# 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 18-19, 2023

## Record of the Proceedings

# Contents

# Executive Summary

The United States (U.S.) Department of Health and Human Services (HHS), the Centers for Disease Control and Prevention (CDC) National Center for HIV, Viral Hepatitis, Sexually Transmitted Diseases (STDs), and Tuberculosis (TB) Prevention (NCHHSTP), and the Health Resources and Services Administration (HRSA) HIV/AIDS Bureau (HAB) convened a meeting of the CDC/HRSA Advisory Committee (CHAC) on HIV, Hepatitis, and STD Prevention and Treatment. In response to the outcomes of the monkeypox (mpox) outbreak, HIV, STDs, and viral hepatitis, the proceedings were held in a hybrid environment onsite at CDC Roybal Campus in Atlanta, GA, and virtually via Zoom on April 18 and 19, 2023.

## CDC and HRSA Welcome and Updates

The meeting began with detailed updates on CHAC as well as individual CDC and HRSA updates. The CHAC update highlighted the Charter renewal, an expanded scope, and new membership stipulations. The CDC update provided a number of important areas of interest including CDC's Moving Forward initiative, the Policy as a Public Health Intervention Initiative, Notice of Funding Opportunities (NOFOs), HIV Criminalization Toolkit, the NCHHSTP Equity Initiative, and updated from each of the NCHHSTP Divisions. Highlights from the HRSA/HAB presentation included the introduction of new changes to the HHS HIV (Human Immunodeficiency Virus) clinical practices for breastfeeding/chestfeeding guidelines, Ending the HIV Epidemic (EHE) funding, new provider resiliency resources on the Ryan White HIV/AIDS Program (RWHAP) website, Opportunities to Apply for a Federal Job Webinar, and efforts around getting recipients ready for the Medicaid continuous enrollment and unwinding.

## Sexual Health as a Holistic Approach to Public Health Implementation

During this panel, CHAC heard from speakers that discussed how to amplify, implement, and promote effective interventions to support greater access to sexual and reproductive health services and safe, supportive environments that impact sexual behaviors. To achieve better responses to sexual health, it is critical to collaborate and discover new and innovative ways to use resources wisely and efficiently, take advantage of multiple disciplines and shared knowledge, and promote holistic, equitable approaches that go beyond disease intervention to address the health and well-being of the individual. Topics included holistic approach to sexual health, new tools for sexually transmitted infections (STI) prevention, disease surveillance, and improved sexual health communications.

## Equitable Scale-Up of New Interventions

This panel focused on the equitable scale up of new interventions. The presentations collectively shared information on strategies, challenges, and ensuring equitable implementation of new preventive interventions, including lessons learned and engagement in the community. Dr. Krakower, Beth Israel Deaconess Medical Center and Research Scientist, presented on improving PrEP (Pre-Exposure Prophylaxis) impact and equity. Dr. Meyers, Aaron Diamond AIDS Research Center, shared advancements in long-acting injectables for underserved populations. Dr. Martinez, Erie County Medical Center, provided an update on the co-localized approach to hepatitis c virus (HCV) elimination which expanded provider capacity to treat HCV. Dr. Hinkle Bachmann, Division of STD and Prevention, discussed the equitable scale-up of new interventions opportunities for doxycycline as PEP (Post-Exposure Prophylaxis) implementation.

## What New Data Is Saying About Youth and STD Testing?

This special presentation focused on recent data on sexual behaviors among youth, with a specific emphasis on sexually transmitted disease testing by sex and by race and ethnicity. The data shared featured findings from the 2021 Youth Risk Behavior Survey (YRBS). The presented findings showcased both at-risk and protective behaviors related to sexual health. Data from the National Survey of Family Growth (NSFG) presented trends in STI testing among sexually active 15 to 24-year-old females and males. Healthcare Effectiveness Data and Information Set (HEDIS) data was provided to identify quality measures published by the National Committee for Quality Assurance (NCQA).

## Mpox Lessons from Research and Implementation

This panel focused on the national mpox response, the equity vaccine strategy, ongoing collaborations, and mpox lessons learned from a publicly funded STD Clinic. Key components on how to assess the benefits of incorporating mpox vaccines into existing HIV/STI programs, ways to explore the challenges and opportunities associated with mpox vaccine integration, concepts for best practices of mpox vaccine integration in HIV/STI programs, and recommendations for effectively integrating mpox vaccines into HIV/STI programs to improve prevention and care outcomes were discussed.

## CHAC Workgroup and Liaison Reports

The workforce workgroup (WFWG) presented a summary of research findings outlining challenges and potential solutions for developing the HIV workforce. The WFWG discussed the alignment of HIV workforce regulation and funding through incentivizing programs that create pathways for more diversity in professional careers for HIV treatment and prevention services. Included in the analysis was the concept of investing in workforce infrastructure for the delivery of decentralized, differentiated status-neutral HIV services to promote a shift toward a comprehensive, whole-person, interdisciplinary, and team-based model of HIV service delivery.

The Self-testing and Self-collection workgroup (STSCWG) presented a summary of research findings outlining challenges and solutions in the development of high quality STI diagnostic testing with self-collected samples. STSCWG highlighted regulatory barriers to the approval of self-collected swabs for STI diagnostic testing within and outside the clinical setting, and strategies on how to improve access to and uptake of affordable, available STI testing for adolescents and adults.

CHAC was provided an update on the PACHA (Presidential Advisory Council on HIV/AIDS) council meeting that convened on March 29-30, 2023, and pre-meeting that was held on March 28, 2023. The PACHA presentation emphasized the importance of the current iteration of PACHA's focus on bringing "PACHA-to-the-people", hearing from the community, and learning about innovative practices and programs and its successes and challenges to better guide the work of the advisory council.

## Business Session

The Business Sessions focused discussions from the presentations, with special attention paid to advice requested from CHAC. These conversations helped stratify the core issues and were used to outline specific recommendations to be voted on by the CHAC as outlined in the CHAC Actions. The November 2022 CHAC minutes were adopted, with no edits proposed. Requests for future topics will be sent via email. The next CHAC meeting is scheduled for October 24-25, 2023, in Rockville, Maryland.

## CHAC Actions

CHAC members voted unanimously to approve the following recommendations and resolutions:

1. Adopt the November 2022 meeting minutes, with no edits proposed.
2. Recommendations on STI Self-testing and Self-Collection to be sent to the HHS Secretary for:
   a. submission of CT/NG/syphilis testing data from swabs collected outside the clinical setting to support validation on self-collected swabs and FDA approval for STI samples collected at home and in non-clinical settings,
   b. creation of a simpler and streamlined system to enable STI reporting of results to all public health jurisdictions (similar to system used for COVID diagnostic test reporting),
   c. collaboration with industry and academia a) to collect safety and stability data for CT/NG NAAT testing outside the clinical setting and b) to develop POCT CT/NG/syphilis testing with optimal sensitivity and specificity (STI Impact Research Consortium network or new partnerships),
   d. identification of success stories (such as I want the kit) that increase access to STI testing for people with barriers to care, and
   e. identification of support systems that are HIV status neutral and ensure linkage to STI care, partner services, HIV PrEP, and case reporting.
3. Recommendation to HRSA on the AIDS Education and Training Center re-competition.
4. Recommendations on workforce to be discussed with PACHA and sent to the Secretary.
5. CHAC recommends that the HIV prevention and treatment infrastructure be broadened to ensure appropriate training and resources for HIV workforce development in a decentralized, differentiated HIV model of care (e.g., including telehealth, community-based delivery of services, etc.), exploring new practice innovations and incentives.
6. CHAC recommends that all HIV team members (e.g. CHWs, RNs, LPNs, Social Workers, Pharmacists, Behavioral/Mental Health Professionals) be integrated as part of the HIV workforce with appropriate training standards, compensation, and paths for promotion.
7. CHAC recommends exploring ways to incentivize programs in creating demand and ensuring pathways for recruitment and retention of a diverse and inclusive HIV workforce, consistent with current and emerging needs and challenges of PLWHIV communities.
8. CHAC recommends that there be a review and synthesis of evidence on current regulatory barriers that place restrictions on practice at the highest level of training and licensure for non-physician HIV providers (e.g., for nurse practitioners, PAs, medical technicians, pharmacists, etc.) and consideration of incentives to remove these barriers.
9. Resolution on Bicillin access to be sent to the Secretary.
   - CHAC expresses great concern regarding the barriers to access to bicillin for syphilis treatment. We recommend that CDC explore alternative treatments (including for pregnant individuals), explore federal subsidies to support access, and consider a national stockpile for this essential drug.
   - Create a Long Acting Injectables WG to address current and emerging issues related to use of long-acting, injectable PrEP and treatment. Scope of work would include 1) identification of system and clinic-level barriers and opportunities (including cost and access issues) and 2) identification of best practices and potential models of care.
10. Create a Community Partnerships WG to address community partnerships with the scope of work to include assessment of current barriers/challenges in collaboration and coordination with best practices, and minimal requirements for grant applicants.

11. Recommendations on Youth data collection and sexual health to be sent to CDC and the Secretary.
    a. Collection of these data through continuation of the YRBS and other relevant sources of data in all states and jurisdictions. Data to include protective factors (including families and trusted adults, use of PrEP, etc) and sites of testing when possible; Evaluation should incorporate and reflect the impact of mental health, COVID pandemic, and Interpersonal violence (including nonbinary/trans) and should intentionally include evaluation at district levels.
    b. Reframing the YRBS positively as Youth Health Behavior Survey.
    c. Support development of routine screening for youth (including STI screening but also mental health, substance and violence screens) and standard protocols for management for youth-relating to sexual health and effective tool development, integrating youth voices throughout planning process.
    d. Mechanism for youth-focused services to incorporate CHW, use of peer-to-peer supports, 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.

# 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 18-19, 2023

## Minutes of the Meeting

The United States (U.S.) Department of Health and Human Services (HHS), the Centers for Disease Control and Prevention (CDC) National Center for HIV, Viral Hepatitis, Sexually Transmitted Diseases (STDs), and Tuberculosis (TB) Prevention (NCHHSTP), and the Health Resources and Services Administration (HRSA) HIV/AIDS Bureau (HAB) convened a meeting of the CDC/HRSA Advisory Committee (CHAC) on HIV, Hepatitis, and STD Prevention and Treatment. In response to the outcomes of the monkeypox (mpox) outbreak, HIV, STDs, and viral hepatitis, the proceedings were held in a hybrid environment onsite at CDC Roybal Campus in Atlanta, GA, and virtually via Zoom on April 18 and 19, 2023.

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 and in-person was published in the *Federal Register*, in accordance with FACA (Federal Advisory Committee Act) rules and regulations. All sessions of the meeting were open to the public. Please see Appendix A for the Participant List.

## Day 1: Opening of the Meeting and Roll Call

**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, called the proceedings to order at 9:05 a.m. Eastern Time (ET), reviewed ground rules, and provided instructions for discussion periods. She indicated that members of the public will have an opportunity to provide comments during today's session at 3:45 p.m. ET, and that public comments will not be accepted at any other point during the meeting.

**Jonathan Mermin, MD, MPH (RADM, USPHS)**
Director, National Center for HIV, Viral Hepatitis, STD and TB Prevention

Centers for Disease Control and Prevention
CHAC Designated Federal Officer (DFO)

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. 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 members and *ex-officio* members who were in attendance and establish quorum with 21 members present. Quorum was maintained during both 2 days of the meeting.

## Conflict of Interest Disclosures

| CHAC Voting Member (Institution/Organization) | Disclosure of Conflict |
|---|---|
| Jean R. Anderson, MD (Co-Chair) (The Johns Hopkins Hospital) | Stock in Merck; Honoraria from AIDS Healthcare Foundation |
| Wendy Armstrong, MD (Emory University School of Medicine) | Recipient of funding from HRSA/Ryan White HIV/AIDS Program |
| Jodie Dionne, MD (University of Alabama, Birmingham) | Recipient of funding from NIH (National Institutes of Health) |
| Shannon Brown Dowler, MD (North Carolina Medicaid) | No Conflict |
| Daniel Driffin, MPH (D3 Consulting) | Honoraria from Gilead Sciences |
| Travis Gayles, MD, PhD (Co-Chair) (Montgomery County Department of Health and Human Services) | No Conflict |
| Meredith Greene, MD (University of California, San Francisco) | Recipient of funding from NIH, HRSA/Ryan White HIV/AIDS Program, and Gilead |
| Vincent Guilamo-Ramos, PhD, MPH (Duke University) | Recipient of funding from NIH, Administration for Children and Families (ACF), speaker for Gilead |
| Kali Lindsey (ETR) | No Conflict |
| Christine Markham, PhD (University of Texas Houston) | Recipient of funding from NIH, CDC/HRSA, OMH, ACF |
| Johanne Morne, MSED (AIDS Institute, New York State Department of Health) | Recipient of funding from CDC and HRSA/Ryan White HIV/AIDS Program |

| | |
|---|---|
| Kneeshe Parkinson<br>(Washington University/Project ARK) | Recipient of funding from CDC; work for Ryan White Funded Organization |
| Robert Riester<br>(Colorado Health Network) | Recipient of funding from CDC; work for Ryan White Funded Organization |
| Leandro Rodriquez, MBA<br>(Latino Commission on AIDS) | Recipient of funding from HRSA/Ryan White HIV/AIDS Program, CDC, Substance Abuse and Mental Health Services Administration (SAMHSA) |
| Samuel So, MBBS, FACS<br>(Stanford University) | Recipient of funding from CDC and NIH |

*Ex-Officio* members in attendance included Dr. Pradip Akolkar of the Food and Drug Administration (FDA); Dr. Christopher Gordon of the National Institutes of Health; Ms. Kaye Hayes of the HHS Office of HIV/AIDS and Infections Disease Policy (OIDP); and Mr. Richard Haverkate of the Indian Health Services (IHS). Liaison member Dr. Ada Stewart of the Presidential Advisory Council on HIV/AIDS (PACHA Liaison Representative) organization, Eau Claire Cooperative Heath Centers, receives Ryan White Funding part B and D and is a speaker for Gilead Sciences.

Dr. Mermin confirmed that quorum was achieved, and that CHAC could move forward with conducting its business on April 18, 2023.

## Welcome and Agenda Review

**Travis Gayles, MD, PhD**
CHAC Co-Chair, CDC Appointee

**Jean Anderson, MD**
CHAC Co-Chair, HRSA Appointee

Drs. Anderson and Gayles welcomed everyone to the April 18, 2023, CHAC meeting and thanked the CHAC members, federal officials, CDC and HRSA staff, and the general public in attendance. Dr. Gayles expressed his excitement for the energy that comes with meeting in-person as this meeting was the first in-person meeting since before the pandemic. He also made note of the continued efforts to overcome challenges faced in the virtual settings and thanked all participants for their patience as the committee was able to accomplish quite a bit, even with the limitations of the virtual environment. Dr. Gayles reviewed the agenda for the day and highlighted the two key areas of focus which were sexual health programming and health equity. He further expounded upon sexual health programming as a role model for implementation of holistic comprehensive programming on a broader public health level, and, explained how equity continues to be a principal topic in how public health practitioners may scale up in their interventions and implementation of programs. He reminded the listeners of the impact of equity through the pandemic response both in terms of COVID-19 and most recently with mpox. He provided logistical reminders to keep microphones on mute when not talking to drown out background noise and to be respectful in comments and exchange of ideas.

## CDC/NCHHSTP Welcome and Update

**Jonathan Mermin, MD, MPH (RADM, USPHS)**

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

Dr. Mermin gave an overview of general updates and activities in NCHHSTP and shared broader reaching activities related directly to CHAC. He provided a brief introduction of the four division directors that would present updates from their individual divisions. The first CHAC update was the Charter which was renewed on November 25, 2022. The Charter update includes a broadened scope of CHAC to include adolescent and school health with a particular focus HIV, viral hepatitis, and STDs. The Charter also stipulates the Committee should include representation from persons with lived experience, such as those who have experienced viral hepatitis, STDs, and drug use; as well as a minimum requirement of at least four members who are persons living with HIV. Second, the new Charter has also allowed CHAC to welcome two new Ex-Officio seats to its membership. From National Institute of Allergy and Infectious Diseases (NIH NIAID), Dr. Carolyn Deal, and her alternate Dr. Carl Dieffenback were welcomed. From National Institute of Mental Health (NIMH), Dr. Christopher Gordon was also welcomed. The Committee welcomed the new CMS Ex-officio Dr. Aditi Mallick who joined in November of 2022. Dr. Mermin gives appreciation and farewell to members who graciously agreed to extend their membership 180 days to continue the important work of CHAC. Special thanks were provided to Dr. Travis Gayles and Dr. Shruti Mehta for their tremendous work on CHAC and to public health. Additionally, farewell to Dr. Maureen Goodenow from NIH/OAR who has changed positions. Ms. Kristin Roha will be unofficially representing SAMHSA in Dr. Neerja Gandotra's absence. Lastly, there were many letters that have gone out since the last meeting. The telehealth letter was originally submitted to HHS in June 2022. An interim response letter was received from the HHS Secretary which was distributed in March 2023. A detailed response from CDC and HRSA was circulated before this meeting and included in the meeting materials. The Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex (LGBTQI+) Letter, originally submitted to HHS in August 2022, interim response was distributed in April 2023. The Committee anticipates the detailed response from CDC and HRSA, with input from a number of other agencies including SAMHSA, ACF, and the Indian Health Service will be sent out later this month. The letter related to HIV Self-Testing and Self-Sample Collection letter, originally submitted to HHS in December 2022, interim response from the Secretary was distributed in February 2023, and the detailed response from CDC and HRSA was circulated before this meeting and is included in your materials. The mpox letter, originally submitted to HHS in March of 2023, anticipates the interim response to be provided soon.

Dr. Mermin shared the CDC Moving Forward initiative. In April 2022, Dr. Rochelle Walensky launched a review of the agency. There were two components to this review, with designated leads for each. The Scientific and Programmatic Review was conducted by Mr. James Macrae. The Structural Review was conducted by three current CDC senior leaders: Dr. Deb Houry, Mr. Robin Bailey, and Ms. Sherri Berger. There are five major recommendations for Structural Review under the Moving Forward initiative. The first is share science and data faster. This recommendation includes release scientific findings and data more quickly, prior to formal publications, in response to the need for information and action, and be transparent about the agency's current level of understanding; and, strengthen and expedite the development and review/approval process for scientific publications and data, including laboratory data, to match the needs of the emergency. The second is translate science into practical policy: develop and implement a standardized policy development process for implementation guidance documents and produce plain language, easy to understand implementation guidance documents. The third is prioritize public health communications, with a focus on the American public: focus communication efforts to the general public first with additional communications tailored to key

partners, and to restructure the agency website and digital communication platforms to eliminate unnecessary content, focusing on key target audiences with a primary emphasis on the public. The fourth is develop a CDC workforce ready to respond to future threats: change the agency's emergency response operating model as well as its rewards and incentive structure to better recognize the importance of the agency's response work; expand and diversify workforce recruitment, retention, training, and development programs and increase senior leadership team engagement with staff throughout the agency. The fifth and final recommendation is promoting results-based partnerships: establish an agency-wide, performance-based framework for operations and programs focused on key agency goals and results, timeliness and quality of products/services, customer/grantee satisfaction (as measured through a new annual grantee survey), and staff satisfaction; work in partnership with others in and outside of government to turn science into public health action and results.

Dr. Mermin identified the next steps to move the agency forward; appointing a seasoned executive to lead a team that will help implement the vision. This seasoned executive will assist in 1) elevating the Science and Laboratory Sciences to report to the director, improving accountability for delivering timely information; 2) starting a process to make structural changes to incentivize public health action, implementation, and impact at all levels of the organization; 3) creating a new executive council—reporting to the Director—that will determine agency priorities, track progress, and align budget decisions, with a bias toward public health impact; 4) creating a one-stop shop for external partners to navigate the agency; and, 5) creating a new equity office that will promote this focus across all of the work CDC does, as well as how the agency operates; a CDC that reflects the diversity of America will be better positioned to respond to outbreaks—from science to communications.

Dr. Mermin provided high impact prevention policy as a means to maximize reach and effectiveness of interventions, act upstream and improve social determinants of health (SDOH) and health equity, provide long-term solutions, and lead to behavior change and improve public health. An update on the Policy as a Public Health Intervention Initiative (PPHI) showcased how policies done well can be tools for public health and can also be more sustainable and possibly more effective. Adversely, policies can have negative effects as well, and should be removed or changed if they do. The PPHI Notice of Funding Opportunity (NOFO) was released and designed to assist leaders who make decisions in public health, including government and non-government leaders, elected and non-elected leaders, identify, assess, and implement EB policy interventions. We will do this through two distinct components, Legal Epidemiology where we leverage emerging methods in coding law and policy over time and cross-sectionally to help us then study how law and policy affect health outcomes; and establishing a robust system of legal technical assistance to aid leaders in navigating complex legal and policy environments. The next CHAC meeting will include a presentation on information about some of the first areas being tackled. CDC works with national partners through the CSTLTS National Partnership NOFO to inform and educate state, county, and local level public leaders and legislators which ensures the dissemination of evidence on which policies work through CDC's national partners including National Conference of State Legislatures (NCSL), National Governors Association (NGA), Association of State and Territorial Health Officials (ASTHO), PPHI, and Change Lab Solutions. Some examples include Syringe Services Program (SSP)/harm reduction laws and policies, public health authorities. Policy and Health Equity Partners inform, educate, equip, and enhance work in navigating complex legal and policy landscapes for integrating health equity approaches into PPHI.

Dr. Mermin expressed his excitement about CDC's HIV Criminalization Legal and Policy

Assessment Tool[1]**.** This tool is a vital resource that provides an objective assessment of a jurisdiction's laws, regulations, and executive orders that control HIV surveillance and prevention. The tool can also help identify opportunities to strengthen legal and policy protections for people with HIV, protections that are also likely to benefit public health more broadly by aligning them with evidence-based best practices.

From February 27 to March 3, NCHHSTP hosted the kick-off meeting for PS23-2302—accelerating the prevention and control of HIV, viral hepatitis STDs and TB in the U.S. affiliated Pacific Islands in Atlanta, GA. This NOFO, now in its 3rd iteration as an integrated NOFO across multiple disease areas, aims to improve the efficient use of resources through integration of screening and treatment, reduce disparities, improve health systems infrastructure and service delivery, to ultimately reduce incidence of HIV, STDs, TB, and viral hepatitis. The program highlights the importance of cross-program and cross-sector collaborations, specifically focusing on 5 main strategies: program collaboration and service integration in high-priority venues and for populations disproportionately affected; surveillance, data management, and reporting; workforce development through training and education; laboratory strengthening for reliable and timely delivery of public health laboratory services; and disease-specific prevention and care including testing, linkage to care, and partner services.

NCHHSTP launched an Equity Initiative in February 2021 to optimize synergies between the Center's existing equity activities, and to support the identification of additional strategic opportunities to embed equity into the fabric of NCHHSTP's workplace operations and public health programs. The Equity Initiative includes an Implementation Plan that outlines the first steps of a long-term strategic process to place equity squarely at the forefront of all internal and external Center activities. The Plan is organized into three focus areas with goals, objectives, and activities to support achieving the goals. Highlights of the activities completed since April 2022 include creation of a formal Evaluation and Monitoring Plan with indicators and measures; and published two additional workforce factsheets and NCHHSTP Workforce: Diversity & Inclusion from 2010 to 2021[2] and NCHHSTP Workforce: Sexual Orientation and Gender Identity Representation[3]. We engaged with partners via a town hall style forum to solicit their individual feedback on intervention and strategies to reduce disparities in the diseases and infections addressed by the Center. We also collaborated with a vendor to adapt an asynchronous online version of a racial and health equity-focused training for the HHS Learning Portal, *Understanding Health and Racial Equity Online*.

The provisional 2022 TB surveillance data was released March 2023 in the Morbidity and Mortality Weekly Report (MMWR)[4]. TB cases increased for the second year in a row. In 2020, the annual rate of decline was substantially greater than in previous years, likely because of factors associated with the COVID-19 pandemic, including a combination of TB underdiagnosis and a true reduction in incidence. TB incidence partially rebounded in 2021, which might be explained by a lessening of the effects of the factors associated with the pandemic, as well as delayed detection of cases with symptom onset during 2020 that were not diagnosed until 2021 because of delayed healthcare access or missed diagnoses. Provisionally, 8,300 cases of TB were reported in 2022. This represents an increase of 5.4% compared to 2021. The 2022 TB incidence rate is 2.5 per 100,000 persons, a 5.0% increase from 2.4 per 100,000 persons in 2021. As the COVID-19 pandemic recedes, the number of TB cases and the TB incidence rate is gradually returning to levels experienced before the pandemic.

[1] HIV Criminalization Legal and Policy Assessment Tool
[2] NCHHSTP Workforce: Diversity & Inclusion from 2010 to 2021
[3] NCHHSTP Workforce: Sexual Orientation and Gender Identity Representation
[4] https://www.cdc.gov/mmwr/volumes/72/wr/pdfs/mm7212-H.pdf

Video directly observed therapy (vDOT) is used increasingly as an alternative to in-person DOT for monitoring tuberculosis treatment. vDOT uses video-enabled devices to facilitate remote interactions between patients and health workers to promote medication adherence and clinical monitoring. vDOT can advance health equity by reducing time and costs for patients and providers and providing greater flexibility during treatment. The increased use of vDOT in practice, published experience, and the results of a randomized trial in New York City, which was sponsored by CDC and published in the Journal of the American Medical Association (JAMA) last January, supported developing guidelines for video DOT. Last month, CDC updated TB treatment recommendations to include vDOT after finding it is an equivalent alternative to in-person DOT. The updated recommendation was published in the MMWR, and supplemental information was also provided on CDC's TB webpage.

## Division Adolescent and School Health Update

**Kathleen Ethier, PhD**
Director, Division of Adolescent and School Health (DASH)
National Center for HIV, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention

Dr. Ethier provided DASH updates. In February 2023, DASH released the 2021 Youth Risk Behavior Survey (YRBS) Data Summary and Trends report. The report provides key data on health risk behaviors and experiences among high school students. This is the first YRBS data collected since the start of the COVID-19 pandemic. Within the overall identified trends, there are substantial disparities for LGBTQ+ students and female students. There were also some disparities by race and ethnicity. For instance, in 2021, Black and Hispanic students were significantly more likely than Asian, White, and multiracial students to not go to school because of safety concerns. And LGBTQ+ youth were two times as likely as their heterosexual peers to be electronically bullied and to miss school because of safety concerns. Female students are experiencing substantial sexual violence; 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, or they have been raped. There are increases among female students in both of those variables from prior YRBS years.

Nearly all indicators of poor mental health and suicidal thoughts and behaviors increased between 2011 and 2021. 42% of students said that they had experienced such persistent sadness and hopelessness in the last year for at least two weeks that they were unable to do their regular activities. Nearly 30% of students said they experienced poor mental health in the past 30 days, and 10% of high school students said that they had attempted suicide in the past year. Here again, there are really striking disparities in the proportion of female students and LGBTQ+ students having these experiences compared to their peers. There are also some differences by race and ethnicity. For instance, in 2021 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.

For the What Works in Schools Program, the data showed significant, positive impact in mental health, substance use, and experience of violence. There are particular improvements in the proportion of students who say they don't go to school because of safety concerns. There is also

significant improvement in the schools that put the program in place, in the percent of students who say they've ever been forced to have sex. This kind of school-based approach really allows for the opportunity to address some of these exact outcomes seen in this data. The What Works in Schools Program has been included in the HHS Behavioral Health Transformation roadmap and is in the President's budget for full scale up at $90 million. That would be about a $52 million increase.

Dr. Ethier noted the ability to collect Youth Risk Behavior Surveillance System (YRBSS) data continues to have difficulties at the state and local level. The YRBSS is the largest, most comprehensive system to monitor the health and well-being of the nation's youth. While continuing to have great success with the national data there is an increasing number of state and local jurisdictions who are declining to continue to participate in the YRBSS and that number is increasing. States that discontinue YRBSS limit their ability to understand and address what's happening among students in their states. This is particularly the case in some areas that are making substantial changes in the policy and practice related to their schools; as such, potentially losing the ability to be able to monitor the impact of those changes.

## Division of Viral Hepatitis Update

**Carolyn Wester, MD MPH**
Director, Division of Viral Hepatitis (DVH)
National Center for HIV, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention

Dr. Wester announced that on March 19, 2023, CDC published *Screening and Testing for Hepatitis B Virus Infection: CDC Recommendations—United States, 2023*[5]. This publication provides an update on hepatitis B screening and testing recommendations which move away from risk-based screening to universal screening; thereby, reducing stigma and promoting health equity around hepatitis B. The updated recommendations advise hep B screening once in a lifetime for all adults and move to a recommendation for triple panel screening. Combined with the recently updated universal hep B vaccination recommendations among adults aged 19 to 59 years of age, both updates provide an opportunity to increase prevention and awareness and then linkage to care and treatment among people at risk for living with hepatitis B.

A central part of tracking progress towards national viral Hepatitis Strategic Plan targets is maintaining current estimates of prevalence, awareness, and clearance of viral hepatitis in the US. The recent prevalence estimates data utilize data from the National Health and Nutrition Examination Survey (NHANES) does exclude people who are unhoused and also non-civilian population. There is a need to adjust for those unaccounted-for populations. According to baseline prevalence data, from 2013 to 2016, there were an estimated 862,000 people in the U.S. with hepatitis B, and only one and three were aware of their infection. While the pre-pandemic file from January 2017 to March of 2020, showed the prevalence declined and awareness of infection rose to about one in two. Note, the confidence intervals are wide, impairing precision. For hep C, the baseline data from 2013 through 2016, estimated 2.1 million. This prevalence remains largely unchanged at 2.2 million in the pre-pandemic file. This is disconcerting, given the fact that 1.2 million people are estimated to have received treatment from 2014 through 2020. The data shows incidence continuing to skyrocket; however, improvement in awareness of infection has increased from about 60% to just about two and three people who are now aware of their infection. This data, combined with other data, shows that even people who are diagnosed and continually

[5] Screening and Testing for Hepatitis B Virus Infection: CDC Recommendations — United States, 2023

insured are only receiving timely treatment in about one out of three cases. These numbers are lower for certain populations such as Medicaid recipients and uninsured populations.

In partnership with state and local health departments, CDC developed guidance to create a simplified laboratory result based hep C viral clearance cascade very similar to how HIV uses CD4 and viral load data to assess engagement in care and viral suppression. We applied the simplified cascade, which can be updated annually, to commercial laboratory data, including deduplicated longitudinal data from people of all ages and with all payers in all 50 states. Characterizing and regularly updating the cascade is critical for monitoring progress towards elimination and also identifying gaps in care. The cascade uses large national clinical laboratory data from the entire Direct-Acting Antivirals (DAA) era, 2013 through the end of 2022, showed that of almost a million people included in this study with initial infection, about one in three had evidence of viral clearance which indicates one of the biggest serious gaps given, that the U.S. 2030 goal is a viral clearance rate of at least 80% among people with diagnosed infection. Of those with evidence of viral clearance, approximately 7% had evidence of persistent infection; whether that's reinfection or lack of response to treatment will be attempted to be untangled with a time to event analysis that's forthcoming.

As part of the President's fiscal year 24 budget released in March, the White House announced a bold national program to eliminate hepatitis C in the United States. The capacity to identify gaps and quantify progress in the clearance cascade will be of salient importance if the initiative is funded. The announcement calls for a national hep C elimination program, which would deliver advanced diagnosis, also treatment and a comprehensive public health elimination strategy. The effort is being led by the White House under the direction of Dr. Francis Collins and Dr. Rachel Florence in coordination with all elements of HHS, including CDC. While it's not yet funded, the White House is working to identify congressional champions and the legislative vehicle to provide support for the initiative. Of note, it is proposed on the mandatory side of the budget.

CDC continues to support comprehensive programming to address the health needs of all people who use drugs in their communities, to reduce net new viral hepatitis infections and increase access to testing and treatment. In this past September, CDC awarded NASTAD $6.9 million dollars through the strengthening syringe services programs cooperative agreement to rapidly deploy resources to SSPs to reduce infectious disease consequences of drug use and communities that need it most. Notably, NASTAD had received almost 200 applications for this $6 million in available funds. Unfortunately, not everybody could be funded at that time, but funds were distributed with the general strategy of funding SSPs that could benefit most from the resources. Overall, 65 programs across 31 jurisdictions, represented were awarded funds. This five-year grant initiative will continue to support organizations around the country to strengthen the capacity of SSPs. Progress towards national viral hepatitis targets for the U.S. will continue to promote and develop innovative, holistic approaches to meet the needs of everyone living with viral hepatitis.

