. All participants were initially provided a three-drug (cabotegravir, abacavir, & lamivudine) oral induction regimen. Those who achieved viral suppression during the induction period were randomized to receive (1) LA injections every 4 weeks, (2) LA injections every 8 weeks, or (3) continue on the daily oral regimen [31]. Sample: 27 trial participants (11 US, 16 Spain), from the LA 4 or 8 week arms, and 12 providers were recruited from LATTE-2; Austin, TX; Long Beach, CA; Ft Lauderdale, FL; and three clinics in Madrid, Spain. Mean age: 37 Spain, 36 US; mostly male; most MSM; 4 participants across the sites received LA injections every 4 weeks while 13 participants received LA injections every 8 weeks. Twelve key informants (2 per site, with 3 sites in each country) were interviewed including study investigators (3 female and 3 male physicians) and staff (2 female nurses and 4 male study coordinators) from the LATTE-2 sites.	*There are side effects but they are worth it. "It might be painful, but it's better than pills–U.S., Male trial participant." "LA ART is convenient and confidential *concerns expressed around the # of clinic appointments. "I was a little nervous about seeing the doctor so often. Even my carpool buddy asked a couple of times, 'Wow. You go to the doctor a lot. They draw a lot of blood.' Then, I started saying, 'Well, I just have an appointment for my roofer, and my plumber is going to be coming in a second.' I stopped saying I was going to the doctor so much.–U.S., Male trial participant; Appropriate for every patient and populations for LA ART; Providers were less enthusiastic - desiring to determine on a day to day basis; need for skilled or trained professionals to administer it;
AIDS AND BEHAVIOR	2020	Andrea Mantsios, Miranda Murray, Tahilin S. Karver, Wendy Davis, David Margolis, Princy Kumar, Susan Swindells, U. Fritz Bredeek, Miguel García del Toro, Mercedes García Gasalla, Rafael Rubio García, Antonio Antela, Krischan Hudson, Sandy Griffith & Deanna Kerrigan	Eval of Phase 3 trial offer an important opportunity to also explore the views of treatment-experienced PLHIV regarding the transition from a daily oral to an injectable ART regimen and to further understand the context of this potentially "game-changing" [23] option prior to its integration into routine care.	53 trial participants in the U.S. and Spain. In the U.S., three urban clinical sites were included: Washington, D.C., Omaha, Nebraska and San Francisco, California. In Spain, eight sites participated in the study from six locations, including two in Madrid, two in Barcelona, and one each in Santiago de Compostela, Ferrol, Valencia, and Palma de Mallorca. years. 33 PLHIV from Spain and 20 PLHIV from the US; Most male 79%, with 85% and 79% men in the US and Spain, respectively. The median age varied by site with participants generally in their 30s in Spain (median 34 years) and in their 40s in the U.S. (median 46.5 years). In both countries, most of the male participants reported being MSM. 38 participants - monthly inj; 15 every 2 month injections; half 26 out of 53 had been receiving for > 6 months.	>18 *It got better over time - with injection side effects (1 person stopped due to pain) - episodic; *concern for clinical efficacy; *logisitcal psychological freedom; *less frequent visits - to lead "normal" lives