## Division of HIV Prevention Update

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

Dr. Fanfair announced that the Integrated HIV Surveillance and Prevention Programs for Health

Departments Program (PS18-1802) has been extended by 17 months to now end on May 31, 2024. The Integrated HIV Programs for Health Departments to Support the Ending the HIV Epidemic (PS20-2010) will end early on May 31, 2024. Please note that these changes are administrative in nature and have been made in an attempt to better coordinate and streamline future NOFO processes and reduce the future burden to CDC grantees. The Division of HIV Prevention (DHP) and CDC's commitment to EHE remains in place.

Dr. Fanfair shared programmatic data and progress from PS2020-10 by EHE pillar (Diagnose, Treat, Prevent, and Respond). In 2021, health departments and EHE jurisdictions conducted almost 250,000 HIV tests, identifying over 3,000 individuals with HIV, of which 1,000 received a new diagnosis. Self-testing was an innovation that ramped up during COVID-19. CDC distributed 100,000, free to consumer, HIV self-test kits to populations disproportionately impacted by HIV, including transgender women, and racial and ethnic minority communities. CDC grantees also distributed over an additional 16,000 HIV self-test kits. CDC grantees used EHE funding to link 84% of persons newly diagnosed with HIV to medical care within 30 days. Note that in 2021, three jurisdictions funded by EHE programs met the 2025 goal linking 95% of newly diagnosed persons to care. These included East Baton Rouge, South Carolina, and Harris County in Texas. Also note, as innovation is ramped up, and lessons are learned through EHE, we anticipate that jurisdictions might have variability in their reported goals or targets.

Over the past year, CDC has hosted HIV prevention and care priorities, regional virtual community engagement town halls, and leadership roundtables by HHS Region. Over 1200 individuals attended these sessions. The goals for convening these community engagement sessions were to work together with community partners, to understand and address the long-standing inequities that continue to contribute to severe HIV-related disparities, and work together to advance the EHE initiative. To address these inequities and reach EHE goals, we must have a shared understanding of the barriers and opportunities to success. We must build trust and provide the space to discuss community-led solutions.

Going back to the EHE pillars, for "Prevent", the funding we sent to health departments through Component A of the main EHE NOFO (PS20-2010) resulted in identifying more than 140,000 people without HIV. Of which 64,000 were screened for PrEP, 76% of those screened were eligible for PrEP, and over 18,000 people were prescribed PrEP. In 2021, five jurisdictions in EHE funded programs met the 2025 goal and were able to link or prescribe PrEP for at least 50% of persons eligible for PrEP. These include Oklahoma, Queens County in New York, and Cook County in Chicago. Dr. Neblett shared successes from the syndemic investments, STI clinics, and syringe service programs. The EHE funded 26 specialty clinics in 16 states to meet people where they already receive care. There were 108 SSPs supported in EHE jurisdictions.

In February 2021, the Georgia Department of Public Health detected four molecular clusters consistent with recent and rapid transmission. These clusters were disproportionately among Hispanic Latino, gay, and bisexual men. The clusters have grown to 58 people by the end of 2021. More than 10 community-based and provider organizations provided key input including a number of Latino serving organizations and community engagement. Highlighted findings included low awareness of HIV and STD services, structural barriers, such as fear of deportation, issues regarding transportation and affordability, and work and family responsibilities. Recommendations included the critical nature of building partnerships and developing services that are trusted, linguistically appropriate, and reach people where they are.

Some of the community engagement themes heard throughout the year included the importance of breaking down silos in funding and cross-collaborative work happening with interagency;

workforce development of the public health workforce; expansion of HIV testing in emergency rooms, primary clinics, pharmacies and urgent care facilities; an increased focus on providing housing, employment opportunities and mental health services; and to ensure that the EHE initiative considers the whole person versus only supporting a biomedical model. This summer we are looking forward to starting cross-agency engagement sessions with CDC's sister agency HRSA.

Dr. Fanfair highlighted a number of new funding opportunities that are forward leaning and focused on improving health equity. These include HER PrEP, which seeks to increase PrEP use among black cisgender women, qualitative work to assess long-acting Antiretroviral Therapy (ART) preferences among Black women and assessing medical mistrust among Hispanic and Latino men who have sex with men.

The CDC will remain focused on the four pillars of EHE and amplify efforts by investing in key strategies to advance health equity. These include self-testing, syndemic approaches, building community-based organization capacity in smaller minority focusing CBOs, and increasing PrEP access and helping to reduce stigma. On April 17, 2023, the CDC announced the notice of award of approximately of a single-source cooperative agreement for $4 million to the United Way of greater Nashville. This measure is put in place from June 1, 2023, through May 31, 2024, and seeks to support the continuation of critical HIV education testing and prevention services in the state of Tennessee.

## Division of STD Prevention Update

**Leandro Mena, MD, MPH, FIDSA**
Director, Division of Viral Hepatitis
National Center for HIV, Viral Hepatitis, STD and TB Prevention
Centers for Disease Control and Prevention

Dr. Mena shared the 2021 surveillance data that showed STIs are continuing to increase and for all the infections that were tracked, all are at historic highs. In 2021, there were increases in chlamydia, gonorrhea, syphilis, and congenital syphilis with 42.5 million cases reported. With chlamydia there was a slight increase that may indicate that access to screening programs may be improving, yet many chlamydia cases continue to be above 2019 levels. The most dramatic increase was noted with syphilis and congenital syphilis. In 2012, two states, the District of Columbia (DC), and one US territory (7.4% of areas with available data) had a rate of reported primary and secondary syphilis greater than or equal to 7.6 cases per 100,000 population. This increased to 42 states, DC, and one US territory (80.0% of areas with available data) in 2021. The STI epidemic has significant disparities geographically, Congenital Syphilis specifically remains concentrated in a small proportion of counties. Only 3% of 2000 counties represent 58% of all Congenital syphilis cases reported in 2021. There are also important disparities when it comes to age, with the youth aged 15 to 24, representing only 14% of the U.S. population, yet account for over 50% of the STIs reported and where racial and ethnic minorities have a disproportionate burden of disease. The national rate of 78 cases per 100,000 live births in 2021 continues to exceed the World Health Organization (WHO) call for the elimination of congenital syphilis.

For the first time, in almost 20 years, the U.S. surpasses those 50 cases per 100,000 U.S. population, which is the WHO goal. Over 20 states in 2001 exceeded the WHO goal. Furthermore, almost half of the states are now reporting rates above the WHO goal. In six years, we have gone

from one state above 50 in 2016, to 20 states in 2021. When we look at cases specifically, we see five states spread through the west and the south accounting for roughly 58% of cases. The top five states are Texas, California, Arizona, Florida, and Louisiana. In addition to the flagship NOFO, which we are extending to include a sixth year into 2024, we have several other recent investments to address the continued STI increase. Both NOFOs build on the belief that CDC and STI programs cannot do this alone. We have to really build collaborations and engage in other sectors. These new efforts use approaches aimed at distributing resources to the geographic areas and populations disproportionately affected. There are also encouraging tailoring interventions engaging with communities and supporting programs using a syndemic approach and holistic patient centered care. The first one is enhancing sexual health clinic infrastructure aimed to expand and support the development of the sexual health infrastructure in our nation, which we recognize is insufficient to provide the kind of sexual health services that our populations need. Especially when it comes to some of the most vulnerable populations. The second one is the support of technical assistance and opportunities for policy and communications to prevent STIs to expand partnerships to communication policy and leadership to identify and support strategies that will help to decrease the STI epidemics.

Dr. Mena mentioned an important collaboration with the National Association of County and City Health Officials which received three NOFOs that target community engagements to strengthen 1) local health department approaches to decrease syphilis; 2) approaches to decreasing syphilis among American Indian/Alaska native populations; and 3) evaluating the integration of STI and harm reduction service. He also drew attention to the STI Impact Research Consortium. The consortium recipients will conduct studies to reverse persistent troubling trends in reported infections. Members of the consortium are a mixture of academic research and public health institutions that will undertake clinical trials and implementation science research both aimed to increase the population focus impact. Research projects will be widening scope and scale and will fall into the following four broad areas: prevention content, prevention methods, field-based prevention research, and diagnostics research. These service delivery areas include clinical trials to develop, test and implement interventions that include efficacious STI prevention content to increase access to an efficient use of STI services. There is focus on research to integrate novel interventions into field investigations including improvement of case and contact monitoring to support access to the use of remote services during field investigations and novel approaches to isolation. Quarantine and other strategies to prevent onward transmission of infections are also included. The diagnostic and research approach will help to develop, test, and implement new diagnostic tools that increase the proportion of infected persons tested and diagnosed.

There has been great excitement in the past 12 months with the new advances in STI innovations. There interventions include DPP HIV-Syphilis point-of-care testing (POCT), Post-Exposure Doxycycline (DoxyPEP), and Meningococcal Vaccine. Point of care (POC) for syphilis is a greatly underutilized tool. New data on DoxyPEP third clinical trial demonstrating the effectiveness of DoxyPEP; the division is finalizing the development of guidance that we hope to release before the end of the summer. The emerging data on the first prospective study on the use of Meningococcal Group B vaccine to prevent a secondary infection shows a 50% reduction in the risk of gonorrhea. There are about eight different clinical trials including at least four funded by NIH, which will provide important changes in the data to frame all these intervention to a sexual health framework that will result in improving the sexual health of the nation.

## HRSA Welcome and Update

**Laura Cheever, MD, ScM**

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

Dr. Laura Cheever expressed her gratitude to CDC for hosting this CHAC meeting and for everyone who traveled to be present in-person. She also gave a special thanks to Shalonda Collins and Andrea Jackson for their support to the HIV/AIDS Bureau in their CHAC role and for pulling together her presentation.

Dr. Cheever reminded everyone that the HIV/AIDS Bureau's vision is "optimal HIV/AIDS care and treatment for all to end the HIV epidemic in the U.S." and that their mission is to "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. The vision and mission acknowledge that that ultimate goal is to end the HIV epidemic in the United States while continuing to support HIV quality of care in the Ryan White program, for those both currently in care and newly diagnosed. Certainly, EHE work is focused on those who are out of care, which is the next great challenge.

On April 10, Dr. Michael Kharfenjoined the HIV/AIDS Bureau as the Director of the Division of Policy and Data; it was the role previously encumbered by Antigone Dempsey. He most recently came from the New York State Department of Health, but prior to that he had been in Washington, D.C. for many years in the HIV/AIDS, Hepatitis and TB administration. A lot of the gains that D.C. has made in the last decade were under his leadership. He is a consummate engager of community, and he brings real experience of what it means in terms of programming, community engagement around using data to direct and make significant movement.

In terms of HAB updates, the current 2023 appropriation is at $2.57 billion to include both the Ryan White program and the Ending the HIV Epidemic funding. The majority of funding does go to Part B, primarily to AIDS Drug Assistance Program (ADAP). It is important to note that the Ryan White program has been maintained since 2012. There have not been any significant increases in the program. Much of the programs' progress is due to doubling down on quality improvement and being more efficient and effective in the use of funds. This year, there was a $40 million increase for EHE and a $36 million increase for Ryan White. That was the first increase for Ryan White in many years. The President's budget for 2024 includes a $125 million increase for EHE that is proposed to Congress. Of note, on the increases received much of the programming of Part A and B gets ran through the formula for HRSA statute. In part C, there was competition for new Part C sites. HAB is competing for 10 new service areas and funding.

In terms of monkeypox, the HIV/AIDS Bureau has worked closely with both the CDC and the White House on monkeypox response. The Ryan White program received some direct vaccine allocations from the stockpile to get to Part C clinics that had significant numbers of LGBTQ populations. Though mpox public health emergency ended on January 31, 2023, there is concern of a summer outbreak of monkeypox. HAB continues to encourage Ryan White HIV/AIDS Program recipients to support and promote mpox vaccination to clients who continue to be at risk for mpox. RWHAP recipients should continue to support mpox prevention, diagnosis, and treatment and encourage clients who are at risk for mpox to complete the series of two vaccines. For new mpox resources about how to stay safe this summer, visit CDC's webpage[6].

[6] Get Healthy and Ready for Summer 2023

There are new changes to the HHS HIV clinical practices for breastfeeding/chestfeeding guidelines. On January 31st, the Panel on Treatment of HIV in Pregnancy and Prevention of Perinatal Transmission updated the Recommendations for the Use of Antiretroviral (ARV) Drugs During Pregnancy and Interventions to Reduce Perinatal HIV Transmission in the United States[7]. The primary recommendation is now to support parental choice through shared decision-making, not a specific infant feeding mode. The updated guidelines ensure a shared decision-making process between people with HIV and their healthcare providers regarding infant feeding and noting that taking HIV medication significantly reduces a person's chance of transmitting HIV through breast milk. For persons who are pregnant and are choosing to breastfeed or chestfeed, it's very important that they are supported in that, if that's their decision, after careful discussion. Importantly, the guidance explicitly states not to report these people to Child Protective Services.

There are new provider resiliency resources on the RWHAP website[8]. HAB has updated the Provider Resources web page, which now includes federal resources focused on reducing burnout and supporting the mental health and well-being of health care team members. Given the impact of COVID-19 and monkeypox, it has been a very difficult few years for the provider workforce. As such, it is important to address burnout among healthcare providers and strengthen provider resiliency. The new resource page provides consolidated organizational resources for health care providers.

To support Ryan White Program community members, NASTAD, through its cooperative agreement with HAB, put out the Trauma-Informed Approach (TIA) Toolkit[9]. This toolkit was developed to assist health departments, AIDS services organizations, and HIV clinics to implement trauma-informed systems of care. The use of TIA acknowledges the impact of trauma on people's health and well-being and prevents re-traumatization. Applying a trauma-informed lens is a critical tool to address the HIV epidemic in the United States, as people with HIV have significant trauma histories when compared to the general population.

On February 8th, HRSA HAB hosted a special webinar: Opportunities to Apply for a Federal Job[10]. The webinar provided guidance and tips on writing a federal resume and applying for federal jobs at HRSA and understanding federal hiring authorities. It is important to maintain a diverse workforce and continue a strong relationship with Ryan White providers, communities, and partners, which is the key to success. To improve outcomes among racial and ethnic minorities, the HIV/AIDS Bureau recruits and retains a diverse workforce. This community-based webinar gave very specific tips on how to understand, veterans preference, and hiring processes for persons with disabilities. The recording of the webinar may be passed around to support the hiring messaging to increase the interest of more people with lived experiences and diverse backgrounds to join the HIV/AIDS Bureau as well as the CDC and other similar.

Dr. Cheever shared policy highlights. Ms. Andrea Jackson has led efforts around getting recipients ready for the Medicaid continuous enrollment and unwinding. During the COVID-19 pandemic, the landscape changed, and people were not required to re-enroll in Medicaid, and were not to be dropped from Medicaid. Now that the public health emergency is ending, appropriate language was developed this year to encourage a more regular process than what people used in the now distant past about how to re-enroll in Medicaid. There is great concern

[7] Recommendations for the Use of Antiretroviral Drugs During Pregnancy and Interventions to Reduce Perinatal HIV Transmission in the United States
[8] Ryan White HIV/AIDS Program (RWHAP) resources for health care providers
[9] Trauma-Informed Approach Toolkit
[10] Opportunities to Apply for a Federal Job Webinar

for many clients that may unintentionally lose Medicaid coverage. Specific actions RWHAP recipients/subrecipients can take to assist clients includes: identify all clients at risk of losing Medicaid coverage and flag their charts for reminders; send clients Medicaid coverage renewal reminders; schedule advance appointments to assist clients with Medicaid coverage renewals; boost staff capacity and increase staff time on engagement, education, renewal, and enrollment activities for Medicaid clients; inform Marketplace-eligible clients losing Medicaid or Children's Health Insurance Program (CHIP) coverage from March 31, 2023 through July 31, 2024 of the temporary Exceptional Circumstances Special Enrollment Period ("Unwinding SEP")[11]; learn your state Medicaid agency's plan for resuming normal operations; work in coalition with trusted organizations in your area; develop and launch a health equity-focused unwinding plan; and, inform clients about the steps they need to take to renew Medicaid coverage. The Access, Care, and Engagement Technical Assistance (ACE TA) Center[12] provides practical tools and resources to support engagement, education, enrollment, and renewal activities.

The HRSA HAB released a new Program Letter[13] outlining how the RWHAP can support community engagement efforts. Of note, HAB's focus on community engagement has been a cornerstone of legislation since it was first enacted by Congress in 1990. Three mechanisms that RWHAP recipients and subrecipients can utilize to maximize community input include: RWHAP funds may be used to provide incentives for clients as per PCN 16-02 Ryan White HIV/AIDS Program Services, *Eligible Individuals & Allowable Uses of Funds*; community engagement activities are allowable costs under the HRSA HAB Outreach Services Support Category; and, if one funding source does not provide enough funding/flexibility, RWHAP recipients and subrecipients can utilize different funding streams and "braid them together" to attain a sufficient funding level and achieve a common community engagement goal, being careful to ensure that all applicable laws and regulations follow each stream of funding.

Dr. Cheever provided RWHAP Part A guidance for planning councils and planning bodies on supporting people with lived experience. Community input process is a requirement per RWHAP legislation. It is important for RWHAP Part A clients to actively participate in the planning process for HIV service delivery. RWHAP legislation prohibits cash payments to recipients (i.e., clients) of RWHAP Part A services. This is not limited to service-related costs, and thus applies to administrative costs like Planning Council (PC) and Planning Body (PB) expenses. RWHAP Part A recipients can support the participation and meaningful engagement of people with lived experience in PC or PB meetings by using non-RWHAP funding sources (e.g., general revenue funds) to provide support that is prohibited by the RWHAP, such as cash payments and food. Using RWHAP funds, Part A recipients can provide: Gift cards, vouchers, coupons, or tickets that can be exchanged for a specific service or commodity; clients with meals during in-person meetings scheduled around mealtimes (only if needed for health reasons); transportation; childcare services; and meeting times for PCs and PBs that are after business hours or on weekends.

On January 17, HRSA HAB and HRSA's Bureau of Primary Health Care (BPHC) and the CDC released a letter[14] encouraging public health partners and grant recipients to implement status neutral approaches to HIV care and prevention. CDC, HRSA HAB, and BPHC support the use of braided funding to reduce barriers to implementation and to help extend the reach of status neutral services. Beyond CDC and HRSA, it is important for grant recipients and public health partners to look across public and private funding streams to identify ways to also braid other

[11] Program Letter on RWHAP and Medicaid Continuous Enrollment Unwinding Released
[12] Access, Care, and Engagement Technical Assistance (ACE TA) Center
[13] New RWHAP and Community Engagement Program Letter
[14] New HRSA/CDC Status Neutral Approach Framework Letter

funds into service delivery to achieve a more robust status neutral suite of services where it's feasible and appropriate. This funding approach can also increase programmatic efficiency.

Dr. Cheever shared information on the release of a NOFO funded by the Department of Minority HIV/AIDS Fund (MHAF) cooperative agreement entitled "A Status Neutral Approach to Improve HIV Prevention and Health Outcomes for Racial and Ethnic Minorities-Demonstration Sites". The goal of this project is to develop, implement, and evaluate status neutral strategies within Ryan White HIV/AIDS Program (RWHAP) Part A jurisdictions for racial and ethnic minority subpopulations who need two coordinated components 1) Implementation sites, and 2) an Evaluation and Technical Assistance Provider (ETAP).

The Special Projects of National Significance (SPNS) Initiative includes emerging strategies to improve health outcomes for people aging with HIV. Implementations involve comprehensive screening and management. Another SPNS Initiative is around telehealth strategies to maximize HIV care. The purpose is to identify and maximize the use of telehealth strategies that are most effective in improving linkage to care, retention in care, and health outcomes. There is also a SPNS Initiative for supporting replication (SURE) of housing interventions in the Ryan White HIV/AIDS Program. SURE Housing uses an implementation science approach to identify, evaluate, and support replication of effective housing interventions in the RWHAP. The goal of these interventions is to decrease health and housing disparities and improve health outcomes along the HIV care continuum.

Another MHAF Cooperative Agreement, "Increasing Uptake of Long-acting Injectable Antiretrovirals Among People with HIV", will develop, implement, modify as needed, and disseminate successful clinical protocols for increasing long-acting injectable antiretroviral uptake and continued use, especially in minority communities facing health inequities and stigma in accessing novel treatments. There is one coordination site and 10 diverse demonstration sites across the U.S.

Dr. Cheever mentioned the March 29, 2023, launch of the RWHAP Part D Communities of Practice. The purpose is to facilitate the delivery of evidence-informed interventions and promising strategies to improve family-centered services to WICY with HIV in HRSA-funded RWHAP Part D provider organizations and HRSA-funded organizations serving similar populations. The Communities of Practice will focus on three important areas: 1) pre-conception counseling, including sexual health, 2) youth transitioning from youth services to adult care, and 3) trauma informed care.

The Center for Quality Improvement and Innovation's (CQII) Impact Now Collaborative is a national quality improvement initiative that aims to maximize the viral suppression rates, focuses on RWHAP recipients and subrecipients that have the highest potential for a measurable national impact. And enrolls up to 30 RWHAP providers to raise their viral suppression rates to the national viral suppression mean and beyond. The 18-month learning collaborative aims to improve health outcomes and advance local quality improvement capacities.

On December 1, 2022, the Ryan White HIV/AIDS Program released the 2021 annual client-level data report. There were 576,076 clients served, 89.7% of RWHAP clients receiving HIV medical care, and 6.6% received temporary housing. Of the RWHAP clients, 48.3% are aged 50 and older; 59.2% are living at or below 100% of the Federal Poverty Level (FPL); and 73.3% are from racial and ethnic minority groups. There was an MMWR publication that highlighted key viral suppression rate among RWHAP Clients, by State, 2010 and 2021—United States and 2 Territories. Significant progress has been made in viral suppression among priority populations,

but inequities remain, particularly among Black/African American clients, transgender clients, youth aged 13–24 years, and clients with unstable housing. There is a new infographic for housing and HIV-Related health care outcomes among HRSA's RWHAP clients, 2021. The RWHAP Oral Health Data Report provides data on RWHAP oral health programs from January 2015 through December 2020. For more information on Ryan White HIV/AIDS Program-related data, reports, and tools, visit the Compass Data Dashboard[15] for data visualization.

Dr. Cheever concluded her updates with the March 2020 to February 2021 highlights on the HAB EHE Qualitative Summary of Progress[16]. EHE recipients delivered expanded RWHAP services and innovative programs, especially to people newly diagnosed and those re-engaged in care. EHE recipients expanded access to services through technology and structural changes. Due to COVID-19, EHE recipients faced unexpected barriers and challenges to implementing their EHE workplans. EHE recipients demonstrated flexibility and resilience in meeting the needs of their clients during the COVID-19 public health emergency. EHE recipients delivered expanded RWHAP services and innovative programs, especially to people newly diagnosed and those re-engaged in care. EHE recipients expanded access to services through technology and structural changes. During the first year, it was strategy spending of $70 million across a $2.3 billion program.

Dr. Gayles closed out the welcome and update session by thanking everyone for all the updates, and the work that they all continue to do. He also reiterated how, in some ways, the Federal environment has become more hospitable in terms of funding and opportunities but there are still headwinds required for local areas and state jurisdictions that have not been as hospitable. As the session led into the member discussion, he provided a reminder for virtual members to please use the raise hand feature to ask a question or make a comment for those in the room to please make sure to turn on their mic before speaking.

## CDC/HRSA Updates Q&A and Member Discussion

*The following questions, observations, and suggestions were raised:*

- Mr. Driffin noted, as a person living with HIV, he sees a great deal of work yet to be done on this issue. Directing his first comment toward Dr. Fanfair, he noted that approximately 90,000 tests were conducted using prevention funding in his state, with Black Men Who Have Sex with Men (MSM) comprising roughly 11% of those tests. Yet, with a 2.6% positivity rate in that community, health departments and community-based organizations need to prioritize those populations, particularly working on prevention in poor communities. Mr. Driffin also noted that approximately 40% of those with monkeypox were also living with HIV, and many people who are HIV-positive are not connected to health care. He wondered what efforts could be taken, such as the Ryan White program, to bring approximately 400,000 people back into care. Finally, he asked whether the CDC, SAMHSA, and the Department of Housing and Urban Development (HUD) would support a community engagement letter to ensure that those living with HIV were kept apprised and included. He concluded by thanking everyone for their participation in the march to reduce HIV across the country.

- Dr. Fanfair responded that she was in complete agreement with Mr. Driffin and that the main focus of the fiscal year would be directed toward Black and Latino MSM, particularly the

[15] Ryan White HIV/AIDS Program-related data, reports, and tools, visit the Compass Data Dashboard
[16] HAB EHE Qualitative Summary of Progress

younger component of this population. This effort will include increasing the awareness and knowledge of these groups and putting out an issue brief targeting HIV in MSM.

- Dr. Cheever, in responding to Mr. Driffin's point about those with mpox often living with HIV as well, said that they'd communicated with the CDC and the White House on this issue about a week prior. One initiative HRSA was taking on with those with HIV involves reaching people that they wouldn't normally reach. This could include new and different partners such as fraternities, sororities, Jack and Jills, and other organizations where African Americans might be, but where HIV may not be often discussed. Although HRSA does not have legislative authority, they want to focus on increasing engagement, specifically focusing on such events as Essence Fest, where they looked last year to see how they might better engage Black women, an Atlanta gay pride event, and an African American festival in Baltimore. Furthermore, while getting those with HIV back in care is important, with the new monies, they are more focused on getting people in care. In Seattle, for example, they've opened a low-barrier clinic to treat those who are also homeless or facing major life challenges; in addition, regular medical care is offered. A similar clinic has opened in another part of the city where many African American and African sex workers are located as well. These low-barrier clinics are serving people that they never could have without their EHE money. The big issue is figuring out how to reach people that are not currently being reached and then determining how to pay for those extended services.

- Dr. Mermin added that from his five months of working as the incident manager for mpox for the CDC, he felt that they were able to bring their work on HIV, STIs, and viral hepatitis to that new health challenge, allowing them to do a better job. For those newly diagnosed with HIV, the HIV Behavioral Surveillance System found that even though over half had touched the health care system in the past year, whether through the Emergency Room (ER), their primary care physician, or some other means, they were never diagnosed with HIV. There is a relatively effective vaccine for mpox that appears to last for about two years; this means that if someone were to go to an STI clinic, this would be an ideal time to vaccinate them from mpox or provide HIV testing. The same scenario holds true for clinical settings, such as an ER, or various community events where African American gay or bisexual men, transgender women, and MSM predominate. Through multiple touchpoints, services can be rendered to those who are disproportionately affected.

- Dr. Dowler commented that during the course of the pandemic, the number of Medicaid beneficiaries grew from two to three million people. Although a potential budget increase could provide coverage for some of those people, if they are not proactive in responding to letters or phone calls, they may end up losing coverage due to workforce shortages at already overwhelmed Medicaid offices around the country. This could prove incredibly disruptive to many people's care, and the medical community may not yet be aware of this issue. Another concern involves telehealth and telephonic care. Although in-person care clearly provides the highest level of care, with telehealth care next, followed by telephonic care, barriers to access may force those who already experience the most inequities to the lowest-level care. The digital divide needs to be addressed in order to ensure that better health care is accessible to disadvantaged populations. In regard to PrEP, in North Carolina, which is a non-expansion state, Medicaid was able to incorporate everything involving PrEP (six visits and STI testing), except for the drug which is available through federal means, into the family planning Medicaid benefit, which is a limited benefit. This was extremely difficult to do, and authority from Centers for Medicare & Medicaid Services (CMS) was needed; however, in non-expansion states, particularly where the highest PrEP-to-need ratios are seen, actions taken at the federal level

to embed PrEP services and the family planning Medicaid benefit could prove to be a beneficial initiative, especially while waiting for all states to expand Medicaid.

- Dr. Markham thanked Dr. Ethier for her work with YRBS. Dr. Markham noted that Texas is one of the states that is actively attempting to criminalize the administration of the YRBS because of the belief that it's a grooming tool for sexual predators due to questions about sexual behavior and identity. Various state policies were implemented this year in schools focusing on sexual health education, healthy relationships, and abuse prevention. Parental opt-in consent is required, which presents a problem since those who most often need YRBS services are not returning the signed parental consent form. Any assistance from the CDC on this issue would be welcome.

- Dr. Ethier replied that although Texas has made it more difficult to implement the YRBS, they have not formally pulled out. Unfortunately, a number of states took the money in 2022 but are not collecting data in 2023, and some other states, while not specifically stating that they will not collect data, have been making it extremely difficult for schools to participate, and monitoring schools is quite difficult. As far as surveillance data, YRBS would like to increase the depth of the survey, which is currently quite broad but not particularly deep. Finally, Dr. Ethier noted that in schools where policies supportive of LGBTQ youths are in place, improved health is seen throughout the school community, which is why LGBTQ inclusivity is so crucial.

- Mr. Rodriguez, who was born and raised in Puerto Rico, asked Dr. Ethier whether the report that was referenced from 2021 contained data just from the 50 states or included the territories as well. Mr. Rodriguez also praised Dr. Ethier for the shift to include gender identity questions.

- Dr. Ethier responded that a nationally representative survey represents only the 50 states; however, data is collected from some of the territories and tribes as well. Dr. Ethier promised to report back on which territories and tribes they had collected data from, probably including 2023 as well.

- Ms. Morne stated that as someone who attended a safe, supportive school, it is extremely important for schools to invest in trauma-informed care. Typically, society devotes much time to the treatment of symptoms rather than the core issues of what people are really living with. Going forward, innovative practices, initiatives, and funding should be allocated toward prevention rather than just the treatment of symptoms. Regarding peer compensation, despite the thorny issue of legalities with cash payments, it is critical to continue to think innovatively about providing reimbursements to those who work so diligently.

- Dr. Anderson, an OB/GYN, wondered about the ability to screen for hepatitis C, which is a relatively new recommendation, for both pregnant women and those undergoing preconception care. From her work with perinatal infections a few years ago, she became aware of the patchwork of recommendations, guidelines, and regulations that exist nationwide in terms of testing. Testing during pregnancy may be the first point of care while STD and adolescent clinics may also present testing opportunities.

- Dr. Wester commented that screening recommendations for all adults and pregnant persons were released by the CDC in early 2020 and endorsed a year later by American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine. In order to monitor further uptake, pregnant live births can be considered; however, that would not provide an accurate picture of hepatitis C since only pregnant women who had live births

would be tested and represented. Rates, though, have increased dramatically in the past 10 years to about .5%, a statistic that merely represents those who have been diagnosed. Actual rates are much higher than that, leaving much room for improvement. We are currently working with ACOG to increase awareness and provide the necessary tools to antenatal providers. While diagnosing a pregnant person so that they can undergo care and treatment and testing their infant is a step in the right direction, treatment during pregnancy is helpful so that they can take advantage of the insurance, engagement, and care that is unique to pregnancy. Hepatitis B screening recommendations have been in place for pregnant people for years. Furthermore, it was only recently that perinatal funding recommendations were issued by the CDC, and those will be released in the late summer or early fall. A recently released cost-effectiveness analysis indicated that viral testing at two to six months of life is preferred to waiting until 18 months with an antibody reflex to RNA, with much of that due to a loss of follow-up engagement and care. There is much opportunity to be realized despite the advances that have already been made.

- Dr. Mena commented that regarding the syphilis component, 70% of congenital syphilis cases are related to not having timely prenatal care or syphilis testing during pregnancy. Treatment of syphilis 90 days before delivery can greatly reduce the chances of the child going into CPS. Geographic regions and populations greatly affect whether people access services; therefore, screening for syphilis should be integrated into other services they may be receiving. Additionally, in certain areas, even when you have already drawn blood, contacting the patient may prove difficult, and reinfection among women before delivery even after they've been properly treated can also be an issue.

- Ms. Parkinson noted that there has been a great deal of work in disseminating information around the country regarding the promotion of breastfeeding and chestfeeding. She wondered how to best help the clinicians, perinatal nurses, and case managers in rural areas who were uneducated or informed about these potential benefits; perhaps small cohorts for clinicians, social workers, and health care workers could be implemented. Regarding PrEP, which was initially perceived as being for gay men, it is also important for Black women to be able to discuss in safe spaces topics such as body autonomy, how to love themselves, and keeping safe. Finally, since cash payments were an earlier topic, a nice honorarium or something that builds community would be helpful.