Culture, Health & Sexuality	2020	"I feel empowered": women's perspectives on and experiences with long-acting injectable antiretroviral therapy in the USA and Spain Andrea Mantsios Department of Sociology, American University, Washington, DC, USA armantsios@gmail.com , Miranda Murray, Tahilin S. Karver, Wendy Davis, David Margolis, Princy Kumar, Susan Swindells, U. Fritz Bredeek, Miguel García Deltoro, Rafael Rubio García, Antonio Antela, Cindy Garris, Mark Shaefer, Santiago Cenoz Gomis, Miguel Pascual Bernáldez & Deanna Kerrigan; Pages 1066-1078; Cite this article https://doi.org/10.1080/13691058.2020.1752397 CrossMark Logo CrossMark	LATTE-2 and Atlas/Flair study of women	80 people living with HIV participating in Phase 2 and 3 clinical trials of long-acting antiretroviral therapy in the USA and Spain. Fifteen percent (12/80) of trial participants interviewed were women	Women shared many of the positive perceptions expressed by men but also had unique perspectives, including finding that long-acting antiretroviral therapy addressed the challenge of remembering pills amidst busy day-to-day realities including multiple roles and responsibilities, is less time consuming and creates less stress compared to oral antiretroviral therapy, and is emotionally freeing and empowering. The gendered nature of women's lives shaped why and how they were satisfied with long-acting antiretroviral therapy.
Lancet HIV	2023	Ramgopal et al	compare long-acting cabotegravir plus rilpivirine every 2 months with continued once-daily bictegravir, emtricitabine, and tenofovir alafenamide for the maintenance of HIV-1 virological suppression in adults living with HIV.	SOLAR is a randomised, open-label, multicentre, phase 3b, non-inferiority study. The study was done in 118 centres across 14 countries. Participants with HIV RNA less than 50 copies per mL were randomly assigned (2:1), stratified by sex at birth and BMI, to either long-acting cabotegravir (600 mg) plus rilpivirine (900 mg) dosed intramuscularly every 2 months or to continue daily oral bictegravir (50 mg), emtricitabine (200 mg), and tenofovir alafenamide (25 mg). Participants randomly assigned to long-acting therapy had a choice to receive cabotegravir (30 mg) plus rilpivirine (25 mg) once daily as an optional oral lead-in for approximately 1 month. The primary efficacy endpoint was the proportion of participants with virological non-response (HIV-1 RNA ≥50 copies per mL; the US Food and Drug Administration snapshot algorithm, 4% non-inferiority margin; modified intention-to-treat exposed population) at month 11 (long-acting start with injections group) and month 12 (long-acting with oral lead-in group and bictegravir, emtricitabine, and tenofovir alafenamide group). The study is registered with ClinicalTrials.gov, NCT04542070, and is ongoing.	Of 670 participants (modified intention-to-treat exposed population), 447 (67%) switched to long-acting therapy (274 [61%] of 447 start with injections; 173 [39%] of 447 with oral lead-in) and 223 (33%) continued bictegravir, emtricitabine, and tenofovir alafenamide. 90% (n=382/425) preferred CAB + RPV LA every 2 months, compared with 5% (n=21/425) who preferred oral BIC/FTC/TAF therapy. Treatment satisfaction was greater among participants in the long-acting group compared with those in the bictegravir, emtricitabine, and tenofovir alafenamide group, with larger improvements in satisfaction observed through to month 4-12 § "I don't have to worry as much about remembering to take HIV medication every day" (324 [85%] of 382), § "It is more convenient for me to receive injections every 2 months" (317 [83%] of 382), § "I do not have to carry my HIV medication with me" (284 [74%] of 382), § "I do not have to think about my HIV status every day" (233 [61%] of 382), § "I do not have to worry about others seeing or finding my HIV pill" (227 [59%] of 382;