- Dr. Dionne commented that, unfortunately, according to annual STD surveillance data, the numbers are not decreasing. The fact that congenital syphilis numbers have gone from 300 to 2,800 per year in this country is unacceptable. Additional research, new tools, better diagnostics, and, eventually, a syphilis vaccine are needed. Just during this meeting, Dr. Dionne received an email from their clinic in Birmingham stating that they are out of Bicillin. Since they are not expected to receive any Bicillin in the near future, patients will have to be sent to the local health department, which is what many tried to avoid by coming to the clinic in the first place.

- Dr. Mena responded that there is only one manufacturer of Bicillin, with one or two suppliers overseas, producing a tremendous vulnerability. Therefore, it's important to explore other alternatives to solve this problem, such as forming a consortium to come up with various solutions. The high cost of treatment, which may include copayments of $250, means that many people are left untreated, especially if they are asymptomatic. The increasing cases of syphilis in this country are a challenge and need to be addressed.

- Dr. Mermin added that a shortage of essential medications, such as those for tuberculosis, for example, has been a fundamental issue for public health in general for over a decade. This is caused by the high cost of production of these medications as well as having only one or two manufacturers. The CDC has been trying to work with the FDA and other entities to address the fundamental causes of this problem.

- Dr. Mena replied that since manufacturers' forecasts are based on demand, sometimes the increase in synchronous, real time doesn't mesh with those forecasts. This also exacerbates the problem, often leaving someone with syphilis, as well as their partner, untreated.

## Panel 1: Sexual Health as a Holistic Approach to Public Health Implementation

***Moderator: Leandro Mena, MD, MPH, FIDSA, Director DSTDP***

### Sexual Health as a Holistic Approach To STI/HIV Prevention And Care—Why Does This Make A Difference?

**Eli Coleman, PhD**
Professor Emeritus at the Institute for Sexual and Gender Health
Family Medicine and Community Health
University of Minnesota Medical School

Dr. Coleman reminded the committee of the importance of recognizing sexual Health and its critical association to overall health and well-being. He mentioned Dr. Satcher's quote that states, "sexual health an essential component of overall individual health; major impact on overall health of communities". He also provided WHO definitions of sexual health; it is a state of physical, emotional, mental, and social well-being related to sexuality. It is not merely the absence of disease, dysfunction, or infirmity. It requires a positive and respectful approach to sexual relationships, as well as the possibility of having pleasurable and safe sexual experiences, free of coercion, discrimination, and violence. For sexual health to be attained and maintained, the sexual rights of all persons must be respected, protected, and fulfilled.

Dr. Coleman shared CDC's efforts to address the sexual health framework and the impact of addressing the "syndemic" responding with a systematic sexual health approach. The conclusion of the 2011 report, yielded a broad, positive, inclusive, and empowering framework with the following recommendations: engage new and diverse partners; normalize conversations; reduce stigma, fear, and discrimination; and, enhance the efficiency and effectiveness of prevention messaging and services. He provided several articles that supported the framework such as the publication from Drs. John Douglas and Kevin Fenton "*Understanding sexual health and its role in more effective prevention programs*[17]*".* These preliminary works set a foundation that promotes the translation of broader strategies into programs and interventions that use this approach as a means to demonstrate the need for more mobilization. There is a call for a paradigm shift from morbidity and a stigmatizing, fear-based approach to an integrated sexual health promotion approach[18].

[17] Douglas JM Jr, Fenton KA. Understanding sexual health and its role in more effective prevention programs. Public Health Rep. 2013 Mar-Apr;128 Suppl 1(Suppl 1):1-4. doi: 10.1177/00333549131282S101. PMID: 23450880; PMCID: PMC3562741.
[18] Ford JV, Ivankovich MB, Douglas JM Jr, Hook EW 3rd, Barclay L, Elders J, Satcher D, Coleman E. The Need to Promote Sexual Health in America: A New Vision for Public Health Action. Sex Transm Dis. 2017 Oct;44(10):579-585. doi: 10.1097/OLQ.0000000000000660. PMID: 28876308.

Sexual health is an essential component of the strategy. The principles required to implement into programs include educate, reduce stigma, fear, and discrimination. These principles help change the sexual and gender climate and normalize sexual conversations. It is equally important to promote research and provide an integrated and sexual health approach. The framework incorporated: the concept of intersectionality that sexual health is inextricably linked to overall health and well-being across the life spa, and that human sexuality is a vital element of mutually consensual love and pleasure, as well as the fundamental prerequisite for procreation. It is a holistic approach that focuses on sexual health in the context of broader health and well-being, thus eradicates stigma while educating the U.S. population on what it means to be sexually healthy and where and how individuals can access comprehensive sexual health services. Though this paradigm shift is needed, it should not be viewed as a political issue nor one that needs to be in conflict with religious beliefs or ethical standards. To support this goal at the federal level, the committee recommends that the Department of Health and Human Services (HHS) develop a vision and blueprint for sexual health and well-being that can guide the inclusion of a sexual health paradigm across all HHS programs, including the major public insurance programs as well as the public health programs administered throughout the department.

Dr. Coleman concludes with findings that provided broad evidence of sub-optimal sexual health in all domains measured, indicating the need for new approaches to meet goals of national initiatives. While the available indicators contain crucial gaps[19], considerations for addressing these gaps include adding new measures, creating research partnerships across disciplines, and developing a new comprehensive survey of sexual health as other countries have done.

## New Tools for STI Prevention

**Stephanie Cohen, MD, MPH**
Medical Director for the San Francisco City Clinic
Director for the STI Prevention and Control
Section of the San Francisco Department of Public Health

Dr. Cohen shared the 2020 state of STI's in the U.S. The U.S. is experiencing steep, sustained increases in STIs with 1.6 million cases of Chlamydia, 677,769 cases of Gonorrhea, 133,945 cases of Syphilis, and 2,148 case of Syphilis among newborns. The global epidemic of STIs disproportionately impacts men who have sex with men (MSM). The trend showed STIs rising while HIV diagnoses decline. If left untreated STDs can cause significant morbidity including increasing risk of transmitting and acquiring HIV infection, causing significant potential morbidity, including neurosyphilis, long-term pelvic pain, infertility, and severe congenital disease. Currently available STI prevention tools include primary prevention (i.e., education, condoms, risk reduction counseling), vaccines (i.e., hep A and B, human papillomavirus [HPV], mpox, Meningococcal vaccine), secondary prevention (STI screening & treatment, partner services), addressing social determinants of health (i.e., mental health& substance use treatment, anti-poverty, anti-racism), and policy (i.e., reproductive rights, LGBTQ rights, criminal justice reform). Focused on some really innovative new tools for STI prevention that fall into the biomedical STI prevention space. It is important to keep in mind that all biomedical prevention tools are also behavioral; they require behavior on the part of patients, providers, and policymakers, in order to be successfully integrated.

[19] Ford JV, Ivankovich MB, Coleman E. Sexual health indicators for the United States: Measuring progress and documenting public health needs. Front Public Health. 2023 Jan 26;10:1040097. doi: 10.3389/fpubh.2022.1040097. PMID: 36777776; PMCID: PMC9909468.

Dr. Cohen presented doxycycline post-exposure prophylaxis (DoxyPEP) data as an STI prevention tool. She stated doxycycline is safe, well tolerated, and inexpensive. It is active against chlamydia (CT) & syphilis. Some resistance seen in gonorrhea (GC), but not used as first line treatment for GC and unknown how much activity is needed for PEP. DoxyPEP significantly reduces STI incidence in cis men who have sex with men and trans women who have sex with men. Doxycycline 200 mg taken after condomless sex reduced the incidence of gonorrhea, chlamydia, and syphilis by 65% per quarter among men who have sex with men and transgender women with history of a recent sexually transmitted infection. There are still questions and concerns about this tool. DoxyPEP was not effective in cis women in D-PEP study in Kenya. Reseachers are still investigating the impact of DoxyPEP on drug resistance, both sexually transmitted infections and other bacteria. And there are questions about the long-term impact that vaccines have on the microbiome, or the commensal bacteria that live in the gut that are important for overall health.

Dr. Cohen reviewed the high-level finds in the Kenya D-PEP study, the first and only to date of the study of DoxyPEP in the prevention of STIs in cis women. The study population was women on PrEP between the ages of 18 and 30, and this was a population with a high prevalence and incidence of STIs. 18% had an STI at enrollment, the annual STI incidence in the study was 27%. There were 109 new STIs, most of which, 78%, were chlamydia. The Kaplan–Meier curves showed no separation between the two lines. There was no difference between the two marks. There is a lot of conversation around why DoxyPEP was not effective for STI prevention in cis women. This is a critical question in this field to further investigate. There are a number of theories related to potential differences in anatomy related to endocervical tissues differences, perhaps in the affinity of the STI for that space or the pharmacodynamic and kinetic uptake of antibiotic, and differences potentially in resistance. Again, this study was done in Kenya whereas the other two studies were conducted in Europe and the US, as well as important questions about adherence, which was certainly the Achilles heel in the early studies of HIV PrEP.

Doxycyline PEP interim guidelines[20] recommend DoxyPEP 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. These were the eligibility criteria used for the DoxyPEP study. Patients with a history of syphilis should be prioritized for D-PEP. Offer DoxyPEP 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. DoxyPEP not recommended for cis women based on currently available evidence from Kenya D-PEP study.

Dr. Cohen provided recommendations for counseling patients about DoxyPEP. These recommendations include utilizing shared decision-making to support patient's choice; guiding self-assessment of risk; reviewing what is known about effectiveness of DoxyPEP; reviewing how to use DoxyPEP; acknowledging the unknowns, such as the impact on microbiome, the impact on antibiotic resistance in STIs and non-STI bacteria; and finally, offering comprehensive package of sexual health services. Dr. Cohen encouraged the shared decision-making approach which is "a collaborative process that allows patients and their providers to make health care decisions together, taking into account the best scientific evidence available, as well as the patient's values and preferences."

Dr. Cohen concluded by sharing next steps for DoxyPEP. CDC guidelines will be critical for supporting safe and equitable access. The implementation science involves interest uptake,

[20] Health Update Doxycycline Post-Exposure Prophylaxis Reduces Incidence of Sexually Transmitted Infections

community engagement, social marketing strategies, and provider education; long-term impacts on antimicrobial health and long-term impacts on individual health; and, modeling studies to assess potential impact on STI incidence. It is important to sustain support for sexual health clinics in the U.S. with ongoing research into vaccines for STIs, including Group B Meningococcal (MenB) for GC prevention.

## Syndemic, Holistic Approaches to Disease Surveillance: Measuring What Really Matters

**Mark Stenger, MA**
Enhanced Surveillance and Special Studies
Acting Team Lead (Acting), Lead Science Officer
STD Surveillance Network (SsuN), DSTDP

Dr. Stenger began his discussion by sharing the historical account of the incidence of STIs data through the National Notifiable Disease and Surveillance System (NNDSS). In the case of HIV, through the National HIV Surveillance System (NHSS), it is important to understand that legal authority for disease reporting resides at the state and jurisdictional level in the United States. States require providers and laboratories to report cases to their state or local health departments. These are then voluntarily reported by states to the CDC, but information associated with cases of STIs is generally quite limited and does not have a unique person identifier associated with reported cases. These data can, however, tell when, where and how many cases occur in a given time period, by sex, by age, by race, by some other strata, which are very useful in assessing differences in measuring gross inequalities in the burden of disease by these important characteristics. These data are also siloed by specific disease, having little or no insight into individual overlap, multiple diseases, or comorbidities. For the most part, these data do not provide any information about underlying behavioral risks. As a result, most of the analysis at the national level describe trends and demographics for one disease at a time. While infectious disease surveillance will not address some of the specific sexual health indicators the committee is most interested in.

Dr. Stenger proposed a model for more integrated disease surveillance to help provide more contextual data. One of the key attributes of a syndemic approach is to focus on unique persons using non-identifiable unique identifiers (IDs) that preserve privacy and confidentiality but allows for the monitoring of events in persons over time. This does allow monitoring of multiple concurrent or subsequent infections or care-seeking at the person level. This also allows for integration of this information with additional health services information, such as screenings or preventive services that people receive in the context of sexual health care visits. Information may be used locally to match persons across multiple disease registries to determine the cooccurrence of chronic conditions, such as HIV and viral hepatitis allowing for the building of a more syndemic focused portrait of patient populations and communities to become an even more powerful tool. Coupling this information with patient-reported behavioral data, gives valuable insight into what interventions might be most efficacious in lowering the community burden of STIs. Also, combine these data with rich contextual information about specific geographic and community settings provides greater insight into the sexual health in the very communities where people live, where they seek care, and where they live, learn, and more importantly, where they love.

Dr. Stenger shared the overall framework for enhanced surveillance and showcased how it provides the public health community with evidence to support locally developed disease prevention intervention programs, and provided insight into possible upstream determinants of

sexual health which helps in monitoring important changes with health equity implications, and the uptake of important biomedical advances with an eye toward assuring more equitable access. In 2005, his division founded the STD Surveillance Network (SsuN), which addresses these enhanced surveillance methods. The SsuN is in the fourth funding cycle supporting 11 jurisdictions with at least two funded sites in each U.S. Census region, covering about a third of the U.S. population. The local collaborators implement two complementary surveillance strategies, the first of which collects health record data for all patients presenting for care in one or more STD clinics, regardless of whether they are diagnosed with an STD. This system provides the extract patient demographics, all lab-based screenings, or point of care tests, all diagnoses received, and all treatments prescribed or administered. It also allows for the monitoring of referrals to preventive services such as PrEP in those settings. The second strategy is an enhanced surveillance investigation based on a representative sample that reported STD cases, regardless of where the case was diagnosed, or what provider setting the individual was seen. Enhanced investigations include provider record reviews and patient interviews with the same focus on complete demographics, laboratory information, treatments and some behavioral risk and preventive services. A key activity across both of these components of SsuN is a frequent match with the jurisdictions' HIV registry—or EHRs—to better understand HIV prevalence among reported STD cases, and among persons presenting for care in STD clinical settings.

The collection of information on the gender of sex partners, using case-based surveillance data, enables reliable estimates of the proportion of reported cases. Gonorrhea in this example, in gay, bisexual, and other men who have sex with men, men who have sex exclusively with women, and among women to describe significant geographic variations. These data also provide numerators that can be used to estimate reported case incidence rates revealing significant inequalities in the burden of disease among gay, bisexual, and other MSM in the participating jurisdictions. These data points are used to model the overall national rate of reported gonorrhea cases among gay, bisexual, and other men who have sex with men over time to help reveal important trends. In 2019–2020 we experienced a pandemic decrease in the number of reported cases, but we appear to be increasing again in trajectory over time in MSM. We are also able to estimate the proportion of reported gonorrhea cases that are treated with recommended treatment regimens[21]. This is an important data point given that Neisseria gonorrhea is quite good at developing resistance to multiple antimicrobials over time. In the STD clinical settings, there is monitoring of what proportion of patients who are gay, bisexual, other men who have sex with men, men who have sex exclusively with women, and women presenting for care who are diagnosed with preventable STI's by age group and in this case, chlamydia. These are similar to data for gonorrhea; in that, the proportion of reported chlamydia cases among gay, bisexual, and other men who have sex with men who are not living with diagnosed HIV disease and to estimate the proportion on PrEP by age and race important in assessing equitable access to PrEP. HIV status is also important among persons presenting for care in STD clinical settings, and we are able to detect differences in STD diagnoses among patients in the clinic by HIV status; using the case-based enhanced investigation data, estimates of the proportion of all cases among gay, bisexual, other men or have sex with men who had sex exclusively with women, and women who are living with HIV disease. Perhaps most importantly, the system can estimate the proportion of patients who report current PrEP use, here stratified by the same group. And from behavioral interviews, we can estimate the proportion of those diagnosed and reported with gonorrhea who report knowing the HIV status of their most recent sex partner. Finally, there are more generalized ecologic analyses that are being explored to combine data from multiple sources at the county level to explore some of the possible determinants of STIs and the relationship between the uptake of biomedical

[21] Stenger M, Pathela P, Anschuetz G, et al. Increases in the rate of Neisseria gonorrhoeae among gay, bisexual and other men who have sex with men (MSM)— findings from the STD Surveillance Network 2010–2015. Sex Transm Dis. 2017;44(7):393–397.

interventions such as PrEP or Post-Exposure Doxycycline (DoxyPEP), at the county level. One of the early preliminary findings was that it appeared that STI among gay, bisexual, and other MSM, either moderating or decreasing over time. This preliminary analysis indicates that there was no correlation with PrEP use—the proportion of patients that are eligible that are on PEP—at the county level, and either increasing or decreasing trajectories of STIs.

Dr. Stenger mentioned that the data limitations included that it was not nationally representative. In that, enhanced, syndemic and holistic surveillance activities are not currently nationally representative – additional resources would permit expansion to more states in future cycles. Previous case-based enhanced surveillance efforts have only focused on diagnosed and reported gonorrhea cases from all providers, and to a census of patients receiving care in STD clinics. Expansion of these activities to include a sample of syphilis cases and data collection in other sexual and reproductive health provider settings is planned, as additional resources become available. In summary, he stated that a sexual health framework for surveillance should take the committee beyond disease outcomes to include additional information on the health of our communities. The STD Surveillance Network is a good example of how the committee might supplement routine case reporting to better understand the health of our communities.

## Leveraging the Power of Communications to Improve Sexual Health

**Susan Gilbert, MPA**
Co-Director for the National Coalition for Sexual Health
Altarum

Ms. Gilbert opened the discussion by making the case that well-designed communications can move the needle with sexual health in the country. She also made the case that effective communication is much more than just putting together a factsheet, issuing a press release, or sharing the latest data. There Is an art and science to effective health communications. The art (i.e., messaging) must rest on a solid foundation of research. This research must be guided by a practical behavior change model (NIMH conference). A recent WHO statement makes a compelling case for behavioral science and research. She stated that the three key variables influence behavior: 1) intention to perform the behavior, 2) skills to perform the behavior, and 3) a supportive environment that includes access to health services and products, access to sex education/information, and positive societal norms free of stigma and discrimination.

Understanding and engaging with audience(s) is essential to well-designed communications. Ms. Gilbert described the key elements of audience research. First, understanding the audience's attitudes, skill levels, knowledge, behaviors, and environmental factors. Second, exploring the barriers to and benefits of performing the behavior. Lastly, it is important to understand the context and the culture for various populations. For example, what matters in their everyday lives? Who do they look up to? What are their core values? Then, it is important to determine if the primary barriers to behavior change relate to attitudes/beliefs, limited skills, lack of knowledge, environmental factors, or a combination of factors. Through this research, we can then pinpoint the primary factor(s) influencing behaviors and address them through relevant messaging that appeals to the audience. Then, we will create measurable communications objectives to drive a campaign.

Ms. Gilbert shared a practical example of effective health communications from the National Coalition for Sexual Health: a national study of young adults, sexual health communications, and relationships funded by the CDC, which explored the National Coalition for Sexual Health's:

relationship and communication experiences, perceived benefits of and barriers to open communication, comfort level talking openly, topics they would like to discuss more openly, skills and information that would help them do so, and the best channels and messengers. The study consisted of 16 focus groups with 79 young adults and an online survey of 1,256 young adults, ages 18-26 years old. The findings showed significant anxiety and fear around open communication and the five top barriers to open communication; in fact, 53% reported a great deal or fair amount of anxiety. The top three barriers to open communication include not wanting to hurt a partner's feelings, not knowing how or when to bring up topics, and low self-esteem or lack of confidence. Understanding the perceived benefits of open communication is essential to creating motivational messaging. In this case, young adults cited benefits including increased feelings of safety and trust, a closer bond with partners, and being on the same page about their relationship. While many young adults care about improving their sexual health, protecting your sexual health ranked much lower on the list of leading benefits, suggesting that messaging should lead with the benefits they care about the most and then integrate sexual health into the content.

Ms. Gilbert identified that there is a need to fill the void for youth, young adults, and parents. Most young adults said they do not have access to comprehensive, accurate sex ed and relationship education and that they lacked positive role models. Nearly all focus group participants said parents were negative role models and that they wanted to do/be the opposite of their parents. This is no surprise since most parents also lacked relationship and sex education as they were growing up.

Based on the research results, communications objectives for a young adult campaign were developed relating to skills, attitudes, and knowledge. For skills, the objectives are to build skills to communicate effectively, build positive relationships, reduce anxiety/fear in having conversations, and increase self-esteem. For attitudes, the objectives are to create beliefs that open communication that will not always disrupt the relationship and can lead to benefits, establish it is "good/cool" to be the person who starts the conversation or talks openly, and demonstrate that communication matters—even in non-serious/short-term relationships. Finally, for increasing knowledge, the objectives are to increase knowledge about how to prepare in advance for conversations and raise topics, what is a healthy relationship, how to discuss trauma, and safer sex and sexual health.

To move the needle forward, health communication needs to be systematic and creative to attract the audience and make an impact. We need to establish measurable communications objectives and measure progress regularly and adjust as needed. It is important to engage creative talent to persuade audience(s) to act, change attitudes, and shift culture. Also, it's important to note that the culture shift is mainly driven by cultural influencers, not institutions. As a result, campaigns should engage and partner with influencers, e.g., social media influencers, entertainment media, and others. Cultural influencers can meet audiences where they are, change attitudes, role-model behaviors, reduce stigma, and drive them to a campaign/resource. Also, tools and activities should be selected based on communications objectives. For young adults, interactive tools are key for skills-building, such as role-playing scenarios, scripts, zines, quizzes, mini-comics, videos, and short-form text. Tone also matters in messaging, and young adults say top-down directives and commands won't work. Instead, it's best to feature peers, friends, and likable health care providers (HCPs)/therapists. To attract their attention, messages should tie into the benefits that matter to them and address their everyday realities and challenges. Finally, developing and pretesting all messages with the intended audiences is essential to help ensure they are appealing, clear, relevant, and motivational. Message and materials development should not be an untested, solitary activity (at your desk) – meaningful audience engagement is key throughout the process.

## Panel 1 Q&A with Speakers and Member Discussion

To focus the discussion, Dr. Anderson 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. How would CHAC recommend proceeding with an operationalized holistic approach to prevention that emphasizes wellness and advances sexual health?
    - What models are feasible?
    - How can we ensure they are equitably implemented?
    - Which specific interventions should be recommended/implemented to address the STI epidemic?

*The following questions, observations, and suggestions were raised:*

- Dr. Stewart questioned Dr. Cohen regarding resistance and the overuse of antibiotics. Ms. Stewart also raised a question about whether the study Dr. Cohen referenced on the use of doxycycline took into consideration the two types of doxycycline, the monohydrate and the hydrate, the latter being much more expensive.

- Dr. Cohen responded by highlighting the fact that the study referred to post-exposure prophylaxis, not PrEP. HIV PrEP is a daily pill taken consistently regardless of sexual activity, but DoxyPEP is titrated to sexual exposure, so it is only taken after a sexual encounter; this means that exposure to DoxyPEP is not necessarily daily. Thus far, studies of DoxyPEP have shown only moderate changes in tetracycline resistance, but these studies have relied solely on short-term data. It is important to note that, at this point, DoxyPEP is not recommended for use with the general population. It is, however, quite inexpensive, costing approximately a few cents per pill.

- Dr. Guilamo-Ramos raised the idea of whether it might be better to talk about collective benefits rather than talking about disparities or inequities. Would it be helpful to focus on the collective benefits of the financial and human components? Dr. Guilamo-Ramos also added that he loved the presentations on youth but cautioned the panel that families and parents matter when it comes to influencing the young people in their lives.

- Ms. Gilbert responded to Dr. Guilamo-Ramos comment by pointing out that while some children clearly have good parental role models, those in the study felt that they did not have positive parental role models; therefore, it may be a mistake to overly rely on parents to play the role of relationship educator.

- Dr. Mermin complimented Dr. Mena for being so thoughtful in assembling such a holistic panel and stressed his eagerness to continue such multifaceted collaborations. He then asked Dr. Coleman whether there have been extremely high-quality, structured studies or, ideally, randomized trials that look at a sexual health approach without merely focusing on the disease but also encompassing sexual health, pleasure, relationship quality, and the like. If not, this might be something to think about. Dr. Mermin then remarked that Ms. Gilbert had done an excellent job in presenting an overview of the importance of all these factors on communication; however, he was interested in finding out whether the respondents might have responded differently if the questions had focused on what the respondents could do to

have more pleasurable sex, better relationships, or avoid disease.

- Ms. Gilbert said that they had focused on communication because it is so closely tied to talking about any issue, whether it is safe sex, STIs, or pleasure.

- Dr. Coleman noted that in the reviews that he had referenced, randomized control studies, including those he had conducted at the University of Minnesota, had demonstrated the efficacy of the sexual health approach. More randomized control studies are needed, yet there have also been other studies that were not randomized but had shown positive results.

- Mr. Driffin remarked that Black and brown people are underrepresented in randomized clinical trials and that it was critical to stratify the SsuN platform for race and ethnicity to focus on the populations who most need interventions for disease prevention and quality care. He directed his next comments to Ms. Gilbert, saying that while it is important to hear what youths are saying, not seeing them reflected in the pictures is a bit of a disconnect.

- Ms. Gilbert elaborated on the sample of young adults, commenting that the sample was diverse by gender identity, sexual orientation, race, ethnicity, and education. The survey oversampled certain key population groups. Further, in terms of the cultural context, the messengers, and the channels, we will be very thoughtful about the best ways to reach various segments of the young adult population. Cross-tabbing the data by various factors will be performed as well.

- Dr. Coleman added that it is also important to look at populations in critical need and was encouraged that the CDC is looking at policy and realizing that the entire climate needs to be changed. This is a big task, but in the meantime, the most concerted efforts need to be devoted to those most in need.

## Panel 2: Equitable Scale-Up of New Interventions

***Moderator: Kirk D. Henny, PhD, MA, Associate Director, Office of Health Equity, DHP***

### Improving PrEP Impact and Equity: What We Need to Do

**Douglas Krakower, MD**
Division of Infectious Diseases
Beth Israel Deaconess Medical Center and Research Scientist
The Fenway Institute, Department of Population Medicine
Harvard Medical School

Dr. Krakower began his presentation by identifying the important factors associated with improving PrEP impact and equity. The first factor is generating trust and demand for PrEP among priority populations. Next, train and engage more healthcare providers to prescribe PrEP. The final factor is to take down all the barriers to make PrEP as easy to access and use as possible. The CDC published the lifetime risk of an HIV diagnosis among men who have sex with men[22].

[22] Hess et al., Annals Epi 2017; Harris et al., MMWR 2019; Centers f or Disease Control and Prev ention. Monitoring selected national HIV prev ention and care objectiv es by using HIV surv eillance data— United States and 6 dependent areas, 2019. HIV Surv eillance Supplemental Report 2021;26.

The findings showed it is disproportionately high among certain racial ethnic subgroups including African American MSM and Hispanic MSM. The PrEP coverage was far lower in the priority populations with the highest risk of HIV acquisition with only 8% of people who identify as Black MSM having access to PrEP, 14% for Hispanic populations. Other populations such as young people and cisgender women, PrEP coverage was extremely low. Limited information was available on the coverage for transgender people or people who inject drugs (PWID) or have other substance use disorders; nonetheless, the inequities are stark and striking and need to be addressed. In terms of the major barriers to PrEP use and equity, data was presented on both the consumer and the provider. On the consumer side, there was low awareness of PrEP with a stigma against HIV, and also PrEP itself. People showed concerns about insurance coverage and the cost of PrEP, in general, and in terms of out-of-pocket costs. People were concerned about the side effects in terms of the toxicity of these medications. People were not trained to accurately assess their own risk of HIV acquisition, therefore not understanding if PrEP would benefit them as individuals. People may not want to bring this up with their healthcare providers due to being worried about being judged, which several research studies revealed may be a realistic concern. For people who are incarcerated, there is much concern as they reenter the communities. Even though PrEP may be beneficial, it may not be at the top of their list. The intensive monitoring that occurs when people use PrEP in terms of quarterly visits can be a lot for people who have jobs and lives.

On the healthcare provider side of the major barriers to PrEP use and equity, the data showed a clear lack of training about sexual health care in general and PrEP. There appeared to be a purview paradox, where a lot of providers in primary care thought PrEP was a task that specialists should engage in, while specialists thought it was a primary care provider's duty. Neither took responsibility for it; thus, it has been slow to scale up for this reason. The data revealed only 6% of providers initiated PrEP discussions with patients; 94% of PrEP discussions were initiated by patients[23]. There are lots of competing demands and a busy healthcare environment with preventive care across the board, so PrEP is just one more thing on the long list of things to-do. The workforce limitations of nurses and physicians in terms of prescribers' time, made it hard to get any additional personnel and visit time to talk about PrEP. Dr. Krakower encouraged the increase in engagement healthcare providers more broadly across diverse specialties to include sexual health clinics, addiction medicine, psychiatry, OBGYN, pediatric and pharmacists and criminal justice settings as well as community-based organizations (CBOs) and telemedicine to name a few. Engaging providers at all stages of training was also encouraged.

The USPSTF cited the need to study the impact of prediction models for PrEP[24]. These instruments would accurately predict risk of incident for HIV infection to help inform decisions regarding eligibility for PrEP. These models would use electronic medical records to automatically assign people an estimated risk of future HIV acquisition based on electronic health histories. This would help frontline clinicians prioritize their valuable time in terms of who they introduce discussions for PrEP, in addition to trying to reach the aspirational goal of universal discussions with sexually active people. Dr. Krakower and Dr. Julia Marcus, also of Harvard Medical School, have developed an EMR based prediction model that were cited in the USPSTF guidelines, that has moderate to high discrimination, which is the accuracy of their prediction of who does or does not want to have an HIV diagnosis, and the USPSTF appropriately says studies are needed to verify the accuracy and most importantly, the impact of these types of algorithms using EMR data

[23] Humphries et al, International AIDS Conference, 2022; Skolnik et al., J Gen Intern Med 2020; Zhang et al., JAIDS 2018; Blumenthal et al., AIDS Behav 2015; Hoffman et al., JIPAC 2016; Maloney et al., LGBT Health 2017; Calabrese et al., JIAS 2018; Calabrese et al., AIDS Behav 2014; Hull et al., JAIDS 2021; Wilson et al., Health Comm 2021

[24] Pre-Exposure Prophylaxis for the Prevention of HIV Infection: A Systematic Review for the U.S. Preventive Services Task Force (2022 Draft)

in real world settings. The impact piece is important because we need to know if it actually helps providers prescribe PrEP more frequently and appropriately.

As part of the NIH funded study, researchers are using these prediction models as part of clinical decision support tool for frontline clinicians in the Oregon Community Health Information Network (OCHIN), which supports a network of Safety Net Community Health Centers all around the country. Dr. Krakower shared screenshots of the types of tools that can be used and built into Electronic Medical Records (EMRs). It showed a prompt that appears when someone is flagged for PrEP discussion. There were examples of scripts that providers who may not feel comfortable introducing PrEP can use which are designed to be non-judgmental and patient centered. This innovation helps to prepare clinicians who may not do this all the time to have non-stigmatizing discussions to patients about PrEP; thus, expand clinical decisions about PrEP beyond traditional heuristics.

The implementation of national PrEP programs could reduce the financial and access barriers to PrEP. Such programs could expand access to the PrEP meds and labs for uninsured people, or people who have Medicaid, thus, allowing the federal government to negotiate fair public health prices for PrEP medications, to bring prices down and scale access to generic meds for the majority of users. This would create an expansive hub and network of community providers supported by telehealth so people can get PrEP from trusted local Community-Based Organizations (CBOs) and increase seamless access at pharmacies for consumers. The WHO also endorses simplified service delivery for PrEP.

Dr. Krakower's final thoughts expressed sentiments on how PrEP is underused, and inequities exist. More effective demand generation in partnership with communities is required. Engaging providers of many specialties at all stages of training, using innovative training and decision support tools would increase efficiency. It is vital to make PrEP easy to access and use by meeting people where they are and removing financial barriers. A national PrEP program would decrease costs and improve access. It is time to think more futuristically about over-the-counter options.