2022	Patient and Physician Preferences Regarding Long Acting Pre-Exposure Prophylaxis and Antiretroviral Therapy: A Mixed-Methods Study in Southern California, USA S Yeager, J Montoya, L Burke, K Chow, D Moore, & S Morris	Adult patients: Understand patient preferences & identify potential advantages & barriers to LAART & LA-PrEP Physicians: Understand physician treatment preferences (i.e., frequency of clinic visits, HIV testing, etc.) for LA ART & LA-PrEP	Eligibility Adults taking ART or PrEP *Age 18+ years old *Strong/variable adherence to ART or PrEP (ineligible if tested positive for HIV in past 6 months) Providers *Age 18+ years old *Reported at least one patient on ART or providing ongoing care for at least one patient on PrEP Mixed-methods Qualitative: *Adult patients - 8 individual interviews (for participants struggling with adherence) and 4 focus groups (participants with strong adherence) *Topics: Experience with ART/PrEP, LA modality preferences, anticipated advantages & barriers to LA, adherence support strategies) Quantitative: *Physician survey *Topics: Preferred frequency for patient clinic visits & renal functioning testing, anticipated patient treatment barriers, beliefs on improving patient adherence, anticipated adherence to LA Analysis Qualitative: Rapid analytic approach Quantitative: Descriptive analysis	Demographics: Adult Patients (n=42) *Demographic info was not collected Physicians (n=13) *10/13 provided HIV treatment (ART) and prevention (PrEP) care *7 had 0-10 years experience; 6 had 10+ years experience *LA knowledge: 100% aware of injectables; 7 heard of oral agents; 6 heard of subdermal implant Qualitative (Patients): Patient preferences:Oral>injectable>subdermal implant *Preference given to which ever modality provided the longest duration of coverage, but only 4/42 indicated subdermal implant as a preference (concern of pain or discomfort) *More likely to prefer injectable LA over oral LA if receiving hormone thera injections as part of care LA ART & PrEP Advantages: *Convenience, potential to improve adherence, reduce clinic visits & testing *ART patients - reduce reminders of their HIV status (oral pill is described as a daily reminder of a past mistake or living with chronic disease) LA ART & PrEP Barriers: *Potential side effects & efficacy (how to discontinue treatment if side effects are intolerable?) *Insurance coverage & medication costs *Increased clinic visits, questions on who would administer Adherence Support: *Text message reminders of injection appts, calendar tracking, smartphone reminders, patient portal messages, yearly pillbox Quantitative (Providers): *Reduced clinic visits and testing (exception: MSM patients complete HIV testing every 3 months) *Renal function testing every 3 months *Preferences of injection/implant admin delivered by: nurse > pharmacist > self-administered > provider *Insurance & medication costs greatest barrier *Other barriers: adherence, limited pharmacy medication access, consistent management, side effects, adverse reactions *Expected adherence to be excellent or good for injectable & implant expected patients attend yearly appointment *Adherence supports: Text reminders, calendar tracking, app reminders, phone calls, patient portal messages	*Patients were more likely to prefer injectable ART or PrEP if they were currently receiving other injectable treatments, such as hormone therapy (emphasized integrating services to ease burden) *Patients & providers anticipated less clinic visits as a benefit *LA modalities have ability to reduce internalized HIV stigma for PLWH *Insurance coverage was the number one barrier identified by providers & patients *Technology must play a role in supporting LA adherence Limitations *Small sample size in southern CA limits generalizability *No demographic information collected on patient participants *Focus groups could result in group think *Self reports of hypothetical treatment preferences not observed behaviors

CHAC Community Partnerships Workgroup

Roster:

- Meredith Greene (Chair)
- Johanne Morne (for 3/6 only)
- Robert Riester
- Keiva Lei Cadena-Fulks
- Marah Condit (CDC DFO)
- Shalonda Colins (HRSA DFO)

Meetings: 3/6/24, 3/19/24 (special guest Kali Lindsey), 4/4/23

Scope: The Community Partnerships Workgroup's primary charge is to provide evidence-based examples to CHAC to further define, structure, and retain effective public health community partnerships that foster trust and adapt to public health context.

Workgroup Focus

How should CDC/HRSA define community partnerships and community engagement

- Fall 2023
- Emphasis on partnerships

Share Best Practices

- Fall 2023
- Syndemic approach

*Involvement PWLE

What metrics of success that CDC/HRSA can and should use to measure its support of community partnerships?

What kind of structure should CDC/HRSA support to provide technical assistance to jurisdictions and community partnerships?

Fall 2023: Community Engagement to Partnerships

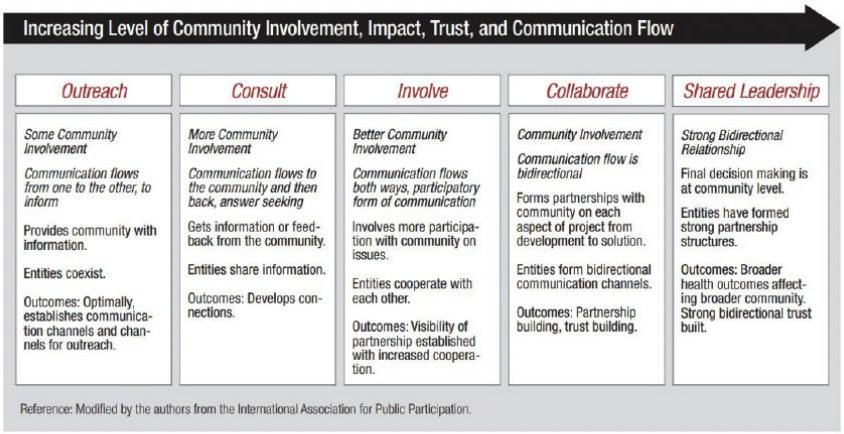
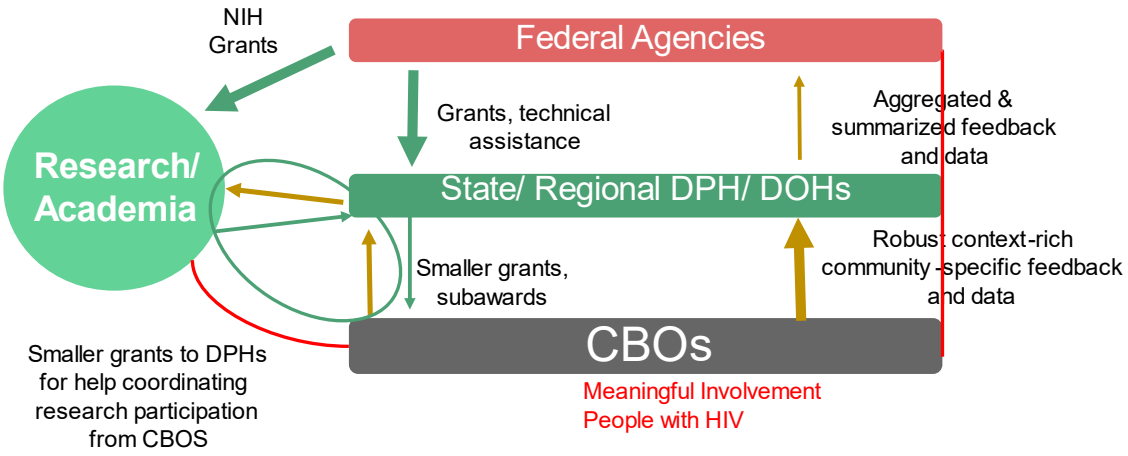


Figure adapted from the International Association for Public Participation and titled "Increasing Level of Community Involvement, Impact, Trust, and Communication Flow."

https://www.cdc.gov/endhiv/partners-grantees/community-involvement.html

Source: https://www.atsdr.cdc.gov/communityengagement/communityengagement-continuum.html#print

Innovative Partnerships



An Approach that Needs More Work: Molecular HIV Surveillance/Cluster detection & response (MHS/CDR)

- 2022 PACHA presented to CHAC their Resolution:
  - Concern about lack of meaningful community engagement
  - Called on CDC to provide guidance to health departments to adapt approach
    - to include meaningful engagement people living with HIV and how can be adapted to avoid harm in jurisdiction (regards to HIV criminality)
  - Require jurisdiction that use MHS establish CABs
    - Not just CABs but that the CABs directly influence the MHS/CDR programs and show how the CABs are being used to move programs forward

CDC Updated MHS/CDR guidelines: February 2024

- Includes wording based on PACHA resolution of engaging PWLE
- But already mistrust in community which needs to be addressed
- Perception that less involvement at state than local levels
    - Need for Meaningful Involvement PWLE all levels government

https://www.cdc.gov/hiv/programresources/guidance/hiv -cluster-detection -and-response-guidance/community -engagement -and-partnerships.html

Community Engagement One Model of Success

All of Us℠ | The Precision Medicine Initiative®
THE FUTURE OF HEALTH BEGINS WITH YOU

Source: NIH *All of Us* Research Program

All of Us Research Program

- **Division of Engagement and Outreach**
  - Communications Design
  - Engagement & Retention Innovators
  - Community advocate Network
  - Community Engagement Partners

- **Community and Provider Gateway Initiative**
  - Infrastructure including an outside firm helped establish and maintains
  - Regular meetings for Continuous quality improvement and information sharing

Source: NIH *All of Us* Research Program, Community and Engagement Partners

Examples of meaningful involvement of PWLE

- **Legislatively mandated spots on HRSA planning bodies**
  - In some cases PWH >50% of membership, active leadership roles
- **5280 Fast Track Cities** Task Force https://www.5280fast -trackcities.org/
  - CBOs, Universities, Hospitals – different groups PWH at the table and others willing to listen
- **HIV One on One – Peer Mentor Program (2010)**
  - Train the trainer; Long term survivors are mentors and newly diagnosed are mentees
- **People Organizing Positively (POP) Grant through AIDS United (2015/2017)**
  - Hawaii: Leadership Workshop series
    - Self-advocacy, person first language, understanding funding steams, understanding RW, elevator speech for key stakeholders
    - Motivated the community to volunteer, write testimony, secure funding, - involvement in the local HIV services/ concerns
  - Long lasting engagement; seat at the table; made a huge impact on how HIV services are implemented
- **KumukahiHealth & Wellness Sexual Health Clinic**
  - Ryan White Part C; first clinic integrated into ASO in HI addressed lack of specialists