## Advancing Long-Acting Injectables for Underserved Populations

**Kathrine Meyers, DrPH, MS, MPP**
Assistant Professor of Bio-Behavioral Sciences
Aaron Diamond AIDS Research Center
Columbia University Vagelos College of Physicians and Surgeons

Dr. Meyers began her presentation by sharing several headlines covering news of injectable treatment and highlighted that, words like "game-changer" and "revolutionary" have been used to describe these injectables from the very beginning. She pointed out that sometimes these words are not statements and more recently they have been shown in news titles accompanied by question marks. She stated that the real question is whether these new pharmacological interventions can be implemented in ways that enhance equity and decrease disparities in health outcomes. Unfortunately, history tells that every pharmacological innovation in HIV has, in fact, exacerbated inequities. Dr. Meyer shared results from a Highly active antiretroviral therapy (HAART) study that documented innovations in HIV treatment led to disparities[25]. She also shared a Conference on Retroviruses and Opportunistic Infections (CROI) presentations that showcase oral PrEP increases disparities in HIV. Sharing the sentiments of Dr. LaRon Nelson at CROI, Dr. Meyer presented a new science of impact, a revolution, that is a combination of interventions to

[25] HIV/AIDS mortality among Blacks and Whites during the pre-, peri-, and post-HAART periods: US, 1987–2005

address challenges (i.e., structural, social, and behavioral). The interventions would be tested together as a package and are intended to be synergistic. Dr. Meyers shared the current landscape of injectable PrEP. A snapshot of September 2022 prescriptions showcased 0.5% of prescriptions were for injectable PrEP (not quite a year after FDA approved injectable PrEP). In an eight-month period from January to August 2022, fewer than 2,000 people filled Cabotegravir Long-Acting (CAB-LA) prescriptions. Of those who got their first dose, 16% did not return for a second dose, which is pretty concerning.

Dr. Meyers reflected on two projects she is involved in through recent HRSA SPNS funding. First is BluPrint which helps clinics create and strengthen HIV prevention programs by synthesizing key research findings, best practices, and implementation resources that promote equity-driven delivery of next generation PrEP products. The other is the Accelerating Implementation of Multilevel-strategies to Advance Long Acting Injectables Project (ALAI UP), which help clinics across the United States develop injectable HIV treatment programs by providing ongoing technical assistance with the goal of addressing inequity in health outcomes. The range of clinic types includes: 8 AIDS services organizations, 5 hospitals, 8 academic medical centers, 6 Federally qualified health centers, 3 departments of health, and 8 primary care doctors. Dr. Meyers shared an implementation science framework called the consolidated framework for implementation research (CFIR)[26] and the three main barriers these clinics faced which included: 1) insurance-related issues, 2) procurement, and 3) narrow label. Potential solutions were: simplification through national program and funding, lower drug costs, add long-acting injectable antiretroviral (LAI ARV) to all state's ADAP formularies, ensure every ADAP pharmacy has unrestricted access, advocate for commercial insurers to cover, advocate for insurers to cover as pharmacy benefit, support accreditation of specialty pharmacies in neighborhoods where clinics that prioritize the underserved are located, increase flexibility in Department of Health and Mental Hygiene (DOHMH) procurement rules, centrally-funded pharmacy liaisons to support clinics that don't have within-system specialty pharmacies, and extending the label. It is important to consider the Framework for Real World Evidence Program to evaluate the potential use of real-world evidence to help support the approval of a new indication for a drug already approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act. These potential options involve randomized controlled trial, single arm prospective observational cohort, and registry of LAI ARV users.

## La Bodega: A Co-Localized Approach to HCV Elimination

**Anthony Martinez, MD, AAHIVS, FAASLD**
Associate Professor of Medicine
University at Buffalo and Medical Director Hepatology
Erie County Medical Center

Dr. Martinez shared the U.S. National HCV elimination plan highlights of the White House that proposed a plan to eliminate hepatitis C in five years in the United States through mandatory authorization which include: supporting the development of point-of-care diagnostic tests to enable a test-to-treat model; broadening access to curative hepatitis C medication, primarily through a national subscription model; and, extending infrastructure needed to reach, test, and treat all affected individuals. This is roughly a $12 billion plan, 8 billion of which will be allocated to drug acquisition. To make this plan work, the net spent would only be about $5 billion. The

[26] The Consolidated Framework for Implementation Research (CFIR) 2.0. Adapted from "The updated Consolidated Framework for Implementation Research based on user feedback," by Damschroder, L.J., Reardon, C.M., Widerquist, M.A.O. et al., 2022, Implementation Sci 17, 75. Image copyright 2022 by The Center for Implementation. https://thecenterforimplementation.com/toolbox/cfir

reason is because it would be a net savings of roughly $7 billion, but to hit that net savings, there would have to be over 300,000 people per year over the next five years under treatment. An effective program would require simplified care delivery. Simplified care delivery enables simplified testing, diagnosis and treatment, non-specialist providers to manage HCV, decentralized care in the community, and increased rates of screening, linkage and Tx starts.

Any elimination plan, especially around hep C, must involve four key pillars: screening, linkage to care, treatment initiation, and harm reduction. Harm reduction really is synonymous with reinfection prevention. There are a lot of different tools in each of these pillars and each approach depends on the target population being served. Dr. Martinez recommended a mix-and-match approach that hones in on the settings, services, and providers. He also mentioned the clinical models to improve linkages to HCV/addiction care and treatment uptake by way of conventional referral, telemedicine, and colocalization.

Dr. Martinez showcased how his clinic, La Bodega, has taken all of the aforementioned elements and merged them into one model for elimination. The clinic is a level one trauma center within a hospital that has become a tailored hybrid of overlapping services. Through its 20-year history, the clinic's screening paradigm includes partnerships with over 40 local pre-hub sites. These partnerships require minimal monitoring and no on TX labs which leads to sustained virologic response (SVR). La Bodega uses a triage system. The first is full support required – meds delivered to clinic or held at clinic; frequent check-ins and reminders via phone, text, social media, The second is an intermediate support – meds delivered to the patient; Bodega staff tracks refills, deliveries; less frequent check in. The last is the minimal support required— script written, next visit would be in 5-6 months. The key success factors of the model are that it meets the patients and the providers where they are. La Bodega outcomes included People Who Use Drugs (PWUD) had high rates of SVR (94%), high rates of adherence (91%) to HCV treatment, low rates of reinfection (2/1000 PY = 1.4%). Adherence and SVR rates were similar with 8- and 12-week therapies; 8000 visits annually, 80% show rate and 85% rate of retention in care, 100% uptake in Opioid Agonist Treatment (OAT) initiation.

Dr. Martinez concluded with the following summary. Efforts at elimination must address 4 pillars: screening, linkage to care, treatment initiation and harm reduction (reinfection prevention). The goal is to hit 100% in each step of the cascade and to minimize reinfection. HCV Ribonucleic Acid (RNA) POC approval is not enough— need plans for deployment, resource allocation, reimbursement. Evaluation is still needed for underlying liver disease. Screening can be improved by elimination of stand-alone antibody testing; use of mandatory reflex testing; provider incentives/disincentives; changes to reimbursement (removal of bundled billing). One size will not fit all for Linkage Treatment/therapy (Tx) initiation; mix and match approach. Widespread access to harm reduction measures is essential.

## Equitable Scale-up of New Interventions: Opportunities for Doxycycline as PEP Implementation

**Laura Hinkle Bachmann, MD, MPH, FIDSA, FACP**
Chief Medical Officer, DSTDP

Dr. Bachmann shared the similarity and differences of doxyPEP roll-out to HIV PrEP roll-out. The similarities were populations, overlap in provider population prescribing intervention, concerns among providers and consumers related to potential harms, i.e., antimicrobial resistance (AMR), that could impede implementation, infrastructure to provide continuity care needed, and can be

offered in context of a comprehensive sexual health approach. The differences were doxycycline is well established antimicrobial with long history of use for multiple purposes, doxycycline relatively inexpensive, safety labs not needed or at least not as frequently, and medication administration dependent on sexual behavior (i.e., not necessarily daily).

Dr. Bachmann identified barriers at the individual level which include lack of awareness on how to disseminate information to populations that would benefit most; psychosocial issues such as stigma, non-disclosure of sexual orientation/same-sex behavior to providers; medical mistrust of health care system, providers, public health officials, pharmaceutical industry, and perceived racism; concern about side effects—AMR; and, barriers related to access which may be structural (e.g., clinic location, hours available) and financial (e.g., co-pay/out-of-pocket costs). The solutions at the individual level noted were increase knowledge/awareness of intervention and engage community to advise in developing materials about doxycycline as PEP, dissemination strategy; explore non-traditional settings for doxycycline as PEP implementation; work with communities to identify "safe" spaces for sexual health care; leave determination of appropriateness of doxycycline as PEP to providers (i.e., don't try to force disclosure of sexual behavior if patient not comfortable); examine ways to understand and address/reduce medical mistrust; provide balanced counseling of benefits/risks; implement evening and weekend hours when possible; explore mobile clinics, telehealth; and, employ peer navigators.

The provider level barriers included lack of knowledge about doxycycline as PEP intervention, culturally competent care, bias, focus on "high-risk" persons, concern about unintended consequences of doxycycline as PEP, stigma, lack of comfort with sexual history taking, and stereotyping. The solutions at the provider level were provide balanced training on doxycycline as PEP intervention – what is known, what is unknown, flip the conversation from one about "high-risk" behaviors to one about sexual health concerns and sexual health goals = sexual health promotion, train providers to ask all patients about sexual orientation and care, routinize sexual health and make sexual health approach standard of care, and involvement of consumers in development of provider training materials. The systems level barriers identified were lack of clinics fluent in culturally competent care, need for clinical spaces appealing to MSM who are not openly gay or bisexual, anti-gay policies, and lack of Medicaid expansion. The solutions at the system level were to expand numbers of clinics providing culturally competent sexual health services, support creative approaches to sexual health care delivery, broaden conceptual framework of space as a modifiable driver of intersectional stigma, and educate the public and policy makers.

Dr. Bachmann concluded by sharing application of lessons learned from HIV PrEP implementation to doxycycline as PEP roll-out: community engagement that identify leaders and influencers to help develop outreach strategy and content; provider outreach through National Network of STD Clinical Prevention Training Centers, AIDS Education and Training Centers, Sexual Health Coalition, professional medical organizations, medical and other health professions schools, other partners—National Coalition of STD Directors (NCSD), National Association of County and City Health Officials (NACCHO), NASTAD, etc.,—establish health equity measures prior to intervention roll-out, and provide technical assistance to jurisdictions to enhance monitoring of equitable roll-out at local level.

## Panel 2 Q&A with Speakers and Member Discussion

To focus the discussion, Dr. Gayles 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. How should CDC/HRSA anticipate equity issues when developing and implementing interventions?
2. How does CDC/HRSA equitably incorporate new interventions and lessons learned in both regular function and emergency response activities?
3. How can CDC/HRSA amplify messaging on successful policies that promote health equity?
4. How can CDC/HRSA leverage EHE to further equitable access of new interventions?

*The following questions, observations, and suggestions were raised:*

- Dr. Dowler asked Dr. Krakower about the concerns of drug resistance when it comes to the idea of over-the-counter PrEP. She also questioned Dr. Martinez regarding the length of funding for La Bodega.

- Dr. Krakower responded that the concerns for over-the-counter (OTC) PrEP would be the same as for a clinic-based model. Some of the data on oral contraceptives, including some studies at the border of Texas in Mexico, indicate that people are actually just as adherent, if not slightly more so, when it comes to over-the-counter access. Further research, however, needs to be undertaken, but the actual biomedical nonadherence that could lead to resistance would probably be about the same if you have the same types of use patterns. Ideally, there should always be some sort of clinic access, particularly for certain populations. Although nothing is perfect, virtually all people can access very effective antiretroviral treatments, especially nowadays with the existence of potent ART regimens. The goal is to provide many more people access to PrEP.

- Dr. Martinez, in responding to who the benefactor of La Bodega was, replied that it was New York State Medicaid, with all visits being billable. The clinics that Dr. Martinez built in New York City, Las Vegas, and San Diego were all built on sustainable revenue because grants end and then so, too, does the funding. When downstream revenue to an institution is analyzed—and this includes lab tests, imaging, and studies—each item may not reap a huge profit, but the revenue adds up. Very little funding was derived through New York's 340b, which has now ended anyway. For every version of a clinic that was established throughout approximately 30 states, revenue cycles were examined. It is not difficult to order labs, identify illnesses, or prescribe medication, but it is difficult to keep the doors of clinics open; this is made easier by using sustainable revenue.

- Dr. Dowler asked whether the clinic was subsidized or totally financially solvent.

- Dr. Martinez replied that it was solvent and does even better than orthopedics.

- Mr. Driffin thanked Dr. Krakower for his presentation, particularly the intentionality in showing Black and brown people using proper treatment as prevention. Nonverbal cues to community matter. Additionally, listing Howard University in the presentation is important in highlighting specific pipeline programs and finding people where they are. Regarding equity, equity means something different to each neighborhood. For example, the staff interacting on a one-on-one basis with participants may have a very different view of equity from that of principal investigators or the speakers on the panel. It is important to be mindful of that. Finally, it is equally important to be mindful of language. In destigmatizing HIV, whether referring to those

living with HIV or those vulnerable to HIV, it is critical to not use the term “target populations” because Black and brown people who are represented in various slides throughout the program are targets every day of their lives. The use of the word “priority” may be a better choice than “infected” since words help move everyone toward justice and liberation.

- Dr. Armstrong thanked Dr. Krakower for his presentation. She then pointed out how important it is to ensure that people become much more comfortable in prescribing PrEP and how this needs to infiltrate into student, resident, fellow, and APP curricula so that it is tested on the boards and becomes another aspect of primary care. It needs to be demedicalized and no longer seen as specialty care. In addition, Dr. Armstrong, who is at one of the clinics featured on the panel regarding injectable LAI, remarked that their clinic is serving far fewer than 25% of the patients who would like to be on long-acting injectables. One of the reasons for this is the enormous cost associated with developing high-quality retention programs and the staffing required to pull out nurses, pharmacists, and other needed aspects of such a program. Thus, cash-strapped clinics face the risk of greater disparities, which is why other clinics with greater resources are able to provide much more long-acting injectable therapy. When a clinic has over 1,000 patients who would like therapy, scale becomes a problem. Regarding inequities, although the data suggest that injectable PrEP for Cabo is better than Truvada or Descovy, cost is clearly an issue. There are many excellent programs that have been proposed to provide PrEP to everyone, but because of the cost of injectables, they are looking at oral therapy, leaving many without access to injectable PrEP programs. The question becomes, how do we bring benefits without inequity?

- Dr. Mermin thanked Dr. Armstrong for her cogent point, adding that the U.S. Preventive Services Task Force has already drafted new guidance as of December, which will hopefully soon be confirmed, that will include all essentially proven PrEP regimes, including Cabotegravir, into their pedigree recommendation. This means that PrEP should be available to almost everyone in the country at no cost, including no copayments. Further, the Ready, Set, PrEP program should accommodate those who are uninsured. This is quite different from the hepatitis C program, which guarantees neither treatment nor insurance. Assuming the preventive service mandate continues, would the various proposals advocating for a generic Truvada purchased by the federal government (which would be very costly but from a different part of the government than from Medicaid or private insurance) result in a situation in which poor people, those of color, or those on Medicaid receive a lesser standard of care with this generic drug? This may result in those with private insurance, for example, having greater access to treatment if they prefer Cabotegravir. Moreover, what does a national PrEP program really look like? What are the ideal components that would be most efficient and effective and decrease disparities from the beginning? What are the estimates regarding the proportion of people eligible for PrEP who want Cabotegravir? Clearly, having to go to the clinic every two months is far more strenuous than receiving a prescription and taking a test, so perhaps the desire for the treatments might balance out, much like oral contraceptives versus an intrauterine device (IUD), for example.

- Dr. Deal thanked everyone for their work with hepatitis C. She agreed wholeheartedly that standalone antibody testing for hepatitis C was creating unnecessary gaps in the cascade. Work has been conducted with commercial labs, with three of the five largest labs having already eliminated standalone testing, one in the process, and one about to make the move from this procedure. Commercial testing, however, only represents 35% of the labs, so the NIH is updating the operational strategies to remove the two-visit requirement. Although the tools to support viral first testing are not yet in place, once FDA-down classifications come into play, they can be leveraged, technology can be implemented, and the window (two-and-

a-half month zero conversion window) can be narrowed. Dr. Deal also asked whether the pregnancies mentioned earlier were being reported to the registry.

- Dr. Martinez confirmed that the pregnancies mentioned earlier were being reported to the registry.

- Dr. Deal wondered how rapid test and treat without access to the RNA point-of-care test was faring.

- Dr. Martinez replied that in many places, most patients have an RNA. Approximately 80% of the patients he sees have had an RNA within four to six weeks, allowing initial treatment and medication to be easily implemented. Unfortunately, in some of the areas, such as rural areas and those in Appalachia, most need point-of-care tests, and may only be able to obtain them through grants, which are not self-sustaining. Point-of-care tests could potentially be utilized more efficiently for SVR analysis. Often, it is difficult to get patients to get a lab draw, but if they were able to test at home without having to mail anything in, this might be helpful although that may not solve the problem at this point. Bundled point-of-care tests encompass RNA platelets, albumin, and total bili, which are important in ensuring that those individuals who haven't yet been treated or need ongoing hepatocellular carcinoma (HCC) surveillance don't fall through the cracks. If a particular cartridge provided a full workup in 15 minutes, which some companies are looking at now, that would be true point of care. Relying solely on viral load tests can enable people to get started on treatment or identify those who need additional labs, but the issue then becomes how many tests will need to be performed.

- Dr. Deal asked what proportion of Dr. Martinez's clients are "red light" in regard to long-acting injectables for DAAs.

- Dr. Martinez answered that with the opioid crisis with fentanyl and xylazine, more patients, probably about 50%, are progressing into red light territory. Medications need to be parceled out little by little because of the different populations receiving treatment even from five years ago.

- Dr. Guilamo-Ramos praised the presentations thus far, especially lauding the innovation. To that end, regarding Dr. Armstrong's comments about schools that are accredited by national organizations, Dr. Guilamo-Ramos noted that that would be the ideal way to ensure that students are being educated about the various issues brought up during the committee meeting. In addition, as a nurse practitioner, he has noticed that one of the major barriers to accomplishing many health goals is not leveraging the workforce to its utmost on a national level despite the four million nurses out there. Although there are regulatory barriers at the state level, ideally, an army of healthcare professionals from all states and territories could be trained, develop competencies, and receive a license to practice for their particular area. Finally, there has been a great deal written about medical mistrust, particularly as it pertains to African Americans. Perhaps investing in trustworthiness while attempting to understand medical mistrust would be beneficial.

- Mr. Driffin commented that the panel has the opportunity to create the positioning for meaningful choice and changing the lives of those who have experienced racism or mistreatment. Going from, perhaps, 365 pills a day for 15 years to being able to receive a shot every two months or so is life-altering. In the Atlanta Emergency Management Agency (EMA), 19,000 people are out of care, but if this is an option for even a third of that population,

discussions about ending HIV in this country may commence. Thus, it is critical that a mechanism be created for individuals to decide on the best course of treatment for themselves.

## Public Comment Period

**Andrea Weddle**
Executive Director
HIV Medicine Association

Good afternoon. My name is Andrea Weddle and I'm the Executive Director of the HIV Medicine Association (HIVMA). Thank you for the opportunity to offer public comments today. HIVMA is part of the Infectious Diseases Society of America for those who may not be familiar with us, and we provide a home for healthcare professionals who provide HIV services on the frontlines in communities across the U.S. Today I'm excited to provide an update on a new loan repayment program for Infectious Disease (ID) and HIV healthcare professionals, as well as share innovations to advance innovative service delivery for people not currently in care. Starting with the loan repayment, we wanted to ensure that the committee was aware that Congress established the biopreparedness workforce pilot program in enacting the Prevent Pandemics Act at the end of 2022. Once funded, the program will offer loan repayment to the ID and HIV healthcare professionals who are providing ID and HIV services in underserved communities and certain federally funded facilities including Ryan White funded clinics, importantly. The Infectious Disease Society, HIVMA, as well as more than 140 other organizations are advocating with Congress to appropriate $50 million to implement the program next year, for fiscal year 2024. Once funded we really look forward to working with HRSA to support implementation of the program as we think it could help move the needle on attracting more healthcare professionals to ID and HIV. Turning to innovative service delivery. We appreciate and support the HIV/AIDS Bureau's focus on reaching people currently not in care. This has been a focus for HIVMA recently as well. Earlier this year, we released a call to action with policy recommendations to accelerate implementation of two models that we think hold a lot of promise. One is street medicine and the other is differentiated service delivery, which I know was talked about earlier this morning as well. The brief includes detailed policy recommendations that really came out of a series of forums that HIVMA hosted with leaders in the field, but for street medicine as well as differentiated service delivery (DSD), and people experiences, our federal partners, other clinicians and HIV and public health advocates. We appreciate the opportunity to meet recently with CDC and HRSA HUD leaders to discuss the recommendations in the brief, and just wanted to take this opportunity to share some additional recommendations with the committee while you're meeting today as—while I haven't been here for the full meeting—it certainly seems like a topic that has come up. Starting with CDC. A top priority is to allow additional flexibility and ID funding opportunities, or NOFOs, to address syndemics. I'll just give an example from one of our forums where a street medicine promoter shared that when he has an encounter with a client, he really needs to be able to provide the full package of services that they need. Whether it's a vaccination for hep A, providing syringe services, as well as PrEP—being able to do that all-in-one encounter, and ideally all under one funding stream. For HRSA and CDC to identify and disseminate specific examples of how Ryan White programs and grantees can use braided funding to support a syndemic approach. And for our providers. They're excited about some of the initiatives that have been talked about and can be supported with braided funding, but they really need specific and concrete examples of what that looks like, and particularly in different types of settings. Ideally in a way that reduces rather than increases administrative burden. For HAB, to fund SPNS initiatives, or an initiative, to really evaluate the implementation of street medicine and DSD

programs with a focus on key components, including quality metrics, as well as evaluating the effectiveness and improving health outcomes for populations marginalized or left out of traditional healthcare systems. Finally, for HAB—and I know this is hard without new authorities—but to look for ways to allow additional flexibilities to non-EHE jurisdictions around service categories to make it easier to support DSD, street medicine, and other innovative models, which Dr. Cheever, you highlighted this this morning, and has been really helpful in EHE in really maximizing the use of those funds. I also want to really thank you for raising the issue this morning—Dr. Cheever shared the work they're doing to support paid opportunities for the inclusion of people with lived experience and that certainly was highlighted as a key component of success for street medicine, as well as DSD. I would really encourage you to continue and to elevate the importance of that, as well as the work that you're doing. With that, I will stop and thank the committee, and our federal partners, and thank you for the opportunity to comment.

**Terri Wilder**
HIV/Aging Policy Advocate
SAGE

Hello, my name is Terri Wilder. I'm the HIV Agent/Policy Advocate at SAGE, the world's largest and oldest organization dedicated to improving the lives of LGBTQ+ elders, including older adults with HIV. I'd like to discuss a crucial need regarding the CDC's HIV testing guidance. Specifically, the CDC should remove the upper recommended age limit for HIV testing. The current U.S. Centers for Disease Control and Prevention Guidelines say that screening for HIV should be performed routinely for all patients aged 13 to 64 years. However, our goal at SAGE is to have the upper age limit remove so that all people aged 13 years and older are included. Despite the fact that many older adults, and their providers, do not think that older people are at risk for HIV, approximately 17% of new HIV diagnoses in the United States in 2020 occurred among people aged 50 years and older. Failure to engage adults of all ages in HIV testing undercuts test and treat strategies of prevention and ending the AIDS epidemic goals. While the CDC has not recommended routine HIV testing for adults over the age of 64, some experts argue that HIV testing should be a routine part of health care for all adults, regardless of age. In 2016, New York State passed public health law 2781-A, which will move the upper age limit for recommended HIV testing. The New York State public health law mandates the offer of HIV testing to all patients aged 13 or older. The 2016 amendment to the New York State public health, remove the previous upper age limit of 64. The offer of HIV testing is most effective when it's presented as a clinical recommendation of the health care provider. The offer of HIV testing must be documented in the patient medical record. SAGE would like to see the change, like New York state made, be the CDC guidance. We've met with CDC staff and look forward to hearing back about next steps. In addition to removing the HIV testing age limit, we must take additional measures to advance all HIV prevention services among older adults. The CDC and its sister agencies should dedicate resources to developing and evaluating HIV prevention campaigns and interventions that target older people aged 50 and older. These campaigns should also encourage the use of PrEP and PEP among older women and men as well as a harm reduction services. The CDC, with the support of the HIV community and older adults, should develop and disseminate HIV testing, prevention, PrEP/PEP social messaging, and marketing campaigns to older adults who are most vulnerable to HIV. In conclusion, we respectfully ask that this be implemented. Thank you for your time and consideration.

## Business Session - Part 1

### Adoption of November 2021 CHAC Minutes

**Jean Anderson, MD**
CHAC Co-Chair, HRSA Appointee

Dr. Anderson indicated that members had been provided with a copy of the November 2022 CHAC minutes for review. No errors or omissions were identified, no questions or concerns were raised, and no edits were suggested.

### CHAC Action

Mr. Driffin made a motion to approve the November 2022 CHAC minutes, which Dr. Armstrong seconded. CHAC members unanimously approved the minutes with no changes or further discussion.

*The following questions, observations, and suggestions were raised:*

- Dr. So raised that no data was presented for Asian Americans in Dr. Laura Cheever's HRSA update and noted that even though the numbers may be small, presenting data for minority populations at the national meetings is meaningful.
- Dr. Cheever heard Dr. So's concern and said she would pull up data reports to show changes over time relating to disparities by race and ethnicity, specifically for Asian Americans.
- Dr. Greene questioned why an upper age limit of 64 years old exists for HIV testing despite the risk that remains for people in this age group. She pointed out that testing for hep B and hep C for all adults was discussed and asked CHAC members to be mindful of the 64+ populations' risk for HIV/AIDS as well.
- Dr. Gayles pointed out, in response to Dr. Ethier's DASH update, that STI prevention can go hand in hand with mental health services. He wondered how intertwined efforts to address mental health issues in young people were with the STI conversation, as increased mental health concerns could perhaps lead to increased risk-taking behaviors, predisposing folks to increased STIs. He was curious if interventions to address this intersection had been proposed.
- Dr. Dowler brought up the continued need to be intentional about overcoming historical inequities in regards to how CDC and HRSA approach access to testing, vaccines, and new interventions. She emphasized how even with considerable effort in the COVID-19 response, the urban, White population in North Carolina received access to testing and vaccine first. She noted the complexity of working across counties and states with vastly differing politics, policies, and public health funding models.
- Dr. Anderson agreed with the importance of Dr. Shannon Dowler's comment, and wondered how CDC and HRSA, as national organizations, could best advise models of care, demonstration projects, and best practices for individual locations, given the importance of local level considerations.
- Mr. Driffin added to the concern of overcoming inequity, suggesting it may look like requesting projects or initiatives that prioritize racial and ethnic minority populations. He also lifted up the importance of taking intentional steps towards inclusionary processes such as panelists on HIV panels reflecting the populations diagnosed with and dying of HIV across the country.

- Dr. Guilamo-Ramos agreed with Dr. Dowler's suggestion about the need for disproportional investments moving forward in order to overcome historical inequity. He added that our society would benefit from messaging around the collective benefit—suggesting evidence showing that when we target the least fortunate, everyone benefits. He urged the group to consider Dr. Jonathan Mermin's question for Dr. Eli Coleman regarding whether evidence exists from interventions around framing sexual health relative to a more than just disease. Dr. Guilamo-Ramos also considered how CHAC could translate conceptual images of equity into practical action. He encouraged CHAC to continue to find new ways to frame the conversation.

- Dr. Dionne stated that in public health there is a tension between doing something for everyone vs targeting a population. We think about cost effective public health. How do we make a system that is fair and equitable and cost saving while targeting populations?

- Dr. Guilamo-Ramos mentioned that he was not saying care for everyone. He thinks there is literature of exemplars of things that work from a policy perspective with strategic investments on a focused universal approach.

- Dr. Gayles brought up the headwinds that agencies are facing at the state and local levels when providing services for those who need them, be it for LGBT youth or persons living with HIV. He urged CHAC to consider what will be the mechanism to address similar blockers as we move forward to ensure that the folks who need services aren't without them.

- Dr. Anderson agreed that state politics affect the issues discussed throughout the day. She also noticed that the foundation of many conversations around HIV and STIs seems to be shifting in a positive direction—more focus on a holistic, interconnected, syndemic approach—compared to previous siloed thinking. She commented that CHAC can take their learnings there and apply them to the frames of the collective good and equity and come up with some action items for CDC and HRSA to move it forward. She urged CHAC members to think of recommendations that might be flexible enough to accommodate the different political situations on the ground, framing them more positively and for the good also of people not affected by HIV or other infectious disease. She noted this as a major task.

- Dr. So broached the idea of CDC working with labs to develop an STI panel to standardize what currently seems fragmented and make comprehensive testing simpler for primary care doctors.

- Dr. Dowler commented how recommendations are often nuanced, depending on the type of sex people are having, with whom, and how often. Standardized STI panels could end up spending a lot of unnecessary health dollars, testing people for things they are not at risk for.

- Dr. So responded that universal testing is easier to implement, and that targeted testing can be a huge burden for clinicians to factor in all risk factors in the decision for testing. He also commented that targeting by risk profile can be stigmatizing.

- Ms. Parkinson agreed with Dr. Samuel So and shared her story of not fitting the risk profile. She agreed that universal care and prioritized standards and protocols could help providers manage care better for populations most at risk.

- Dr. Gayles provided a slightly opposite opinion based on experience in a clinic that drew labs before you saw a provider, but eventually flipped to waiting for a provider to recommend specific tests to save on additional trips to the lab. He did concur that standardized labs make it easier to routinize testing, and that there are strategies—often with technological

assistance—to more efficiently focus testing based on set criteria and make billing and coding easier.

- Dr. So replied that he thinks universal testing is feasible based on recent experience with CDC's recommendation for hep B testing, a test previously resisted at Stanford but now prioritized. He noted that the patient testing process can be simple, with the doctor not necessarily seeing what test is called for and integrating coding for reimbursement and electronic medical records.

- Dr. Greene linked Dr. Anderson's point about needing to be flexible in implementation with the mix-and-match approach of La Bodega that Dr. Anthony Martinez mentioned during his Panel 2 presentation (La Bodega: A Co-Localized Approach to HCV Elimination) and encouraged CHAC members to keep that approach in mind. She also brought up exposing medical students across all disciplines to experiences that destigmatize addiction and issues surrounding STIs to change the mindset of future generations of the workforce. Finally, Dr. Greene raised the concern about COVID-19 emergency support ending. She shared that her patients already struggle navigating Medicare and Medicaid reenrollment and open enrollment every year, and now her patients are also struggling to cover basic needs due to the ending federal emergency funding. Dr. Greene wondered if there's something to do to ease this transition for patients.

- Dr. Dowler pointed out that not only do "easy buttons" work, so do metrics. She noted that often healthcare providers are motivated by performance against metrics next to their colleagues, but that very few of the quality national guidelines coming through are related to STIs. She suggested that payers start incorporating more measures and metrics around sexual health into value-based payment to incentivize ordering the tests and doing work differently. She posed the questions of how to destigmatize at the level of payers and how to put more pressure on to have quality metrics around sexual health.

- Mr. Driffin affirmed Dr. Greene's comment and connected it with the question of how CDC/HRSA can leverage EHE to further equitable access of new interventions. He suggested lifting these conversations up at the Ryan White conference in 2024, or the United States Conference on HIV/AIDS (USCHA) and having specific days to leverage and highlight community discussion around what EHE has done for communities. He also praised seeing clear cut examples of specific projects to help generate other innovations across the platforms.

- Dr. Dionne likened public health's responses to running to a fire, not quite putting it out, and then taking off to another fire. She posed the question of what is being done that is significant in regard to achieving health equity or reducing disparities. She exhorted CHAC to break the cycle, take lessons learned, and focus on work that is significant.

- Dr. Anderson drew the discussion to a close. She affirmed that the comments have helped stratify the core issues and that there would be opportunities to outline specific action items and recommendations to move forward on day two.

- Dr. Cheever pulled up the slide that Dr. So had requested relating to changes in disparities over time by race and ethnicity. She noted continued disparities and brought up work with IHS to improve data sharing with HRSA, to pull from the data and see what can be done differently with African American, American Indian, and Alaskan Native populations, in particular. She said that for people that identify as Asian American, there are better viral suppression rates, as there also are for Hispanics and Whites.

## Recap of Day 1

**Travis Gayles, MD, PhD**
CHAC Co-Chair, CDC Appointee

**Jean Anderson, MD**
CHAC Co-Chair, HRSA Appointee

Drs. Anderson and Gayles observed that it had been a tremendous day with a lot of information. Due to time constraints a Recap of Day 1 was not provided.

## Recess

Dr. Cheever officially adjourned the meeting for April 18, 2023, and CHAC stood in recess until 9:00 a.m. ET on April 19, 2023.

## Day 2: Welcome and Roll Call

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

The proceedings were called to order at 9:00 a.m. ET. 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 8 of this document. He confirmed that 20 members were in attendance, which established quorum for the CHAC to conduct its business on April 19, 2023.

## Recap of Day 1 and Outline of Objectives, Process for Day 2

**Travis Gayles, MD, PhD**
CHAC Co-Chair, CDC Appointee

**Jean Anderson, MD**
CHAC Co-Chair, HRSA Appointee

Dr. Gayles provided high-level highlights from the previous day. He mentioned the growing impact of mental health concerns in young people, and how that continues to worsen. He pointed out STI statistics with considerations for the insights provided for congenital syphilis. Different strategies for promoting innovation, enhancing, and promoting equity across the board in all intervention areas and the associated solutions to the different issues were identified. Dr. Gayles shared the topics for the days ongoing conversation on young people risk-taking behavior and sexual health. He provided an overview of a case study type presentation around monkeypox, what happened in the pandemic and what continues to happen, and CHAC approach to the response. He stated the sessions on lessons learned will showcase present and future impact. He concluded with the reminder that the continued discussions and conversations are not in a neutral environment when it comes to funding and politics. It is important to be mindful and thoughtful of how CHAC continues to construct solutions and provide positive, sustainable impact to the patients and communities being served.

Dr. Anderson reflected on the overarching representation of CHAC's movement towards the collective good. She emphasized the holistic approach and the role of overlapping the idea of syndemic in conjunction with increasing recognition by both CDC and HRSA of the importance of these concepts. One other take home mentioned was the need to incorporate more than randomized control trials (RCTs), but to incorporate implementation science, which she thinks both CDC and HRSA are doing. She articulated the need for recognizing there is no one size fits all solution and that more guidance to help clinicians and public health officials figure out best models are required.

## Special Presentation: What New Data Is Saying About Youth and STD Testing

***Moderator: Catherine Rasberry, PhD, Chief, Research Application and Evaluation Branch, DASH***

## What 2021 YRBS Data is Saying About Youth And STD Testing

**Catherine Rasberry, PhD *(on behalf of Dr. Kathleen Ethier)***
Chief, Research Application and Evaluation Branch
Division of Adolescent and School Health
National Center for HIV, Viral Hepatitis, STD, and TB Prevention

Dr. Rasberry, on behalf of Dr. Eithier, provided sexual behavior trends of high school students. There were three trends that were in the right direction: ever had sex, had four or more lifetime sexual partners, and were currently sexually active. There were three trends that were in the wrong direction: used a condom during last sexual intercourse, were ever tested for HIV, and were tested for STDs during the past year. There were two trends that had no statistical significance due to a shift in the question during 2021: used effective hormonal birth control and used a condom and effective hormonal birth control (dual use). Generally, sexual risk behaviors and preventative behaviors have been decreasing over the past decade. The YRBS data tells the "what" but not the "how." Certainly, more work to understand the role that the pandemic played in access to services can potentially help the data make more sense.

Dr. Rasberry also presented YRBS data per sub-populations of youth in the U.S. for 2011 to 2021. There was a decline among all of the groups for "had sex with four or more partners during life. Asian students were less likely than other racial and ethnic groups to have ever had sex, to have had four or more lifetime sexual partners, and to be currently sexually active. For condom use, decreases in the proportion of Black, Hispanic, and multiracial students who used a condom the last time they had sexual intercourse. The proportion of White students and Asian students who reported using a condom at last sex did not change. White and multiracial students were more likely than Black and Hispanic students to use effective hormonal birth control. Source: National Youth Risk Behavior Survey, 2021. Female students were more likely than male students to be tested for STDs. Black, Hispanic, and multiracial students were more likely than Asian and White students to be tested for STDs. In terms of sexual identity, LGBTQ+ youth were more likely than heterosexual youth to report STD testing, but there was not a significant difference based on sexual contact. For Native Hawaiian or Pacific Islander youth, the cell size and statistical significance were too small; thus, not included in the data summary or trends report.

## Trends In STI Testing Among Adolescents and Young Adults

**Thomas Gift, PhD**
Chief, Clinical
Economic and Health Services Research Branch
DSTDP

Dr. Gift present data from the National Survey of Family Growth. This is a national probability sample of non-institutionalized persons in the US, aged fifteen to forty-four. It runs in two-year cycles, September one year to September two years in the future. Participants are asked if they had chlamydia, gonorrhea, syphilis, or HIV testing in the last twelve months; they provide their current health insurance, contraceptive use, and asked if sexually active, at least one partner in the prior twelve months. Trends were examined in self-reported STI testing among sexually active 15 to 24-year-old females in the NSFG. The most recent data are from 2017 through 2019. The data was shown for the 15 to 19-year-olds and 20 to 24-year-olds separately, and together.

Trends in STI testing among sexually active 15 to 24-year-old females showed a recent decline among women aged 15-19. Trends in STI testing among sexually active 15 to 24-year-old males revealed a small decline among males aged 15-19. Trends in STI testing among sexually active 15 to 24-year-old females showed recent decline among non-Hispanic black and smaller decline among other/multiracial. Trends in STI testing among sexually active 15 to 24-year-old females: current insurance type showed recent declines among uninsured and those on government plan; contraceptive use at last sex decline among both groups. HEDIS chlamydia screening rates, commercial and Medicaid plans, 2011-2021, revealed screening rates among sexually-active females were largely flat through 2019, then declined.

In closing, Dr. Gift shared the following, NSFG 2-year cycles were not designed to examine data by multiple factors. There was a data collection paused between contracts until 2022. Consideration should be given to recent issues that could impact STI testing. There was increased use of telehealth, consent, and confidentiality of STI testing. The potential reasons for decline in STD testing among adolescents who received contraceptive service was due to telehealth. In that, the use of telehealth for contraceptive services increased during the COVID-19 pandemic[27]. As for confidentiality in adolescent concerns and STD testing, one in five of 15 to 17-year-olds would not seek sexual and reproductive health care because of concerns that their parents might find out[28]. Among 15 to 25-year-olds, males who were on their parent's insurance had lower STD testing and are more likely to avoid care overall because of confidentiality concerns. Non-Hispanic White adolescents more likely to avoid STI testing than other adolescents[29]. Females aged 18-25 who were on their parent's insurance plan were less likely to receive CT testing than self-insured women aged 18-25. There are state laws governing confidentiality. Among states that have addressed confidentiality, the most common rule is to allow clinicians to exercise discretion over which information they disclose to guardians. For states without laws, there is a Health Insurance Portability and Accountability Act of 1996 (HIPPA) default that allows clinicians to exercise discretion over disclosures "to the extent allowed by law" when minors consent independently to care.

## Special Presentation Q&A with Speakers and Member Discussion

To focus the discussion, Dr. Anderson 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 does CHAC recommend for increasing access to and provisions for reproductive health services, including STD testing, for young people?
2. How does CDC/HRSA address challenges to young people using reproductive health services in the wake of the COVID-19 pandemic?

*The following questions, observations, and suggestions were raised:*

- Dr. Markham thanked the previous speakers for their presentation and then introduced herself

[27] Zapata LB, et al. Prev Med 2021; 150:106664
[28] Leichliter JS, Copen C, Dittus PJ. Confidentiality Issues and Use of Sexually Transmitted Disease Services Among Sexually Experienced Persons Aged 15–25 Years — United States, 2013–2015. MMWR Morb Mortal Wkly Rep 2017;66:237–241. DOI: http://dx.doi.org/10.15585/mmwr.mm6609a1external icon
[29] Cuffe KM, Newton-Levinson A, Gift TL, McFarlane M, Leichliter JS. Sexually Transmitted Infection Testing Among Adolescents and Young Adults in the United States. J Adolesc Health. 2016 May;58(5):512-9. doi: 10.1016/j.jadohealth.2016.01.002. Epub 2016 Mar 15. PMID: 26987687.

as Chris Markham from University of Texas Health (UT Health) in Texas. She also praised Dr. Rasberry for including American Indians, Alaska Natives, Native Hawaiians, and Pacific Islanders in her data pertaining to YRBS, saying that it highlighted the importance of non-clinical home testing, remote testing, and self-testing for HIV and STI for youth. In those remote and rural areas of American Indian and Alaskan Native youths, the work that Johns Hopkins has been doing with I Want the Kit (IWTK) clearly demonstrates that young people are availing themselves of this program, its confidentiality, and its linkage to services. A program such as this should be brought to scale.

- Dr. Rasberry mentioned that they are trying to do an even better job in representing a wide variety of sub-populations of youth in their data although this is sometimes curtailed by size issues that do not allow for significant findings. One of the things that DASH is thinking about a great deal is how schools play a role in connecting youths to services; because schools have such a wide variety of young people available, they provide an excellent opportunity to expand services as do community sources.

- Dr. Dionne thanked the panel for the excellent presentations. She then introduced herself as Jodie Dionne from the University of Alabama at Birmingham and stated that she was interested in regional questions. She wondered if there were any findings in the data regarding the southern region or other regions of the US.

- Dr. Rasberry replied that she was unable to speak to regional issues since the data was part of a national sample. Once the full data from YRBS are released at the end of the month, there will be some state data available, which is a critical component of any set of data.

- Dr. Gift responded that the HEDIS data are available at the state level although it must be remembered that the numbers include whoever wishes to be included, so it may not be representative although a further analysis could be conducted. Something like that is in the works but not yet available for dissemination.

- Dr. Leichliter added that NSFG incorporates U.S. Census region variables into its restricted access data; however, in order to present it publicly, it must go through a proposal process, which is why it was not included in the day's presentation. This can be further looked into.

- Mr. Rodriguez commented that the lack of condom use particularly caught his attention. At his center, they found that while older adults began using PrEP, they were often not using condoms. Although this is obviously a matter of choice, it was important that they understood that PrEP protected against HIV but not STDs, which is why condoms are relevant. Due to the pandemic, many kids who might ordinarily have obtained condoms in school were unable to do so since they were not at school. CBOs were also shut down, further limiting free condom access, which is a problem since condoms are expensive. Finally, eroticizing condoms for young adults is an issue worth exploring. For young adults, this can be a sex-positive message, but in today's woke culture, kids may see such a message as aggressive, so we need to combat this and ensure that condoms are made relevant for kids and young adults.

- Dr. Rasberry pointed out that although young people did lose access to a number of school services during the pandemic, there is no hard data to support the idea that schools were not still providing students with condoms. The data present some interesting findings with the raw numbers of sexually active youth at 54% in 2019, pre-pandemic, and 52% post-pandemic. This was not a big difference compared to the numbers for ever having sex, which dropped

from 38% to 30%, but it does raise the question of how much access students lost and how the pandemic played a role. Some schools are more sex-positive than others, so condom use may vary greatly depending on the context.

- Dr. Leichliter confirmed that the findings that YRBS had for condom use were also found in NSFG, with the largest decline being found in young males. In clinics, condoms are usually represented as a way to prevent STDs rather than a sex-positive approach.

- Dr. Mena stressed that as a culture, Americans need to accept sex as part of a normal, healthy lifestyle just like exercise and good nutrition. The definition of health should include approaches to prevent some of the negative consequences this activity can have. This includes, particularly for young adults and adolescents, providing age-appropriate information about sexual health, STIs, and pregnancy and the available tools, such as contraception and condoms, to minimize those consequences.

- Dr. Mermin brought up two questions. He noticed that for the data on hormonal contraception with LGBTQ students and same-sex sexual partners, there was an extremely high proportion using hormonal contraception, and not just for those who might be bisexual. He wondered if that could be explained. In addition, regarding the huge reduction in the proportion of students having sex and, with that, a reduction in condom use for those having sex, he questioned whether they were the same people; in essence, since there has been a nearly 50% reduction in the proportion of students having sex, perhaps those having sex are likely to be greater risk-takers and are not using condoms.

- Dr. Rasberry answered that with respect to hormonal contraception, the data on the slide presented information on those who had an opposite-sex partner in regard to the use of hormonal birth control. Again, the large difference in the percentage of youths who had ever had sex dropped from 38% in 2019 to 30% in 2021, and the role the pandemic played in that brings up many questions. Many students were isolated and away from their usual social networks in real life, and that could contribute to the findings. Thus, the challenge for YRBS is that the data provides the what but not the why.

- Dr. Deal mentioned that any additional information provided by subgroups, as Dr. Dionne suggested, would be helpful.

- Dr. Gift thought that chlamydia testing is asked about separately for females but the other testing is together.

- Dr. Leichliter added that in NSFG, for males, STD testing is a single question, and in parentheses, it will include chlamydia, gonorrhea, syphilis, and herpes.

- Dr. Deal wondered whether since provider viewpoints vary regarding what constitutes an STI testing panel and the prevalence of those infections varies among geographic regions in the US, there was a way to determine where those different tests were being ordered. That sort of data may provide insight into controlling those infections because gonorrhea and chlamydia affect very different populations than syphilis does, for example.

- Dr. Gift responded that although this had not been done previously, he would use administrative claims data to look into this, specifically in regard to the state and also the three-digit zip code.

- Dr. Morne commented that in thinking broadly about sexual health, it is important to balance disease prevention messaging with positive sexual health messaging. In the US, people often struggle to discuss sex and sexuality. TV commercials, for example, focus on sex prevention messages, and yet, if the focus is also on sexual health, that information needs to be presented as well. As Dr. Guilamo-Ramos pointed out, the family can be a safe space; however, for those who do not have such a safe space, where is this safe space where young people can gain access to information? Schools cannot be this consistently safe space due to the varying rules from state to state. Even progressive New York does not have the level of sexual health education that would be ideal. Therefore, there is still a great deal of work to be done in assisting young people in gaining access to this information.

- Dr. Gayles reminded the panel that in the previous day's data from DASH, it was found that young people are facing many mental health concerns. Young women saw increased rates of physical violence or were exposed to physical violence. He asked how that was being looked at in terms of potential solutions to address both the increased violence as well as the sexual health issue.

- Dr. Rasberry mentioned that one of the great things about the program approach supported in DASH is that it provides evidence of working across multiple areas of outcomes. This includes sexual health as well as violence-related outcomes, substance abuse, and the like. It is important that the approach DASH takes, which also consists of directly funding school districts, be as holistic as possible. So sexual health education requires more than just explaining how to put on a condom; talking about feelings in a relationship is equally as vital. Thus, health education can specifically address mental and sexual health, with the potential outcomes impacting each other synergistically.

- Dr. Guilamo-Ramos remarked that based on the reading of available literature on condom behavior across developed countries, the same pattern exists in those countries as well, particularly for boys. Another issue is what is happening in regard to hormonal contraception in states where Medicaid has not expanded or someone lacks insurance. Many of those in Latino communities will most likely be uninsured, and so data is presented showing that a certain population is less likely to use contraception. Finally, there seems to be a tendency to push aside "natural resources," meaning schools or families, which can be some of the best resources for young people. This in no way suggests that parents should be the ones to decide, and obviously in certain states, things are trending in that direction with parental permission required for sexual health education; however, there needs to be some balance between autonomy, confidentiality, access, and so forth, and providers, parents, or family members may help provide that balance in some situations.

- Dr. Rasberry added that DASH relies on data to help evaluate the effectiveness of the program approach used in schools and the districts it funds. One analysis looked at the level of variance accounted for in the outcomes—specifically, whether it is at the individual, school, or district level. The analysis found that for many health service-related outcomes such as contraception testing, there was a very large proportion of variance that was accounted for at the district level. This could be due to district policy, the available resources, the broader community, available health care providers, or whether CBOs exist to serve students there. It is therefore important to also think beyond the individual level when creating those environments that support good decision-making. In essence, if someone wants a condom but doesn't know how to easily find one, that's a problem.

- Dr. Dowler stated that although a comment was made that the decline in the number of youths with four or more partners over time was good news, this may not be the case at all. It is unlikely that young adults and teenagers have suddenly become monogamous; rather, it is likely a reflection of the anxiety and depression from which they are suffering. Thus, this data may actually reflect a negative situation.

- Dr. Rasberry commended Dr. Dowler for her point. Good news in one way may not always be good news in other ways.

- Mr. Lindsey added that perhaps the data presented was really just a blip and not necessarily a trend. It is possible that the pandemic discouraged sexual behavior and physical contact, so it may be equally possible that the data could tick back upward in the next assessment. Furthermore, although there have been downward trends in mpox and Covid, there have also been upticks in attacks on comprehensive science-based education in many conservative districts across the country. The resulting misinformation going to young people may encourage behaviors that are not science-based or medically accurate and may even exacerbate trends beyond what is currently being seen. Unfortunately, much of the aggressive behavior from a vocal, powerful minority is impacting access to accurate, scientifically based information, contributing to potentially negative trends in the future.

- Dr. Rasberry shared that as data is collected, it will be interesting to see if there is an uptick, and it will also be important to analyze data at the regional level to understand shifting outcomes when practices are or are not in place.

- Dr. So asked whether there was any data indicating the prevalence of kids using over-the-counter rapid tests for STIs.

- Dr. Gift acknowledged that OTC testing may become an issue in the future. For bacterial STIs, it is not at present. HIV is different, however.

- Dr. So commented that if a kid was aware that they could purchase chlamydia or gonorrhea rapid tests over the counter, they may buy one rather than inform their parents.

- Dr. Gift mentioned that in some areas, billboards advertised places where chlamydia and gonorrhea testing was available without a doctor's referral. Ultimately, if people have the ability to test on their own without a clinician's intervention, that would be a factor.

- Dr. Rasberry asked about the cost of those tests and theorized that even the cost of HIV tests may be beyond the reach of many students.

- Dr. So responded that Walgreens offered a pack of three tests for $68. Two may be cheaper.

- Dr. Anderson questioned Dr. Gift about the ability to stratify data regarding insurance. She also wondered about the type of reproductive health clinics in terms of how much testing is done. The changing political landscape in certain states and regions may affect the ability of some reproductive health clinics, such as Planned Parenthood, to remain open. While many girls go to such clinics for contraception, others go for confidential testing.

- Dr. Gift said that the place of testing in NSFG is not asked.

- Dr. Leichliter replied that the place of testing was asked originally but was then dropped to reduce the length of the survey. When the venue was asked about, family planning clinics, STD clinics, and so forth were among the options.

- Dr. Gift added that it is possible to look at administrative claims data to determine if people are receiving services; however, administrative claims data only appear if there is an administrative claim, the data will not come up if people are going to free family planning clinics.

- Mr. Lindsey commented that self-testing or self-collection is something that is not advertised or marketed enough. He wondered how much of the data is showing trends in STD testing that are based on the invasiveness of STD testing. In other words, it is possible that young people would be more willing to participate in STD testing if they knew they could go to a clinic and participate in self-collection as part of the process. It may be interesting to tease out self-testing from self-collection in STD testing.

- Dr. Gift replied that beyond the I Want the Kit test, which can be ordered, self-collected, and then mailed back, he did not believe data sources existed that formally assessed self-collection versus clinician-collected specimens.

- Dr. Morne asked if the response to the question related to same-sex individuals could be repeated.

- Dr. Rasberry clarified that that question related to hormonal birth control use in same-sex couples. The data referred to the percentage of youths who used effective hormonal birth control the last time they had sex with an opposite-sex partner. There are two groups: one group of students reported only having sexual contact with an opposite-sex partner, and the other group reported having any same-sex sexual contact. Theoretically, then, the group presented would be those who have had one or more same-sex partners but reported on their last sex with an opposite-sex partner.

- Dr. Markham commented that that reflects the fluidity of sexual identity and orientation for young people today and the high rates of teen pregnancy among youth who self-identify as gay, lesbian, or bisexual.

- Dr. Rasberry reminded everyone that most of the graphs and visuals from her presentation were available in the Data Summary and Trends Report, currently available on their website.

- Dr. Anderson thanked everyone for their wonderful presentations and important discussion.

## Co-Chair Brief: HHS LGBTQI+ Coordinating Committee

Dr. Gayles reported that the HHS LGBTQI+ letter was well-received, and that HHS and SAMHSA were enthusiastic about communicating what they're doing beyond legislative approaches. He highlighted a SAMHSA funding a center of excellence for LGBTQI+ health and mental health, and a TA support center for families funded through different sources.

Additionally, the Office of Adolescent Health, under the direction and directive of Admiral Levine, noted they've been looking at different ways to expand their programming related to this population. They expressed a shared concerned about the recent YRBS data, indicating the disturbing trends in terms of the impact of mental health, the impact of all the different policies in different states across the country, the impact on this population, and a shared sense of urgency around the need to work together in partnership to address these issues.

Dr. Gayles confirmed that CHAC members had a copy of the Secretary's letter and response that was sent and reiterated that this was another example of the impact of CHAC sending such letters.

## Business Session - Part 2

Dr. Gayles opened the floor up for an annotated business session discussion, inviting CHAC members to continue the discussion from day one, and adding in any additional feedback based upon the morning's presentation, as well of potential action items.

*The following questions, observations, and suggestions were raised:*

- Dr. Cheever mentioned that HRSA is reconvening the AIDS Education and Training Centers, the regional programs for 2024 competition. She noted HRSA will be drafting the notice of funding opportunities soon, so anyone interested in inputting guidance formally would need to do so soon.

- Dr. Anderson raised several potential recommendations, in draft language, to the group, and invited discussion.

    - CHAC recommends that the best practices compendium generated by HRSA be expanded and expedited to identify key variables that can be used to guide implementation in different settings based on available resources and needs.

    - CHAC recommends that treatment or prevention RFAs generated by CDC and HRSA include a requirement that grantees include a transition plan to include sustainability considerations and transfer of knowledge gained to the community and other relevant stakeholders.

- Dr. Dionne brought up the DASH presentation and the concerning data. This data is critical and must be collected in light of states pulling out.

- Dr. Greene broached making a recommendation about long-acting antiretrovirals, including possible language around DoxyPEP and other emerging tools.

  Dr. Dowler states it takes a long time for the government to make a statement to the public. Can we make an interim statement to guide people?

- Dr. Mermin responded that interim considerations are publicly available, and that CDC was rapidly moving forward on the formal guidance.

- Ms. Parkinson agreed with Dr. Greene, sharing how important education is at the local level. Based on her own research and now deciding to start an injectable soon, so recognized the

importance of equipping people with information to have robust conversations with their their clinicians about options for injectables.

- Dr. Anderson asked if CDC had conducted focus groups related to long-acting injectables or DoxyPEP, in order to understand what people do know. She wondered if there was research on their fears, etc. in preparing to move forward.

- Dr. Mermin confirmed that related to long-acting injectables, CDC has done groundbreaking research and advocated for the importance of making a healthy choice an easy choice, but was unsure on focus group engagements, and noted it was worth reflection.

- Dr. Mena said that in regard to DoxyPEP, it was also important to understand how the community can benefit the most from this intervention, how they think and what are their concerns. He shared that a recent consultation included representation from the community, including individuals that participate in the clinical trial who shared their experience. He affirmed the importance of doing everything possible to engage with the community to help message information about DoxyPEP.

- Dr. Anderson brought up, based on data about heard over the past two days, that she heard appetite to suggest some recommendation to encourage continued collection of relevant data. She said that language could be figured out but should include capturing sites of testing which may help stratify and identify out where some of the problems are. She asked if there were other specific recommendations regarding reproductive health services for youth related to the discussion.

- Dr. Gayles raised the connection between the mental health challenges that young people are facing and the challenges around sexual health, noting how they are integrated in some way. He suggested a recommendation to ensure that efforts to better understand trends in sexual health take a more syndemic approach and look at the impacts of the pandemic and mental health concerns on those sexual health trends. He noted that this could also be a great source of information for designing interventions to address the trends from a holistic perspective.

- Ms. Parkinson agreed with Dr. Gayles, and shared how through COVID-19 over the last three and a half years intimate partner of domestic violence has been on the rise in not just Black women, but trans women as well. She urged that trauma-informed care could be improved in terms of more innovative messaging, building safe places around school and clinic settings, and providing social workers and clinicians with a more robust protocol to deal with situations that arise, and using community health workers to intersect with the whole person going through a difficult situation. She noted that once a patient leaves the door they go back into that same situation, or a worse situation. She said she would like to see more listening sessions with youth ages 13-29, as well as older adults coming back on the scene after COVID, around relational, whole sex.

- Dr. Guilamo-Ramos raised several thoughts around young people. The first was regarding the compelling presentations on day one, and encouraged CHAC members to keep the focus on young people. The second was a note that, in the efforts to come up with innovative strategies to reach young people, there seemed to be a missing component around what makes young people different from a social and developmental perspective. He noted that at

various clinics he's worked at, particularly the adolescent AIDS program, they were very aligned with the needs of young people in a way that not all clinics are.

- Dr. Markham commented that listening sessions with youth are critical. We R native has done great work with youth, and we need youth voices at the table.

Dr. Gayles thanked CHAC members for their feedback and noted that the recommendations will be put into a working document to be discussed throughout the day.

## Panel 3: Mpox Lessons from Research and Implementation

***Moderator: Demetre Daskalakis, MD, MPH, White House National Mpox Response Deputy Coordinator***

### CDC Update on Mpox Response

**Leandro Mena, MD, MPH, FIDSA**
Director DSTDP

As of February 1, 2023, there has been 85,500 cases and 111 total deaths, globally; and, 30,123 cases and 28 total deaths, nationally. During this period, mpox cases by gender were 96% cisgender men, 3% cisgender women, and 1.6% transgender men, women, or other gender[30] and mpox cases for men who have sex with men (MSM) was 84.2%. Of the confirmed mpox cases, 41% were also HIV positive, 29% had a concurrent STI, and 55% had an STI in past year. Gay, bisexual, and other men who have sex with men are taking steps to protect themselves and their partners from mpox; 48% had a reduction in number of sex partners, 50% reduced one-time sexual encounters, and 50% reported reducing sex with partners met on dating apps or at sex venues[31].

The CDC is continuing efforts to inform the affected communities about mpox by providing guidance to health departments and healthcare providers on symptoms and how to manage illness and making timely updates to information on CDC's website, social media, and via press briefings. The CDC is also helping to get vaccines and treatments to health departments and clinics as well as supporting diagnostic testing. CDC works closely with state/local partners to raise awareness within the LGBTQ+ community and other affected communities by seeking feedback from public health partners and affected populations. CDC is also consulting with health officials in other countries.

CDC is working with partners to remove barriers to vaccination for populations that have been disproportionally affected by this outbreak. These populations include Black, Hispanic/Latino, Asian and Native American gay, bisexual and other MSM communities. Barriers may include language, stigma, location of vaccination sites, vaccine hesitancy and mistrust of government. Prior to mpox there was inadequate STI infrastructure that was compounded by a reduction in spending power by public health STD programs. Disparities are multi-factorial, multi-level and complicated by social determinants of health, including poverty, racism, stigma, unstable housing, and substance use.

[30] Thornhill 2022, N Engl J Med; Tarin-Vincente 2022, Lancet; UK HSA 2022, Monkeypox Technical Briefing #6, August 19, Source: Philpott 2022 MMWR
[31] American Men's Internet Survey, 2022 Monkeypox Supplemental Survey. https://emoryamis.org/

Ongoing collaboration with partners has resulted in $46 million awarded to jurisdictions via Public Health Crisis Response cooperative agreement. These awards covered activities including vaccination, community engagement, case and cluster investigation, data collection, and other mpox related activities.

Preparation greatly benefited the mpox response, but more work is needed. The mpox vaccine must have more data on safety, efficacy, and durability of immunity to be included in the national stockpile. There are many potential treatments available, but more data is needed on effectiveness. We have accurate diagnostics available, but still need point-of-care diagnostics. Long-term goals include ensconcing mpox vaccination in HIV, STI, PrEP clinics, and linkage with community-based organizations; normalizing mpox as part of STI services; continuing venue and event-based vaccine equity initiatives; and, continuing research on treatment, vaccine effectiveness and mode of administration, animal reservoirs and zoonotic risk, viral shedding and transmission dynamics, diagnostics, and surveillance.

## Mpox Lessons from a Publicly Funded STD Clinic

**Jason Beverley, NP**
STD and TB Control Division Chief
HIV, AIDS, Hepatitis, STD, and TB Administration

**Bruce "Bryce" W. Furness, MD, MPH**
CDC Medical Epidemiologist at the DC Health and Wellness Center

Clinicians Beverley and Furness discussed Mpox Lessons from a Publicly Funded STD Clinic. The DC Health and Wellness Center (DCHWC) offers a full suite of sexual health and TB services. The first case at DCHWC was June 6, 2022. Direct contact with the District of Columbia Public Health Laboratory Division (DCPHL) began May 25, 2022. Updated guidelines sent to DCHWC May 27, 2022. "Trial run" on May 27, 2022: samples submitted on mpox suspect, all were negative. In May/June, DCHWC was the only DC location to offer mpox testing and treatment. Initially, vaccinations at DCHWC were limited to PEP (close contacts of confirmed mpox cases). Total JYNNEOS doses at DCHWC was 546 doses to 317 discrete patients. 140 total samples submitted to DCPHL from DCHWC. First supply of tecovirimat arrived at DCHWC June 27, 2022. 77 courses of tecovirimat dispensed from DCHWC (65 were for DCHWC patients). Weekly calls with community-based providers began June 27, 2022.

Some of the mpox challenges included initial investigational new drug (IND) protocol requirements for tecovirimat were arduous: At least 6 separate required forms and requests for photos of lesions and blood pharmacokinetic (PK) sampling. The modified, simplified IND protocol requirements were released on July 25, 2022. Requisition forms for mpox testing—CDC/DCPHL. The criteria for use of tecovirimat had to evolve to include anogenital presentations. Some advantages of Department of Health (DOH) STD Clinic were the existing templates in EMR for detailed sexual history taking, comfort level among providers in obtaining detailed MSM sexual histories, existing panel of MSM patients for PrEP and HIV care, established, active relationship with DCPHL (including courier, monthly meetings for other projects), and easy interdepartmental collaboration with Epi/surveillance team with Center for Policy, Planning, and Evaluation (CPPE), Health Emergency Preparedness and Response Administration (HEPRA). The disadvantages of DOH STD clinic were staffing concerns—at the time, DCHWC had 5 FT providers, multiple PT providers; mpox diverted staff from other DCHWC patient needs (PrEP, basic STD

testing/treatment); some staff detailed to DC Health's overall mpox response; EMR not set up for controlled substance e-prescribing, DCHWC providers not accustomed to moderate-severe pain management; and lack of on-site mental health support. There was cross-departmental collaboration between DC Health's HIV/AIDS, Hepatitis, STD, and TB Administration and Division of Epidemiology—Disease Surveillance and Investigation.

## Integrating Mpox Vaccines in HIV/STI Programs

**Keshia Lynch**
HIV Program Director
One Community Health

Ms. Lynch provided insights on integrating mpox vaccines in HIV/STI programs. She shared how One Community Health provides medical care to 2,556 patients living with HIV in the greater Sacramento area. She offered strategies for the mpox vaccination process. In that, the first step of the process includes marketing of vaccine through patient facing website, in-clinic screens, clinician education and word of mouth. The second step is initial screening amongst front desk for symptomatic patients. Vaccine eligibility by clinicians utilizing dot phrase based on local Department of Public Health guidelines. The final step is nurse administers vaccine and schedules 2nd dose.

Ms. Lynch shared challenges included initial vaccine supply with restrictive eligibility criteria; medical mistrust and the need for transparent communication; adverse effects of COVID-19 vaccine and concerns over potential side effects; and, lack of visible mpox prevalence and difficulty in perceiving the risk of mpox. The opportunities were educating patients and communities, strengthening trust between healthcare system and patients, and leveraging success stories and testimonials. Key best practices identified were HIV/STI integration of one base-sexual heath services, nurse led efforts of those trusted in the community for efficient resource management, clinical wide training amongst all medical and non-medical personnel, and collaboration with local and federal partner to increase supply of mpox vaccine. She provided the following recommendations: collaborate with community organizations and stakeholders; develop targeted and culturally sensitive communication strategies; monitor and evaluate HIV/STI integration process; provide training and resources to clinicians and staff; and prioritize patient centered care and support.