CHAC Considerations: Examples Best Practices

- PWLE must have a seat at the table – but must be meaningful involvement!
  - Funding and mandates can help start but need to create sustained, shared leadership
- Trainings and opportunities for discussion can help achieve
  - Bi-directional; departments, organizations must know community -based engagement

Objectives:

1. Increase leadership capacity, representation, and engagement in RWHAP planning, development, implementation, evaluation, and clinical quality management (CQM)
2. Develop skills and support knowledge transfer through peer learning for people with HIV
3. Support the readiness of PWH to meaningfully engage in activities that impact HIV systems of care and operations

Supporting People with HIV as Leaders in HIV Systems of Care

About the program

Funding Opportunity Number: **HRSA-24-055**
Dates to Apply: **01/31/2024 to 04/01/2024**

Metrics: Needs to be an area of research

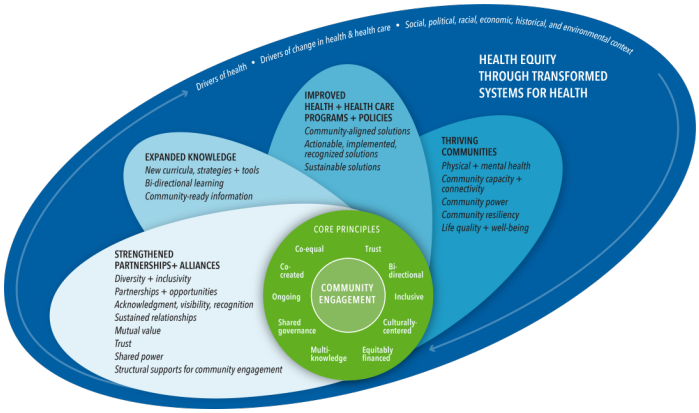
- **OUTCOMES:**
  - Improved health, reduction in disparities
  - Community building & Empowerment
  - Meaningful Engagement
  - System & Capacity Improvement
  - Skills that last beyond funding
- **METRICS:**
  - Less literature on how to measure (qualitative & quantitative; logic models)
  - MIPA/GIPA frameworks
  - **HIV & Aging SPNS** surveys examples
  - **National Academy Medicine** for community based participatory research

https://data.unaids.org/pub/briefingnote/2007/jc1299_policy_brief_gipa.pdf; Coleman et al. *Journal Racial Ethnic Health Disparities* 2023

Example Emerging Metrics

SPNS Capacity Building Survey Questions:

- types activities
- Self-assessment
- What is still needed



Assessment Instruments for Measuring Community Engagement

What Instruments & questions can be used in different communities & contexts to assess engagement?

1 Conceptual Model | 2 Impact Stories | 3 Assessment Instruments

https://nam.edu/programs/value -science-driven-health-care/achieving-health-equity-and-systems-transformation-through-community-engagement-a-conceptual-model/

Technical Assistance Considerations

Emphasis on skill building that can have long lasting effects beyond grant lifespan

- Infrastructure for meetings with community partners to share best practices that can continue beyond grants
  - Opportunities for real discussion, open dialogue, listening and including diverse voices
  - Consistent policies, cultural competency, pay people for time
- Train the Trainer models and skill building**trainings**– bi-directional, within and separate from grant mechanisms
  - Train PWLE to have a seat at the table and what to do with that seat
  - Ensure universities/health departments/fed agencies expertise in community engagement & can actively listen

Other Considerations for TA from the CHAC survey

- Infrastructure to continue capacity building to organizations that receive funding after the formal grant ends
  - Technical support esp. Around data
  - Leadership development
- Consider looking at all levels grant process/project development including maybe grant review and awardee selection for Meaningful involvement PWLE

Summary of Considerations

- Ask CDC/HRSA to ensure that PWLE have meaningful involvement at all levels (local to national, including employment)
- Ask CDC/HRSA to support Bi-directional TA – trainings for PWLE and health departments/organizations for skills that last beyond funding
- Ask CDC/HRSA to support opportunities for knowledge sharing (bi-directional)
- Ask CDC/HRSA to research further and prioritize developing Metrics to assess meaningful involvement of PWLE and successful community partnerships
    - Shared metrics across agencies considering syndemic, status neutral approaches, translating CBPR to service delivery