## Centering Health Equity, Authentic Storytelling, and Community Power in the Mpox Response

**Justin C. Smith, MS, MPH**
Director of the Campaign to End AIDS
Positive Impact Health Centers

Mr. Smith shared strategies for how to center health equity in practice and examples of what it looks like. He noted that committees are not hard to reach, systems are hard to access. He provided key concepts for authentic storytelling among gay, bisexual and other MSM of color as a health equity practice during mpox; in that, authentic storytelling uses personal narratives that center and value the voices of those most impacted and engages them as a part of the solution with both upstream and downstream approaches. As a health equity strategy, activating authentic storytelling proactively engages and promotes the voices of gay, bisexual men (GBSM) community early on in such outbreak. It also recognizes and values the community's expertise to

enhance the public health solution. It creates opportunities for communities to develop their own health narratives, harness the power of new and emerging communication technology, and increases the awareness of implications of the political determinants of health.

## Panel 3 Q&A with Speakers and Member Discussion

To focus the discussion, Dr. Gayles 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. How can CDC/HRSA integrate lessons learned from mpox into programing and science?

*The following questions, observations, and suggestions were raised:*

- Dr. Mermin asked questions directed mainly to Ms. Lynch and Mr. Smith. He noted that despite having clinics previously established that served large populations of Latinx and African American populations, there was a relative reduction in the number of African Americans who were vaccinated for mpox as compared to those who were Latinx. This somewhat mirrored the national response to this epidemic. Dr. Mermin wondered what could be learned from this for future responses and what could be applied to HIV, STI, or hepatitis work.

- Ms. Lynch answered that going out into the communities rather than waiting for people to come to them for vaccinations is key. Partnering with grass-roots organizations, such as those that are Black-led or minority-led, that work with communities of color provides great opportunities to reach out.

- Mr. Smith added that this sort of work could not possibly happen quickly enough. He praised the contributions of the White House Mpox Equity Task Force, which provided a model at the federal level; however, bringing in the community at the onset is really the lesson learned because it improves public health and produces better outcomes.

- Dr. Daskalakis asked Dr. Beverley and Dr. Furness about what worked particularly well in their environments and what lessons were learned.

- Dr. Beverley responded that their emergency preparedness and response administration with its ability to establish several walk-in clinics capable of dosing hundreds of people per day was crucial. At last count, they had given out over 39,000 doses of the mpox vaccine. However, the same issue was present in regard to MSM of color, where, in the beginning, White MSM originally consumed most of their efforts. Again, reaching out to the community is incredibly helpful. Pop-up vaccination clinics at community-based organizations that see mostly MSM of color helped reach that population, but opportunities for improvement remain.

- Dr Furness added that what was most helpful in increasing mpox vaccinations among men of color in Washington, DC was when the PEP++ clinics switched from appointment only visits to all walk-in visits.

- Mr. Daskalakis echoed that the ease of access and time was very important in reaching more people.

- Mr. Rodriguez highlighted some of the incredible challenges that were faced in New York City. One challenge arose when his clinic first addressed the monkeypox issue. He received two calls from two of the clinics stating that they had plenty of vaccination spots but Latinx and Black men were not coming in. This brought up an immediate disparity because his clinic lacked vaccinations but, within 24 hours, was able to provide the other two clinics with approximately 150-people waiting lists. After that, the New York City DOH reacted to that and told them to bring in community-based organizations, which they did, in addition to helping the NYC DOH schedule people for vaccinations despite an outdated system using a Word document. Many mistakes were made due to the use of this outdated system in which people had appointments and were only sometimes able to get in. Excel sheets were used for the next two weeks, and after much pushing, they were given access to the portal. Unfortunately, even the portal broke down several times. About a month later, DOH called again to question why their clinic had not yet submitted a request for proposal (RFP) to apply for funding. Mr. Rodriguez replied that they did not have the time to submit for funding when they were already doing what needed to be done for free. By this time, as mentioned by several on the panel, many White gay men had been vaccinated; however, it was around this time that we were informed that due to a shortage of vaccines, the remaining doses would be divided into two. Of course, the country had been informed that two doses were required to be fully immune, and yet the local community in NYC had to be told that one vaccine was better than none. We later realized that many White gay men had manipulated the system to ensure they received second doses. Clearly, there were many issues with the response that impugned the CBO's credibility and hindered its ability to respond to everyone's needs. The lesson learned is that community-based organizations need to be brought to the same table as the clinics because the clinics cannot do the work alone. Clinics extended their hours and their reach, yet there was a lack of recognition for their efforts. In a tipping culture such as New York City, clinics could have been tipped for their work since they were the ones involving the community and putting forth extreme efforts to ensure that the greatest number of people were vaccinated.

- Mr. Daskalakis commented that Mr. Rodriguez brought up some very important points, including building and maintaining public health infrastructure and realizing that community-based organizations are a part of that infrastructure. In addition, the need to be flexible and trauma-informed in approaching service providers and public health is critical. He commended Mr. Rodriguez for all of his work in New York and the impact that it had on the national response as well.

- Mr. Lindsey complimented Mr. Rodriguez as well and yielded his time.

- Dr. So noticed that about one-third of the global burden of mpox is in the U.S. and wondered whether there were any lessons that the country could take from others in how they dealt with mpox.

- Mr. Daskalakis responded that there has been some important bi-directional communication with people who have been working with mpox internationally and that learning could be achieved in both directions. The idea of leveraging how President's Emergency Plan for AIDS Relief (PEPFAR) conducted business even without a great deal of vaccine but from a prevention standpoint is one model that the U.S. has adopted. Another area that is being pursued is vaccine donation although that has not happened yet due to the various regulatory and administrative complexities in other countries. Working with WHO in terms of their strategy and communications approach is also helpful. There is much to be learned

internationally because, as we are in a global environment these days, and success in the U.S. with mpox is hinged on international success with mpox.

- Dr. Mermin wondered why, despite strong connections with WHO and the CDC's emergency response, the U.S. fared much worse than other countries. He theorized that perhaps some of that is due to the public health infrastructure and environment, which is challenging and underfunded in the US, combined with the social determinants of health, economic disparities, and racism. Although the U.S. vaccination response resulted in vaccinating a much higher proportion of people who would be eligible anywhere else in the world, other countries did a fairly good job over time tackling their outbreaks through information, possibly due to communication and a more receptive background environment in those places.

- Dr. So wondered what lessons could be learned to be applied to the next potential epidemic.

- Mr. Daskalakis replied that looking at much of the work that happened in response to COVID-19 and HIV is important as the world shifts to a more global strategy for pandemic preparedness. Improving communication and identifying countermeasures are both areas that could be ameliorated. It has been challenging to move the vaccine because, for some countries, a vaccine supply is nonexistent.

- Dr. Guilamo-Ramos took notes on many of the topics and issues that he felt were important. These included such ideas as clear goals of equity and health equity, understanding problems elsewhere and not allowing those to continue in new contexts, authentic stories and the appropriate use of language, community-centered approaches, and mechanisms of delivery, such as Black Pride. He also noted partnership and clear roles, leveraging the workforce such that nurses led the initiative and delivered the vaccine, laser-focused data and geography, and medical epidemiologists who identify with the community and bring that to practice. Further, he recorded topics of novel approaches, mass vaccinations, leadership, and alignment of systems. Finally, he cautioned the panel that some truths can be difficult, but when the collective benefit is at stake, it is important to be careful when comparing groups.

- Mr. Daskalakis commented that Dr. Guilamo-Ramos just provided a great wrap-up.

- Dr. Armstrong praised Mr. Smith for his discussion on the response in Atlanta, the value of storytelling, and the many things that were done correctly. Unfortunately, in the very early days, there were many things not done correctly, including not having a plan in place ad having a finite number of vaccines available that were offered via the internet, which created somewhat of a dog-eat-dog mentality and favored those with rapid access to the internet. Again, the value of community and the vision of CBOs as trusted partners rang true.

- Dr. Armstrong said that, going forward, the goal should be to bring CBOs and clinics together, rather than have them compete. In that way, they could formulate a plan together to distribute vaccines, knowing that high-risk individuals or those at risk for worse outcomes need to be prioritized. All in all, they were able to vaccinate more than 1,000 people, all of whom received two doses. Further, it appears that different approaches work for different people, which can be seen in areas other than Covid, such as PrEP clinics, for example. It should be a priority for clinics, CBOs, and other parties in Atlanta to get together, knowing who the vulnerable populations and patients are, and design a plan before another pandemic occurs. In that way, the various entities could work in unison and coordinate a better response.

- Mr. Daskalakis echoed Dr. Armstrong's comments regarding response preparedness. When emergency responders were questioned as to how they were able to coordinate so well in response to the Boston Marathon bombing, they replied that because they had won so many sports championships, the coordination was already in place. So, continuing these relationships after an emergency is an excellent practice to continue.

- Ms. Parkinson mentioned that despite all the good that was done, women were forgotten, even when it came to HIV. Therefore, it is crucial to provide information to women, ensure that they can have dialogues with their clinicians, and feel at ease when receiving sexual health screenings. This would be especially important for young women who are 19, 20, and 21. In addition, more talking points in webinars for high school and college-age students would be helpful because sex is obviously happening in those places. Yet, there seems to have been limited discussions of sexual health, which should be prioritized.

- Dr. Furness noted that Washington, D.C. was one of the first program areas to open PrEP and PEP+ clinics and enable everyone to receive mpox vaccines regardless of gender or the gender of sexual partners. Because D.C. is a small city with numerous universities, having young, sexually active people return to the city at the end of the summer and be exposed to something that they had not previously been exposed to at home was a major concern. This echoes what Ms. Parkinson noted.

- Dr. Morne stressed the value of storytelling in driving home salient points. She wondered, however, why it seemed to be the case that for the 30 years she has been working in the health arena, everyone has continually been speaking about harnessing the power of community-based organizations, but yet, this has not been accomplished. What is it that still needs to be done in order to ensure that CBOs and community stakeholders are part of the conversation? Additionally, it is important to build awareness, education, and access to the mpox vaccine, a process that New York has just begun by issuing provider letters and initiating a campaign shortly before June. Unfortunately, the public seems to be tired of public health and disease prevention issues. Finally, Dr. Morne wondered at what point should clinicians be held responsible. Originally, HIV screenings, for example, were conducted by infectious disease doctors, and this practice was sanctioned; however, it was then decided that such screenings should be part of general care. This dynamic has complicated efforts, especially when clinicians need to continue to be updated on what they should be talking about and doing.

- Mr. Driffin remarked that there has to be some conversation regarding the mistreatment, undervaluing, and not listening to Black people impacted by various health outcomes. Community-based organizations, however, are always there, even after hours for these people; however, a CDC PhD, trained EIS responder went to an Atlanta hospital twice and was turned away and told that they did not have monkeypox. If no one listened to this credentialed EIS responder, it does not seem likely that the average person will be listened to. Being listened to is equity. Additionally, as a Southerner, Mr. Driffin wondered about the impact of high-speed internet and the ability to gain access to appointments and the like. Conversations that focus on the response on a community level are key.

- Mr. Smith affirmed that an article in *ProPublica* pointed out the failures of the public health system and how someone who writes MMWRs could not even get the care he needed. This is a very damning account of the health system and echoes Mr. Driffin's point. Mr. Smith added that he received his mpox vaccine when he attended the International AIDS Conference in

Canada because it is easy to do there due to universal health care. Sadly, this agency does not have as much power as we might wish since there are basically 50 states acting and reacting rather than formulating one coordinated response. There is not really a public health system in the U.S. but rather a medical system that public health sits underneath, which is in contrast to many other countries that have a public health care approach. This has to do with the orientation of our system and is probably an issue beyond the scope of this discussion, but in the future, if our country wants to be fit for the purpose of responding to emerging disease trends, this is something that may need to be addressed. At this point, what is being done in the U.S. is not the best that can be done.

- Dr. Gayles wrapped up the panel, complementing the participants on their great storytelling and data points. Some of what was discussed is difficult to hear, especially those issues that continue to recur. When COVID-19 hit, it seemed that this would be the spark that finally ignited the push for public health infrastructure; unfortunately, this was not the case, and again, as it has for decades, the conversation centers on response, the engagement of CBOs, and the engagement of communities of color. Either no one is learning anything, or what is being learned is not being put into practice. Perhaps it's a fundamental root cause issue, but whatever the case, it is discouraging that nothing has yet been solved.

## CHAC Workgroup and Liaison Reports

### Workforce Workgroup

#### Workgroup Meetings and Membership:

Term: November 2022-April 2023
Met December 7, 2022 and March 7, 2023

Workgroup Members:
Vincent Guilamo-Ramos (Chair)
Jean Anderson
Wendy Armstrong
Daniel Driffin
Kali Lindsey
Kneeshe Parkinson
Robert Riester

- Designated Federal Officials:
  - Shalonda Collins, MPH, CHES
  - Marah Condit, MS

The workforce workgroup was tasked with developing the evidence base on priority issues for the HIV workforce, including aligning HIV workforce regulation and funding through:

- Incentivizing programs that create pathways for more diversity in professional careers for HIV treatment and prevention services
- Investing in workforce infrastructure for the delivery of decentralized, differentiated status-neutral HIV services to promote a shift toward a comprehensive, whole-person, interdisciplinary, and team-based model of HIV service delivery.

HIV Workforce Priority Challenges:

- Insufficient trainees entering HIV specialties[32]
  - Sub-Challenge: Diversifying the HIV Workforce
  - Available HIV-specialty programs are limited in number and geographically clustered
  - Trainee exposure to HIV-specific education and clinical context is inconsistent
- Aging HIV workforce[33]
  - Increasing numbers of HIV clinicians are reaching retirement age
  - 68.2% of HIV Clinicians are ≥ 45 years old
- Diversion of HIV providers to other infectious disease areas[34]
  - e.g., COVID-19 response directly impacted HIV and infectious disease specialty workforce by siphoning specialists and funding

HIV Workforce Priority Challenges and Potential Strategies

- Recruit: Create pathways to increase the recruitment of a diverse cohort of HIV-specialty trainees[35]
  - Pathway Programs for HIV-Specialization - Further development and expansion of HIV-specialist pathway programs, including the integration of HIV-specialist training in Graduate Medical Education and Graduate Nursing Education
  - *Why specialize in HIV?:* Elevating the Benefits of HIV-Specialization - HIV epidemic response continues to serve as an exemplar for health activism, calling attention to health inequities and challenging the current paradigm of healthcare
  - Financial Incentives for HIV-Specialist Trainees - Examples: Loan repayment options and funding streams such as HRSA primary care grants, HRSA Bio-preparedness Workforce Pilot Program
- Retain: Maintain the current HIV workforce through educational, financial, work environment, and policy incentives[36]
  - Innovative Payment Structures for Reimbursement of HIV Services - Examples: Increased Medicaid and Medicare reimbursement rates for HIV-specialists providing primary care, risk-adjusted provider reimbursement, reimbursement for alternative models of service delivery
  - Regulatory Barriers Limiting Providers from Practicing to Highest Level of Training/Licensure - i.e., Nurse practitioner- and physician assistant-delivered primary care results in comparable patient outcomes to physicians
  - Work Environment Considerations - Ensure viable pathways for continued education and training, career advancement, and adequate compensation
- Reimagine: Develop infrastructure for a new model of HIV service delivery and workforce configuration

[32] Source: Institute of Medicine. 2011. *HIV Screening and Access to Care: Health Care System Capacity for Increased HIV Testing and Provision of Care.* Washington, DC: The National Academies Press,

[33] Gilman et al. The HIV Clinician Workforce in the United States. HIV Specialist. Retrieved from: https://aidsetc.org/resource/first-look-hrsa-hiv-workforce-study; HIV Specialists: 2015 estimates, HRSA, HIV Specialist; ; U.S. Bureau of Labor Statistics, Occupational Employment and Wage Statistics, 2020: HIV.gov U.S. Statistics, 2022

[34] Giovanni G, Milic J, Martinez E, et al. Human Immunodeficiency Virus (HIV) Care Models During the Corona Virus Disease 2019 (COVID-19) Era, *Clinical Infectious Diseases*. 2021. 73(5);1222-1227.

[35] Budak et al., Human Immunodeficiency Virus Training Pathways in Residency: A National Survey of Curricula and Outcomes, Clinical Infectious Diseases, Volume 72, Issue 9, 1 May 2021, Pages 1623–1626, https://doi.org/10.1093/cid/ciaa301; Steward et al. 2020. *Practice transformations to optimize the delivery of HIV primary care in community healthcare settings in the United States: A program implementation study.* PLOS Medicine. https://doi.org/10.1371/journal.pmed.1003079

[36] WArmstrong WS. The Human Immunodeficiency Virus orkforce in Crisis: An Urgent Need to Build the Foundation Required to End the Epidemic, Clinical Infectious Diseases, Volume 72, Issue 9, 1 May 2021, Pages 1627–1630, https://doi.org/10.1093/cid/ciaa302; Institute of Medicine. 2011. *HIV Screening and Access to Care: Health Care System Capacity for Increased HIV Testing and Provision of Care.* Washington, DC: The National Academies Press; Laurant, M, et al. Cochrane Database Syst Rev. 2018;7(7); Kurtzman ET, Barnow BS. Med Care. 2017;55(6):615-622; Zhang C, et al. AIDS patient care and STDs. 2019;33(12):507-527.; Owen JA, Skelton JB, Maine LL. Pharmacy. 2020;8(3):157.

- Policy and infrastructure levers for delivering decentralized, differentiated HIV prevention and care - Example: COVID-19 Public Health Emergency (PHE) flexibilities allowed healthcare workforce to provide responsive infectious disease prevention and treatment at a large-scale
- Redefine the HIV workforce for comprehensive health and social service provision - Involve People living with HIV (PLWHIV), Primary Care Providers, Registered Nursess (RNs), Licensed Practical Nurses (LPNs), Pharmacists, Dentists, Social Workers, Behavioral/Mental Health Professionals, Community Health Workers (CHWs), etc.
- Expand and maximize the existing HIV workforce to include entire available, qualified workforce - Examples: Practice transformation demonstrations (e.g. "share-the-care" and increased care coordination) to maximize the existing workforce

## Self-Testing and Self-Collection Workgroup

### Workgroup Meetings and Membership

- Workgroup Term: November 2022 – April 2023
  - Meetings were held in January, February and April 2023
  - Invited two guest speakers:
    - Dr. Ellen Kersh, Branch Chief, CDC Division of STD Prevention Laboratory
    - Dr. Barbara Van Der Pol, Professor of Medicine & Public Health, STI Laboratory Director, University of Alabama at Birmingham
- Workgroup Members:
  - Jodie Dionne (Chair)
  - Johanne Morne
  - Shannon Dowler
  - Shruti Mehta
  - Christine Markham
- Designated Federal Officials:
  - Marah Condit, MS
  - Shalonda Collins, MPH, CHES

Focus Areas and Scope of Workgroup Research Activities:

1. Knowledge gaps in the development of high quality STI diagnostic testing with self-collected samples (CT/NG/syphilis)
2. Regulatory barriers to the approval of self-collected swabs for STI diagnostic testing within and outside the clinical setting
3. How to improve access to and uptake of affordable, available STI testing for adolescents and adults who need it.

Definitions:

- STI self-collection can occur in a clinical or non-clinical setting. CT/NG samples are genital or extragenital.
- STI self-testing is collected, performed, and interpreted by the user (at point of care [POC]) without input from a provider (i.e., Clinical Laboratory Improvement Amendments [CLIA] waived urine pregnancy test)
- Direct to consumer (OTC) testing can be ordered by the user (often online) without input from a provider

WHO Recommendation Summary:

- Self-Collection Benefits

    - Person-centered
    - Can reduce barriers to STI testing (privacy, stigma)
    - Complementary to existing programs and approaches
    - Benefit measured in terms of improved outcomes for the individual and at the population level
- Self-Collection Risks
    - Exposure to buffer
    - Harm with self-swab
    - Lack of stability data - Nucleic Acid Amplification Test (NAAT) performance if samples are heated or testing delay

Current Landscape for STI Self-Testing

- Published data shows efficacy and cost-effectiveness of CT/NG NAAT self-testing in a variety of populations.
    - 14-19 million CT/NG NAAT performed each year in the US.
- COVID self-testing outside the clinical setting suggested a path for FDA approval (EUA).
- In many clinics, genital CT/NG self-collection (vaginal swabs in women, first-catch urine in men as preferred specimens) is standard of care.
    - Self-testing for urogenital CT/NG has been recommended by CDC since 2014 due to equivalent test performance and higher patient acceptability compared to clinician-collected samples.
- Barrier: FDA has not approved any STI self-collection testing for use in a non-clinical setting. Labs are out of compliance if they perform validation procedures on swabs collected in the non-clinical setting.
- CDC Division of STD Prevention is working to publish a systematic review on the efficacy and acceptability of self-collected STI testing
- ASTDA recently published a position statement about the pitfalls and opportunities with the rapid spread of direct to consumer STI testing.

Challenges

- Regulatory barriers have prevented FDA licensure of CT/NG self-collection outside of the clinical setting.
- Manufacturer Perspective
    - FDA submission requirements for self-collect indication ($$$$)
    - Complex, poorly defined requirements (STI reporting, treatment, linkage to care)
- Self-collection of extra-genital CT/NG NAAT specimens in the non-clinical setting requires instruction. (readily available)
- Syphilis testing requires blood sampling – more complex than CT/NG
    - Dried blood spots for treponemal antibody testing
    - Microtainers (1 mL) can allow for non-treponemal testing

Regulatory Solutions

- Formal FDA guidance and a streamlined process to allow assay claims to include CT/NG sample self-collection in non-clinical settings.
- Define acceptable performance loss in terms of test sensitivity for CT/NG testing outside the clinical setting.
    - Oraquick POC HIV test was approved by FDA at 92% sensitivity.
- Allow laboratories to perform validation procedures on self-collected swabs.
    - Specify transport conditions.
    - Address safety concerns.

- Regulations for quality control for CT/NG testing by all vendors.

Other Solutions and Knowledge Gaps
- Partnership with public health can help ensure that STI reporting, treatment, and partner notification is connected to testing outside clinical settings. Linkage to care based on test results is critical to improving STI outcomes.
  - CDC STI Lab is working to develop self-collection guidelines
- Novel approaches to improving access: vending machines, telehealth
- Standardized aligned STI reporting mechanisms are needed (i.e. COVID-19)
- STI diagnosis as a sentinel event: opportunity to link to HIV PrEP and DoxyPEP
- Research Needs:
  - Improve high quality CT/NG/syphilis POC testing and comparative performance
  - Cost-effectiveness analyses to compare performance characteristics and case finding
  - Increase access to affordable STI testing especially in populations with existing barriers

Conclusions
- Rates of curable CT/NG/syphilis in the U.S. are rising with 15 million NAAT tests performed each year.
  - There is high demand for STI testing online - quality and cost varies.
- Published data suggests that STI self-collection in the non-clinical setting is feasible and highly acceptable. Test sensitivity is lower than in clinic.
- One regulatory barrier to improving access to STI testing is the current FDA requirement for sample collection in the clinical setting.
- CDC, FDA, local public health officials, and frontline providers are committed to improving access to high-quality STI diagnosis. The best programs ensure high treatment rates, linkage to care, and timely reporting.

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

**Ada Stewart, RPH, MD, FAAFP, AAHIVS, HMDC**
PACHA Liaison Representative for CHAC

Dr. Stewart apologized for being unable to provide an update in person but explained that due to being mobilized soon, her presence was required for in-person care. She added that she would highlight items for the most recent full council meeting of PACHA, which met from March 29-30 in Washington, D.C. Prior to that meeting, there was a pre-meeting on March 28, which consisted of site visits to three community organizations to see firsthand the work being done. The current iteration of PACHA focuses on bringing PACHA to the people, hearing from the community, and learning about innovative practices and programs and its successes and challenges to better guide the work of the advisory council. Dr. and Admiral Levine was able to accompany PACHA on these visits, which was very helpful. Most of PACHA's work is done via subcommittees, which occur in between full council meetings. There are three subcommittees: one on global issues, one on stigmas and disparities, and one on ending the HIV epidemic in the U.S. and the updated national HIV strategy.

PACHA first visited Recovery Enhanced by Access to Comprehensive Healthcare (REACH) Health Services in Baltimore, Maryland. REACH is an opioid treatment program that defines itself as "a health home program designed to promote overall wellness and health, assess and assist

clients in opioid treatment programs with coordinating their healthcare services and navigating the healthcare system and managing chronic diseases through education referrals and other supportive activities." REACH aims to reduce the unique barriers these individuals face by providing holistic, integrative, healthcare coordination for primary, specialty, and behavioral health by providing a patient-centered, trauma-informed approach to addiction and recovery. Patients receive limited primary care services, including hepatitis C treatment. Some of the challenges we observed were patients receiving opioid treatment but also presenting with other conditions, such as hepatitis C, and individuals without stable housing. Further, same-day visits were not allowed through insurance payment reimbursement in addition to being offered PrEP or continuing their HIV care.

Next, PACHA visited U.S. Helping U.S. in Washington, D.C., which was established by a group of volunteers in 1985, with two locations in the D.C. area, and has now expanded to a staff of over 40. U.S. Helping U.S. focuses on providing holistic health information, including clinical and behavioral healthcare, for those in communities of color living with HIV and AIDS. The organization also provides PrEP for those at risk and treatment adherence counseling. It employs a trauma-informed approach to psychotherapy and provides support for the social, legal, and financial needs of clients and patients. In addition, U.S. Helping U.S. also engages in research projects related to PrEP uptake and the syndemics of HIV/AIDS, hepatitis C, substance abuse disorders, and STIs. Finally, the organization helps homeless youth by providing them with job skills so that they can become part of the workforce.

Last, PACHA paid a visit to Federally Qualified Health Center (FQHC) La Clinica del Pueblo, which receives Ryan White funding and addresses the distinct health needs of the Latino community through comprehensive primary medical care, wraparound services, mental health, substance use treatment, advocacy, and health education. The staff there highlighted the importance of primary care, the continuity of care, and the Ryan White program and its resources while also emphasizing some of the challenges they face, including administrative issues that accompany that type of funding.

The three visits inspired the next two days of the full council meeting, whose robust agenda began with opening remarks from Assistant Secretary Dr. Rachel Levine, who reiterated the administration's commitment to ending the HIV epidemic. Director Harold Phillips from the White House Office of National AIDS Policy (ONAP) then provided a response to PACHA's resolution on molecular HIV surveillance and cluster detection response. This was presented by Dr. Stewart on the last CHAC day, was passed in October 2022, and can be seen online at HIV.gov. This marked the first time that PACHA had heard this response, so PACHA will now need to consider the information provided in order to consider its response in turn.

Director Phillips highlighted that Molecular HIV Surveillance (MHS) and Cluster Detection and Response (CDR) are valuable tools and critical components of the EHE strategy in that it allows for the equitable allocation of resources to those who most need it. It identifies HIV service gaps especially in those communities already marginalized, such as transgender, women of color, and MSMs of color, and Director Phillips shared examples of MHS CDR helping increase equity in

communities such as Detroit and Atlanta. He discussed how community involvement happens at various levels in CDR, beginning with the development of jurisdiction-specific plans as required in NOFOs, with examples provided from Michigan and San Antonio. Phillips emphasized the importance of surveillance and its value to public health; however, he also noted that some of the activities proposed by the resolution actually conflicted with some of these. Such items as stopping the collection of data to identify HIV outbreaks will neglect public health, and giving people the option to opt out of HIV data sharing could result in incomplete surveillance and weaken justifications for needed resources to end the epidemic. Further, other challenges exist such as state criminalization laws and recognizing that each jurisdiction is different.

To that end, Director Phillips offered the following to address the resolution:

1) The CDC will continue to support national efforts to protect molecular HIV data, modernize HIV criminalization laws, and ensure CDR activities benefit communities. Although the CDC will not fully enact suggestions in the resolution as written, it is working to incorporate components into practice by assisting providers in better communicating surveillance and public health data usage to patients, continuing to require that consent be gained before HIV sequences collected through the national HIV surveillance systems are added to a public repository.

2) The CDC has learned from partners implementing MHS/CDR that the requirements are too strict for some areas and would benefit from additional contextualization; thus, the CDC is considering an adaptable framework for MHS/CDR activities, such that MHS/CDR may vary from one jurisdiction to another to be responsive to jurisdictional trends, needs, and circumstances.

Phillips also mentioned the importance of strengthening data protections; for example, regarding collected information, CDC guidance requirement data are not submitted to a public repository unless individual consent is obtained. Further, it should not be used to determine directionality and is limited to Sanger or consequence sequencing.

Additionally, Phillips noted that the CDC is updating the National Center for HIV viral hepatitis, STD, and TB prevention data security and confidentiality guidelines and is also limiting data reporting to information that can advance specific HIV prevention efforts. In regard to HIV criminalization laws, the CDC cannot advocate, but it can help states understand the areas in which laws go against science, and it launched HIV criminalization, legal, and policy tools to assess the alignment of laws with science. Flagship funding can be employed to assess criminalization laws and provide education to prosecutors and law enforcement.

Finally, Phillips mentioned that the CDC has added a science brief website that compiles evidence through CDR. Currently, the website includes 100 publications, and the CDC is also working on provider education about data use and public health and building a clearing house for CDR information and resources. PACHA is grateful to Director Phillips for his work and will consider the information he presented in formulating its response.

Following that presentation, PACHA heard reports from 10 of its federal partners, including HRSA, the HIV/AIDS Bureau, HUD, Office of HIV/AIDS Housing, HHS, Office of Infectious Disease and HIV/AIDS Policy, Indian Health Service, NIH Office of AIDS Research, the Bureau of Primary Health Care, CMS, CDC, SAMSHA, and many more. Stressing the importance of PACHA and looking from a global lens continues to be a priority.

Dr. Mamadi Yilla, the Acting Principal Deputy U.S. Global AIDS Coordinator then provided an update from PEPFAR, which is celebrating 20 years as a program that has impacted and saved over 25 million lives. It released its five-year strategy in December 2022, confirming its commitment to end HIV as a public health threat by 2030.

Next, Dr. Jen Kates, co-chair of PACHA's global subcommittee, facilitated a panel discussion on addressing stigma through bidirectional learning from both global and domestic perspectives. Justin Smith, co-chair of the stigma and disparities subcommittee, also participated. Thus, the panel discussed lessons learned in relation to stigma issues, such as those occurring domestically in Tennessee as well as those occurring globally in Uganda, and reviewed success and challenges moving forward. Public participants then brought up such issues as MHS/CDR, the workforce, stigma, and disparities, which are ongoing challenges faced by the community.

Day two began with subcommittee reports and an additional report from Director Phillips about the proposed presidential budget for fiscal year 2024 and ADAP's updates and priorities. Dr. Daskalakis then provided an mpox update and emphasized how important it was to continue efforts in regard to this issue. Afterward, Dr. Peter Marx provided the group with a blood donor update, which relates to issues on the stigma and disparities work group and offers PACHA the opportunity to improve the FDA's proposed changes for blood donations. These alterations will change from a time-based deferral to an actual individual donor assessment, which will level the playing field by implementing a gender-inclusive assessment plan regardless of sexual orientation. Finally, a federal update on substance misuse and drug abuse was presented, which is an issue that PACHA has realized it must devote more time and energy to, specifically in regard to intravenous (IV) drug use of those living with HIV and those at risk. An excellent panel addressed HIV and substance misuse from a community perspective, and the work that is being done on the ground is phenomenal.

In summary, PACHA continues to work on MHS/CDR, the workforce, women, and youth and collaborate with its federal partners to discuss what is being done with the EHE initiative, including the Department of Justice and the Department of Labor. PACHA will also further discuss status-neutral approaches and PrEP access and use. Future meetings are scheduled for June 27-29 in Arizona, September 19-20 with a tentative virtual platform, and December 5-7 in Houston. PACHA continues to do much work, with a plethora of activity within its subcommittees.

## Member Discussion

*The following questions, observations, and suggestions were raised:*

- Dr. Anderson stated that any clarifying questions for Dr. Stewart or questions regarding the workforce, self-collection, or self-testing reports, they should be addressed before moving to discuss potential recommendations.

- Dr. Mermin asked Dr. Dionne about the self-sample collection kits that are then sent to labs for testing. In addition to the I Want the Kit campaign, there are multiple other commercial products available, and it seemed as though the FDA had signaled its interest in regulating those products because they have not yet been evaluated in the same way as others; for example, if they change in accuracy after being in the mail for a week, that would be important to note. Dr. Mermin wondered about whether the FDA was involved in the committee thinking about potential opportunities for I Want the Kit and whether the company producing the kit has validated it outside of its own laboratories.

- Dr. Dionne replied that she was unsure as to what the FDA's plans were; however, due to the nature of products that are so easily available to order on the internet, it's difficult for the FDA to regulate everything. That said, knowing the lab director at Johns Hopkins, it is difficult to imagine that interval validation was not conducted.

- Dr. Deal directed her comments toward Dr. Dionne, saying that the clarification of self-collection, self-testing, and over-the-counter was extremely helpful and related to three very different regulatory discussions. It may be helpful, though, to add the definition of where the test is conducted—point-of-care of home testing—to the definition. As far as the I Want the Kit, Johns Hopkins used an already commercially available platform and then validated the shipping and testing under the CLIA regulations. The company itself did not validate the shipping. Each laboratory did the same thing as the L.A. Public Health Department in regard to their large chlamydia testing program when Peter Current was there. A complex series of regulations exists now, and some companies produce self-collection kits that refer to a clinical setting while others maintain that a CLIA-certified laboratory, such as Johns Hopkins with I Want the Kit, validates the shipping. Companies should also provide 1 24/7 medical helpline.

- Dr. Dionne commented that that was very helpful.

- Dr. Anderson complimented the two work groups and asked if there were any other clarifying questions.

- Ms. Parkinson wondered whether an app-based approach would be effective for those who are in their homes and need a readily available attachment to services while the 24-hour processing was being conducted.

- Dr. Deal said that the 24-hour number refers to a call number in case of a question; it's like a 911 number for doing the test.

- Ms. Parkinson asked what happens after the test has been completed and what is the timeframe for an individual to get contacted or walk in to care.

- Dr. Deal responded that she did not know.

- Dr. Dionne clarified that for the over-the-counter test, there is no number to call. The person

testing merely receives a result, which may or may not be accurate, at their home; there is no linkage.

- Ms. Parkinson remarked that there was no linkage for STI but there was for HIV.

- Dr. Mermin added that there is a great cost saving with centralized services like telehealth. In regard to the test-take-me-home initial scientific work, they were able to have a call center similar to what has been described for people to call in and obtain results. Additionally, there are potential methods to expand the concept of HIV self-testing to STI self-collection, self-testing, and over-the-counter testing in which the testing is accurate and has been approved; Finally, although it is expensive, warmlines and hotlines, which have been used for a variety of issues including mpox, have been supported in the past. If the practice were to continue, centralizing the services may make sense.

- Dr. So said that if STI testing is considered class 3, it may not get approval, but if it is class 2, it might.

- Dr. Mermin replied that most are class 2.

- Dr. Dionne thought it was class 2, but Dr. Michelle Owen, who is on the call, could answer that.

- Dr. Owen responded that STI testing is considered a class 2 device. She also clarified that the testing conducted at Johns Hopkins was validated by Dr. Gaydos in her laboratory. The question still remains whether the FDA would regulate their testing since it is an off-label use of the test. While Dr. Gaydos is using an FDA-cleared platform, her use of the platform was different from what was intended, it now becomes off-label use. Again, theoretically, the FDA could probably regulate this if it wanted to.

## Business Session - Part 3

### Action Item #1: STI self-test and self-collection letter

**Dr. Jodie Dionne, MD**
University of Alabama, Birmingham

Dr. Dionne brought forward her points for discussion around STI self-testing and self-collection, based on feedback received earlier.

### CHAC Member Observations/Suggestions: STI self-test and self-collection letter

*The following questions, observations, and suggestions were raised:*

1) Allow labs and investigators to submit samples of CT/NG/syphilis testing data from swabs collected outside the clinical setting to support validation on self-collected swabs and swabs collected outside the clinical setting for investigation into the FDA for approval.

- Dr. Dionne noted that this was seen as one of the major barriers. She clarified that the recommendation is allowing testing data from non-clinically obtained samples be permissible for submission. She reiterated that the current requirement is only in the clinical setting. She noted that this recommendation is more directed to the FDA than CDC and HRSA, and is open to thoughts on how to focus it towards CDC and HRSA.

- Dr. Anderson suggested voting on each recommendation and then putting them in a letter. It was confirmed by Dr. Jonathan Mermin and Marah Condit that the letter could be finalized after the meeting.

- Dr. Cheever indicated that it's fine to write HRSA/CDC as we go through the recommendations in the letter.

**2)** Create a simpler and streamlined system to enable STI reporting results to all public health jurisdictions (similar to system used for COVID-19 diagnostic test reporting).

- Dr. Dionne noted that based on discussions, they found that a simpler process is already in the works, and that this recommendation could go far to encourage the team already doing this to continue the work.

**3)** Collaborate with industry and academia a) to collect safety and stability data for CT/NG NAAT testing outside the clinical setting, and b) to develop POCT CT/NG/syphilis testing with optimal sensitivity and specificity (STI Impact Research Consortium network or new partnerships).

- Dr. Dionne highlighted that the FDA is most interested in this safety and stability data for CT/NG NAAT testing outside the clinical setting. She shared that two different platforms could be considered for point of care (POCT) CT/NG/syphilis testing, and flagged that the STI Impact Research Consortium Network has been established and to do these types of STI studies, and there is an opportunity to do a Federal Register Notice (FRN).

**4)** Identify success stories (such as I Want the Kit) that increase access to STI testing for people with barrier to care.

- Dr. Jodie Dionne connected this to earlier conversations about stories, and highlighted this is an example of a success story that's thought carefully about high-performance testing linked to public health, that does increase access to STI testing for people with barriers to care.

**5)** Identify support systems that are HIV status-neutral and ensure linkage to STI care, partner services, HIV PrEP, and case reporting.

- Dr. Jodie Dionne noted the similarities between this and the fourth recommendation. This is the identification of the support systems needed to create and establish new success stories that are HIV status-neutral, that ensure linkage to STI care, partner services, HIV PrEP, and case reporting anytime we're talking about diagnostic STI testing outside the clinical setting. She commented on how crucial it is to keep making sure these pieces are all part of the conversation.

Clarification was made that this letter will go to the Secretary.

- Ms. Kneeshe Parkinson asked if it's possible to work with PACHA to move this letter along. It was clarified that there is great collaboration between CHAC and PACHA, with Dr. Wendy Armstrong and Dr. Ada Steward as great partners in the process, and there was agreement that PACHA support lends to the strength of the narrative. However, it was also suggested by Dr. Jonathan Mermin and Dr. Jean Anderson that for the sake of time and simplicity to have the two committees share out the topics through their own procedures.

### CHAC Action

Motions were made to approve all five STI self-test and self-collection recommendations presented. The recommendation included:

**Recommendation 1:** Allow labs and investigators to submit samples of CT/NG/syphilis testing data from swabs collected outside the clinical setting to support validation on self-collected swabs and swabs collected outside the clinical setting for investigation into the FDA for approval.

**Recommendation 2:** Create a simpler and streamlined system to enable STI reporting of results to all public health jurisdictions (similar to system used for COVID-19 diagnostic test reporting).

**Recommendation 3:** Collaborate with industry and academia a) to collect safety and stability data for CT/NG NAAT testing outside the clinical setting, and b) to develop POCT CT/NG/syphilis testing with optimal sensitivity and specificity (STI Impact Research Consortium network or new partnerships).

**Recommendation 4:** Identify success stories (such as I Want the Kit) that increase access to STI testing for people with barrier to care.

**Recommendation 5:** Identify support systems that are HIV status-neutral and ensure linkage to STI care, partner services, HIV PrEP, and case reporting.

CHAC unanimously approved the STI self-test and self-collection recommendations, to be developed into a letter to the Secretary.

## Action Item #2: AETC Re-compensation guidance

### Vincent Guilamo-Ramos, PhD, MPH

Dr. Guilamo-Ramos brought to the group a response to Dr. Laura Cheever's earlier request for guidance regarding the upcoming re-competition for the AETC.

### Recommendations

Regarding the **upcoming AETC re-competition**, Dr. Guilamo-Ramos proposed the following recommendation:

- Encourage HRSA to require grant applicants to utilize and emphasize holistic and trauma-informed approaches to prevention and care, and to address syndemic considerations; to address the role of long-acting, injectable PrEP and treatment; to incorporate training for community health workers.

## CHAC Member Observations/Suggestions: AETC Re-compensation guidance

*The following questions, observations, and suggestions were raised:*

Regarding **upcoming re-competition for the AETC**:

- Discussed whether to include the need for an interprofessional workforce, in addition to the highlighted community health workers. Agreed this should be included.

- Dr. Cheever surfaced the topic of pipeline that had been discussed, and whether topic of thinking more strategically about moving people through a pipeline should be addressed.

- Dr. Anderson suggested taking this as a separate recommendation related to AETC re-competition, but to amend it to incorporate training for community health workers and an interprofessional workforce with attention to the pipeline of the HIV/AIDS workforce and pathways for their advancement.

### CHAC Action

Motion was made to approve the recommendations relating to AETC re-competition, including suggested amendments and pending final wording, as follows: .

- CHAC encourages HRSA to require grant applicants to utilize and emphasize holistic and trauma-informed approaches to prevention and care, and to address syndemic considerations; to address the role of long-acting, injectable PrEP and treatment; to incorporate training for community health workers and an interprofessional workforce with attention to the pipeline of the HIV/AIDS workforce and pathways for their advancement.
    - With the amendment to incorporate training for community health workers and an interprofessional workforce with attention to the pipeline of the HIV/AIDS workforce and pathways for their advancement.

Motion was seconded. CHAC unanimously approved the AETC re-competition recommendation to be sent to HRSA.

## Action Item #3: Workforce Letter

### Vincent Guilamo-Ramos, PhD, MPH

Dr. Guilamo-Ramos noted that several recommendations arose during the discussion after the Workforce Workgroup presentation that afternoon. He proposed incorporating these recommendations into a letter to CDC/HRSA.

Regarding **workforce-specific recommendations**, Dr. Guilamo-Ramos proposed the following for discussion:

- Infrastructure development for delivery of decentralized, differentiated HIV prevention and care (e.g., telehealth, community-based delivery of services, etc.).

- Integration of all team members (e.g., CHWs, RNs, LPNs, Social Workers, Pharmacists, Behavioral/Mental Health Professionals) into the HIV workforce in partnership with other care providers and address appropriate training standards, compensations, and paths for promotion.

- Incentivization of programs that create pathways for more diversity in professional careers beyond CHR (e.g., fellowship programs) of the workforce with current and emerging needs and challenges of PLWHIV communities.

- Removal of regulatory barriers that place restrictions on practice at the highest level of training and licensure (e.g., for nurse practitioners, PAs, medical technicians, pharmacists, etc.).

**CHAC Member Observations/Suggestions: Workforce Letter**

*The following questions, observations, and suggestions were raised:*

**Recommendation 1:** Infrastructure development for delivery of decentralized, differentiated HIV prevention and care (e.g., telehealth, community-based delivery of services, etc.).

- Dr. Guilamo-Ramos asked for help with the framing and language of the first recommendation around infrastructure.

- Mr. Lindsey raised the question around how this recommendation fits into workgroup as opposed to alternative models of care.

- Mr. Driffin emphasized that within the continuing conversation of truly meeting community where they are, this recommendation would give space to develop efforts of finding the best fit pieces of the workforce to perform in that telecare, telephonic, non-face-to-face, under-a-roof mechanism.

- Dr. Guilamo-Ramos noted that the sentiment of this recommendation was related to the story Mr. Leandro Rodriguez shared earlier in the day relating to infrastructure development for a workforce that can provide decentralized, differentiated HIV prevention, and care, and ensure that we're adopting telehealth, community-based delivery, and non-traditional approaches to leveraging workforce.

- Mr. Lindsey clarified the three issues at play. The first being practice innovation and the need to understand what the models are to integrate those different kinds of professionals into the delivery of care systems. He noted that is assumed in the infrastructure, but that perhaps CDC and HRSA could provide some guidance out to the jurisdictions and the states about how those models can be integrated into the current delivery models, whether through clinic-based systems or through some clinic community-based collaboration. The second piece being resources, because infrastructure can't be built without actually paying the people. There is a need to figure out how the support that goes out to jurisdictions at the community-based organization level and at the clinics offers reimbursement and payment models that support the integration of this diversified and interprofessional workforce. The third being the training aspect. He pointed out, when talking about the integration of people that don't have access to

certain training, it is needed to figure out how they work in the system, and how we upskill them to enter the workforce, and then integrate into the care provision team. He noted that CDC/HRSA could play a critical role in highlighting these roles.

- Dr. Anderson noted that some of these issues would be in subsequent recommendations, but can be wordsmithed.

- Dr. Guilamo-Ramos restated the recommendation for vote, as follows:

    - Broaden the HIV prevention and care infrastructure to ensure a workforce that has the appropriate training, resources, reimbursement for a delivery model of decentralized and differentiated HIV prevention and care.

- Mr. Lindsey noted to lift up investment that HRSA made in the development of CHW, with focus on the HIV WF.

**Recommendation 2:** Integration of all team members (e.g., CHWs, RNs, LPNs, Social Workers, Pharmacists, Behavioral/Mental Health Professionals) into the HIV workforce in partnership with other care providers and address appropriate training standards, compensations, and paths for promotion.

- Dr. Guilamo-Ramos raised that this recommendation may have been covered with the HRSA AETC re-compete, but this sentiment was also the integration of all team members, so a broader workforce, and thinking about appropriate training standards, compensation, and pathways.

- Dr. Anderson pointed out that the AETC re-competition is one thing, but if these recommendations are going to be included in a letter that goes to someone else, like the Secretary, it's a slightly different audience, and recognizing the importance of all of these who maybe have not been totally incorporated into the workforce.

- Mr. Driffin brought up that infrastructure was brought up in the first recommendation and cautioned against duplication.

- Dr. Guilamo-Ramos said that he sensed the group would like to re-express the point of infrastructure. Dr. Jean Anderson reinforced re-expression of the concept.

**Recommendation 3:** Incentivization of programs that create pathways for diversity in professional careers beyond CHR (e.g., fellowship programs) of the workforce with current and emerging needs and challenges of PLWHIV communities.

- Dr. Guilamo-Ramos noted that this recommendation is about pathways for more diversity in health care and public health workforce. He reiterated the question of how we think about opportunities to align the current and emerging needs of people living with HIV with a workforce.

- Dr. Dionne urged that the conversation should include starting much younger, in high school, college, or graduate programs, to create a workforce demand for the future. She cautioned the word “incentivize” often evokes money, which may not be available, and was curious about examples of incentivization.

- Dr. Guilamo-Ramos acknowledged that the recommendation was regarding money, based on the discussion regarding money, loan repayment, and ways of using GME and GNE, and strategies for supporting the workforce. He concurred that starting earlier was a great suggestion, but also emphasized the sense of urgency around utilizing the current workforce and drawing proximal people into HIV.

- Mr. Lindsey highlighted incentivization regarding graduate programs and school costs, but also brought up incentivizing jurisdictions to do a better job of recruitment and retention of diverse workforces, whether in leveraging Minority AIDS Initiative Funds to support jurisdictions that are being intentional about recruiting and diversifying their workforce or other models that give jurisdictions incentives to be more intentional about that effort.

- Dr. Anderson suggested including the financial piece, as well as incentivizing jurisdictional programs to capture people earlier.

- Dr. Guilamo-Ramos restated the recommendation based on discussion as follows:

    - Greater financial investments in programs that create pathways for diversity in professional careers beyond CHR (e.g., fellowship programs) of the workforce with current and future or emerging challenges of people living with HIV. Starting younger.

**Recommendation 4:** Removal of regulatory barriers that place restrictions on practice at the highest level of training and licensure (e.g., for nurse practitioners, PAs, medical technicians, pharmacists, etc.).

- Dr. Guilamo-Ramos noted that this recommendation is tricky due to the nature of them being state-level issues. He said the question this recommendation seeks to answer is how to leverage health and public health workforce at the top of their competencies, education, and license that allows the broadest workforce, most inclusive workforce, to respond to HIV and other public health emergencies.

- Dr. Dionne requested a point of clarification regarding whether there is a national regulatory group that can decide standards, or if it's a state-by-state decision. She noted that in Alabama nurses are more limited in what they can do compared to in Vermont. She asked if this recommendation was for CDC/HRSA to do something in discussion with the state boards.

- Dr. Guilamo-Ramos provided that he agreed with Dr. Cheever's state boards concerns, but emphasized the complexity, as there have been periods where, for example, during the COVID-19 emergency, states were able to create waivers where those regulatory restrictions went away, and we saw there was a national response. Post-pandemic, some of the states reversed. He noted that the vast majority of states, 27 and two territories, for example, allow nurse practitioners to practice at full-scope, full-license. He indicated that there are states that allow pharmacists to do some of the things that we need pharmacists to do. He noted that while it is a state issue, some large groups, such as the American Medical Association and others, lobby against this. He said that CHAC needs to be really clear about the evidence, what our country needs, who is shaping this issue, and why that is.

- Dr. Anderson emphasized this as an important issue, and asked for Dr. Laura Cheever's input on what the role of CDC and HRSA could be to move this forward.

- Dr. Cheever provided that this has been an ongoing discussion for 30 years in the Bureau of Health Workforce. She suggested bringing in a specialist from the Bureau of Health Workforce to speak with CHAC about the complexities and what can be done.

- Dr. Anderson confirmed that CHAC could generate these recommendations in a letter to the Secretary expressing the importance of this issue. She also asked Dr. Laura Cheever if CHAC can recommend that CDC and HRSA interact with professional societies to advocate for this.

- Dr. Cheever suggested expressing interest in CDC and HRSA exploring what can be done, with the context that the Bureau of Health Workforce has worked on this for 30 years, and these are the parameters of what we can and can't do.

- Dr. Guilamo-Ramos provided two more points. The first point is that there is a role for CDC/HRSA around the review of evidence, due to the volume of evidence that demonstrates the efficacy in terms of outcomes that should be informing our policy. Two, there have been some convenings at the federal level that have centered around pharmacists. Those meetings, particularly with private sector partners, have made a big difference and shaped things locally.

- Dr. Cheever confirmed that going to the Secretary might be a good idea because the response could be parsed, as there are a series of things that could happen at the department level as well. She highlighted looking at the HHS level, the OS level, as they've got a work plan around primary care. Dr. Cheever also brought up that another review of the evidence may not be necessary—unless CHAC wants the evidence—as she doesn't think that's where the blocker is.

- Dr. Anderson liked Dr. Cheever's suggestion of recommending that CDC and HRSA explore options to move this forward and thought sending a letter to the Secretary making statements like that seemed appropriate, given the importance of the issue.

- Dr. Dionne raised that it could be worded to make a compelling case, that as we already have these trained providers in the communities that we're trying to reach, by not letting them practice at their highest level, we're handicapping some of our most trained professionals to do the work that we need them to do.

- Dr. Anderson agreed that could go in the background of the letter.

- Mr. Lindsey brought up the point that recommendations two through four are very linked to recommendation one. Both the diversification and compensation of the workforce goes to infrastructure. The financial incentives to create pathways goes to infrastructure, as well as these regulatory big areas. He wondered if more context and support could be given to the recommendation by linking these as sub-recommendations. Mr. Lindsey noted that we're asking for evidence from these convenings and these evidence reviews, and in some way to either provide some support from CDC/HRSA to jurisdictions to address the removal of these regulatory barriers, as a means to incentivize or to develop infrastructure for a diverse and decentralized, differentiated HIV care.

- Dr. Anderson clarified and confirmed Mr. Lindsey's request to include the language discussed, but also making a recommendation of an evidence review of the regulatory barriers, and the evidence of practice effectiveness.

- Dr. Anderson restated the final recommendation as follows:

    - To explore removal of regulatory barriers that place restrictions on practice at the highest level of training and licensure, and to ask that there be an evidence-based review of the current restrictions and effectiveness of practice of different health care cadres.

### CHAC Action

Motions were made to approve all four original recommendations presented, including suggested amendments, and pending final wording, to be developed into a letter to the Secretary. The recommendation included:

- Recommendation 1: Broaden the HIV prevention and care infrastructure to ensure a workforce that has the appropriate training, resources, reimbursement for a delivery model of decentralized and differentiated HIV prevention and care.

- Recommendation 2: Integrate all team members (e.g., CHWs, RNs, LPNs, Social Workers, Pharmacists, Behavioral/Mental Health Professionals) into the HIV workforce in partnership with other care providers and address appropriate training standards, compensations, and paths for promotion.

- Recommendation 3: Increase financial investments in programs that create pathways for diversity in professional careers beyond CHR (e.g., fellowship programs) of the workforce with current and future or emerging challenges of people living with HIV. Starting younger.

- Recommendation 4: Explore removal of regulatory barriers that place restrictions on practice at the highest level of training and licensure, and to ask that there be an evidence-based review of the current restrictions and effectiveness of practice of different health care cadres.

Motions were seconded. CHAC unanimously approved the workforce recommendations to go into a letter that will be shared with PACHA, as determined in the November 2022 meeting.

## Action Item #4: Grant RFA guidance

**Jean Anderson, MD**
CHAC Co-Chair, HRSA Appointee

Dr. Anderson shared that a robust discussion about potential recommendations occurred during the meeting.

Dr. Anderson reviewed the proposed resolution:

- Treatment and/or prevention RFAs include a requirement that grantees include a transition plan, to include **sustainability considerations**, and transfer of knowledge gained to the community and other relevant stakeholders.

**CHAC Member Observations/Suggestions: RFA guidance**

*No questions, observations, or suggestions were raised.*

**CHAC Action**

Motion was made to approve the recommendation relating to sustainability guidance, as follows:

**Resolution:** Treatment and/or prevention request for applications (RFAs) include a requirement that grantees include a transition plan, to include **sustainability considerations**, and transfer of knowledge gained to the community and other relevant stakeholders.

Motion was seconded. CHAC unanimously approved the RFA guidance recommendation to be sent to HRSA and CDC.

**Action Item #5: HRSA Best Practices Compendium**

**Jean Anderson, MD**
CHAC Co-Chair, HRSA Appointee

Dr. Anderson reviewed the proposed recommendation, based on the discussed need for greater flexibility:

- This recommendation is that the **best practices compendium generated by HRSA** be expanded and expedited to identify key variables that can be used to guide implementation in **different settings based on available resources and needs**.

**CHAC Member Observations/Suggestions:** HRSA Best Practices Compendium **guidance**

*No questions, observations, or suggestions were raised.*

**CHAC Action**

Motion was made to approve the recommendation relating to the HRSA Best Practices Compendium guidance, as follows:

- This recommendation is that the **best practices compendium generated by HRSA** be expanded and expedited to identify key variables that can be used to guide implementation in **different settings based on available resources and needs**.

Motion was seconded. CHAC unanimously approved the HRSA Best Practices Compendium recommendation, to be sent to HRSA.

## Action Item #6: Bicillin Drug Shortage letter

**Jean Anderson, MD**
CHAC Co-Chair, HRSA Appointee

Dr. Anderson reviewed the proposed recommendation:

- CHAC expresses great concern **concerning the barriers to access to bicillin for syphilis treatment**. We recommend that CDC explore alternative treatments (including for pregnant individuals), explore federal subsidies to support access, and consider a national stockpile for this essential drug.

## CHAC Member Observations/Suggestions: Bicillin Drug Shortage letter

*The following questions, observations, and suggestions were raised:*

- Dr. Jonathan Mermin brought up the fact that other agencies may have valid space in the availability of drugs that are currently experiencing these shortages in the local and national level, and CHAC should consider including them as well, as CDC could assist in a cross-HHS approach.

### CHAC Action

Motion was made to approve the recommendation relating to bicillin access, to be developed into a letter to the Secretary. The recommendation included:

- CHAC expresses great concern **concerning the barriers to access to bicillin for syphilis treatment**. We recommend that CDC explore alternative treatments (including for pregnant individuals), explore federal subsidies to support access, and consider a national stockpile for this essential drug.

Motion was seconded. CHAC unanimously approved the bicillin access recommendation to be sent to the HHS Secretary.

## Action Item #7: Injectables PrEP Workgroup formation

**Jean Anderson, MD**
CHAC Co-Chair, HRSA Appointee

Dr. Anderson reviewed the proposed recommendation:

- Form workgroup to address current and emerging issues related to use of long-acting, injectable PrEP and treatment. Scope of work would include identification of system and clinic-level barriers and opportunities (including cost and access issues) and identification of best practices and potential models of care.

**CHAC Member Observations/Suggestions: Injectables PrEP Workgroup formation**

*The following questions, observations, and suggestions were raised:*

- Discussed specificity of the workgroup scope of work, including addressing equity.
- Discussed limiting to injectables so as not to make the scope too large and as that is what the specifics are related to.

**CHAC Action**

Motion was made to form an Injectables PrEP Workgroup to address current and emerging issues related to use of long-acting, injectable PrEP and treatment. Scope of work would include:

1) Identification of system and clinic-level barriers and opportunities (including cost and access issues)
2) Identification of best practices and potential models of care.

Motion was seconded. CHAC unanimously approved the motion to form an Injectables PrEP Workgroup.

**Action Item #8: Community Partnerships Workgroup formation**

**Jean Anderson, MD**
CHAC Co-Chair, HRSA Appointee

Dr. Anderson reviewed the proposed recommendation:

**Recommendation:**

- Form workgroup to address community partnerships with the scope of work to include assessment of current barriers/challenges in collaboration and coordination best practices; and minimal requirements for grant applicants.

**CHAC Member Observations/Suggestions: Community Partnerships Workgroup formation**

*No questions, observations, or suggestions were raised.*

**CHAC Action**

Motion was made to form a Community Partnerships Workgroup to address community partnerships with the scope of work to include assessment of current barriers/challenges in

collaboration and coordination best practices; and minimal requirements for grant applicants.

Motion was seconded. CHAC unanimously approved the motion to form a Community Partnerships Workgroup.

## Action Item #9: Youth and Sexual Health Letter

**Jean Anderson, MD**
CHAC Co-Chair, HRSA Appointee

Dr. Anderson brought up recommendations related to youth, and particularly sexual health, that would be in the form of a letter. She brought up the shared feeling that the data on sexual risk and behavior in youth is critical to identifying trends in preventive and therapeutic sexual health. She affirmed that a lot of thought went into these recommendations based on conversations early in the day.

### Recommendations

- Collection of data on sexual risk and behavior through continuation of the YRBS, and other relevant sources of data in all states and jurisdictions.
    - Data should include protective factors (including families and trusted adults, use of PrEP, etc.) and sites of testing when possible;
    - Evaluation should incorporate and reflect the impact of mental health, COVID-19 pandemic, and violence, and should intentionally include evaluation at district levels.
- Reframing the YRBS positively as Youth Health Behavior Survey.
- Support development of routine screening for youth (including STI screening but also mental health, substance and violence screens) and protocols for management for youth-relating to sexual health, integrating youth voices throughout planning processes.
- Mechanism for youth-focused services to incorporate CHW, use of peer-to-peer supports, 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.

## CHAC Member Observations/Suggestions: Youth and Sexual Health Letter

*The following questions, observations, and suggestions were raised: .*

- Distinguished the objectives as collecting data and developing routine screening protocols to implement as standardized for evaluation of kids.

- Suggested amending the routine screening recommendation to include support for standardized protocols and effective tool development.

- Suggested wordsmithing for concision.

Dr. Mermin suggested addressing the letter to CDC and HRSA to effectively reach the appropriate agencies within CDC, including the Division of Adolescent and School Health.

### CHAC Action

Motions were made to approve all four original recommendations presented, including suggested amendments, and pending final wording, to be developed into a letter to the Secretary. The recommendations included:

- Recommendation 1: Collect data on sexual risk and behavior in youth through continuation of the YRBS, and other relevant sources of data in all states and jurisdictions.
    - Data should include protective factors (including families and trusted adults, use of PrEP, etc.) and sites of testing when possible;
    - Evaluation should incorporate and reflect the impact of mental health, COVID-19 pandemic, and violence, and should intentionally include evaluation at district levels.
- Recommendation 2: Reframe the YRBS positively as Youth Health Behavior Survey.
- Recommendation 3: Support the development of standardized protocols around routine screening recommendation for youth (including STI screening, but also mental health, substance, and violence screens), and protocols for management for youth relating to sexual health, integrating youth voices throughout the planning process, as well as support for standard protocols and effective tool development.
- Recommendation 4: Create a mechanism for youth-focused services to incorporate community health workers (CHW), use of peer-to-peer support, use of champions or influencers and listening sessions with youth to identify and implement best strategies to engage, educate, link to care and impact behavior, recognizing and how differences change over time and vary between individuals.

Motion was seconded. CHAC unanimously approved the recommendations for the Youth and Sexual Health letter to be sent to CDC and HHS.

## Future Agenda Topics

The next CHAC meeting is scheduled for October 24-26, 2023, in Rockville, Maryland. Due to time constraints CHAC members were advised to email future agenda items.

## Recap and Closing

Dr. Cheever reiterated that the dates for the fall meeting were given in the morning session. She

thanked all participants and noted that being in person had a different level of thinking and engagement, which came out in the discussion and motions. She thanked everyone able to come for making the effort.

## Adjournment

Dr. Laura Cheever officially adjourned the session for the day and thanked everyone for their work.

# Certification

## CHAC Co-Chairs' Certification

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

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

Date

Travis Gayles, MD, PhD, Co-Chair
CDC/HRSA Advisory Committee on HIV,
Viral Hepatitis, and STD Prevention and Treatment

Date

10/26/23

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

Date

# Attachment A: Participant List

### CHAC Members Present

Dr. Jean Anderson (Chair)
Dr. Wendy Armstrong
Dr. Jodie Dionne
Dr. Shannon Brown Dowler
Mr. Daniel Driffin
Dr. Travis Andre Gayles (Chair)
Dr. Meredith Greene
Dr. Vincent Guilamo-Ramos
Mr. Kali Lindsey
Dr. Johanne Morne
Ms. Kneeshe Parkinson
Mr. Robert Riester
Mr. Leandro Rodriquez
Dr. Samuel So
Dr. Christine Markham

### CHAC Members Absent

Mr. Venton Hill-Jones
Dr. Shruti Mehta

### CHAC *Ex-Officio* Members Present

Dr. Pradip N. Akolkar
US Food and Drug Administration

Dr. Richard Wild
Centers for Medicare and Medicaid Services

Dr. Christopher Gordon
National Institutes of Health NIMH

Ms. Kaye Hayes
U.S. Department of Health and Human Services, HIV/AIDS and Infectious Disease Policy

Dr. Carolyn Deal
National Institutes of Health NIAD

### CHAC *Ex-Officio* Members Absent

Dr. Neerja Gandotra
Substance Abuse and Mental Health Services Administration

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

### CHAC *Ex-Officio* Members Absent (continued)

Dr. Aditi Mallick
Centers for Medicare and Medicaid Services

Mr. Richard Haverkate
Indian Health Service

### CHAC Liaison Representatives Present

Dr. Ada Stewart
Presidential Advisory Council on HIV/AIDS

### CHAC Designated Federal Officers

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

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

### Presenters

Dr. Laura Hinkle Bachmann
Chief Medical Officer, DSTDP

Mr. Jason Beverley
STD and TB Control Division Chief in the HIV, AIDS, Hepatitis, STD, and TB Administration

Dr. Eli Coleman
Professor Emeritus at the Institute for Sexual and Gender Health, Family Medicine and Community Health, University of Minnesota Medical School

Dr. Stephanie Cohen
Medical Director for the San Francisco City Clinic and Director for the STI Prevention and Control Section of the San Francisco Department of Public Health

**Presenters (continued)**

Dr. Demetre Daskalakis
White House National Mpox Response Deputy Coordinator

Dr. Kathleen Ethier
Director, Division of Adolescent and School Health

Dr. Robyn Neblett Fanfair
Acting Director Division of HIV Prevention

Dr. Bruce “Bryce” W. Furness
CDC Medical Epidemiologist at the DC Health and Wellness Center

Dr. Thomas Gift
Chief, Clinical, Economic and Health Services Research Branch, DSTDP

Ms. Susan Gilbert
Co-Director for the National Coalition for Sexual Health, Altarum

Dr. Kirk D. Henny
Associate Director, Office of Health Equity

Dr. Douglas Krakower
Division of Infectious Diseases, Beth Israel Deaconess Medical Center and Research Scientist, The Fenway Institute, Department of Population Medicine, Harvard Medical School

Dr. Jami Leichliter
Acting Associate Director of Science, DSTDP

Ms. Keshia Lynch
HIV Program Director, One Community Health

Dr. Anthony Martinez
Associate Professor of Medicine, University at Buffalo and Medical Director, Hepatology, Erie County Medical Center

Dr. Leandro Mena
Director, Division of STD Prevention

Dr. Kathrine Meyers
Assistant Professor of Bio-Behavioral Sciences, Aaron Diamond AIDS Research Center, Columbia University Vagelos College of Physicians and Surgeons

Dr. Mahyar Mofidi
Director of the Division of Community HIV/AIDS Programs, HIV/AIDS Bureau, HRSA

Dr. Catherine Rasberry
Chief, Research Application and Evaluation Branch, DASH

Mr. Justin C. Smith
Director of the Campaign to End AIDS, Positive Impact Health Centers

Mr. Mark Stenger
Enhanced Surveillance and Special Studies Acting Team Lead (Acting), Lead Science Officer, STD Surveillance Network

Dr. Carolyn Wester
Director, Division of Viral Hepatitis

# Attachment B: List of Acronyms

| | |
|---|---|
| ACE TA | Access, Care, and Engagement Technical Assistance |
| ACF | Administration for Children and Families |
| ACOG | American College of Obstetricians and Gynecologists |
| ADAP | AIDS Drug Assistance Program |
| AETC | AIDS Education and Training Center |
| ALAI UP | Accelerating Implementation of Multilevel-strategies to Advance Long Acting Injectables for Underserved Populations |
| AMR | Antimicrobial Resistance |
| ART | Antiretroviral Therapy |
| ARV | Antiretroviral |
| ASTHO | Association of State and Territorial Health Officials |
| BPHC | Bureau of Primary Health Care |
| CBOs | Community-Based Organizations |
| CDC | Centers for Disease Control and Prevention |
| CDR | Cluster Detection and Response |
| CHAC | CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment |
| CHIP | Children's Health Insurance Program |
| CHR | Comprehensive Harm Reduction |
| CHW | Community Health Worker |
| CLIA | Clinical Laboratory Improvement Amendments |
| CMO | Committee Management Office |
| CMS | Centers for Medicare & Medicaid Services |
| COI | Conflicts of Interest |
| CPPE | Center for Policy, Planning, and Evaluation |
| CQII | Center for Quality Improvement and Innovation |
| CROI | Conference on Retroviruses and Opportunistic Infections |
| *CT* | *Chlamydia Trachomatis* |
| DAAs | Direct-Acting Antivirals |
| DASH | Division of Adolescent and School Health |
| DCHWC | District of Columbia Health and Wellness Center |
| DCPHL | District of Columbia Public Health Laboratory Division |
| DFO | Designated Federal Officer |
| DHP | Division of HIV Prevention |
| DOH | Department of Health |
| DOHMH | Department of Health and Mental Hygiene |
| DoxyPEP | Post-Exposure Doxycycline |
| DPEP | Pre-Exposure Doxycycline |
| DSD | Differentiated Service Delivery |
| DVH | Division of Viral Hepatitis |
| EHE | Ending the HIV Epidemic |

| | |
|---|---|
| EHRs | Electronic Health Records |
| EMA | Emergency Management Agency |
| EMR | Electronic Medical Record |
| ER | Emergency Room |
| ETAP | Evaluation and Technical Assistance Provider |
| FACA | Federal Advisory Committee Act |
| FDA | Food and Drug Administration |
| FPL | Federal Poverty Level |
| FQHC | Federally Qualified Health Center |
| FRN | Federal Register Notice |
| GBSM | Gay, Bisexual men |
| GC | Gonorrhea |
| GME | Graduate Medical Education |
| HAART | Highly Active Antiretroviral Therapy |
| HAB | HIV/AIDS Bureau |
| HCC | Hepatocellular Carcinoma |
| HCP | Health Care Provider |
| HCV | Hepatitis C Virus |
| HEDIS | Healthcare Effectiveness Data and Information Set |
| HEPRA | Health Emergency Preparedness and Response Administration |
| HHS | Health and Human Services |
| HIPAA | Health Insurance Portability and Accountability Act of 1996 |
| HIV | Human Immunodeficiency Virus |
| HIVMA | HIV Medicine Association |
| HPV | Human Papillomavirus |
| HRSA | Health Resources and Services Administration |
| HUD | U.S. Department of Housing and Urban Development |
| ID | Infectious Disease |
| IND | Investigational New Drug |
| IUD | Intrauterine device |
| IV | Intravenous |
| IWTK | I Want The Kit |
| JAMA | Journal of the American Medical Association |
| LAI ARV | Long-acting Injectable Antiretroviral |
| LGBTQ | Lesbian, Gay, Bisexual, and Transgender |
| LGBTQI+ | Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex |
| LPN | Licensed Practical Nurse |
| MenB | Group B Meningococcal |
| MHAF | Minority HIV/AIDS Fund |
| MHS | Molecular HIV Surveillance |
| MMWR | Morbidity and Mortality Weekly Report |
| MSM | Men Who Have Sex with Men |
| NAAT | Nucleic Acid Amplification Test |

| | |
|---|---|
| NACCHO | National Association of County and City Health Officials |
| NASTAD | National Alliance of State and Territorial AIDS Directors |
| NCHHSTP | National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention |
| NCQA | National Committee for Quality Assurance |
| NCSD | National Coalition of STD Directors |
| NCSH | National Center for Health Statistics |
| NCSL | National Conference of State Legislatures |
| NG | Neisseria Gonorrhoeae |
| NGA | National Governors Association |
| NHANES | National Health and Nutrition Examination Survey |
| NHSS | National HIV Surveillance System |
| NIAID | National Institute of Allergy and Infectious Diseases |
| NIH | National Institutes of Health |
| NIMH | National Institute of Mental Health |
| NNDSS | National Notifiable Disease and Surveillance System |
| NOFO | Notice of Funding Opportunity |
| NSFG | National Survey of Family Growth |
| OAT | Opioid Agonist Treatment |
| OCHIN | Oregon Community Health Information Network |
| OIDP | HHS Office of HIV/AIDS and Infections Disease Policy |
| OMH | Office of Minority Health |
| ONAP | Office of National AIDS Policy |
| OTC | Over-The-Counter |
| PA | Physician Assistant |
| PACHA | Presidential Advisory Council on HIV/AIDS |
| PB | Planning Body |
| PC | Planning Council |
| PEP | Post-Exposure Prophylaxis |
| PEPFAR | President's Emergency Plan for AIDS Relief |
| PHE | Public Health Emergency |
| PK | Pharmacokinetic |
| PLWHIV | People Living with HIV |
| POC | Point-of-Care |
| POCT | Point-of-Care Testing |
| PPHI | Public Health Intervention Initiative |
| PrEP | Pre-Exposure Prophylaxis |
| PWID | People Who Inject Drugs |
| PWUD | People Who Use Drugs |
| RCT | Randomized Controlled Trial |
| REACH | Recovery Enhanced by Access to Comprehensive Healthcare |
| RFA | Request for Appointment |
| RFP | Request for Proposal |
| RN | Registered Nurse |

| | |
|---|---|
| RNA | Ribonucleic Acid |
| RWHAP | Ryan White HIV/AIDS Program |
| STSCWG | Self-testing and Self-collection Workgroup |
| SAMHSA | Substance Abuse and Mental Health Services Administration |
| SDOH | Social Determinants of Health |
| SEP | Special Enrollment Period |
| SPNS | Special Project of National Significance |
| SSP | Syringe Services Program |
| SSuN | STD Surveillance Network |
| STD | Sexually Transmitted Disease |
| STI | Sexually Transmitted Infection |
| SURE | Supporting Replication |
| SVR | Sustained Virologic Response |
| TB | Tuberculosis |
| TIA | Trauma-Informed Approach |
| Tx | Treatment/Therapy |
| U.S. | United States |
| USCHA | United States Conference on HIV/AIDS |
| UT HEALTH | University of Texas Health |
| vDOT | Video Directly Observed Therapy |
| WFWG | Workforce Workgroup |
| WHO | World Health Organization |
| YRBS | Youth Risk Behavior Survey |
| YRBSS | Youth Risk Behavior Surveillance System |

# Attachment C: Public Comment Letters


April 28, 2023

**Written Comments Re: April 18 Meeting of the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment – Via email to nchhstppolicy@cdc.gov**

I write on behalf of the Big Cities Health Coalition (BCHC) to provide comment to the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis, and STD Prevention and Treatment regarding select matters on the docket for consideration at the meeting on April 18, 2023. BCHC is comprised of health officials leading 35 of the nation's largest metropolitan health departments, which together serve more than 61 million – or about one in five – Americans. We seek to advance a shared, equitable actionable vision to transform urban health, where all government agencies, healthcare providers and systems, and community-based organizations work together to promote and produce health, safety, and equity.

Big city health departments are on the front lines of responding to the most challenging public health issues across the U.S., and the HIV epidemic is a notable example of this. While most BCHC jurisdictions receive dollars for care and treatment through Ryan White Part A, only eight receive HIV prevention dollars from CDC. BCHC is thankful for the Ending the Epidemic dollars that went to 52 large jurisdictions (including 29 of our 35 member jurisdictions). As CDC considers next steps on that and other 'routine' HIV funding support, we look forward to engaging in discussion. We appreciate the efforts of CDC, HRSA, and other HHS agencies in thinking through how best to strike a balance among the immediate and longer-term resource needs in governmental public health departments and the communities they serve, including the importance of getting dollars local.

An illustrative case of the importance of direct funding to local health departments (LHDs) is happening in Tennessee, where the state's elected leadership has declined $8–10 million in federal HIV dollars. State policymakers plan to replace some of the federal dollars with state funds. Still, in doing so, the state will have the authority to restrict spending to those activities and populations it chooses, rather than abiding by data-informed federal guidelines about those populations most at risk. For example, it has been reported that the state intends to prioritize victims of human trafficking, first responders, and transmission between mothers and babies. While notable for their effort, these are neither the populations most at risk in Tennessee nor those that we know are more like to acquire HIV.[i] Funding and policy that shifts away from best practices and data-informed activities will have a negative impact statewide, but it will be especially detrimental in communities like Shelby County (Memphis and its surrounding areas) where HIV/AIDS prevalence has trended higher than the U.S. average since 2010. In 2021, prevalence was 73.3% higher than the US average in Shelby County.[ii]

Tennessee may be the first state to do this, but it certainly may not be the last, which can set a dangerous precedent and jeopardize a host of gains we have achieved with HIV and other preventable illnesses. As CDC thinks about scaling up support and resources equitably, we offer the following recommendations.:

6909 LAUREL AVE. #11442, TAKOMA PARK, MD 20913 // BIGCITIESHEALTH.ORG

# Attachment D: Workgroup Presentations


**CHAC Workforce Workgroup Members**:
Vincent Guilamo-Ramos (Chair)
Jean Anderson
Wendy Armstrong
Daniel Driffin
Kali Lindsey
Kneeshe Parkinson
Robert Riester


This term of the workgroup was from Nov 2022 – April 2023

- Met twice in December and March

DFOs:

- Shalonda Collins, MPH, CHES
- Marah Condit, MS

Duke University School of Nursing
Center for Latino Adolescent and Family Health

## Presentation Overview

1. Scope of the Workforce Workgroup's Work
2. Setting the Context: Workforce Challenges and Priorities
3. Discussion

## Scope of Work

The workforce working group was tasked with developing the evidence base on priority issues for the HIV workforce, including aligning HIV workforce regulation and funding through:

- Incentivizing programs that create pathways for more diversity in professional careers for HIV treatment and prevention services
- Investing in workforce infrastructure for the delivery of decentralized, differentiated status-neutral HIV services to promote a shift toward a comprehensive, whole-person, interdisciplinary, and team-based model of HIV service delivery.

# HIV Workforce Priority Challenges and Potential Strategies

## Challenges

**Insufficient trainees entering HIV specialties**

*Sub-Challenge:*
*Diversifying the HIV Workforce*

**Aging HIV workforce**

**Diversion of HIV providers to other infectious disease areas**

## Potential Strategies

**Recruit:**
Create pathways to increase the recruitment of a diverse cohort of HIV-specialty trainees

**Retain:**
Maintain the current HIV workforce through educational, financial, work environment, and policy incentives

**Reimagine:**
Develop infrastructure for a new model of HIV service delivery and workforce configuration

# HIV Workforce Priority Challenges

### Insufficient trainees entering HIV specialties

*Sub-Challenge:*
*Diversifying the HIV Workforce*

- Available HIV-specialty programs are limited in number and geographically clustered
- Trainee exposure to HIV-specific education and clinical context is inconsistent

Source: Institute of Medicine. 2011. *HIV Screening and Access to Care: Health Care System Capacity for Increased HIV Testing and Provision of Care.* Washington, DC: The National Academies Press.

### Aging HIV workforce

- Increasing numbers of HIV clinicians are reaching retirement age
- 68.2% of HIV Clinicians are ≥ 45 years old

Gilman et al. The HIV Clinician Workforce in the United States. HIV Specialist. Retrieved from: https://aidsetc.org/resource/first-look-hrsa-hiv-workforce-study; HIV Specialists: 2015 estimates, HRSA, HIV Specialist ; U.S. Bureau of Labor Statistics, Occupational Employment and Wage Statistics, 2020; HIV.gov U.S. Statistics, 2022

### Diversion of HIV providers to other infectious disease areas

- e.g. COVID-19 response directly impacted HIV and infectious disease specialty workforce by siphoning specialists and funding

Giovanni G, Milic J, Martinez E, et al. Human Immunodeficiency Virus (HIV) Care Models During the Corona Virus Disease 2019 (COVID-19) Era, *Clinical Infectious Diseases*. 2021. 73(5):1222-1227.

# Strategy #1: Increased Recruitment Efforts

**Recruit:**
Create pathways to increase the recruitment of a diverse cohort of HIV-specialty trainees

**Potential mechanisms for consideration:**

**Pathway Programs for HIV-Specialization**

Further development and expansion of HIV-specialist **pathway programs**, including the integration of HIV-specialist training in **GME** and **GNE**

***Why specialize in HIV?:* Elevating the Benefits of HIV-Specialization**

HIV epidemic response continues to serve as an **exemplar for health activism**, calling attention to **health inequities** and **challenging the current paradigm** of healthcare

**Financial Incentives for HIV-Specialist Trainees**

Examples: **Loan repayment** options and funding streams such as **HRSA primary care grants**, **HRSA Bio-preparedness Workforce Pilot Program**

Buciak et al., Human Immunodeficiency Virus Training Pathways in Residency: A National Survey of Curricula and Outcomes, Clinical Infectious Diseases, Volume 72, Issue 9, 1 May 2021, Pages 1623–1626, https://doi.org/10.1093/cid/ciaa301; Steward et al. 2020. *Practice transformations to optimize the delivery of HIV primary care in community health care settings in the United States: A program implementation study.* PLOS Medicine. https://doi.org/10.137/.journal.pmed.1003079

# Strategy #2: Retaining the Current HIV Workforce

**Retain:**
Maintain the current HIV workforce through educational, financial, work environment, and policy incentives

**Potential mechanisms for consideration:**

**Innovative Payment Structures for Reimbursement of HIV Services**

Examples: Increased **Medicaid and Medicare reimbursement rates** for HIV-specialists providing primary care, **risk-adjusted provider reimbursement**, **reimbursement for alternative models** of service delivery

**Regulatory Barriers Limiting Providers from Practicing to Highest Level of Training/Licensure**

i.e. Nurse practitioner- and physician assistant-delivered primary care results in comparable patient outcomes to physicians.

**Work Environment Considerations**

Ensure viable pathways for continued **education and training**, **career advancement**, and adequate **compensation**

Armstrong WS. The Human Immunodeficiency Virus Workforce in Crisis: An Urgent Need to Build the Foundation Required to End the Epidemic. Clinical Infectious Diseases. Volume 72, Issue 9, 1 May 2021, Pages 1627–1630. https://doi.org/10.1093/cid/ciaa302; Institute of Medicine. 2011. *HIV Screening and Access to Care: Health Care System Capacity for Increased HIV Testing and Provision of Care.* Washington, DC: The National Academies Press; Laurant, M, et al. Cochrane Database Syst Rev. 2018;/(/): Kurtzman ET, Barnow BS. Med Care. 2017;55(6):615-622; Zhang C, et al. AIDS patient care and STDs. 2019;33(12):507-527.: Owen IA. Skelton IB. Maine LL. Pharmacy. 2020;8(3):157.

# Strategy #3: Reimagining the Model for HIV Service Delivery

**Reimagine:**
Develop infrastructure for a new model of HIV service delivery and workforce configuration

**Potential mechanisms for consideration:**

**Policy and infrastructure levers for delivering decentralized, differentiated HIV prevention and care**

Example: **COVID-19 PHE flexibilities** allowed healthcare workforce to provide responsive infectious disease prevention and treatment at a large-scale

**Redefine the HIV workforce for comprehensive health and social service provision**

Involve **PLWHIV, Primary Care Providers, RNs, LPNs, Pharmacists, Dentists, Social Workers, Behavioral/Mental Health Professionals, Community Health Workers**, etc.

**Expand and maximize the existing HIV workforce to include entire available, qualified workforce**

Examples: **Practice transformation** demonstrations (e.g. "share-the-care" and increased care coordination) to maximize the existing workforce

HHS. (2023). Fact Sheet: COVID-19 Public Health Emergency Transition Roadmap. https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html; Steward et al. 2020. *Practice transformations to optimize the delivery of HIV primary care in community healthcare settings in the United States: A program implementation study.* PLOS Medicine. https://doi.org/10.1371/journal.pmed.1003079

# Discussion

1. **Infrastructure development for delivery of decentralized, differentiated HIV prevention and care (e.g., telehealth, community-based delivery of services, etc.)**

2. **Integration of all team members (e.g. CHWs, RNs, LPNs, Social Workers, Pharmacists, Behavioral/Mental Health Professionals) into the HIV workforce in partnership with other care providers and address appropriate training standards, compensation, and paths for promotion**

3. **Removal of regulatory barriers that place restrictions on practice at the highest level of training and licensure (e.g., for nurse practitioners, Pas, medical technicians, pharmacists, etc.)**

4. **Incentivization of programs that create pathways for more diversity in professional careers beyond CHR (e.g. fellowship programs) of the workforce with current and emerging needs and challenges of PLWHIV communities**

Source: Institute of Medicine. 2011. *HIV Screening and Access to Care: Health Care System Capacity for Increased HIV Testing and Provision of Care.* Washington, DC: The National Academies Press,

# CHAC STI Self-Testing Workgroup Report

CHAC Atlanta Meeting

April 19, 2023

## Workgroup Meetings and Membership

- Workgroup Term: November 2022 – April 2023
  - Meetings were held in January, February and April 2023
  - Invited two guest speakers:
    - Dr. Ellen Kersh, Branch Chief, CDC Division of STD Prevention Laboratory
    - Dr. Barbara Van Der Pol, Professor of Medicine & Public Health, STI Laboratory Director, University of Alabama at Birmingham

Workgroup Members:
- Jodie Dionne (Chair)
- Johanne Morne
- Shannon Dowler
- Shruti Mehta
- Christine Markham

Designated Federal Officials:
- Marah Condit, MS
- Shalonda Collins, MPH, CHES

# Focus Areas

01

Knowledge gaps in the development of high quality STI diagnostic testing with self-collected samples (CT/NG/syphilis)

02

Regulatory barriers to the approval of self-collected swabs for STI diagnostic testing within and **outside** the clinical setting

03

How to improve access to and uptake of affordable, available STI testing for adolescents and adults who need it.

# Definitions

**STI self collection** can occur in a clinical or non-clinical setting.

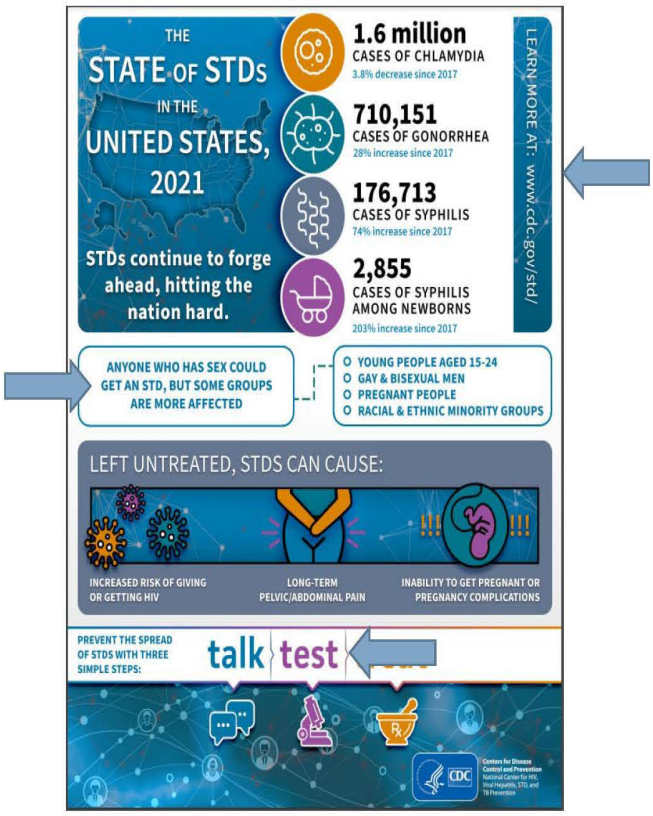
CT/NG samples are genital or extragenital.

**STI self-testing** is collected, performed, and interpreted by the user (at point of care [POC]) without input from a provider (i.e. CLIA waived urine pregnancy test)

**Direct to consumer (OTC) testing** can be ordered by the user (often online) without input from a provider

# 2021 CDC STI Surveillance

Released 11 April 2023




## WHO 2019 Recommendations

**Recommendation on self-collection of samples for STI testing**

**GC/CT**
Self-collection of samples for Neisseria gonorrhoeae and Chlamydia trachomatis should be made available as an additional approach to deliver STI testing services for individuals using STI testing services.
(*strong recommendation, moderate-certainty evidence*)

**Syphilis**
Self-collection of samples for Treponema pallidum (syphilis) and Trichomonas vaginalis may be considered as an additional approach to deliver STI testing services for individuals using STI testing services.
(*conditional recommendation, low-certainty evidence*)

**WHO Consolidated Guideline on Self-Care Interventions for Health**
Sexual and Reproductive Health and Rights

Systematic review of 11 studies 1998-2018*:
RR for STI uptake 2.9 (95% CI 1.2-7.3)
RR for STI case finding 2.2 (95% CI 1.0-4.5)
(compared to clinician collected or no testing)
*11 in HIC, 6 in US

SELF-COLLECTION BENEFITS

- Person-centered
- Can reduce barriers to STI testing (privacy, stigma)
- Complementary to existing programs and approaches
- Benefit measured in terms of improved outcomes for the individual and at the population level

SELF-COLLECTION RISKS

- Exposure to buffer
- Harm with self-swab
- Lack of stability data - NAAT performance if samples are heated or testing delay

Slides courtesy of
Amanda C. Smith, PhD

Review › Cochrane Database Syst Rev. 2015 Sep 29;2015(9):CD011317.
doi: 10.1002/14651858.CD011317.pub2.

## Home-based versus clinic-based specimen collection in the management of Chlamydia trachomatis and Neisseria gonorrhoeae infections

Luisa Fajardo-Bernal [1], Johanna Aponte-Gonzalez, Patrick Vigil, Edith Angel-Müller, Carlos Rincon, Hernando G Gaitán, Nicola Low

- **Objective:** To assess the **effectiveness and safety of home-based specimen collection** as part of the management strategy for CT and GC infections compared to clinic-based
- 10 randomized controlled trials (RCTs) published 1998-2013
- Selection criteria: sexually active, persons engaged in higher risk behavior (MSM and sex workers), symptomatic or asymptomatic
- Results:
  - In 8/10 studies more home-collected specimens were tested compared to clinic based
  - 9/10 studies showed lower proportion of positive results in home-based collection
  - 96% of women found self collection comfortable and easy

## Lower proportion of positive tests in the home collection group

**Analysis 1.7. Comparison 1 Home-based vs clinic-based specimen collection for CT and NG, Outcome 7 Positive test prevalence.**

Review: Home-based versus clinic-based specimen collection in the management of Chlamydia trachomatis and Neisseria gonorrhoeae infections

Comparison: 1 Home-based vs clinic-based specimen collection for CT and NG

Outcome: 7 Positive test prevalence

| Study or subgroup | Home n/N | Clinic n/N | Risk Ratio M-H,Fixed,95% CI | Weight | Risk Ratio M-H,Fixed,95% CI |
|---|---|---|---|---|---|
| Andersen 1998 | 12/44 | 7/19 | | 4.5 % | 0.74 [ 0.35, 1.58 ] |
| Graseck 2010 | 3/151 | 5/92 | | 2.9 % | 0.37 [ 0.09, 1.49 ] |
| Götz 2013 | 8/50 | 5/25 | | 3.1 % | 0.80 [ 0.29, 2.19 ] |
| Jones 2007 | 21/143 | 35/131 | | 16.8 % | 0.55 [ 0.34, 0.89 ] |
| Lippman 2007 | 39/393 | 43/394 | | 19.8 % | 0.91 [ 0.60, 1.37 ] |
| Ostergaard 1998 | 33/799 | 4/41 | | 3.5 % | 0.42 [ 0.16, 1.14 ] |
| Ostergaard 2003 | 91/233 | 50/97 | | 32.5 % | 0.76 [ 0.59, 0.97 ] |
| Reagan 2012 | 4/72 | 3/48 | | 1.7 % | 0.89 [ 0.21, 3.80 ] |
| Xu 2011 | 29/189 | 27/120 | | 15.2 % | 0.68 [ 0.43, 1.09 ] |
| **Total (95% CI)** | **2074** | **967** | | **100.0 %** | **0.72 [ 0.61, 0.86 ]** |

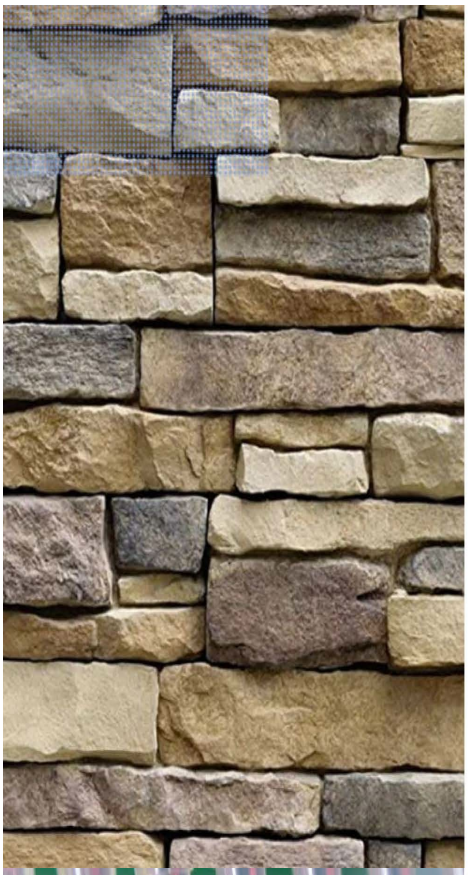
Total events: 240 (Home), 179 (Clinic)
Heterogeneity: $Chi^2 = 4.76$, df = 8 (P = 0.78); $I^2 = 0.0\%$
Test for overall effect: Z = 3.71 (P = 0.00020)
Test for subgroup differences: Not applicable

# Current Landscape for STI Self-Testing

- Published data shows efficacy and cost-effectiveness of CT/NG NAAT self-testing in a variety of populations.
  - 14-19 million CT/NG NAAT performed each year in the US.
- COVID self-testing outside the clinical setting suggested a path for FDA approval (EUA).
- In many clinics, genital CT/NG self-collection (vaginal swabs in women, first-catch urine in men as preferred specimens) is **standard of care**.
  - Self-testing for urogenital CT/NG has been recommended by CDC since 2014 due to equivalent test performance and higher patient acceptability compared to clinician-collected samples.

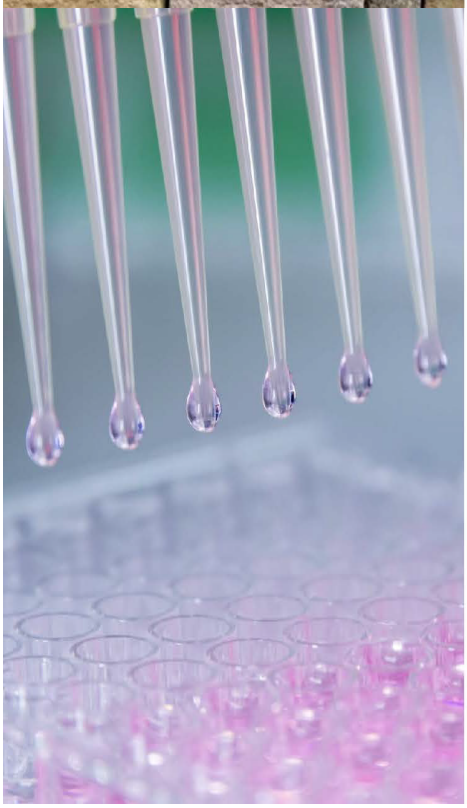
# Current Landscape for STI Self-Testing

- **Barrier:** FDA has not approved any STI self-collection testing for use in a non-clinical setting. Labs are out of compliance if they perform validation procedures on swabs collected in the non-clinical setting.
- CDC Division of STD Prevention is working to publish a systematic review on the efficacy and acceptability of self-collected STI testing
- ASTDA recently published a position statement about the pitfalls and opportunities with the rapid spread of direct to consumer STI testing.
  - $280 for CT/NG/TV/Mycoplasma testing. Some testing has poor sens/spec.



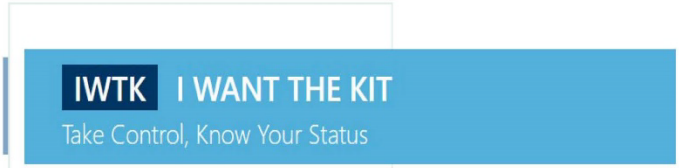
# Challenges

- Regulatory barriers have prevented FDA licensure of CT/NG self-collection outside of the clinical setting.
- Manufacturer Perspective
  - FDA submission requirements for self-collect indication ($$$$)
  - Complex, poorly defined requirements (STI reporting, treatment, linkage to care)
- Self-collection of extra-genital CT/NG NAAT specimens in the non-clinical setting requires instruction. (readily available)
- Syphilis testing requires blood sampling – more complex than CT/NG
  - Dried blood spots for treponemal antibody testing
  - Microtainers (1 mL) can allow for non-treponemal testing



# Regulatory Solutions

- Formal FDA guidance and a streamlined process to allow assay claims to include CT/NG sample self-collection in non-clinical settings.
- Define acceptable performance loss in terms of test sensitivity for CT/NG testing outside the clinical setting.
  - Oraquick POC HIV test was approved by FDA at 92% sensitivity.
- Allow laboratories to perform validation procedures on self-collected swabs.
  - Specify transport conditions.
  - Address safety concerns.
- Regulations for quality control for CT/NG testing by all vendors.




In partnership with MD Dept of Health, Baltimore City HD, NIH, Tribal Health Boards

- "I want the kit" CT/NG home test kit from Johns Hopkins is free for residents of Maryland, Alaska, Oklahoma, Kansas, New Mexico, Utah, Nevada, Arizona.

# Other Solutions and Knowledge Gaps

- Partnership with public health can help ensure that STI reporting, treatment, and partner notification is connected to testing outside clinical settings. Linkage to care based on test results is critical to improving STI outcomes.
  - CDC STI Lab is working to develop self-collection guidelines
- Novel approaches to improving access: vending machines, telehealth
- Standardized aligned STI reporting mechanisms are needed (i.e. COVID-19)
- STI diagnosis as a sentinel event: opportunity to link to HIV PrEP and doxy PEP
- Research Needs:
  - Improve high quality CT/NG/syphilis POC testing and comparative performance
  - Cost-effectiveness analyses to compare performance characteristics and case finding
  - Increase access to affordable STI testing especially in populations with existing barriers

# Conclusions


- Rates of curable CT/NG/syphilis in the US are rising with 15 million NAAT tests performed each year.
  - There is high demand for STI testing online - quality and cost varies.
- Published data suggests that STI self-collection in the non-clinical setting is feasible and highly acceptable. Test sensitivity is lower than in clinic.
- One regulatory barrier to improving access to STI testing is the current FDA requirement for sample collection in the clinical setting.
- CDC, FDA, local public health officials, and frontline providers are committed to improving access to high-quality STI diagnosis. The best programs ensure high treatment rates, linkage to care, and timely reporting.

## Questions


- Thanks to Marah Condit for all her expertise and support of workgroup activities.
- Thanks to Drs. Kersh and Van Der Pol for sharing their input and experience on STI testing.